Achilles Tendon Rupture: Epidemiology, Outcomes after Treatment and an Analysis of Plantar Foot Pressures

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Abstract

The influence of socioeconomic deprivation status (SEDS) on the epidemiology of primary Achilles tendon rupture (ATR) has not been explored, while the general epidemiology of Achilles tendon re-ruptures (ATRR) is poorly understood. The optimal management of ATR remains controversial and recent trends towards functional rehabilitation are not supported by robust evidence.

The studies comprising this thesis sought to define the epidemiology of primary ATR, with particular focus on the influence of SEDS; to describe the epidemiology and risk factors for ATRR; to report on comparative outcomes from randomised controlled trials comparing long-term outcomes after traditional operative and non-operative management and short-term outcomes after traditional and functional non-operative rehabilitation; and to report on changes in static plantar loading patterns, physical and patient reported parameters after functional non-operative treatment of ATR.

ATR and ATRR were commoner in males and individuals with lower levels of socioeconomic deprivation. The nature of ATR varied with variations in SEDS. Risk factors for ATRR were identified, including younger age and immobilising treatment of ATR. Patients treated surgically did not report superior long-term outcomes to those treated non-operatively. Functional rehabilitation was found to be a safe alternative to immobilising treatment, giving better early outcomes, albeit with a higher incidence of minor skin complications. There was no difference in outcomes beyond one year after injury. Functional, non-operative rehabilitation was associated with reduced forefoot loading and increased rearfoot loading. These changes reduced with time

but persisted nine months after injury and were accompanied by progressive changes in uninjured foot loading.

Key words: Achilles, tendon, rupture, re-rupture, functional rehabilitation

To my wife…Clarissa. I am eternally grateful for your patience and constant support, without which neither this project, nor many of my career achievements would have been possible.

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AAOS	American Academy of Orthopaedic Surgeons
ATLM	Achilles Tendon Length Measure
AT	Achilles Tendon
ATR	Achilles Tendon Rupture
ATRA	Achilles Tendon Resting Angle
ATRR	Achilles Tendon Re-rupture
ATRS	Achilles Tendon Total Rupture Score
BMI	Body mass index
EQ-5D	EuroQol 5 Dimension
FET	Fisher's Exact Test
FFT	Friends and Family Test

FFRF	Forefoot to rearfoot
GPa	Gigapascals
HRQoL	Health Related Quality of Life
IQR	Inter quartile range
LD	Least Deprived
MCID	Minimum Clinical Important Difference
MD	Most Deprived
MDC	Minimum Detectable Change
MPa	Megapascals
MRI	Magnetic Resonance Imaging
N/m^2	Newtons per metre squared
NHS	National Health Service (UK)
NPS	Net Promoter Score

NRS	National Records of Scotland
PP	Peak Pressure
PROMs	Patient reported outcome measures
RCT	Randomised Controlled Trials
SEDS	Socioeconomic deprivation status
SMFA	Short Musculoskeletal Functional Assessment
VAS	Visual analogue scale

I hereby declare that the material presented in this thesis is my own original work and that the greater portion of the work was undertaken after registration for this degree. References to the works of others are appropriately documented.

J Zammit Maempel

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Chapter 1: Introduction

The Achilles tendon is the largest and strongest tendon in the human body, formed by the fusion of the soleus tendon and the medial and lateral gastrocnemius tendons.[1] It derives its name from Greek mythology, where the nymph Thetis is said to have dipped her son Achilles into the River Styx, making him invincible. However, she is said to have held him by one heel and thus his foot never touched the water, leaving this as his only vulnerable part. He is said to have been brought down in battle in the Trojan war by a poison tip arrow aimed at his heel by Paris of Troy.[2] To this day, the term 'Achilles heel' is used in non-medical parlance to refer to a vulnerable or weak spot, with the first such use recorded in 1705.[3] The term 'tendo Achilles' was first penned by the Dutch anatomist Philip Verheyen in 1693 in his text *Corporis Humani Anatomia*, where he stated that it was commonly called the cord of Achilles. It has also been variably referred to as the tendo Achillis,[2, 4] tendo Achilles,[5, 6] calcaneal tendon,[7, 8] tendo-calcaneus[9] and the heel cord.[10]

1.1 Anatomy and Function of the Achilles Tendon

1.1.1 Anatomy of the Achilles Tendon[1]

The Achilles tendon is formed around the mid-level of the calf by the convergence of gastrocnemius and soleus to form a common tendon. The functional unit that these two muscles form is sometimes referred to as the triceps surae.[11] The gastrocnemius muscle lies superficially in the posterior calf and is the main contributor to the typical surface contour of the proximal calf. It arises as two heads (medial and lateral) from the posterior aspects of the medial and lateral

femoral condyles via tendinous origins and from the intervening posterior knee capsule. The tendons expand into a posterior surface aponeurosis and muscle fibres arise from the anterior surface of this, running distally. The two heads of gastrocnemius form the inferior borders of the popliteal fossa. The medial head is larger than the lateral and the medial muscle belly extends further distally than the lateral. Distally, a broad anterior aponeurosis is formed and the muscle fibres insert into this. It is at this point that the two heads begin to merge into a single entity. The aponeurosis is broad proximally, but narrows as it runs distally into the Achilles tendon. The soleus muscle lies deep to gastrocnemius. Proximally, it is completely covered by the wider gastrocnemius muscle, however, more distally, the soleus muscle is wider than the overlying gastrocnemius. Soleus arises from the proximal quarter of the fibula as well as the soleal line on the posterior surface of the tibia and further distally from the medial border of the tibia. Between the two lies a fibrous arch. The popliteal vessels and tibial nerve run deep to the arch. Soleal fibres arise mainly from the posterior surface of the proximal aponeurosis and run distally to the Achilles tendon, although there are some fibres which arise from the anterior surface of the aponeurosis in a bipennate fashion and form a small, tubular intra-muscular tendon which merges with the main soleus tendon distally. The tendon of soleus becomes more tubular in shape as it passes distally, merging with the tendon of gastrocnemius to form the Achilles tendon. The Achilles tendon receives fibres from soleus on its anterior aspect, almost as far down as its insertion. Innervation of both gastrocnemius and soleus is from the tibial nerve, consisting of fibres from S1 and S2 nerve roots. The plantaris muscle, when present (it is absent in around 8% of individuals), lies between gastrocnemius and soleus[12] and its long and slender tendon runs distally and medially, coming to lie medial to the Achilles tendon and then insert onto the calcaneum medial to it, although on occasion, it may fuse with the Achilles tendon or insert into the plantar fascia.

The Achilles tendon does not have a synovial sheath but is surrounded by the paratenon which is composed of flexible connective tissue which facilitates gliding of the tendon with movement.[13] At a histological level, the tendon is composed of cells (fibroblasts) and extra cellular matrix containing mainly collagen (type I collagen being by far the predominant type) with small amounts of elastin and proteoglycans. Type I collagen molecules consisting of two α-1 polypeptide chains and one α-2 polypeptide chain arranged in a right handed triple helix are arranged in a staggered array to form microfibrils, which are in turn arranged into fibrils and bundles (fascicles). Collagen fibres are arranged longitudinally in the direction of stress and impart the main tensile strength of the tendon.[11, 14, 15] At rest and under low loads, the collagen fibrils exhibit crimp (i.e. they adopt a wavy configuration), which is lost with progressive stretching of the tendon.[12]

The Achilles tendon is around 15cm in total length on average[12, 16] and is thinnest at the midsection, forming a rounded cord, before splaying in its terminal part (approximately 4cm at the distal end), to insert into the posterior aspect of the calcaneum, in a crescentic fashion.[17] However, absolute tendon length varies significantly between individuals and does not appear to be correlated with patient height.[18] The retrocalcaneal bursa lies between the Achilles tendon posteriorly and the posterior surface of the calcaneum anteriorly. The posterior wall of the bursa is thin and blends with the epitenon of the Achilles tendon while its anterior wall is thicker and composed of fibrocartilage. There may be a second bursa lying superficial to the tendon, although this is a less frequent finding.

The AT fibres rotate in a spiral fashion en route to their insertion in the calcaneum, so that the more superficial fibres arising from the continuation of gastrocnemius insert more laterally while the deep soleal fibres insert more medially on the calcaneum,[17] a phenomenon first noted by Cummins and Anson in 1946.[19] The insertion is through a fibrocartilage enthesis characterised by a gradual transition from tendon to uncalcified fibrocartilage, then to calcified fibrocartilage

and then bone. This arrangement allows for a gradual transition from flexible to stiff tissue and dissipates stress.[11]

The AT lies subcutaneously just deep to the skin and its contour can easily be appreciated in slim individuals. Medially lies the plantaris tendon (when present) and laterally, the sural nerve, which crosses the lateral border of the AT and is potentially at risk during surgical exposure of the Achilles tendon. Deep (anterior) to the AT is the fascia of the deep posterior compartment overlying the flexor hallucis longus belly.

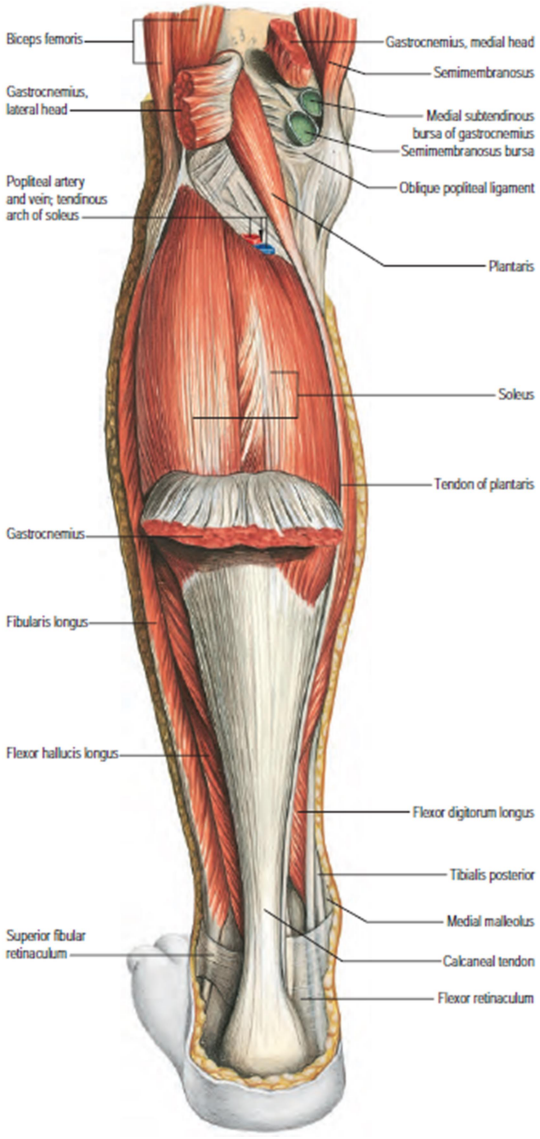


Figure 1.1. Muscles of the posterior aspect of the leg. Gastrocnemius has been partially removed to facilitate visualisation of the underlying soleus muscle proximally. The Achilles tendon, labelled as the 'calcaneal tendon', is visible distally in the posterior aspect of the leg. Reproduced with permission from Gray's Anatomy. The Anatomic Basis of Clinical Practice. 41st edition. Standring S (2016).

1.1.2 Vascular Supply of the Achilles Tendon

The AT predominantly receives its arterial supply from two main sources – branches of the posterior tibial artery and the peroneal (fibular) artery.[16] The main arterial supply of the AT is to peritendinous tissues via a recurrent branch of the posterior tibial artery with further blood supply from the paratenon and from branches extending from the muscles of origin proximally and the os calcis distally.[1] These feed into a network of vessels arranged in three primary orientations: transverse, longitudinal and deep. The superficial transverse vessels are the largest calibre and longitudinal vessels running parallel to the tendon fibres in turn arise from these, running along the inter-fibrillar striations.[16] The longitudinal arteries penetrate the tendon fibres and spiral with these, facilitating supply to the deeper tendon tissue. The arteries have been shown to exhibit a progressive fractal pattern, whereby each branching artery reproduces the parent artery pattern. Hence, the arteries spread out at right angles to each other reproducing the same pattern on progressively smaller scales. This pattern enables vessels to reach all areas of the Achilles tendon.[16]

The posterior tibial supply enters medially while the peroneal supply reaches the tendon laterally. Between them, they supply three vascular 'territories' (figure 1.2). Branches of the posterior tibial vessel supply the proximal (on average the part >7cm proximal to its insertion) and distal (on average the terminal 4cm) while branches of the peroneal artery supply the intervening part of the tendon. The mid-section of the AT is markedly hypovascular in comparison to the rest of the structure and this is also the region at highest risk of rupture.[16, 17, 20]

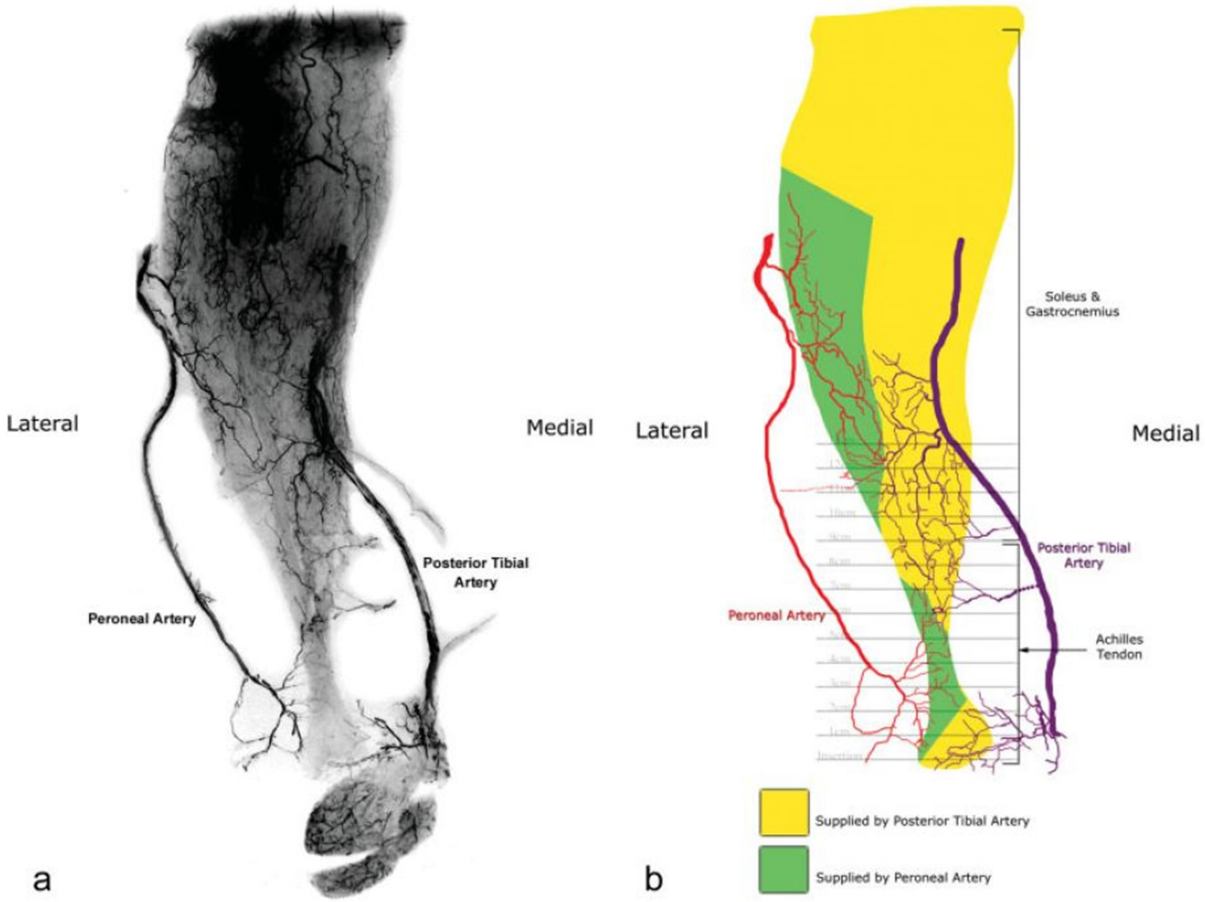


Figure 1.2. Vascular supply of the Achilles tendon. Figure A shows a radiograph of the vascular supply of the Achilles tendon. Figure b shows a schematic representation of the vascular supply to the Achilles tendon. The posterior tibial artery supplies the proximal and distal sections, while the peroneal artery supplies the mid-section. Reproduced with permission from The arterial anatomy of the Achilles tendon: anatomical study and clinical implications. Chen et al in Clinical Anatomy, 2009.

Vessels enter through the layer of deep fascia covering the AT and then spread as a thin network of arteries within the paratenon, which is wrapped around the tendon. Surgical stripping of this layer would therefore compromise the blood supply to the tendon.[16] Open surgery to the Achilles tendon requires incision through the deep fascia and paratenon in order to access the tendon, with the potential to compromise blood supply to the tendon to some degree. Knowledge of the vascular anatomy and respect for the soft tissues are vital to minimise disruption to the tendon blood supply. Median based incisions in the paratenon have been advised, as have medial sided longitudinal incisions in the central portion of the tendon (to protect the laterally based peroneal supply to this part of the tendon) for open surgery and minimally or less invasive

approaches and techniques have also been described which may be associated with reduced tendon stripping and vascular compromise.[16]

The skin over the medial aspect of the AT is supplied by branches of the posterior tibial artery and that over the lateral aspect by the peroneal artery. The skin lying centrally over the posterior aspect of the tendon is a watershed area between the two and has the poorest blood supply.[1, 21] This, together with the relation to the sural nerve, is why surgical midline and lateral approaches to the tendon are best avoided.

1.1.3 Function of the Achilles Tendon

The AT forms part of a musculotendinous unit spanning three joints, whose action results in knee flexion, ankle plantar flexion and also inversion of the subtalar joint by virtue of its stronger medial pull on the calcaneum.[13] It is the main, but not the only, plantar flexor of the ankle and residual plantar flexion due to the action of the long toe flexors, tibialis posterior and the peroneal muscles may result in Achilles tendon injuries being missed on clinical assessment.[1] The Achilles tendon can also exert an inversion or eversion moment in varus or valgus hindfoot alignment respectively and in such scenarios can contribute to deforming forces, whereas in the extremes of these movements, it may resist them.[11]

Humans are bipedal mammals. Additionally, they are plantigrade, meaning that the full length of the foot is set down on the ground. This is in contradistinction to other large mammals, many of which are digitgrade (i.e. walk and stand on their toes) or ungulates (who walk and stand on hooves on the tips of their toes). In the sagittal plane, the human centre of gravity falls through a point anterior to the tibiotalar joint and this exerts a dorsiflexion moment on the ankle that must be countered by the plantar flexor muscles, acting largely through the Achilles tendon, to maintain an erect posture. Additionally, during walking, running or jumping, plantarflexion is important for propulsion. The gastrocnemius contains a higher proportion of fast-twitch muscle

fibres, which are used during periods of rapid propulsion (e.g. running or jumping). Conversely, soleus is more of a postural muscle, with a significantly higher proportion of slow-twitch fibres, which are recruited during simple standing and have lower fatigaubility.[1]

Forces acting on the Achilles tendon are significant, with studies showing that these are in the region of 2.1 times body weight with barefoot walking[22] and can reach as much as 12.5 times the body weight during running.[23]

1.2 Biomechanics and Pathophysiology of Achilles Tendon Rupture

The relationship between load and deformation in the Achilles tendon has been studied and shares many properties with those of other tendons.[24, 25] The stress-strain curve of a tendon (figure 1.3) is typically made up of various regions.[15, 24] Stress refers to the force applied per unit area of the structure and is measured in Newtons per metre squared (N/m^2). Strain refers to a ratio of the change in length relative to the original length of the structure and therefore has no units (since it is a ratio). A concave, non-linear toe region, which has been attributed to the resting crimp of collagen fibrils in a tendon, is observed at low levels of stress. Here, there is little resistance to tension as the fibres lengthen. With progressive stretching, the crimped fibres begin to straighten and an increasing number of fibres are recruited under tension. Thus the stiffness of the tissue increases and the stress-strain curve enters the linear region, where the slope of the curve is much steeper (i.e. the amount of load required to produce progressive deformation is higher). This region of the curve depicts an almost linear relationship between load and deformation, hence its name. The elastic modulus (a concept often referred to as Young's elastic modulus when applied to materials) is the stress per unit strain over the elastic or linear portion of the graph, i.e. the gradient of the graph in its linear portion, measured in N/m^2.

Its units are those of the numerator in this relationship (i.e. those of stress), since the denominator (strain), being a simple ratio, has no units of its own. Beyond the linear region, with increasing stress, failure of the tendon occurs. Initially this is at a microscopic level, as inter-molecular cross links fail and collagen fibres slide past one another.[24] There may be failure of a few greatly stretched fibres at the terminal extent of the linear region, that cause small reductions in stress, characterised by 'dips' in the stress-strain curve.[15] Eventually, with progressive loading, the ultimate tensile strength (P_{max} in figure 1.3) is reached and complete failure occurs rapidly, leading to macroscopic tendon rupture.

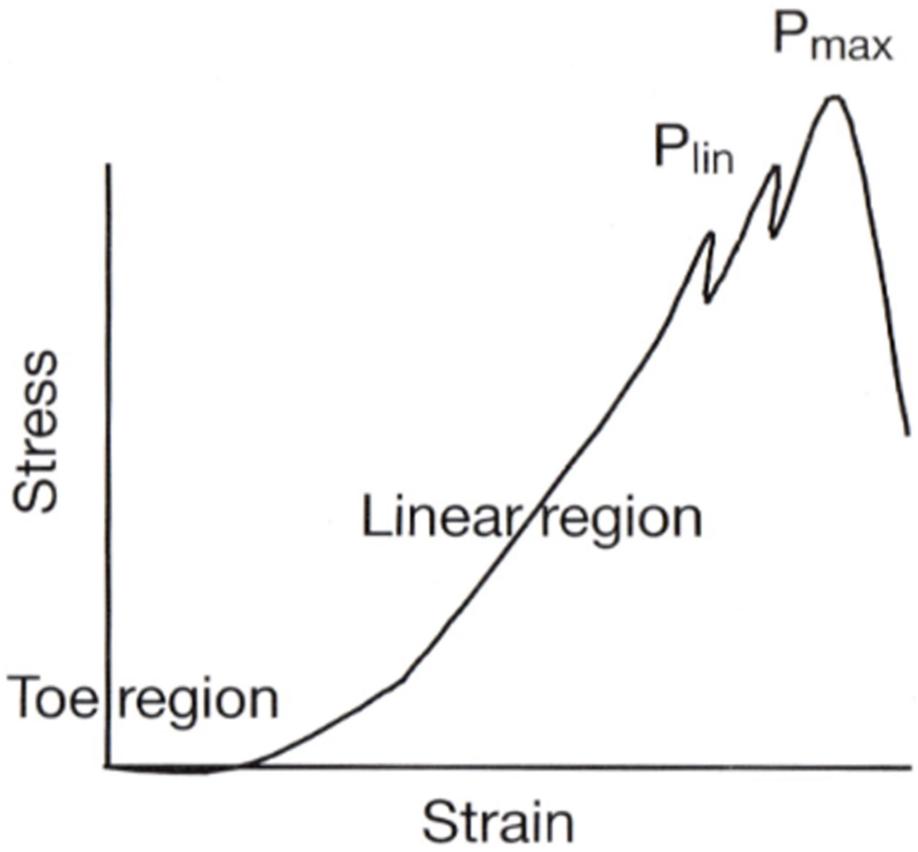


Figure 1.3. Stress-strain curve for tendon tissue. Stress refers to the force applied per unit area of the structure and is measured in Newtons per metre squared (N/m^2). Strain refers to a ratio of the change in length relative to the original length of the structure and therefore has no units (since it is a ratio). Reproduced with permission from Basic Orthopaedic Sciences: The Stanmore Guide, 2006. M Ramachandran.

Additionally, tendons are known to be viscoelastic in nature,[26] i.e. they exhibit stress-strain behaviour that is time and loading rate dependent.[15] It is generally thought that crimp is lost at a

strain of around 2% and that deformation is reversible up to a strain of around 4%, with progressive failure starting to occur between strains of 4 and 8% and ultimate failure and macroscopic rupture occurring at strains greater than 8%.[24] Although the concepts are widely accepted, there is some variation in the precise figures reported by different authors, which may be attributable to differing methodologies employed to measure the relationship between load and deformation,[17] with other studies reporting that crimp may persist until strains of 4% or even 6% are reached and that the ultimate strain at failure may be as high as 10%,[25, 27] while estimates of Young's modulus of Achilles tendons have ranged between 0.3 and 2 Gigapascals[17] and ultimate tensile strength has been reported to be between 20 and 100 Megapascals.[17] The Pascal is the unit of pressure utilised in the International System of Units (SI) and equates to one Newton per metre squared. The lower values were observed in sedentary adults.[17] Young's modulus, also known as the elastic modulus, refers to the gradient of the linear portion of the stress-strain graph and is defined as the stress per unit strain (expressed in N/m^2).[15]

Given the viscoelastic properties of tendons, it is unsurprising that both failure stress and failure strain have been shown to vary with the rate of loading[25] and these findings may explain why an in-vivo tendon may appear to be able to withstand higher stresses with certain activities or types of loading than others.[17] They may also explain some of the differences in key values noted between different studies.

Additionally, as stress (defined as the force per unit area and expressed in N/m^2) is dependent on both the cross sectional area of the tendon and the forces acting across the tendon, both these variables are of relevance to its ability to remain intact. Sex and age-related differences are also known to impact the biomechanical characteristics of the Achilles tendon. Male tendons have been shown to generally have greater cross sectional area than female tendons and to be stiffer and exhibit greater ultimate tensile strength.[12, 13] Despite this, however, they rupture more frequently and this may be due to differences in activity or forces generated, or other, as yet

unknown factors.[24] With ageing, the Achilles tendon becomes stiffer and its ultimate tensile strength decreases, while immobilisation and physical inactivity are associated with changes in cross-sectional area and negative effects on tendon properties.[13, 17]

Conditions that alter the mechanical properties of the Achilles tendon, altering the stress-strain curve, may predispose to ATR. Pathologic Achilles tendons are known to differ histologically from healthy tendons[17, 28] and in one large study, histological degenerative changes were noted in 97% (864 of 891) of spontaneously ruptured tendons.[29] Various processes that may lead to Achilles tendon degeneration and rupture have been described, among them tendinosis (a non-inflammatory, degenerative process which may predispose to rupture without prodromal symptoms) and chronic tendinopathy (characterised by paratenon inflammation and oedema which manifest with activity related pain).[20, 28] Tendinosis is characterised by disorientation of the parallel collagen fibres, enlarging tenocytes and vascular spaces and increased amounts of type III collagen.[20] Chronic tendinopathy often occurs with over-use and inflammation is associated with thickening, impaired tendon gliding and subsequent mucoid degeneration with or without calcific deposits which cause fissuring within the tendon.[20, 30] Prolonged chronic tendinopathy can also lead to degenerative changes similar to those observed in tendinosis.[20] Partial ruptures of the AT incite an inflammatory response and formation of type III collagen and also therefore alter the mechanics of the tendon.[17]

Ultimately, whatever the aetiological pathway, ATR is the result of an imbalance between the forces acting on the Achilles tendon and its ability to withstand and resist them. Any variable that effects either of these can therefore predispose to ATR.

1.3 Clinical Features and Diagnostic Imaging of Achilles Tendon Rupture

Achilles tendon rupture (ATR) is a common injury[31] and its incidence is rising.[32-40] It occurs most frequently with active, forceful plantarflexion of the foot,[41] although other described mechanisms include sudden unexpected, or forced, ankle dorsiflexion.[13] It is most commonly the result of a non-contact sporting injury.[40, 42-44] The commonest sports involved vary with location, although racket sports[43, 44] and jumping sports such as basketball[40] and volleyball[40, 44] feature particularly commonly, as does football.[38, 45] Other less common mechanisms include ascending or descending stairs, trips and falls or spontaneous rupture while walking.[42]

Patients typically report a painful popping sensation at the back of the ankle and often state that it feels like they were kicked in the back of the leg.[24, 46] There may be an accompanying audible snap.[24] Pain is felt around the posterior region of the ankle and there may be localised swelling or bruising as well as weakness of active plantarflexion. Around one third of patients may report prodromal symptoms preceding the rupture.[13] Clinical examination is most easily undertaken with the patient kneeling on the edge of a chair or lying prone. A tender, palpable gap along the length of the tendon is typical and may be best appreciated by applying gentle passive dorsiflexion to put the tendon on stretch, however it may be difficult to palpate in the presence of associated swelling[46] and has been reported to be a less sensitive and specific test than both calf squeeze and Matles' tests.[47] Calf-squeeze tests, known by their eponymous names, are the most well-known clinical tests for this injury. Thompson described the calf squeeze test in 1962, having first noted this clinical sign in 1955 and he confirmed his findings in a series of 21 patients with ruptured Achilles tendons.[48, 49] However, by the time he published his findings, Franklin Simmonds had independently described a similar test some five years earlier, in 1957.[50] The absence of foot plantar flexion on calf squeeze by the examiner is considered a positive test

indicative of complete tendon rupture.[51] Calf squeeze in an intact Achilles tendon is thought to induce plantar flexion by deforming the fleshy soleus tendon, causing the overlying gastrocnemius musculotendinous complex to bow and exert traction on the calcaneum. Proximal displacement of the tapered gastrocnemius muscle also occurs with calf squeeze, but its effect is relatively minor compared to the above described displacement caused by soleus.[52] Calf squeeze tests are reported to have very high sensitivity (96%-100%) and specificity (93%) in the diagnosis of Achilles tendon rupture.[47, 53, 54] It is postulated that an intact plantaris tendon may cause false negative calf squeeze tests even in the presence of a ruptured Achilles tendon, although this theory has not been scientifically proven.[24] Matles' test was described in 1975 and involves the patient lying prone and actively flexing the knees to 90 degrees. The ankle on the injured side remains in a neutral or dorsiflexed position with this manoeuver, while the uninjured ankle plantarflexes, indicating a positive test.[55] Matles' test is said to be more sensitive (88%) than palpation of a gap in the tendon (73%), although it is a less specific test (85% vs 89%).[47] All clinical tests should be performed on both the injured and uninjured ankles for comparison.

In the majority of cases, the diagnosis can be made clinically and imaging modalities are not required.[56] Although imaging modalities are used routinely in some protocols to confirm the diagnosis and more recently to measure tendon gaps to aid with decision making,[57, 58] surveys have indicated that the use of imaging modalities to confirm a diagnosis of Achilles tendon rupture is not routine practice in most units[59] and many modern treatment regimens do not use imaging modalities.[60-62] American Association of Orthopaedic Surgeons guidelines, albeit now somewhat dated, previously found insufficient evidence to make any recommendation for the routine use of imaging modalities in the diagnosis of Achilles tendon rupture.[63]

Plain radiographs may demonstrate abnormalities including a Toygar's angle <150° (this is the angle formed by the posterior skin surface curve on a lateral radiograph of the ankle), a positive Arner's sign[64] (characterised by the anterior contour of the Achilles tendon curving away from

the upper part of the posterior calcaneus) and reduced size and loss of sharp borders of Kager's triangle, a fat-pad filled space bounded posteriorly by the Achilles tendon, anteriorly by the flexor muscles of the calf and inferiorly by the superior border of the calcaneum.[65] The former two signs have low sensitivity.[65] Plain radiographs are not routinely used in the diagnosis of ATR, although they are routinely used in A&E when assessing ankle injuries and for this reason many patients with an as yet undiagnosed Achilles tendon injury may get radiographs of their ankle taken.

Ultrasonography is the most commonly used imaging modality for diagnosis of Achilles tendon rupture.[57, 58] It has been shown to be very sensitive and specific in differentiating complete ruptures from partial ruptures and tendinopathy.[66] In the presence of a ruptured Achilles tendon, hyperechogenicity is generally seen at the rupture site, along with irregular tendon edges, although a rupture site haematoma may also have hypoechogenic appearences.[56] Ultrasound has the benefits of allowing dynamic assessment, measurement of gap size and tendon thickness and it is relatively inexpensive but operator dependent.[13, 56, 67]

Magnetic Resonance Imaging (MRI) demonstrates disruption of the tendon signal on T1 sequences, while T2 sequences are characterised by increased signal intensity associated with oedema and haemorrhage, however it is non-dynamic and relatively expensive and less accessible.[24, 56] It has been suggested that MRI is time consuming and expensive and may lead to delays in treatment, while it is less sensitive than clinical examination and therefore should not be used for diagnosis in routine acute cases of rupture, although it may be useful in the assessment of chronic ruptures.[53]

Despite the high reported sensitivity and specificity of clinical tests for Achilles tendon rupture, the diagnosis has been said to be initially missed in up to 25% of acute presentations.[54, 56, 68, 69] Missed diagnoses may be due to a haematoma obscuring the tendon defect, retained plantar flexion of the foot due to extrinsic foot flexors or a false negative calf squeeze test due to

pressure exerted on the accessory foot flexors.[13, 54] Missed diagnosis leads to delayed or no treatment, resulting in a chronic rupture, with tendon elongation and worse long term outcomes, often requiring surgical intervention.[70-74] Despite this, factors predisposing to a missed diagnosis are poorly understood. It is therefore imperative that acute ATR are not only diagnosed, but appropriately treated, to prevent negative sequelae. However, there is much debate as to what constitutes the best current treatment for acute Achilles tendon ruptures.

1.4 Evolution and Controversies in the Treatment of Achilles Tendon Rupture

The first recorded description of Achilles tendon rupture was by Hippocrates, the ancient Greek physician who lived in the 4th and 5th centuries BC and is sometimes referred to as the 'father of Medicine'. He called it the 'tendo magnus' or 'neura megula', reflecting the confusion between tendons and nerves at the time and stated that 'this tendon, if bruised or cut, causes the most acute fevers, induces choking, deranges the mind and at length brings death.'[7] It is suspected that this description related to sepsis resulting from an open injury to the Achilles, although at the time there was neither detailed knowledge of infection, nor a clear distinction between nerve and tendon anatomy and function.[75] Hippocrates' proposed treatment is not described, but Galen advocated against tendon repair in the second century AD, while it is known that an Arabian surgeon by the name of Avicenna was attempting tendon repair in the tenth century AD. The Italian surgeon Guglielmo di Faliceto, in the twelfth century AD, believed that nature could not heal divided tendon ends and that these were best treated surgically, while in the fourteenth century AD, the French surgeon Guy De Chauliac attempted to defend surgical management of tendon injuries with moderate success.[2, 75] In the sixteenth century AD, Ambroise Paré described successful instances of Achilles tendon repair as well as a significant

incidence of wound problems with open Achilles tendon injuries and also gave the first clear description of closed subcutaneous rupture of the Achilles tendon. He stated that it could be caused by 'a little jump, the slipping aside of the foot, the too nimble getting on horseback, or the slipping of the foot out of the stirrup on mounting the horseback'. From his description, it appears that this injury was not uncommon. He also described symptoms and signs including an audible crack, a palpable gap in the tendon and difficulty walking due to plantarflexion weakness. His proposed treatment involved a long period of rest with the leg strapped in bandages dipped in wines and spices, however, he warned that outcomes were poor.[2, 24, 75] Jean Louis Petit, one of the foremost surgeons in Paris during the first half of the eighteenth century, reported three cases of acute ATR treated non-operatively with immobilisation in knee flexion and ankle plantar flexion, reporting good results, while in the same century, John Hunter, a famous Scottish surgeon, described treatment of his own closed Achilles tendon rupture with plantarflexion splinting using Munro's bandage and then a shoe with a heel raise. Munro, a Professor of Anatomy and Surgery in Edinburgh, had used this bandage, which maintained foot plantarflexion, as well as a subsequent splint and shoes with heel raises, to treat his own closed Achilles tendon rupture previously.[2] With advances in anaesthesia and antiseptic technique at the end of the nineteenth century, surgical treatment of these injuries became a viable alternative to non-operative treatment and the French surgeon Pollailon described the first case of surgical repair of a closed ATR in 1888.[75] The controversy regarding optimal treatment of ATR intensified thereafter in the twentieth century.

In 1929, Quénu and Stoianovitch reviewed the literature and compared surgical treatment in 29 patients (of whom 2 were their own patients) with non-surgical treatment in 39 patients. The authors' claimed excellent results in their own patients and were clearly in favour of surgical repair.[2, 76] Sir Harry Platt reported a series of eleven cases of surgically treated ATR in 1931 with 'perfect' or 'excellent' function reported for ten of these and 'good results with some calf

elongation' for one.[77] Lawrence et al reported experience with surgical repair for ATR at the Massachusetts General Hospital in the United States of America, between 1900 and 1954 and also advocated in favour of surgery, stating that 'although an occasional case has been reported as being successfully treated with conservative measures, these patients undoubtedly had incomplete tears'.[69] There was no evidence put forward to support their claim that successfully treated non-operative cases were partial tears of the Achilles tendon. The trend towards surgical treatment continued through much of the 20th century such that it became the preferred method of treatment in many centres,[78, 79] although some studies in the 1970s and 1980s reported good results with non-operative treatment of ATR,[7, 80-83] re-igniting debate as to the best treatment for these injuries.

Both traditional operative and non-operative treatment regimes involved prolonged periods of immobilisation in varying degrees of ankle equinus.[4, 78, 84, 85] The main benefit of surgery was found to be a lower re-rupture rate, with the difference in re-rupture rates being more marked with traditional immobilising rehabilitation regimes[86-89] and significantly less so with more modern functional rehabilitation regimes.[89-91] Considerable debate as to whether surgical treatment yielded superior results to non-operative management and discussion around the risks associated with surgical treatment persisted[78, 82, 85, 86, 91, 92] and both continue to be widely used in mainstream practice, with significant geographical variation.[32, 37, 93, 94] This has led to multiple randomised controlled trials comparing operative and non-operative management of these injuries, however all of these reported only on short term outcomes at one or two years,[4, 57, 62, 84, 88, 95-97] with only one comparative study reporting on mid-term outcomes at a mean of seven years after injury[60] and no comparative studies reporting on long term results have previously been published in the medical literature. This is surprising, given that ATR often affects middle aged individuals[32, 35, 37, 38, 43] who are expected to remain physically active for many years after their injury.

Isolated reports of functional non-operative management regimes appeared as far back as the mid-1990s[98] but it was only more recently that authors began to question whether prolonged periods of immobilisation are required[99] and functional rehabilitation regimes permitting earlier weight-bearing and/or controlled mobilisation have become popular.[61, 62, 88, 95, 99-107] It has also been reported that early weight bearing is associated with an improved early healing response in the ruptured Achilles tendon.[108] Re-rupture rates with modern functional rehabilitation regimes have been reported to be comparable for surgical and non-surgical treatment[89, 90, 103] although some large studies and meta-analyses continue to show clinically small differences in re-rupture rate in favour of surgical management but with a demonstrable incidence of surgical complications.[91, 109-116] Although regimes with elements of functional rehabilitation have been in use for a number of years,[107, 117-125] it was the publication of some high-profile prospective randomised comparative studies, published after the turn of the century and advocating functional non-operative treatment on the basis of a low re-rupture rate and avoidance of the potential risks associated with surgery, that appears to have spurred recent trends towards non-operative management, which became increasingly popular from the end of the first decade of the twenty first century.[32, 37, 62, 88, 90, 95, 97, 105, 126-128] The trend towards non-operative functional rehabilitation has, as with most previous treatments for ATR, exhibited marked geographic variation,[129] being most notable in Europe and Canada,[32, 37, 105, 128] while studies from other countries, such as the United States of America and Japan, continued to report increasing rates of surgical management in comparison to non-operative management.[93, 94]

Controversy therefore persists in modern day practice[130, 131] and although practice in most countries appears to be shifting towards functional non-operative management, the evidence base underlying this shift has been criticised for its quality and also because the conclusions drawn by some authors are not necessarily supported by the underlying study design and methodology[99] and it has been shown that widely employed clinical practices are often not supported by robust

scientific evidence.[131-133] There is therefore a need for adequately powered studies that directly compare traditional and modern functional rehabilitation regimes.

1.5 How Can Outcomes Be Measured After Rupture of the Achilles Tendon?

1.5.1 Evolution of Outcome Measurement in Orthopaedics and Achilles Tendon Injury

Outcome reporting is essential to quantify the effects of an injury or condition and to measure the success or failure of a given intervention, enabling it to be compared objectively with other potential treatment methods. Outcome reporting is also important as it aides medical professionals and patients to make informed decisions about treatment and to discuss expected outcomes and the likelihood of adverse events with patients when embarking on a treatment regime. Outcome measures in medicine have evolved significantly over the years.

Early research in the field of trauma and orthopaedics tended to focus on binary outcome measures, often relating to patient or implant survival[134] or the incidence of adverse events or complications.[135, 136] The same is true for research in the field of Achilles tendon rupture where re-rupture or surgical complications were frequently the main outcome measure reported.[87, 137] While these are undoubtedly important negative outcomes, they are relatively rare and such reports usually did not give information about outcomes in unaffected patients who represent the majority of those treated.[138] Furthermore, the effect of occurrence of these events on function was often not quantified.[87, 134-137]

Additionally, authors often reported subjectively on outcomes, for example, claiming ‘fair’, ‘good’ or ‘excellent’ results, without defining these terms to readers[54, 69, 77] or using only relatively vague criteria to define these groupings.[139] Subjective outcome measures are

misleading and do not allow reliable comparison with the results of other author groups in the wider literature.

As research methodology progressed, physical measures of patient status were undertaken and reported (for example calf circumference or range of motion of the ankle joint) and attempts were made to quantify function after treatment for these injuries, often using crude and indirect measures of function (e.g. return to work or sports).[7, 80, 84, 87] Physical measurements provided a more objective (albeit at times non-standardised) measure of outcome and allowed direct comparison of individual patients' status with the results from studies as well as facilitating comparison between studies. Physical measures commonly used in the field of Achilles tendon rupture include clinical measurements taken at the time of examination (e.g. calf circumference or ankle joint range of motion)[4, 84] and attempts to measure power of ankle plantar flexion.[4, 80, 83, 124, 139]

Physical measures of outcome continue to be reported today, although the methods for recording and reporting these have become more complex and refined with the passage of time. Initially, range of motion measurements were reported to the nearest 5 degrees,[80] whereas more modern studies, including those in this thesis, utilise goniometers that are able to record range of motion to the nearest degree. Measurements of plantar flexion power were originally undertaken using relatively crude contraptions constructed by investigators,[139] or basic spring devices,[124] but with the increasing availability and use of technology, more complex measures of function have become possible, for example, measuring dynamic forces generated at the ankle joint using a dynamometer,[4, 95, 140] calculating work done using linear encoders,[60] or the measurement of plantar pressures under the foot using footplates.[98]

It was also realised that subjective and arbitrary classification of outcomes could be misleading and efforts were made in many fields of orthopaedic study to derive scores that allowed a degree of standardisation. Early scoring systems in orthopaedics[141, 142] and also in the

field of Achilles tendon rupture,[143] tended to combine physical clinical measurements (e.g. range of motion) with some basic patient answered questions about pain and function, which facilitated the combination of multiple measurements into a single numerical value said to represent the patient's overall status. This approach reflected prevalent beliefs at the time that physician reported outcomes were the gold standard. However, such scores continued to often be divided by researchers into arbitrary categories of function (e.g. 'fair', 'good' and 'excellent')[144, 145] to facilitate statistical analysis.

In modern practice, it is increasingly recognised that assessment of outcomes after treatment is a complex and nuanced field, which is multi-faceted. It is acknowledged that there are often significant differences between patients' and physicians' perceptions of outcomes[146, 147] and that more importance must be given to the patients' perception of outcome.[138] Many authors advocate that this is in fact the most important measure of outcome,[148, 149] given that the focus in many modern health systems is on improving and maintaining quality of life. Patient reported outcome measures (PROMs) have therefore become increasingly prominent in the medical literature and also in the assessment of healthcare delivery on a wider scale,[138] where they are also being used to guide management decisions and to set benchmarks for expected standards.[150]

PROMs can be simply described as a patients' report of the status of their health.[151, 152] Advocates of the use of PROMS state that they provide a sophisticated measure of whether a patient feels better and quantify by how much.[138] These tools allow quantification of the patient's perspective of outcome as a single score, which facilitates comparison between patients and studies. While outcomes reported by patients were initially described as subjective outcomes by some authors,[146] with increasing evidence of their robustness, they have come to be regarded as objective measures of outcome on which important decisions can be based.[151] In modern orthopaedic practice, PROMs are used extremely widely in clinical research,[153-156] including in the field of Achilles tendon rupture[4, 60-62, 97, 157, 158] and are routinely collected for various elective

orthopaedic procedures in large national orthopaedic registries,[159-162] which utilise PROMs to measure outcomes.

Various different types of PROM scores exist, including those designed to measure outcome after a specific type of injury (e.g. the Achilles Tendon Total Rupture Score – ATRS),[163] those designed to measure functional outcomes in a specific joint (e.g. the Foot and Ankle Questionnaire,[164] the Oxford Knee Score[165] and the Oxford Hip Score[166]) or limb (e.g. the Quick Disabilities of the Arm Shoulder and Hand (QuickDASH) score[167]) and those designed to assess general musculoskeletal function (e.g. SMFA[168]). Just as the measurement of physical and clinical parameters has advanced with time, it was increasingly appreciated that not all scoring systems previously used in the field of orthopaedics were necessarily appropriate and the importance of objectivity, validity, reliability and responsiveness of scoring systems became increasingly evident.[147, 151, 169-171] Successful modern scoring systems, including the SMFA[168] and ATRS scores,[163, 169, 172]have been subjected to detailed psychometric and statistical analysis to ensure that they meet these criteria.[169, 171]

The term validity encompasses concepts including construct validity, criterion validity and content validity[171] and essentially refers to the ability of the tool to measure what it actually proposes to measure.[151] Responsiveness refers to the ability of the PROM to detect clinically important changes over time, even if these are small.[173] Reliability refers to the ability of an outcome measure to distinguish between patients[171] and is often evaluated by assessing test-retest reproducibility.[151] Additionally, some authors argue that PROMs are more objective than physician administered outcome tools, since they negate the need for an observer to administer the tool, thereby reducing the risk of observer bias.[151] As may be expected, many PROMs have also been shown to correlate with physical clinical measures,[174] although it is clear that these are distinct entities measuring different aspects of outcome[175] and that many other factors also influence patient reported outcomes.[149, 175, 176]

Patient reported outcome tools have also been developed to measure patient reported health related quality of life (e.g.: EQ-5D, SF-36).[177-179] More recently in the wider field of orthopaedics, there has been a trend towards reporting not only on an affected joint or bone, but also on its effect on patients' overall perception of their general health. In addition, there is increasing use of other overarching measures of patient satisfaction and sentiment, which have been explored to complement the reporting of PROMs, using concepts such as overall patient satisfaction, patient willingness to undergo similar treatment again or to recommend similar treatment to others.[149, 180-182] However, there is minimal existing data in this regard for Achilles tendon rupture,[81, 88, 96]with this type of research lagging behind that in the wider orthopaedic field and implying a lack of detailed understanding of patient sentiment towards treatment regimes for ATR, beyond the previously reported physical measures and PROM scores.

PROMs and measures of patient satisfaction and sentiment are increasingly being used to guide decisions in healthcare provision and management.[138, 183] They have been routinely collected for patients undergoing some elective procedures in the National Health Service in the UK, as well as private healthcare institutions,[150, 184] while the NHS in England has also mandated the widespread use of the NHS Friends and Family Test.[185, 186]

Outcome reporting in medicine and more specifically in the field of trauma and orthopaedics and Achilles tendon rupture has progressed significantly over a number of years from initial reporting of 'lack of complications', to measurement of physical parameters and latterly, to a patient-centred approach to outcome measurement.[180] Study design and methodology has also improved dramatically with the passage of time, while reported results are subjected to significantly greater scrutiny and statistical review with great rigour during the peer-review process.

In order to give readers a well-rounded and multi-faceted understanding of outcomes, modern high quality studies should therefore include a selection of outcome measures from various

categories discussed above, including both physical and clinically measured outcomes as well as a variety of patient reported outcomes that give an overview of patient perceived outcomes relating specifically to their injury as well as to joint function, musculoskeletal system function and health related quality of life. These should be complemented by other measures of patient sentiment and satisfaction and the relationships between these variables explored to give a more complete understanding of outcomes after treatment for these injuries.

The clinical outcome studies included in this thesis (Chapters 4, 5 and 6) include a variety of outcome measures from the above categories and aim to give a better understanding of outcomes after ATR, adding long-term PROMs and patient satisfaction and sentiment data to the earlier physical measurement and PROMs data from a randomised controlled trial comparing traditional non-operative and operative management regimes and also reporting on short term PROMs data from a prospective trial comparing traditional non-operative management with a modern functional rehabilitation regime. Additionally, the final study in this thesis aims to further explore more detailed physical measures of function in the modern non-operative functional rehabilitation regime, including plantar pressure data and various Achilles-specific parameters (e.g. Achilles Tendon resting angle and Achilles tendon length measure) in addition to routinely collected physical measures and to report on PROMs, HRQoL and measures of patient satisfaction and sentiment, to give a detailed understanding of the interaction between biomechanical and functional outcomes after treatment of ATR with a modern functional rehabilitation programme and how these change in the months following injury.

1.5.2 Patient Reported Outcome Measures Used in the Studies Comprising this Thesis

The studies undertaken for this thesis have been designed to report on a variety of outcome measures including the incidence of adverse events at short and longer term time points, clinical and physical measures of outcome (e.g. calf circumference, range of motion, ability to heel-raise) and an array of PROMs covering injury specific function (e.g. ATRS),[163] joint specific function (e.g. Foot and Ankle Outcomes Score)[164] and general musculoskeletal dysfunction and disability (e.g. SMFA).[168] Additional measures of outcome that have recently become topical are also reported on, including health related quality of life PROMs, patient satisfaction, net promoter scores,[180, 187] the friends and family test[185, 186] and willingness to undergo similar treatment again, thereby giving a multi-faceted and holistic overview of outcomes after acute Achilles tendon rupture.

Some of the scores reported in multiple studies in this thesis are detailed below.

1.5.2.1 Short Musculoskeletal Function Assessment (SMFA)

The SMFA is a 46 question PROM[168] derived from the longer (101 question) Musculoskeletal Function Assessment.[188] The Musculoskeletal Function Assessment is a valid and reliable outcome tool that compares favourably to other disease specific and generic outcome PROM tools,[189] but is best suited to research rather than clinical settings due to its length and detail.[168] In completing the SMFA questionnaire, patients answer each of the 46 questions using a 5 point Likert scale (where 1 represents good function or less bother and 5 represents poor function or more bother).

Dysfunction and bother indices are then calculated from their responses. The dysfunction index is calculated from 34 questions (questions 1-34) and reports patients' perception of their functional performance, using 25 items that assess how much difficulty patients have when

performing certain functions and 9 items that assess the frequency of difficulty when performing certain functions. Additional mobility, daily activities, emotional status, and arm/hand disability *category* indices can also be calculated from the dysfunction section of the score. The bother index is based on 12 items (questions 35-46) and records how much patients are bothered by problems in broad functional areas.

All indices are calculated using an algorithm (the basic algorithm formula for index standardisation is shown in figure 1.4) that can be applied to either the dysfunction (questions 1-34) or bother (questions 35-46) questions, or to the individual disability categories (see Appendix 1.1). Indices are reported on a scale between zero and 100, where lower scores represent better function. Missing scores can be accounted for in the dysfunction section of the score, by substituting them for the mean value of the corresponding category question responses, provided that less than 50% of responses are missing in any one category. Missing scores in the bother section of the questionnaire cannot be accounted for and preclude calculation of the bother index.

The SMFA has been shown to be valid and reliable as well as responsive to change in status in patients with musculoskeletal disease and injury. On this basis, it is reported to be suitable for clinical assessment of impact of treatment in patients with musculoskeletal injury.[168] It has been widely used in orthopaedic research and has been translated into a number of other languages, with each of these translations confirming its validity, reliability and responsiveness.[190-192]

The SMFA was utilised in the original randomised controlled trial that forms the basis for the long term follow up study in Chapter 4,[4] facilitating direct comparison of short and long-term scores for the patient cohorts in this study. The SMFA is particularly useful for demonstrating changes over time, given its reported excellent reliability.[168] It was chosen as the primary outcome measure in two of the clinical studies due to its favourable psychometric properties[168] and the defined minimum clinical important difference (MCID),[193] which facilitated a prospective power analysis.

$$\text{Standardised Index} = \left(\frac{(\text{actual raw score}) - (\text{lowest possible raw score})}{\text{possible raw score range}} \right) \times 100$$

Figure 1.4. Standardisation algorithm that is applied to SMFA dysfunction and bother questions and SMFA categories to calculate standardised indices.

Please see Appendix 1.1 for the full SMFA questionnaire and a list of the individual index and category constituent questions.

1.5.2.2 Achilles Tendon Total Rupture Score (ATRS)

The Achilles Tendon Total Rupture Score (ATRS) is a 10 question PROM that was described in 2007[163] and has been shown to be sensitive, valid and reliable in the assessment of patients with Achilles tendon rupture.[163, 194] Patients are asked to answer each question on a ten point scale, where a lower score indicates more disability. The sum of these 10 individual question scores constitutes the ATRS, which ranges from 0 (most disability due to their Achilles tendon) to 100 (least disability relating to their Achilles tendon).[163] Missing question responses are calculated as a score of 0 provided that no questionnaire has more than 2 missing questions.[163]

It is a modern, injury-specific PROM and has been shown to be highly reliable, valid and responsive.[163, 172, 194] In recent years, it has been widely used in clinical studies of outcome after ATR.[60-62, 97, 101, 157, 195, 196] Systematic reviews of PROMs used in Achilles Tendon Rupture have concluded that it is valid and presently the most appropriate PROM for evaluating ATR management[169] and it has become the most widely used PROM in high level studies in the field of ATR.[195] Thus, its ubiquitous inclusion in all clinical studies in this thesis is considered a strength of these studies and also facilitates comparison of results with other studies in this field.

Despite the above, the ATRS was not used as the primary outcome measure in the clinical studies comprising this thesis. The reason for this is that the MCID for this score has not been

scientifically defined and therefore a robust power analysis is not possible without making significant assumptions. This is reflected in the wider literature on ATR: although many trials report the ATRS as part of their outcomes,[60, 62, 97, 157] few use it as the primary outcome measure.[62, 157, 158] Interestingly, a RCT undertaken by the authors who described the ATRS similarly reports on the ATRS as a secondary outcome measure, but is powered on tendon re-rupture as the primary outcome measure, in keeping with this trend.[97]

Of those who used the ATRS as the primary outcome measure, Olsson et al[62] used the minimum detectable change (MDC) to power their study, but this raises questions, since studies are normally powered on the MCID not the MDC and the MDC is a completely different variable to the MCID. Furthermore, they used an MDC of 6.8, as described by Carmont et al,[197] while other studies have reported very significantly different values for the MDC.[198] Barfod et al[157] used the ATRS as the primary outcome measure in their study but stated that they 'assumed' a clinically relevant difference to be that of 10 points. For a power of 0.9, they determined that 22 patients would be required in each group. No scientific basis was provided to substantiate this assumption. A recent large RCT by Costa et al also[158] used the ATRS as the primary outcome measure, but the trial protocol described by the authors[199] stated 'We have *chosen* a minimum clinically important difference (MCID) for the ATRS of 8 Points' which was justified by stating that 'at a population level, 8 points represents the difference between a 'healthy patient' and a 'patient with a minor disability'.' The work of Kearney et al was referenced to support this statement although it should be noted that the paper by Kearney et al did *not* define an MCID for the ATRS and in fact called for further study to determine the MCID and other score metrics for the ATRS.[172] Therefore, this choice of 8 points, while based on a logical thought process, also makes assumptions as to the MCID, reflected in the terminology used by the authors when they state that this MCID was 'chosen' from the available data.

Please see Appendix 1.2 for the full ATRS questionnaire.

1.5.2.3 Foot and Ankle Questionnaire (FAQ)

The Foot and Ankle Questionnaire (FAQ) is a 25 question PROM developed by the American Academy of Orthopaedic Surgeons (AAOS) in 2005 to measure foot and ankle related disability.[164] It is reported as foot and ankle core and shoe comfort scales, calculated from 20 and 5 question responses respectively. The questions assess 5 categories (pain, function, stiffness and swelling, giving way and shoe comfort). Each question is scored on a scale of 1 to 5 (or 6 in some instances), with lower scores representing better function. Raw scores are then converted into a standardised percentile score ranging between 0 and 100, with higher scores now representing better function. It has been reported to be reliable and valid[164] and to correlate with other foot and ankle specific outcome measures.[200] It was included in the randomised controlled trial comprising Chapter 5 of this thesis as it was felt that an anatomic-specific PROM would complement the injury-specific (ATRS) and general musculoskeletal (SMFA) PROMs being collected in this study.

Please see Appendix 1.3 for the full FAQ.

1.5.2.4 EuroQol 5-Dimension Questionnaire (EQ-5D)

The EuroQol 5 dimension, 5 level questionnaire (EQ-5D-5L) consists of a patient completed questionnaire comprising of 5 domains (mobility, self-care, usual activities, pain and discomfort and anxiety and depression).[177] The patient response for each domain is scored between levels 1 and 5, with lower levels representing less problems, while higher levels represent more problems in the corresponding domain. The 5 responses are summarised into a 5-digit code, which represents a unique health state and which can be converted into a single numerical EQ-5D index value which summarises the patient's overall health state. A total of 3125 different possible health states are defined in this way. Index values are calculated using an algorithm that attaches

weights to each of the levels in each dimension and are adjusted to be population specific.[201] EQ-5D-5L Index scores in the United Kingdom range between +1 (indicating full health) and -0.59.

The EQ-5D health today visual analogue score asks patients to rate their overall health on a vertical visual analogue scale between 0 (worst imaginable health) and 100 (best imaginable health) and to then transcribe the numerical value that corresponds to the chosen point on the linear scale.[201]

The EQ-5D-5L tool has favourable psychometric properties[202] and has been shown to exhibit significantly less ceiling effect than its predecessor, the EQ-5D-3L.[178, 203]

It is widely used in various fields of research and provides a measure of patient perceived Health Related Quality of Life as compared to the general population. It facilitates comparison of patients' scores with their corresponding general population and also facilitates comparison of cohorts with a particular condition with others suffering from other conditions. Health status for cohorts can also be followed over time and the EQ-5D also permits economic evaluations. Thus, it is widely used in the planning of healthcare and to help make decisions as to the most cost effective treatments.[204]

Collection of EQ-5D data in the clinical studies included in this thesis permits reporting on HRQoL in addition to the musculoskeletal and disease specific PROMs, in patients treated for ATR. It also facilitates analysis of the relationship between persistent functional residual deficits after ATR, as demonstrated on PROMs scores, with general HRQoL, to determine whether patient perceived functional deficits that persist after ATR result in a corresponding reduction in patient perceived HRQoL. Such relationships have not previously been explored in the field of ATR, although they have been demonstrated in other injuries.[181, 205]

Please see Appendix 1.4 for the full EQ-5D-5L and EQ-5D VAS score questionnaires.

1.5.2.5 Net Promoter Score (NPS)

The net promoter score is a single-question metric, first described by Reicheld in 2003 and focusing on the likeliness of an individual to recommend a good or service to others. It is widely used in industry, where positive scores are generally well regarded and scores greater than 50 are said to represent good performance.[187] Service users are directly asked whether they would recommend the service to others. Based on their response, respondents are then classified as 'promoters' (who are certain to recommend the service), 'passives' (users who are happy overall but may not actively promote it), or 'detractors' (who actively discourage others from using the service). The NPS is then calculated by subtracting the number of detractors from the number of promoters and dividing the resulting value by the total number of respondents, multiplying the resulting value by 100 (figure 1.5). Possible Net Promoter Scores range between -100 (if all service users are detractors) and +100 (if all service users are promoters). Proponents of this system argue that it correlates strongly with business growth in industry[187]

$$NPS = \left(\frac{[Promoters\ (n)] - [Detractors\ (n)]}{[Total\ Responders\ (n)]} \right) x100$$

Figure 1.5. Net promoter score algorithm.

The NPS formed the basis for the original NHS Friends and Family Test,[185] thrusting it into the spotlight in the medical world, although it had already previously been reported in the field of otorhinolaryngology some years earlier.[206] Subsequent to this, the NPS became more topical in medical circles and in recent years it has been studied and reported for various procedures in the field of orthopaedics, including lower limb arthroplasty,[180] elective hand surgery[207] and hip arthroscopy for femoroacetabular impingement.[181]

In the original NPS, customers were asked to rate the likelihood of them recommending a service on a scale of 1-10, with those scoring 9 or 10 termed 'promoters' and those scoring ≤6 termed 'detractors'.[208] Subsequently, various modifications on this theme have been used, retaining largely similar proportions on different scales, for example analogue scales ranging between 0 and 100,[207] or Likert scales with ordinal responses.[180, 181]

Regardless of the precise form, the aim of the NPS is to quantify patient sentiment in a single numeric value and using a single simple question. While the NPS has been shown to correlate with satisfaction and PROM scores in orthopaedic studies, it is clear that it is also influenced by other independent factors (e.g. patients' hospital experience) and that it is a separate measure of outcome from these, falling within a spectrum of patient reported measures that can be reported together to give a comprehensive overview of outcomes.[180, 207] It has been suggested that it may be a useful tool when counselling patients and that they may be reassured by data coming from peers undergoing similar treatment as opposed to relying only on functional assessments reported by a surgeon.[207]

There are no reports of NPS data in the context of Achilles tendon rupture and collection of this data in two of the clinical studies in this thesis, spanning traditional non-operative and surgical management and functional rehabilitation with early weight bearing, will help improve understanding of these injuries and patient perceived outcomes after treatment for ATR and will facilitate assessment of factors influencing NPS after treatment for ATR.

Please see Appendix 1.5 for the NPS questionnaires used in the clinical studies in this thesis.

1.5.2.6 Friends and Family Test (FFT)

The Friends and Family test was introduced in the NHS in England in 2013.[209] Its use was based on the premise that patients have a right to participate in giving feedback to the NHS pertaining to care received and additionally, in relation to their future care, have a right to be able

to see what others have said after experiencing this care. At its inception, it was a modified version of the Net Promoter Score and was reported as such,[185] although guidelines for data analysis were subsequently updated to recommend simply reporting the likelihood of an individual to recommend a service as a percentage.[186]

The question posed in the FFT up until April 2020 was structured in the same way as that posed to patients in two of the clinical studies included in this thesis,[185] i.e. How likely are you to recommend this treatment to friends and family if they needed similar care or treatment? The same six Likert options were also available to patients in the studies in this thesis and patients completing the FFT in the NHS: 'Extremely likely', 'Likely', 'Neither Likely nor Unlikely', 'Unlikely', 'Extremely Unlikely' and 'Don't know'. Data in this thesis is presented in both the original FFT format (NPS) and the subsequent updated FFT format.[186]

Initially FFT data was collected for emergency services in A&E, but it was rapidly rolled out across various sectors and is now used routinely in all major parts of the NHS in England.[209] By 2019, over 75 million episodes of FFT feedback had been collected by NHS England. Results are published monthly online by the NHS in England,[209] facilitating the monitoring of standards in a given service over time, as well as comparison with other similar services, although both critics[210] and NHS England[185] have warned that while measurements within a service or institution can be safely compared, FFT scores are affected by multiple variables and are also dependent on the precise method of data collection, such that comparisons between institutions may be problematic, given variation in conditions and data collection.

However, FFT results reported in this thesis should not be susceptible to these concerns, since the treatments were administered within the same service and the question wording was identical. In April 2020, a new question began to be implemented in the place of the previous recommendation question, which solicited feedback from patients on the overall experience of using the service.[209]

The widespread use of this metric has resulted in a high profile and studies have reported FFT metrics in combination with the NPS metric for various orthopaedic procedures,[180, 181, 207] although data pertaining to ATR is lacking.

Please see Appendix 1.5 for the FFT questionnaire used in the clinical studies in this thesis.

1.6 Rationale for the Studies Comprising this Thesis

Achilles tendon rupture is a common soft tissue injury.[31] Various management options exist and the optimal management of these injuries has been the subject of intense debate through the years, with clear trends emerging and reversing, towards one or other management preference over time.

Prior to attempting to describe the potential solution to a problem (in this case, optimal treatment for Achilles tendon rupture), one must have a thorough understanding of both the scale and nature of that problem. This sentiment is one articulated by various luminaries and successful leaders. Albert Einstein once said 'Given one hour to save the world, I would spend 55 minutes defining the problem and 5 minutes finding the solution'. Similarly, Claudia Juech, managing director of the Rockerfeller Foundation, a multi-billion dollar medical science and arts funding philanthropic organisation, stated in an interview, that 'Before we can solve a problem, we need to know exactly what the problem is, and we should put a good amount of thinking and resources into understanding it.'[211] Hence, the second chapter of this study seeks to describe the epidemiology of ATR in a defined population and to better understand the causes of these injuries, while the third does the same for Achilles tendon re-ruptures. Together, these chapters effectively attempt to better understand how and why these injuries occur and define the scale of the problem.

Studies have consistently demonstrated an increasing incidence of these injuries,[32, 33, 36-38, 212] thus ensuring that research into ATR remains topical. These and other studies have defined the commonest modes of injury and identified certain risk factors for ATR, including male gender, age and use of specific medications such as steroids or fluoroquinolone antibiotics.[32, 36, 213, 214] Socioeconomic deprivation status (SEDS) is known to influence the incidence of various traumatic and degenerative orthopaedic conditions.[215-219] However, no studies have previously assessed whether incidence of ATR varies with SEDS. If such a relationship were shown to exist, then further analysis would be warranted to explore the context of this relationship. This may facilitate explanation of any such relationship and provide insight into patterns of geographic variation in incidence of ATR, which would be useful in the planning of healthcare provision across geographical regions. The second chapter in this thesis seeks to address these issues by reporting on the incidence of ATR in a defined population and exploring its relation to both known and unknown potential risk factors, including SEDS.

An integral part of the exercise of defining the scale of the problem faced, is formulating a better understanding of the potential consequences of the problem (in this case Achilles tendon rupture). Perhaps the most well-known and feared complication of ATR is re-rupture of the tendon. While re-rupture rates are widely reported for various different treatment regimes[85, 91, 97, 99, 220-222] and have been used as the primary outcome measure in meta-analyses,[91, 99] few studies explore re-ruptures in any greater detail than simply reporting their incidence in study cohorts and there is a distinct lack of epidemiological studies on Achilles tendon re-rupture (ATRR). Additionally, there are only a handful of studies focusing on the context of repeat injuries and seeking to establish who is at risk of these. One study suggested that males are at increased risk of re-rupture.[223] Surgical management of the primary injury has been reported to reduce re-rupture rate.[91] While it has been suggested that modern functional rehabilitation regimes for primary ATR may be associated with lower levels of re-rupture, the authors of a previous meta-

analysis lamented the lack of direct data to support this theory.[99] The study in Chapter 3 therefore seeks better understanding of ATRR. It aims to determine the epidemiology of ATRR in a health-board population and review the context of these injuries and also to identify risk factors that predispose to ATRR at the time of primary ATR. Identification of any such risk factors will inform patient counselling for high risk patients and potentially facilitate targeted preventive interventions for such individuals.

The controversies surrounding optimal treatment for ATR have resulted in various studies being undertaken to report on outcomes using different management protocols and randomised controlled trials being set up to directly compare competing treatment regimes, with their results collated in a number of systematic reviews and meta-analyses.[91, 92, 220-222, 224-226] The medical literature is therefore replete with various studies in this field. Choice of management regimes and therefore clinical practice have clearly been affected by some of these studies over the years.[32, 37] However, objective reviews of practice have demonstrated that despite a wealth of published studies, chosen treatment regimes often do not follow a robust evidence base or evidence based guidelines and that current trends in mainstream clinical practice do not necessarily reflect those of most academic interest in the published literature.[99, 131-133, 227]

Additionally, despite the large number of published studies in the field of ATR, there are some surprising and significant gaps in the existing literature. Two major controversies have dominated debate on the management of ATR in recent decades. The first is the choice between operative or non-operative management for these injuries,[78, 91] while more recently, despite persisting arguments for and against surgical and non-operative management of ATR, the focus of debate has shifted to the use of functional rehabilitation over traditional rehabilitation techniques, despite an apparent lack of direct data to support this concept.[99, 132] Following on from the second and third chapters which shed light on the incidence and nature of ATR and

ATRR, the next chapters in the thesis examine the treatment of ATR in detail, while also reporting on re-rupture rates for the various treatment regimes under review.

The traditional debate over the merits of operative and non-operative management has been informed by several randomised controlled trials but these only report on short-term outcomes, with a complete lack of any long-term comparative studies.[4, 57, 62, 81, 84, 88, 95-97] This is surprising, given that these injuries are common, their incidence is rising and their predominant occurrence in middle-aged individuals means that patients are expected to continue to remain active for many years after their injury.[32, 36, 37] There appears to have been a shift from surgical to non-operative management of ATR in many regions in recent years, despite a lack of understanding of the long term outcomes for patients treated with either of these regimes.[32, 36, 37] There is therefore a need for a randomised controlled study that utilises modern outcome measures and compares outcomes between traditional operative and non-operative management at long term follow up. Such a study is described in Chapter 4 of this thesis.

If longer term outcomes after traditional non-operative management are shown to be comparable to those achieved with surgical management, this would provide justification for its ongoing use and indicate a need for further studies of different non-operative management regimes to assess their relative efficacy, in particular to compare traditional non-operative management of ATR with more modern functional rehabilitation of these injuries.

Functional rehabilitation has become increasingly topical and it is increasingly utilised in mainstream practice.[32, 37, 99, 132, 133] Studies that advocated the use of functional rehabilitation are said to have been one of the main factors driving recent trends towards increasing levels of non-operative management after a period where surgical management was favoured by many in the 20th century and early 2000s.[32, 36, 37, 105] However, careful review of many of these studies reveals that the conclusions reached are often based on assumptions and are not directly supported by the study methodology.[99] Furthermore, a survey from the UK reported that despite the

overwhelming focus on functional rehabilitation in the medical literature in recent years, plaster cast immobilisation remained in widespread use in clinical practice,[133] suggesting that newer concepts that are given prominence in the published literature may take some time to be adopted in mainstream clinical practice and calling into question the previous presumptions that the recent trends towards non-operative management are attributable to the published studies on functional rehabilitation regimes. Previous studies that have compared functional and traditional non-operative management were small and used bracing techniques that are obsolete and do not reflect modern practice.[118, 124] In this context, the lack of prospective randomised studies directly comparing traditional immobilising non-operative management of ATR in a plaster cast with modern non-operative functional regimes is surprising, since such studies are needed to justify the reported trends towards functional non-operative management of ATR. The study in Chapter 5 therefore seeks to fill this lacuna in the medical literature, by comparing the traditional immobilising non-operative regime from Chapter 4, which has been in widespread use for many years, with a modern non-operative functional regime permitting early weight bearing in a walking boot.

If the concept of functional non-operative treatment of ATR is shown to be equivalent or superior to traditional non-operative management and also to be safe, thereby justifying its ongoing use, it then becomes desirable to study the functional treatment regime in greater detail to precisely define the underlying biomechanics, physical changes and physiological processes that occur through the course of this treatment and understand how these relate to the observed outcomes (both physical and patient reported) at various time points throughout the recovery and rehabilitation programme. Some studies have reported on outcomes after functional rehabilitation for ATR but these have largely focussed on PROM and questionnaire data.[61, 101, 110, 158] A better understanding of functional rehabilitation regimes is increasingly necessary as they become ever more popular and widely used. The study in Chapter 6 aims to assess a number of

physical parameters, including plantar pressures under the feet and other clinical measurements and correlate these with PROMs during the course of recovery from an acute ATR.

The aims of the studies that comprise this thesis were therefore:

- to review the epidemiology of primary ATR, with a specific focus on the influence (if any) of socioeconomic deprivation status; and to determine whether there were any variations in previously described risk factors and features of ATR between more and less socioeconomically deprived individuals with ATR.
- to review the incidence and epidemiology of ATRR and identify potential predictors of increased risk of re-rupture at the time of presentation with a primary ATR;
- to address significant gaps in the medical literature regarding the optimal management regime for these injuries, specifically by providing long term patient reported outcome and health related quality of life data from a randomised controlled trial comparing traditional operative and non-operative management of ATR; and by providing direct comparative data from a RCT comparing traditional non-operative management with modern functional non-operative management, in terms of patient reported outcomes, clinically measured parameters, complication rates and return to activity after injury.
- to explore the physical and biomechanical changes that occur through the course of recovery with a modern non-operative functional rehabilitation regime and relate these to patient reported outcomes, with a particular focus on static loading patterns under the foot in the months after ATR.

Chapter 2: Epidemiology of Acute Achilles Tendon Rupture

2.1 Introduction

Achilles tendon rupture (ATR) is a common soft tissue injury and the incidence is reported to be rising.[32-39, 228] ATR occur most frequently in middle-aged adults, with the median age of affliction commonly reported within the fifth decade of life[32, 33, 35, 37, 42, 229] and males are most frequently affected.[32, 33, 35-37, 42, 229] They occur most commonly during sporting activity and seasonal variation in incidence has also been described.[32, 37]

The epidemiology of ATR has previously been described in general terms,[31-33, 36, 37, 42] however the influence of socioeconomic deprivation status (SEDS) on the incidence of ATR is unknown. SEDS has been shown to influence the epidemiology of musculoskeletal pain[230] and various orthopaedic conditions, including carpal tunnel syndrome,[215] proximal humeral fractures,[216] osteoarthritis of the hand, hip and knee,[217] Perthe's disease[231-233] and adult trauma[218] and fractures[219] in general. An improved understanding of the potential influence of SEDS on the epidemiology of ATR may give insight into underlying causes of injury and provide important information about at-risk populations that may aide planning of medical service provision, while a detailed analysis of the circumstances of injury will give clinicians more insight into the clinical

features of ATR in different population groups, which may provide opportunities for targeted preventive interventions or treatment.

The aim of this study was to describe the incidence and epidemiology of ATR in a defined population and to determine whether there was an association with SEDS. The hypothesis was that ATR occur more frequently in socioeconomically deprived patients. The secondary aim was to determine whether there were variations in previously described risk factors and features of ATR between more and less socioeconomically deprived individuals with ATR.

2.2 Methods

2.2.1 Setting

A retrospective electronic search of all medical records was undertaken to identify patients treated for ATR between 1st January 2011 and 31st December 2016 at NHS Lothian. The health-board is one of fourteen that make up NHS Scotland and was formed in 2001 from the incorporation of the previous NHS trusts operating in the area (Lothian University Hospitals, Lothian Primary Care and West Lothian Healthcare). It is the only authority overseeing delivery of regional healthcare services to a defined population in the City of Edinburgh, East Lothian, Mid-Lothian and West Lothian and there are no other National Health Service (NHS) providers in this region. Emergency services are provided through 3 emergency departments and one minor injuries unit; orthopaedic surgery is performed at two locations and outpatient clinics are based at five locations. There are two private hospitals in the region but none of these have an emergency department and therefore acute presentations are routed through the NHS and should be identified by the search algorithm employed.

2.2.2 Study Design

All outpatient medical records, A&E records and inpatient discharge summaries in the health-board are electronically recorded using TRAKCare software (InterSystems Corporation, Massachusetts, USA). These were retrospectively screened for the following search terms: 'Achilles', 'tendoachilles', 'TA', 'rupture', 'tear', 'torn', to identify any patients treated for Achilles tendon rupture in any of the Accident and Emergency, outpatient or inpatient services. The preliminary search returned 4521 records. Each record was then screened according to the inclusion and exclusion criteria (Table 2.1). Patients residing in the catchment area were included if they sustained their rupture elsewhere and returned for ongoing treatment, while non-resident visitors presenting to the emergency service for acute management were excluded from analyses. There were 816 patients with acute Achilles tendon rupture identified during the time period under review, of whom 791 patients resided within the defined geographical area under review and were identified as suitable for inclusion in the study. Of these, 8 presented for the first time during the study period with a re-rupture of a previously ruptured Achilles tendon and were therefore excluded, leaving 783 patients presenting with a primary ATR, who form the study cohort under review (figure 2.1)

This study was part of a service review of ATR presenting within the health-board region that was approved departmentally. It was reviewed by the scientific officer for the regional ethics committee (REC) who advised that REC review was not necessary.

Inclusion criteria	Exclusion criteria
Achilles tendon rupture	Achilles tendinitis without rupture
Date of injury 01/01/2011 to 31/12/2016	Patients whose first presentation during the study period was a re-rupture of the Achilles tendon
Patients residing within the health-board geographical region as defined by the Scottish Government National Records of Scotland Small Area Population Estimate data zones (i.e. patients residing within the 1083 data zones that make up the health-board catchment area), even if: • they initially presented elsewhere and only returned to the health-board for on-going care. • they presented initially to the health-board but subsequently underwent on-going care in the private sector.	Patients residing out with the health-board geographical region as defined by Scottish Government National Records of Scotland Small Area Population Estimate data zones (i.e. patients residing out with the 1083 data zones that make up the Health-board catchment area).

Table 2.1. Inclusion and exclusion criteria.

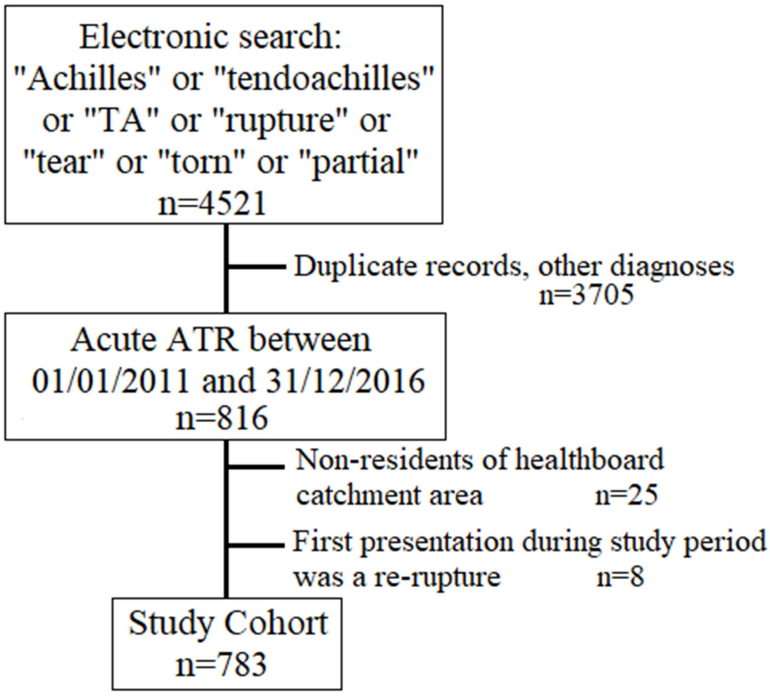


Figure 2.1. Flow diagram for the study cohort.

2.2.3 Population-level data

The health-board population (total, gender-specific and with reference to age brackets) for each year of study was determined using Scottish Government population data from the National Records of Scotland (NRS), who issue annual mid-year population estimates for each health-board.[234] This data is published annually for each health-board, in the form of the total population as well as population by year of age and by gender. The relevant age and gender specific data was combined to calculate gender-specific, ten year age bracket populations in the health-board area for each year of study.

Socioeconomic deprivation status was determined using the Scottish Index of Multiple Deprivation (SIMD-16).[235] This is an official Scottish government resource that takes into account employment, income, crime, housing, health, education and access to services to assess

and classify population SEDS across 6,500 data-zones nationwide (Appendix 2 Figure 1). The SIMD is used by the Scottish government to target funding and resources and has been widely used in medical research.[215, 216, 218, 219, 236-240] Each data-zone comprises a small geographic area with between 500 and 1,000 residents. The data-zones are ranked by SEDS and after all data-zones have been ranked, they are placed into the appropriate quintile of the national population. SEDS data is published for each data zone and the health-board serves a geographic region made up of 1083 data zones. Detailed information including population size and socioeconomic deprivation rank status are available for each data zone and data for these (1083) data zones was combined to determine the socioeconomic deprivation status characteristics of the health-board population, since such data is not routinely published in summary format. Patients were matched to their corresponding data zone using their postcode and appropriately classified in their corresponding quintile of the national population (via the 'SIMD-16 postcode to SIMD rank' look-up tool). The health-board serving the patients' data zone was then confirmed (via the 'data zone to health board' look up tool).[235] SEDS data was available for all patients. Patients were categorised into quintiles on an ordinal scale where quintile one represents the most deprived 20% of the national population and quintile 5 represents the least deprived 20% of the national population.

2.2.4 Definitions

A history of preceding tendinitis was defined as preceding pain or a formal diagnosis of tendinitis in the 6 months preceding ATR. Body mass index (BMI) was determined from height and weight documented at the closest-available time-point to injury; this was known for 74.5% of patients (n=583/783). Seasonality was defined according to the Northern Hemisphere meteorological system.[241] Late presentation was defined as presentation >14 days after injury, as previously stated by Hutchison et al.[101] Four patients who underwent ongoing follow up for their

injury at institutions elsewhere despite initial presentation to the NHS, were excluded from analyses pertaining to complications but included in demographic and injury-related analyses.

2.2.5 Statistical Analysis

The annual incidence of ATR per 100,000 population was calculated as the number of cases occurring between 1st January and 31st December, divided by the health-board population (or relevant population bracket), as defined in the mid-year population estimate for that year.[234] The resulting figure was multiplied by 100,000. This analysis was undertaken for each year of study and ten year age brackets were used for age based calculations. SIMD data is released quadrennially and the SIMD-16 dataset was used.[235] The incidence of ATR in each SIMD quintile per 100,000 population per year was determined by calculating the average annual occurrences in the quintile over the study period and dividing this by the SIMD-16 quintile health-board population, then multiplying the resulting number by 100,000.

The ATR cohort was then subdivided into most deprived (MD; comprising of patients in national quintiles 1 and 2) and least deprived (LD; patients in quintiles 4 and 5) subgroups for further analysis. Within this cohort, data parametricity was assessed using Kolmogorov-Smirnov testing. Non-parametric data was reported as median values with interquartile range (IQR) and was compared using independent samples Mann Whitney U tests. Nominal variables were compared using Chi-Squared tests (or Fisher's Exact test if cell count was <5 in any cell) and reported with accompanying odds ratios and 95% confidence intervals where relevant. Binary logistic regression was undertaken to identify variables that were independently associated with SEDS. Variables were included in the regression analysis if $p \leq 0.1$ on univariate analysis. This lax threshold was chosen since a relationship that is narrowly statistically insignificant on initial analysis may be found to be statistically significant after adjusting for confounding relationships.

Statistical analysis was undertaken using Statistical Package for Social Sciences (SPSS) v20 (SPSS Inc., Chicago, IL, USA). A p-value of ≤0.05 was considered significant.[242]

2.3 Results

2.3.1 Part 1: Epidemiology of primary Achilles tendon rupture

Seven hundred and eighty three patients residing in the catchment population sustained a primary ATR between 1st January 2011 and 31st December 2016. There were 567 males (72%) and 216 females (28%). The median age was 48 years for both females (IQR 41-65) and males (IQR 38-60). Median BMI was 26.6 (IQR 24.2-30.4) for all patients (median 26.5, IQR 24.4-29.9 for males and median 26.8, IQR 23.5-31.7 for females). The majority of patients self-identified as either 'white Scottish' (64%) or 'white British' (21%; figure 2.2). Forty nine patients (6.3%) were 'late presenters'. Quinolone antibiotics were implicated in 18 cases (2.3%) and systemic steroids in 38 cases (4.85%) while 56 patients (7.2%) gave a history of preceding tendinitis.

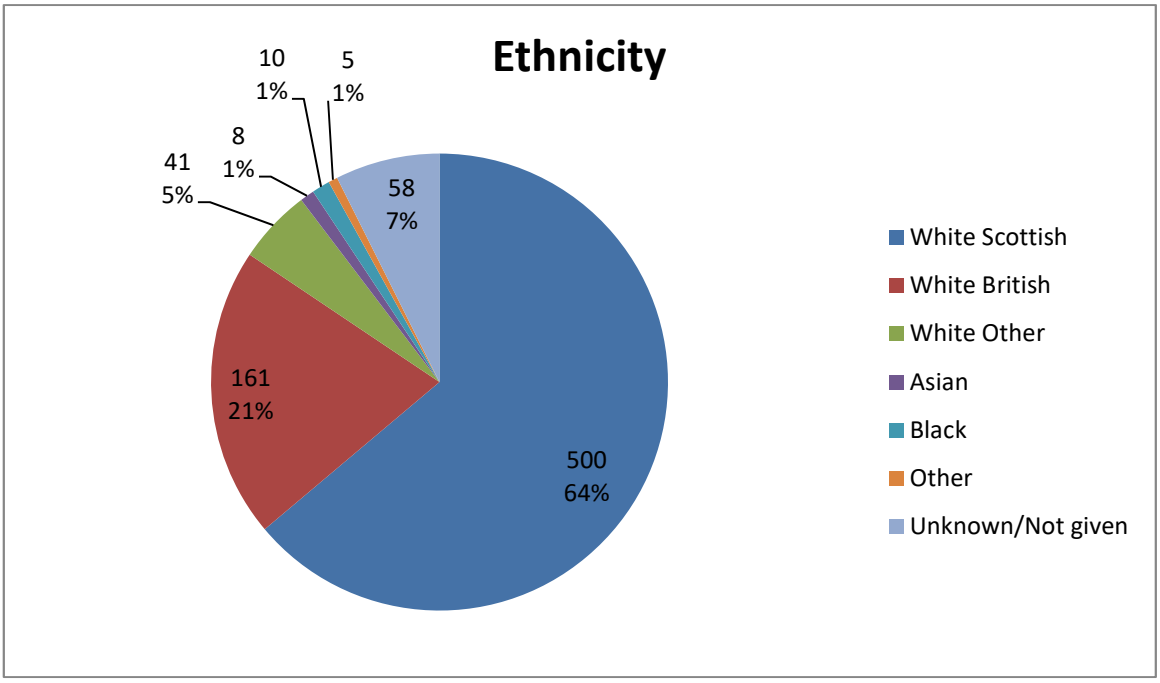


Figure 2.2. Patient reported ethnicity (absolute numbers and %).

The mean incidence of ATR for patients of all ages over the study period was 15.26/100,000 per year (range 13.51 to 19.07; figure 2.3) and was higher in males (22.73/100,000 per year, range 18.22-27.12) than females (8.19/100,000 per year, range 6.63-11.45; OR=2.88, 95% CI 1.29-6.43; p=0.007). The mean incidence in adults (aged ≥18 years) was 18.75/100,000 per year (range 16.56-23.57), again being higher in males (28.28/100,000 per year) than females (9.95/100,000 per year; OR = 2.81, 95%CI 1.36-5.77; p=0.003). Age-related incidence was bimodal, with peak incidence for both sexes in the fifth decade, with smaller peaks in incidence noted in the seventh decade in males and the eighth decade in females (figure 2.4).

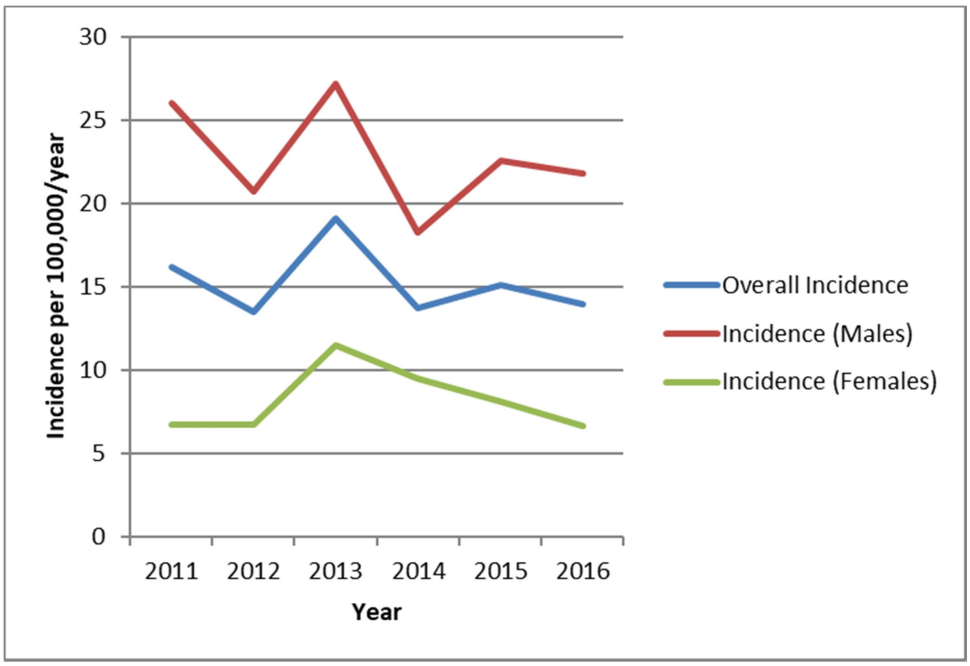


Figure 2.3. Annual incidence of Achilles tendon rupture across all age groups.

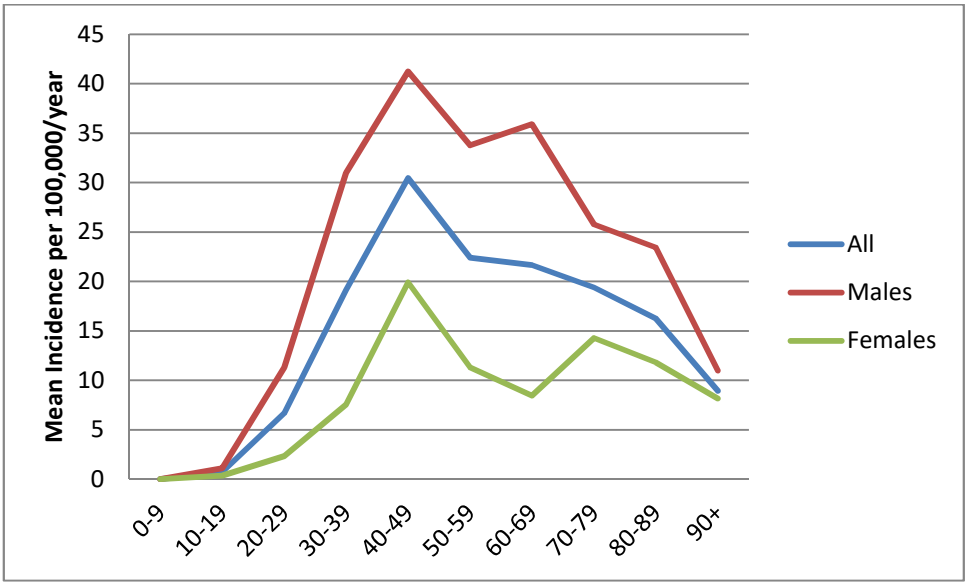


Figure 2.4. Mean annual incidence per 100,000 in each ten year age bracket.

The incidence of ATR in each SEDS quintile (Figure 2.5) of the health-board population is shown in Table 2.2. There was a statistically significant relationship between SEDS and incidence of Achilles tendon rupture, with patients in the less deprived group (4th and 5th national quintiles) demonstrating a significantly higher incidence of ATR (18.07/100,000 per year) than those in the more deprived (1st and 2nd quintiles) group (11.32/100,000 per year; OR = 1.60, 95%CI 1.35-1.89; p<0.001).

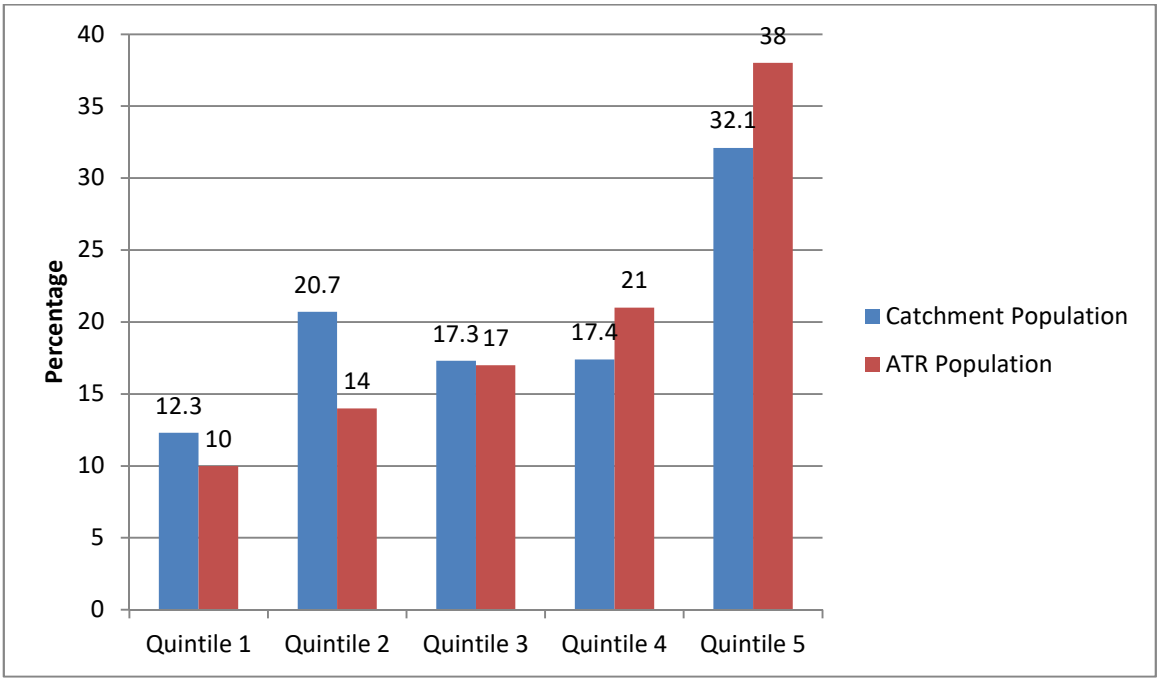


Figure 2.5. Percentage of individuals in each SIMD Social deprivation quintile for Achilles tendon rupture cases (n=783) and for the whole population of the health-board area (n=858,090). The relative incidence is lower in the most deprived quintiles, crossing over around the third quintile and it is higher in the least deprived quintiles.

	Achilles Tendon Ruptures	Health-board population excluding ATR[a]	Total health-board population[a]	Mean Incidence /100,000 per year[b]	Odds Ratio (95%CI)	*p*-value
Quintile 1	81	106,241	106,322	12.70	Reference	
Quintile 2	112	177,816	177,928	10.49	0.83 (0.62-1.10)	ns
Quintile 3	129	148,457	148,586	14.47	1.14 (0.86-1.50)	ns
Quintile 4	165	149,433	149,598	18.38	1.45 (1.11-1.89)	**0.0061**
Quintile 5	296	275,360	275,656	17.90	1.41 (1.10-1.80)	**0.0059**
Total	783	857,307	858,090			

Table 2.2. Incidence of Achilles Tendon rupture in the health-board population by social deprivation quintile. [a]Health-board population as per SIMD-16 dataset. [b]Calculated from incidence over six year study period, divided by 6.

Additionally, patients in the most deprived quintile were more likely to present in a delayed fashion (Table 2.3).

Quintile	Proportion late presenters (%)	OR (95% CI)	*p*-value
Quintile 1	10 of 81 (12.3%)	Reference	Reference
Quintile 2	5 of 112 (4.5%)	0.33 (0.11-1.01)	0.04
Quintile 3	9 of 129 (7.0%)	0.53 (0.21-1.37)	0.19
Quintile 4	7 of 165 (4.2%)	0.32 (0.12-0.86)	0.019
Quintile 5	18 of 295 (6.1%)	0.46 (0.20-1.04)	0.058

Table 2.3. Late presentation (>14 days) according to SIMD quintile. Chi square tests comparing quintile 1 late presentation with that in each other quintile. Data available for 782 patients for whom date of first presentation was known.

2.3.2 Part 2: Patient and Injury Characteristics and Variation with SEDS

2.3.2.1 SEDS and Patient Demographics

There was no significant difference in gender (p=0.85) or ethnicity (p=0.39) between MD and LD groups with ATR. However, there was a small but statistically significant difference in median age between patients in the MD (median age 47, IQR 39-56.5) and LD (median age 48, IQR 40-63) groups (p=0.05) and patients in the MD group also had a higher median BMI (27.8, IQR 25.2-33.4) than those in the LD (26.04, IQR 23.9-29.2; p<0.001) group (Table 2.4).

	Most deprived (Quintiles 1 and 2)	Least deprived (Quintiles 4 and 5)	*p*-value
Gender (male:female)			
Male	141 (73.1%)	340 (73.8%)	0.85*
Female	52 (26.9%)	121 (26.2%)	
Age (median, IQR)	47 (39-56.5)	48 (40-63)	0.050**
Ethnicity			
White British	162	387	
White Other	11	22	
Asian	2	6	0.39†
Black	4	4	
Other	2	3	
Unknown	12	39	
BMI (median, IQR)	27.78 (25.18-33.41)	26.04 (23.87-29.20)	<0.001**

Table 2.4. Baseline characteristics for patients, according to social deprivation status. *Chi Square test; **Independent Samples Mann Whitney U-test. †Chi Square test for proportion of patients who self-identified as White British (including Scottish) compared to all other known ethnicities.

2.3.2.2 SEDS and Seasonality of ATR

ATR occurred most frequently during the summer. June was the mode month of injury for the whole cohort (figure 2.6a) and also individually for the MD and LD groups (figure 2.6b). Although both groups had a peak incidence in summer months (figure 2.6c), patients in the LD group exhibited statistically insignificant trends towards higher relative incidence of spring-time injuries (27.4% vs 20.7%; p=0.074) and lower relative incidence of summer time (29.8% vs 37.3%; p=0.060) injuries compared to those in the MD group (table 2.5).

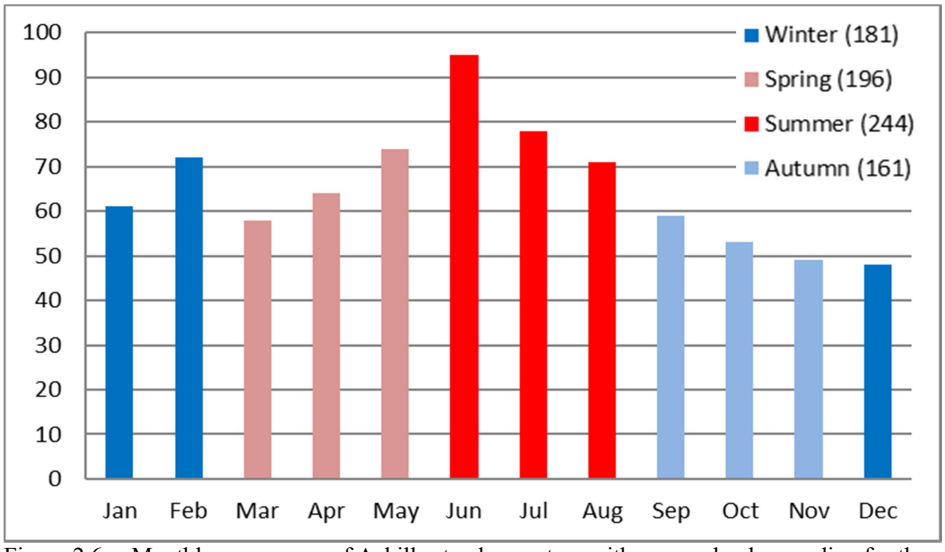


Figure 2.6a. Monthly occurrence of Achilles tendon rupture with seasonal colour coding for the whole cohort.

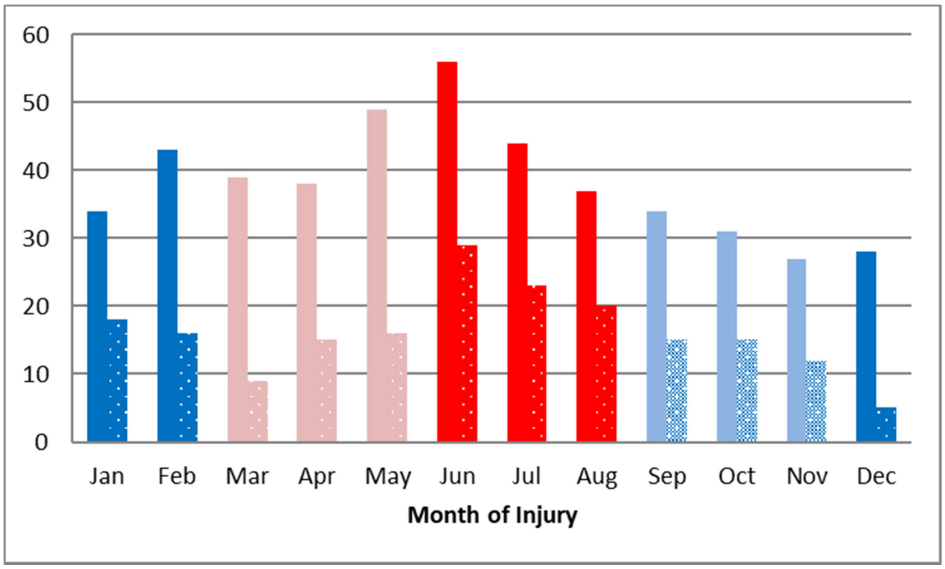


Figure 2.6b. Monthly incidence of ATR in relation to social deprivation status. Solid bars represent the LD cohort and spotted bars represent the MD cohort.

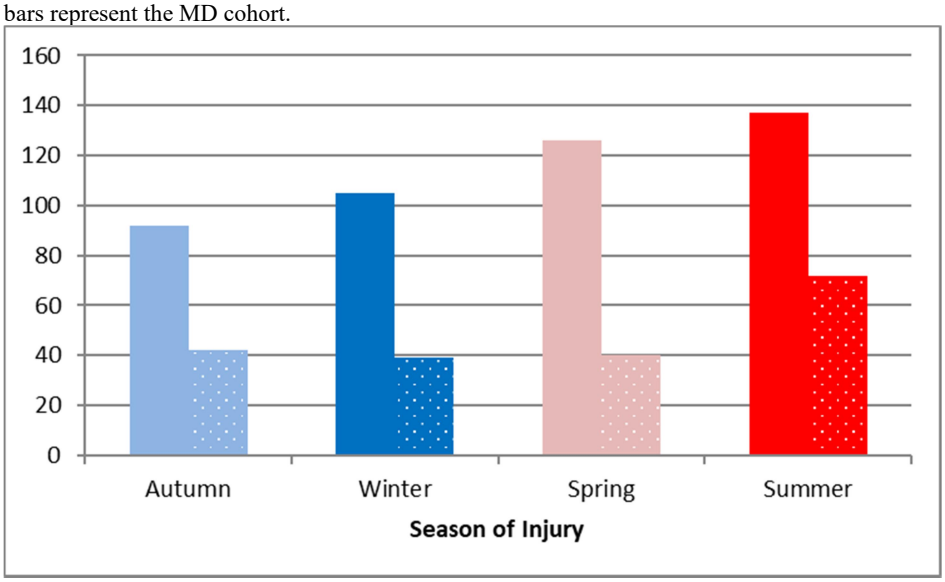


Figure 2.6c. Seasonal incidence of ATR in relation to social deprivation status. Solid bars represent the LD cohort and spotted bars represent the MD cohort.

	Most deprived	Least deprived	OR (95% CI)	*p*-value
Autumn	42 of 193 (21.8%)	92 of 460 (20%)	0.90 (0.60-1.36)	0.61
Winter	39 of 193 (20.2%)	105 of 460 (22.8%)	1.17 (0.77-1.77)	0.46
Spring	40 of 193 (20.7%)	126 of 460 (27.4%)	1.44 (0.96-2.16)	0.074
Summer	72 of 193 (37.3%)	137 of 460 (29.8%)	0.71 (0.50-1.02)	0.060

Table 2.5. Seasonality of injuries in MD and LD groups. Odds ratio (OR) is reported for the least deprived cohort relative to the most deprived cohort.

2.3.2.3 SEDS and Mechanism of Injury

The mechanism of injury was known in 772 (98.6%) cases and sport-related injuries accounted for the majority (388 of 772, 50.3%) of these. Dancing (81 of 772, 10.5%), walking and simple slips, trips or falls from standing height were other common mechanisms of injury (Figure 2.7). Both sporting and non-sporting injuries exhibited temporal variations in incidence through the year, being commonest in summer (Appendix 2 Figure 2).

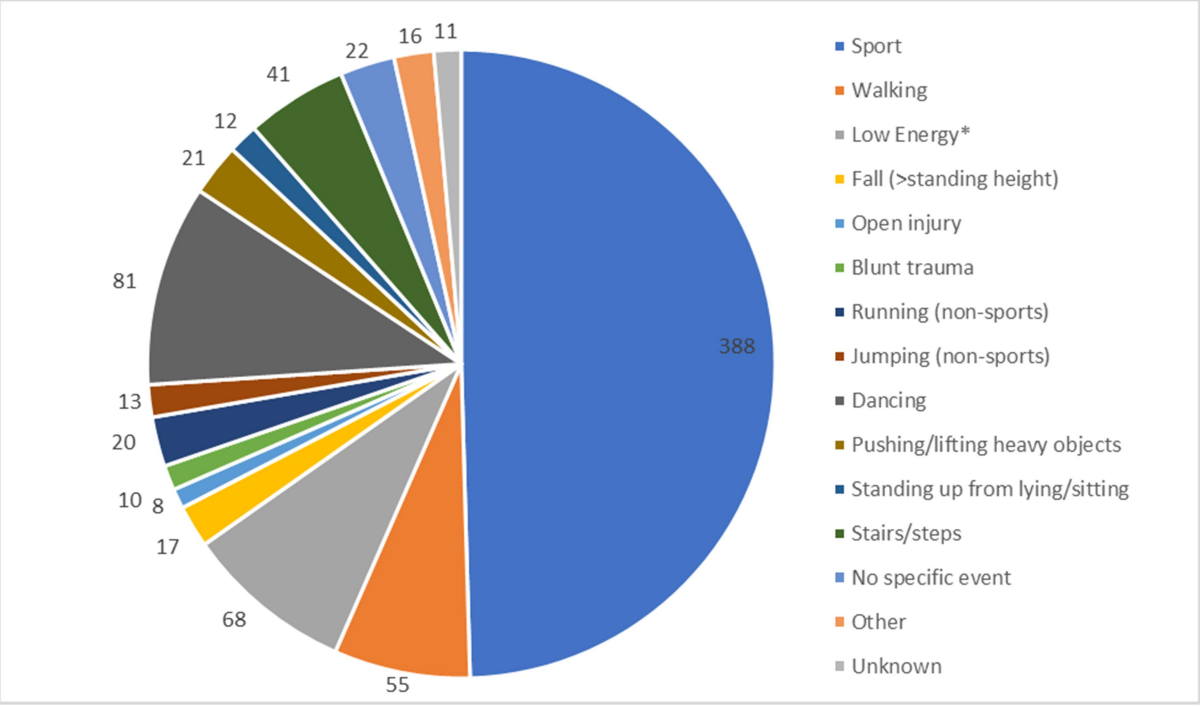


Figure 2.7. Mechanism of injury for primary ATR. *Low energy classification includes slip, trip, stumble, ankle inversion or fall from standing height.

Patients in the LD group were more likely to sustain their injuries during the course of sporting activity (55.6% vs 42.3%; OR=1.71, 95%CI 1.21-2.40; *p*=0.002) and less likely to sustain low energy injuries (7% vs 12.7%; OR=0.52, 95%CI 0.3-0.91; *p*=0.02), while there were statistically insignificant trends towards increased incidence of open injuries (2% vs 0.4%; *p*=0.065) and stair related injuries (7.9% vs 4.2%; *p*=0.052) in most deprived patients (Table 2.6).

	Whole cohort	Most Deprived[a] (n=189)	Least Deprived[b] (n=455)	OR (95%CI)	*p*-value
Sport	388 (50.3%)	80 (42.3%)	253 (55.6%)	1.71 (1.21-2.40)	**0.002**
Walking	55 (7.1%)	14 (7.4%)	30 (6.6%)	0.88 (0.46-1.70)	0.71
Low Energy*	68 (8.8%)	24 (12.7%)	32 (7%)	0.52 (0.3-0.91)	**0.02**
Fall (>standing height)	17 (2.2%)	5 (2.6%)	9 (2%)	0.74 (0.25-2.25)	0.57
Open injury	8 (1%)	4 (2.1%)	2 (0.4%)	0.20 (0.04-1.12)	0.065
Blunt trauma	10 (1.3%)	3 (1.6%)	7 (1.5%)	0.97 (0.25-3.79)	1
Running (non-sports)	20 (2.6%)	7 (3.7%)	9 (2%)	0.53 (0.19-1.43)	0.26
Jumping (non-sports)	13 (1.7%)	3 (1.6%)	9 (2%)	1.25 (0.34-4.67)	1
Dancing	81 (10.5%)	18 (9.5%)	48 (10.5%)	1.12 (0.63 to 1.98)	0.7
Pushing/lifting heavy objects	21 (2.7%)	4 (2.1%)	12 (2.6%)	1.25 (0.4-3.94)	1
Standing up from sitting/lying	12 (1.6%)	4 (2.1%)	5 (1.1%)	0.51 (0.14-1.94)	0.46
Stairs/steps	41 (5.3%)	15 (7.9%)	19 (4.2%)	0.51 (0.25-1.02)	0.052
No specific event	22 (2.8%)	4 (2.1%)	12 (2.6%)	1.25 (0.40-3.94)	1
Other	16 (2.1%)	4 (2.1%)	8 (1.8%)	0.83 (0.25-2.78)	0.75
Total	772	189	455		

Table 2.6. Mechanism of injury for whole cohort and for most and least deprived patients. [a]Patients in the two most deprived national quintiles. [b] Patients in the two least deprived national quintiles. Odds ratio (OR) is reported for the least deprived cohort relative to the most deprived cohort. * Low energy category includes slips, trips, stumbles, ankle inversion injuries and falls from standing height.

Amongst sport-related ATR, the type of sport also varied with SEDS (Table 2.7), with soccer accounting for 56.2% of sport-related injuries in the MD group and 42.3% of sport-related injuries in the LD group (p=0.029) while conversely, racket sports accounted for 24.9% of sport-related injuries in the LD group and 13.8% in the MD group (p=0.037).

	Whole cohort	Most Deprived[a] (n=80)	Least Deprived[b] (n=253)	OR (95% CI)	*p*-value
Soccer	174	45 (56.2%)	107 (42.3%)	0.57 (0.34-0.95)	**0.029**
Racket sports	86	11 (13.8%)	63 (24.9%)	2.08 (1.04-4.18)	**0.037**
Gym/gym class	14	0 (0%)	10 (4.0%)	1.33 (1.25-1.42)	0.13
Basketball/Netball	23	7 (8.8%)	12 (4.7%)	0.52 (0.20-1.37)	0.18
Running/Jogging	22	5 (6.2%)	13 (5.1%)	0.81 (0.28-2.35)	0.78
Rugby	17	3 (3.8%)	12 (4.7%)	1.28 (0.35-4.65)	1.0
Other	52	9 (11.2%)	36 (14.2%)	1.31 (0.60-2.85)	0.50
Total	388	80	253		

Table 2.7. Sport-related ATR and socioeconomic deprivation status. [a]Patients in the two most deprived national quintiles. [b]Patients in the two least deprived national quintiles. Odds ratio (OR) is reported for the least deprived cohort relative to the most deprived cohort.

2.3.2.4 SEDS and Preceding or Predisposing Events

Patients in the LD group were more likely (p=0.01; OR = 3.29, 95%CI 1.27-8.50) to give a history of recent symptomatic tendinitis (37 of 460; 8.04%), than their MD counterparts (5 of 193; 2.59%). There was a trend towards increased prevalence of diabetes mellitus within the MD group (20 of 193; 10.4%), compared to the LD group (29 of 461; 6.3%; p=0.07; OR = 1.72, 95% CI 0.95-3.13). Patients in the MD group also had a higher incidence of inflammatory arthropathy (8 of 193, 4.15%) than those in the LD group (7 of 461 or 1.52%; p=0.049; OR = 2.81, 95%CI 1.003-7.85), however there was no detectable difference in recorded use of corticosteroids (23 of 460 or 5% in the LD group vs 8 of 193 or 4.15% in the MD group; OR=1.22, 95%CI=0.54-2.77;

p=0.64) or fluoroquinolones (7 of 460 or 1.5% in the LD group vs 7 of 187 or 3.7% in the MD group; OR=0.41, 95%CI=0.14-1.19; *p*=0.13) in the six months preceding ATR.

2.3.2.5 SEDS and Complication Rates

Tendon re-rupture occurred in 42 of 779 patients (5.4%) and there was no difference in incidence between MD (9 of 192, 4.7%) and LD (28 of 459, 6.1%) groups (OR=1.32, 95%CI=0.61-2.86; *p*=0.58). Symptomatic venous thromboembolism occurred in 27 of 779 patients (3.5%) and there was no difference in incidence between MD (5 of 192, 2.6%) and LD (17 of 459, 3.7%) groups (OR=1.44, 95%CI=0.52-3.96; *p*=0.48). There was no difference in age (median 51, IQR 40-67 vs median 48, IQR 39-61; *p*=0.21) or gender distribution (23 of 563 males and 4 of 216 females; *p*=0.13) in patients who sustained a VTE compared to those who did not. However, patients sustaining a VTE had a higher BMI (median 29.0, IQR 26.9-32.3) than their counterparts who did not (median 26.5, IQR 24.2-30.3; *p*=0.03).

2.3.2.6 Regression model

Binary logistic regression demonstrated independent variations in patient factors, mechanism of injury and seasonality with SEDS (Table 2.8). Patients in the LD group were more likely to be aged >50 years (OR=1.97, 95%CI 1.24-3.12; *p*=0.004), more likely to sustain sport-related injuries (OR=1.72 (95%CI=1.11-2.67; *p*=0.02) and less likely to suffer low energy injuries (OR=0.44, 95%CI=0.23-0.87; *p*=0.02) and to be obese (*p*≤0.03). Spring time injuries were commoner in the LD group (OR=1.65, 95%CI=1.01-2.70; *p*=0.045), as was a history of preceding tendinitis (OR=4.04, 95%CI=1.49-10.95; *p*=0.006).

	Adjusted Odds Ratio (95%CI)	*p*-value
Age		
40-50 years	Reference	
<40 years	0.86 (0.533-1.39)	0.54
>50 years	1.97 (1.24-3.12)	**0.004**
MOI		
Other	Reference	
Sports	1.72 (1.11-2.67)	**0.02**
Steps	0.53 (0.24-1.18)	0.12
Low Energy	0.44 (0.23-0.87)	**0.02**
Open Laceration	0.26 (0.04-1.60)	0.15
Season		
Summer	Reference	
Autumn	1.14 (0.69-1.87)	0.61
Winter	1.34 (0.81-2.22)	0.25
Spring	1.65 (1.01-2.70)	**0.045**
Preceding Tendinitis	4.04 (1.49-10.95)	**0.006**
Inflammatory Arthropathy	0.32 (0.10-1.03)	0.057
Diabetes Mellitus	0.75 (0.37-1.54)	0.44
BMI		
<25	Reference	
25-29.99 (overweight)	0.74 (0.44-1.26)	0.27
30-34.99 (class I obesity)	0.41 (0.22-0.76)	**0.005**
35-39.99 (class II obesity)	0.27 (0.12-0.62)	**0.002**
>40 (class III obesity)	0.25 (0.07-0.90)	**0.03**
BMI Unknown	0.61 (0.36-1.04)	0.07

Table 2.8. Binary logistic regression model for more and less deprived patients. The more deprived group is the reference group and all adjusted odds ratios are reported for the least deprived group relative to the more deprived group. BMI is classified as per WHO categories for the purposes of this model.

2.4 Discussion

The epidemiology of ATR was described and the hypothesis was rejected. This study demonstrated an inverse relationship between incidence of ATR and SEDS, with a higher

incidence of ATR in patients with lower levels of socioeconomic deprivation. In addition, SEDS has been shown to be associated with independent variations in patient factors (e.g. BMI and preceding tendinitis), mechanisms of injury and seasonality in patients presenting with ATR, suggesting that the circumstances and nature of ATR may vary with SEDS. This is the first study to assess the relationship between SEDS and ATR.

2.4.1 Epidemiology of ATR

Males outnumbered females by approximately 3:1 and the median age of patients with ATR was in the fifth decade of life. Patient demographics reported in this study were similar to those reported in other large epidemiological studies,[32, 36] suggesting that the study population was representative of general ATR populations encountered elsewhere and lending credence to these findings. This could also suggest that the novel findings in this study with respect to SEDS may mirror the situation elsewhere, although this cannot be known with any degree of certainty until studies assessing the relationship between SEDS and ATR are repeated in other geographic regions. Previous studies have reported wide variation in the incidence of ATR[32, 33, 37, 40, 42] and the incidence reported in this study falls centrally within this range. Interestingly, studies reporting a higher incidence of ATR originate largely in Scandinavia, in countries that score very highly on socioeconomic indices, even in comparison to the United Kingdom.[243] This would appear to support the finding of a higher incidence of ATR being associated with lower levels of deprivation. Additionally, most studies reporting a higher incidence than the current study exclude children and adolescents,[36, 37] who have a very low incidence of ATR. Whole-population, age-bracket specific and adult population data are presented in this study, to give complete data for the population while also facilitating comparison with other studies. The finding of a second, smaller peak in incidence among older patients is consistent with recent

reports of rising incidence of ATR in this demographic.[32, 36] Other authors have reported that the mean age at presentation with ATR is rising and have attributed this to an increasing incidence in older patients and an ageing population.[32, 35, 36]

An epidemiological study of soft tissue injuries originating in the same region, 15 years prior to the current study, reported an incidence of ATR of 11.1/100,000 per year,[31] while the current study reports a significantly higher incidence of ATR. This suggests a significant increase in the incidence of ATR in the region in recent decades, which would again be in keeping with trends reported elsewhere.[32, 36, 38] The reasons for increased incidence of ATR observed in various regions in recent years are likely multiple, although it has been postulated by some authors that increases in physical activity and sporting activity among the general population and in particular older individuals, may play a role.[32, 36, 244]

The SIMD is a national index and quintiles are not uniformly distributed through the country geographically. The study methodology accounted for this, using data from the 1083 data zones in the health board area to determine specific health board population deprivation data, which was used for the uninjured comparator group in this study. This should allay any concerns that the increased number of ATR observed in the LD category could simply be a reflection of the make-up of the health-board population being studied and confirms that the observed increased incidence of ATR in areas with lower levels of deprivation is a genuine finding.

The authors of a recent study on the epidemiology of soft tissue injuries noted a lack of data relating epidemiology of these injuries to SEDS and called for studies to be undertaken in this field.[245] SEDS has been shown to influence the epidemiology of traumatic injuries in general,[218, 246, 247] facial trauma,[240] many types of fracture[216, 219, 248] and osteoarthritis,[217] carpal tunnel syndrome,[215] Perthe's disease[231-233] and other musculoskeletal conditions.[230] In addition, socioeconomic deprivation has also been linked with increased incidence of various non-orthopaedic conditions, including hospitalisation with peripheral arterial disease[249] and other

chronic medical ailments.[250] However, the relationship between SEDS and incidence of ATR identified in this study is the *inverse* of that seen with respect to all of the above, where increasing levels of deprivation are associated with higher rates of incidence.[215-219, 230-233, 249-251] This has important implications for the planning of clinical services and resource allocation in relation to the population served. Reasons for this relationship may include differing activity profiles in cohorts of varying SEDS.[244] It is known that individuals with lower levels of deprivation are more active and have higher levels of sports participation, potentially predisposing them to ATR, while more deprived individuals are more likely to lead sedentary lifestyles.[244, 252-254] This theory is further supported by the findings of variation in mechanism of injury and sporting involvement between deprivation groups discussed below.

Additionally, patients in the most deprived quintile were more likely to present in a delayed fashion, which may have significant implications on treatment strategy in areas of high socioeconomic deprivation, since surgical management is usually advocated after delayed diagnosis of ATR.[255]

2.4.2 Patient and Injury Characteristics and Variation with SEDS

The male preponderance for ATR observed in this and other studies[32, 36] did not vary with SEDS and this known predictor of ATR is unlikely to be a major driver of the discrepancy in ATR across different SEDS categories. There was a notably higher proportion of patients >50 years old in the LD group and there may be an association between trends towards increased incidence of ATR in older patients[32, 36] and the higher incidence of ATR in LD individuals.

Seasonality is another known predictor of ATR and other authors have similarly reported a higher incidence of ATR in the summer and spring.[37, 256] The reasons for seasonal variation are unknown but may relate to differing sporting preferences,[42] implications of climate on sports,[37] or other factors such as SEDS, which has, for the first time been shown to have an independent

association with seasonality. While both groups had the highest ATR incidence in summer, MD patients had relatively constant incidence through the rest of the year with a large summer peak, while LD patients demonstrated steadily increasing incidence between autumn and summer, with the largest relative increase occurring between winter and spring and they had a significantly higher spring-time incidence than the MD group. It has been postulated that variations in seasonality of ATR are influenced by the mechanism of injury, with certain activities being more popular during particular seasons.[32] However, even after adjusting for mechanism of injury and other confounders, seasonal variation was confirmed, suggesting a degree of independence between these factors and that differences in injury mechanism alone do not explain the differences in seasonal variation observed between deprivation groups.

Mechanism of injury also differed independently with SEDS. Sporting injuries accounted for the majority of ATR, particularly in the LD group. Socioeconomic deprivation is known to be associated with reduced participation in sports[253, 254] and this would support the findings of this study. It may be one reason why ATR, unlike many other medical afflictions, is commoner in less deprived individuals and also supports the finding that incidence of ATR in the study population was lower than that in some Scandinavian studies, since Scandinavian populations are known to be especially active.[254] Racket sports are considered a 'textbook' mechanism of injury for ATR. While these were common injuries, soccer accounted for approximately double the number of ATR in this study. Variations in the type of sporting activity engaged in at the time of injury were also observed between SEDS groupings, with soccer being commoner among MD individuals and racket sports being commoner amongst LD individuals. It is known that more deprived individuals are more likely to engage in team sports while less deprived individuals are more likely to engage in solo sports and reasons for this may include cost and access to facilities.[257] MD individuals were also more likely to sustain low energy ATR, which is consistent with higher levels of sedentary lifestyle in this demographic group.[254] There was a

statistically insignificant trend towards greater numbers of open injuries in the more deprived cohort in this study. This would be in keeping with previous reports by Corfield et al and Zarzaur et al, of higher incidence of penetrating trauma in individuals with greater levels of socioeconomic deprivation.[218, 246] As open Achilles tendon injuries are relatively rare, it is possible that the inability to demonstrate a statistically significant difference in incidence of these between the MD and LD groups, despite a more than five-fold higher incidence in the MD group, relates to type II error.

There is little evidence to support or refute a link between BMI and the incidence of ATR: one study suggested that increasing BMI confers increased risk of ATR[258] while another reported no significant variation in BMI between ATR cases and controls.[259] There is, however, a well-known association between increasing levels of social deprivation and increasing BMI[260-263] and this is likely to explain the increased BMI in the MD group. Whatever the relationship between BMI and the incidence of ATR, this study found that all classes of obesity were commoner in MD individuals with ATR. This may have important implications on treatment outcomes for ATR in deprived patients, since both surgical complications[264] and inadequacy of ankle plaster immobilisation[265] are commoner in obese patients.

Fluoroquinolone antibiotics and systemic steroid use have been reported to be risk factors for ATR.[266-269] Fluoroquinolones are a class of bactericidal antibiotics that exert their action through the inhibition of topoisomerase enzymes (DNA gyrase and topoisomerase IV) which have important functions in controlling the topological state of DNA, including supercoiling. These enzymes are essential for DNA replication, transcription, recombination and repair.[270] Fluoroquinolones are derived from nalidixic acid, a substance first synthesised by Lesher et al in 1962[271] and became commercially available in the 1980s, with norfloxacin the first fluoroquinolone in mainstream use, followed by ciprofloxacin.[270] They are one of the most commonly prescribed antibiotic classes.[272, 273] Case reports of tendon rupture in the context of

fluoroquinolone use began to appear in the medical literature in the early 1990s[274] and were followed by case-control and cohort studies[269, 275] and eventually systematic reviews.[214, 276] The exact mechanisms by which fluoroquinolones mediate tendon injury are not fully understood, but may relate to oxidative stress and possibly mitochondrial damage.[277] It has been estimated that fluoroquinolone use triples the risk of ATR but the incidence of ATR in patients on fluoroquinolones remains low[269] and they are implicated in between 0.3% and 3.8% of ATR.[267, 269, 278] Recent quinolone use was noted in 2.3% of ATR in this study, in keeping with the previous descriptions. Systemic corticosteroids are also reported to increase the risk of ATR, possibly by causing tendon atrophy and weakening[258] and their use was noted in just under 5% of cases in this study. However there was no demonstrable difference in use of these drugs preceding ATR, between the MD and LD groups.

Patients in the LD group were more likely to give a history of tendinitis prior to ATR. Conversely, a history of inflammatory arthropathy was commoner in the MD group, although this trend was narrowly statistically insignificant (p=0.057) after adjusting for confounders with regression analysis. Inflammatory arthropathies are known to occur more commonly in more deprived individuals[279] and have also been linked to ATR, independently of the corticosteroids often used in their treatment.[258] Although these cases make up only a small proportion of total ATR, the findings do suggest that there are significant variations in patient factors, co-morbidities and preceding symptoms across SEDS groupings, which may account for some of the variation in incidence observed with SEDS and that ATR are not a homogenous group of injuries.

Taken together, these findings suggest that the cause of ATR is multifactorial,[280] with differences identified in mechanism of injury, seasonality and patient factors between more and less deprived groups.

The reported incidence of clinically symptomatic VTE after ATR in the medical literature varies widely,[281-284] while the rate reported in this study was 3.5%, and like the incidence of re-rupture, it was not found to vary significantly with SEDS. However, patients who sustained a VTE had a higher BMI than their counterparts who did not. Increasing BMI is well known to correlate with increased risk of VTE in general terms.[285] In addition to this, other authors have reported that increased BMI is associated with VTE risk in the context of foot and ankle surgery.[286] It is perhaps therefore not surprising that obese patients with ATR may be at increased risk of VTE. Clinicians should be aware of this potential association when counselling patients with ATR.

The study is clinically relevant since it documents a new association between socioeconomic deprivation status and ATR, which has important implications for health service planning and resource allocation, particularly as socioeconomic deprivation status is known to exhibit marked geographic variation.[235, 287] It has previously been reported that ATR are frequently misdiagnosed on presentation and this is especially the case in older individuals.[288] The reporting of a second peak in incidence of ATR in older individuals, which was more marked in LD individuals, should raise awareness among clinicians that ATR are not exclusively injuries of the young adult, as they are commonly perceived to be. Unlike registry or database epidemiological studies, which are limited by the collection of only basic demographic data,[32, 33, 36, 37, 40], this study permitted more detailed analysis of the circumstances surrounding injuries, including the mechanism of injury, co-morbid conditions and preceding symptoms, giving clinicians a comprehensive picture of the epidemiology and clinical features of ATR at population level.

2.4.3 Limitations

This study does have limitations, including its retrospective nature and the potential for type II error when analysing some less common variables. As with all epidemiological studies, patients

who were misdiagnosed by their clinicians or who failed to present for medical attention will have been missed, although any patients diagnosed in a delayed fashion will have been included in the study.

2.5 Conclusion

The incidence of ATR was related to SEDS, being higher in patients with lower levels of socioeconomic deprivation. Furthermore, significant variations in patient and predisposing factors, mechanisms of injury and seasonality were demonstrated between more and less deprived patients with acute ATR, suggesting that the circumstances and nature of ATR may vary with SEDS status and that these are not a homogenous group of injuries.

Chapter 3: Achilles Tendon Re-Ruptures: Epidemiology and Associated Risk Factors

3.1 Introduction

Primary ATR are common soft tissue injuries and their incidence is rising.[31, 32, 38] ATRR is a much-feared and widely discussed complication of primary ATR.[91, 99, 289] ATRR is given significant publicity in the medical literature. The re-rupture rate is reported in almost every published study on ATR and ATRR has been an outcome measure of multiple randomised studies[290, 291] and meta-analyses[91, 99, 292] in the field. Despite this, studies detailing the epidemiology of ATRR are lacking. This is in contrast to the epidemiology of primary ATR, which has been extensively documented[31-34, 36-38, 245] and whose incidence is known to have risen in recent decades.[32-34, 36-38, 212] This is surprising, given that ATRR is by far the most frequently reported complication of primary ATR[91, 99, 292] and that it is also known to be associated with poorer patient reported and functional outcomes and lower rates of return to sports[289, 293] than uncomplicated primary ATR, while patients who sustain ATRR are subjected to further treatment that often requires additional surgery and further prolonged periods of rehabilitation.[289, 294-296]

It is also unclear which patients with primary ATR are at increased risk of ATRR and only a few studies have attempted to identify risk factors for ATRR,[103, 119, 223, 297] with most of these unable to identify any associated factors.[103, 119, 297] Surgical repair may result in a reduction in re-rupture rate although the relative risk reduction is small and often only identifiable when results from individual studies are pooled into meta-analyses[91, 298] and this potential benefit must be weighed against the potential risk of surgical complications.[299] Although it is believed that

modern functional rehabilitation regimes for primary ATR may be associated with lower levels of re-rupture than traditional cast immobilising regimes, the authors of a previous meta-analysis lamented a lack of direct evidence in this regard.[99] Subsequent randomised controlled trials comparing traditional and functional rehabilitation, including the study in Chapter 5,[291] have suggested trends towards higher re-rupture rate with traditional immobilising techniques but these were not statistically significant.[158, 291] This may be the result of difficulty with adequately powering prospective randomised controlled trials to detect differences in the rate of occurrence of relatively uncommon complications. In such scenarios, larger observational studies (such as the one that comprises this chapter of the thesis) may be better able to detect such differences, if indeed they exist. A better understanding of the risk factors for ATRR would allow higher risk patients to be identified and counselled accordingly and any modifiable risk factors identified may present opportunities to reduce the risk of ATRR.

The primary aim of this study was to describe the epidemiology of ATRR. The secondary aim of this study was to determine whether it is possible to identify factors that predispose patients to increased risk of ATRR at the time of primary ATR.

3.2 Methods

3.2.1 Study Design

A retrospective electronic search of all health-board medical records was undertaken to identify patients treated for primary ATR and ATRR between 1st January 2011 and 31st December 2016. All records in the health-board are electronically recorded and were searched for the following search terms: 'Achilles', 'tendoachilles', 'TA', 'rupture', 'tear', 'torn', to identify any patients treated for Achilles tendon rupture in any of the Accident and Emergency, outpatient or inpatient services. The preliminary search returned 4521 records. Each was

screened according to the inclusion and exclusion criteria (table 3.1), leaving 791 patients eligible for inclusion in this study. Records were assessed up to the time of study, with a minimum review period of 1.5 years after the primary ATR. The nature and circumstances of primary ATR and ATRR were recorded. ATR were diagnosed clinically, with ultrasound used at the discretion of the treating physician if there was doubt as to the diagnosis.

Two separate databases were compiled from this data (figure 3.1): the first, consisting of 791 entries, which included any patient presenting with a rupture of the Achilles tendon (either primary ATR or ATRR) between January 2011 and December 2016, permitted the epidemiological study of ATRR; and the second database, consisting of 779 entries, which included only patients presenting with a primary ATR between 1st January 2011 and 31st December 2016 and completing treatment for this at the study institution and recorded re-ruptures occurring at any subsequent time point with a minimum review period of 1.5 years from the date of primary injury (which thereby permitted analysis of factors that might predict ATRR at the time of presentation with primary ATR). Seasonality was defined according to the northern hemisphere meteorological system.[241] This study was part of a departmentally approved service review of ATR which was reviewed by the scientific officer for the regional ethics committee (REC) who advised that REC review was not necessary.

Inclusion criteria	Exclusion criteria
Any Achilles tendon rupture (primary or re-rupture) within the period 01/01/2011-31/12/2016 Rupture of any anatomic region of the Achilles tendon Patients residing within the NHS Lothian health-board geographical region as defined by the Scottish Government National Records of Scotland Small Area Population Estimate data zones (i.e. patients residing within the 1083 data zones that make up the health-board catchment area), even if they initially presented elsewhere and only returned to the health-board for ongoing care.	Patients residing out with the NHS Lothian health-board geographical region For part 2 only: • Patients whose first presentation during the study period was with a re-rupture. • Patients who initially presented to the health-board with their primary ATR but completed their treatment for this injury elsewhere.

Table 3.1. Inclusion and exclusion criteria.

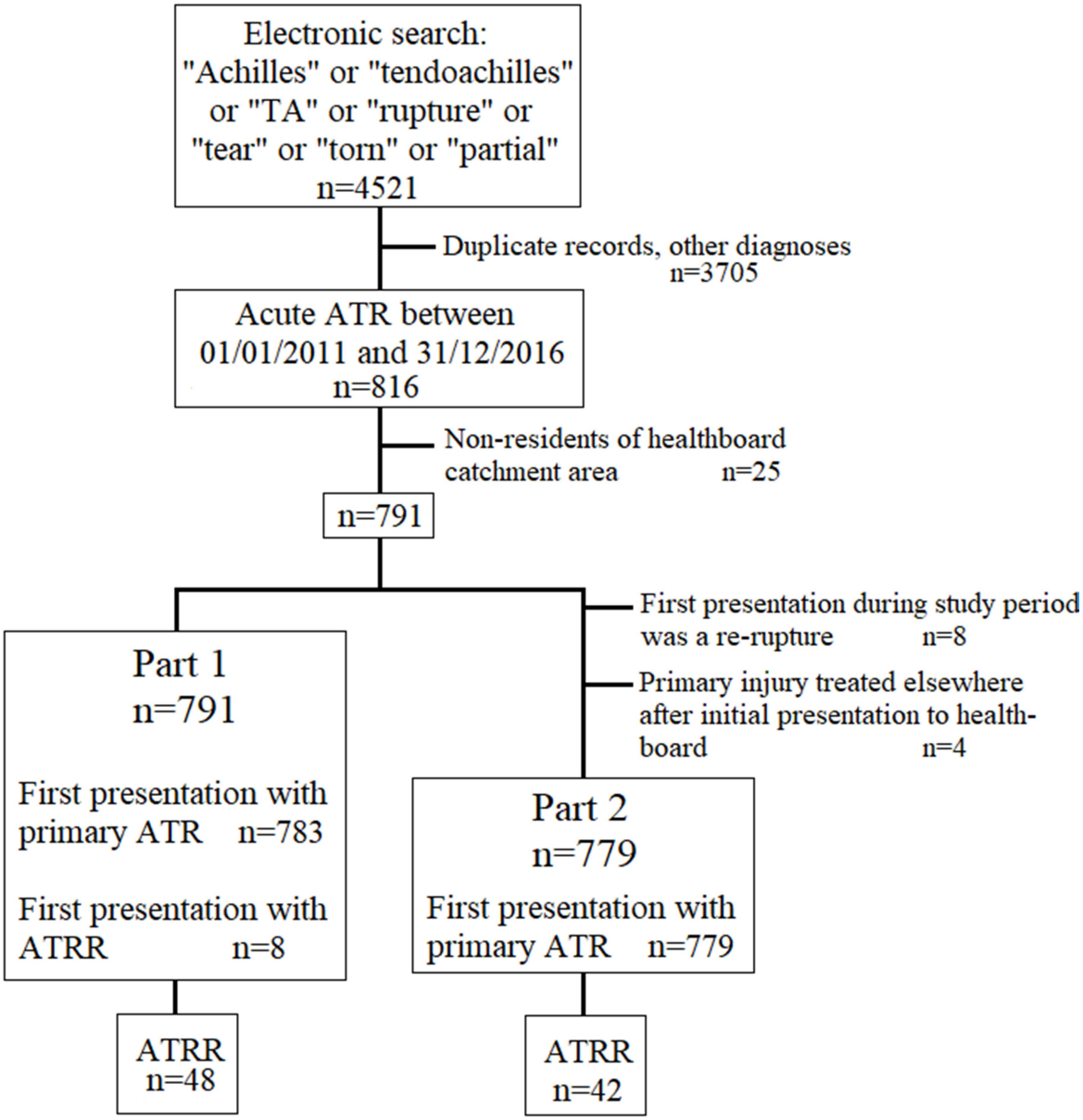


Figure 3.1. Flow diagram for the study. Part 1 consists of 791 acutely presenting ATR, including eight patients whose first presentation during the study period was with a re-rupture and 783 who first presented with a primary ATR. Of these 783, 40 developed a subsequent re-rupture between January 2011 and December 2016. Thus there were 48 ATRR in total, occurring between January 2011 and December 2016. This data was used for epidemiological descriptions relating to ATRR during the study period and for comparison of presenting features of the 48 identified ATRR with those of primary ATR injuries. Part 2 consists of 779 patients presenting with acute primary ATR between January 2011 and December 2016, who completed treatment for the primary injury at the study institution. In this group, there were 42 patients with ATRR, comprising the 40 patients mentioned previously in part 1 and a further two patients who had presented with primary ATR before December 2016, but who developed an ATRR during the review period after 1st January 2017. This data was used to compare variables at primary ATR presentation for patients who did and did not go on to develop ATRR to determine whether any risk factors for ATRR at the time of presentation with primary ATR could be identified.

3.2.2 Setting

As previously described (Chapter 2.2.1), the health-board is the only authority overseeing delivery of regional healthcare services in the National Health Service (NHS) and there are no other NHS providers in this region. Emergency services are provided through 3 emergency departments and one minor injuries unit; orthopaedic surgery is performed at two locations and outpatient clinics are based at five locations. There are two private hospitals in the region but none of these have an emergency department and therefore acute presentations are routed through the NHS and should be identified by the search algorithm employed.

3.2.3 Population-level definitions

The health board population (total, gender-specific and with reference to age brackets) for each year of study was determined using Scottish Government population data from the National Records of Scotland (NRS), who issue annual mid-year population estimates for each health board.[234] SEDS and health-board population characteristics were determined using the Scottish Index of Multiple Deprivation (SIMD-16) in the same fashion as that employed in Chapter 2. SIMD data is published quadrennially, unlike the mid-year population estimates for the health board and therefore, for the socioeconomic deprivation analysis only, the SIMD-16 health board population data was used to determine the size of more and less deprived components of the health board population, which were assumed to be static during the period of study. Patients were matched to their corresponding data zone using their postcode and SEDS data was available for all patients. They were categorised into biquintiles, each comprising of patients from data zones in the most deprived 40% and least deprived 40% bands of the national population.

3.2.4 Treatment of Primary Achilles Tendon Rupture

Non-operative management is routinely employed at the study institution unless there are specific indications for surgery (e.g. delayed presentation or patient request) and the period of study straddled a move from traditional immobilising cast treatment (with 10 weeks of cast immobilisation comprising of 4 weeks in equinus and 4 weeks in semi-equinus, non-weight bearing, followed by 2 weeks in a neutral, weight bearing cast and then a further 2 weeks with a shoe heel raise) to a modern functional early weight-bearing regime (with immediate weight bearing in a walking boot orthosis and progressive reduction of heel wedges such that the foot was in full equinus for 4 weeks and then semi-equinus for 2 weeks, reaching a neutral position by 6 weeks and the boot was removed at 8 weeks) as the standard treatment for primary ATR. Surgical treatment, when performed, was by open means. For the purposes of statistical analysis, treatment type was defined as the first commenced definitive treatment after the initial A&E treatment (A&E management usually comprises of a temporary equinus backslab and crutches).

3.2.5 Statistical Analysis

The annual incidence of ATRR per 100,000 was calculated as the number of cases occurring between 1st January and 31st December, divided by the health-board population (or relevant population bracket), as defined in the government mid-year population estimate for that year. The resulting figure was multiplied by 100,000. The occurrence of ATRR was reported in the most and least socioeconomically deprived national biquintiles (40% bands) in the health-board population, over the period of study, as described above.

Data parametricity in the ATR cohorts was assessed using Kolmogorov-Smirnov testing. Non-parametric data was reported as median with interquartile range and compared using Independent Samples Mann Whitney U tests. Nominal variables were compared using Chi-

Squared tests (or Fisher's Exact test if cell count was <5 in any cell). Binary logistic regression was undertaken to identify variables that were independently associated with ATRR at the time of presentation with primary ATR. Variables with a p-value of ≤0.05 on initial analysis were included in the regression model. The threshold for age used in the regression analysis was determined using a receiver operator characteristic curve to identify the threshold value that predicted ATRR with maximum combined sensitivity and specificity (Appendix 3.1). A p-value of ≤0.05 was considered significant.[242]

3.3 Results

3.3.1 Part 1 (Primary Outcome): Epidemiology of re-rupture of the Achilles Tendon

Seven hundred and eighty three patients (567 males, 72.4% and 216 females, 27.6%) residing in the health-board catchment population presented with a primary ATR and 48 patients (41 males, 85.4% and 7 females, 14.6%) presented with an Achilles tendon re-rupture between January 2011 and December 2016. For those presenting with a re-rupture of the Achilles tendon during this time period, the median time between their primary ATR and the re-rupture was 99.5 days (IQR 82.25-130.75), although 8 ATRR (16.7%) occurred late, between 3 and 50 years after the primary injury (figure 3.2). Males (mean 6.83 cases per year, range 2-10; in an average male population of 416,096) were affected more commonly than females (mean 1.17 cases per year, range 0-3; in an average female population of 439,902; *p*=0.034 FET; OR=7.40, 95%CI=0.91-60.15).

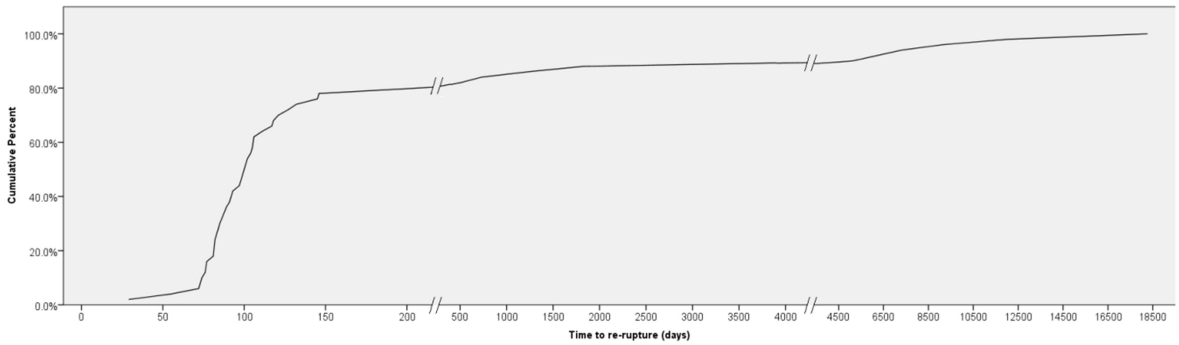


Figure 3.2. Cumulative incidence (%) of ATRR over time relative to date of primary ATR. Note the differing scales used on the x-axis in different parts of the graph representing the short, medium and longer-term.

The median age at time of presentation with an Achilles tendon re-rupture was 44 years (IQR 33-54) and there was a trend towards older age in females presenting with ATRR (median age 47 years, IQR 42-66), as compared to males (median age 41 years, IQR 33-52; p=0.10). The gender divide in favour of males was more pronounced in the re-rupture group as compared to the primary ATR cohort (p=0.048; OR=2.23, 95%CI=0.99-5.05).

The mean incidence of ATRR over the study period was 0.94/100,000 per year (range 0.45 to 1.17/100,000 per year) for all ages (figure 3.3) and 1.16/100,000 per year (range 0.56-1.44/100,000 per year) for the adult population (≥18 years). This compares to a mean incidence of primary ATR of 15.26/100,000 per year (range 13.51 to 19.07) for all ages and 18.75/100,000 per year (range 16.56-23.57) in adults (≥18 years). The peak incidence of both primary ATR and ATRR was in the fifth decade of life for both genders and a bimodal age distribution was observed (figures 3.4a and 3.4b).

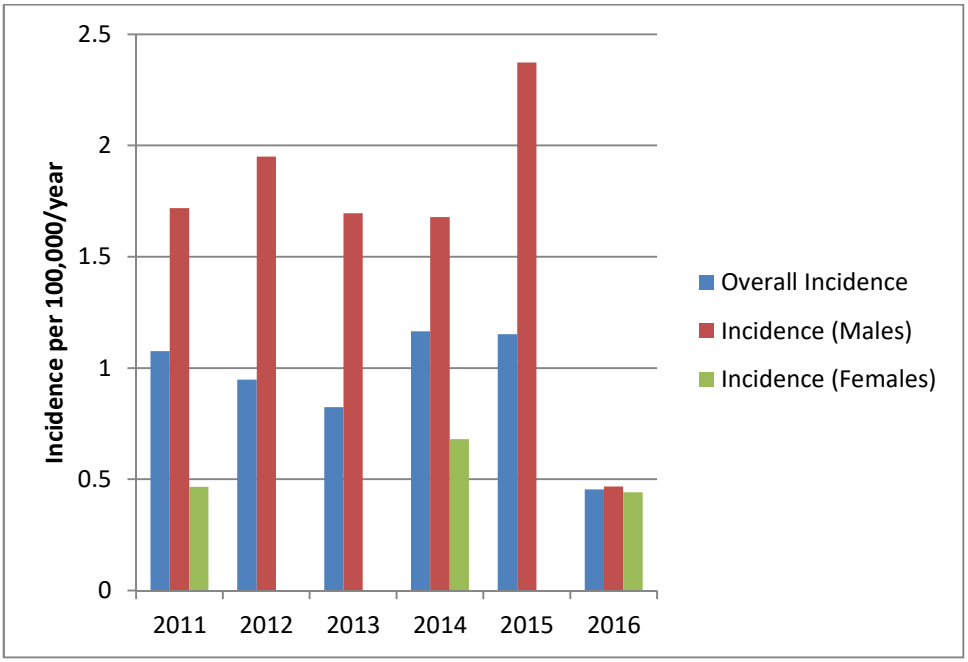


Figure 3.3. Incidence of Achilles tendon re-rupture.

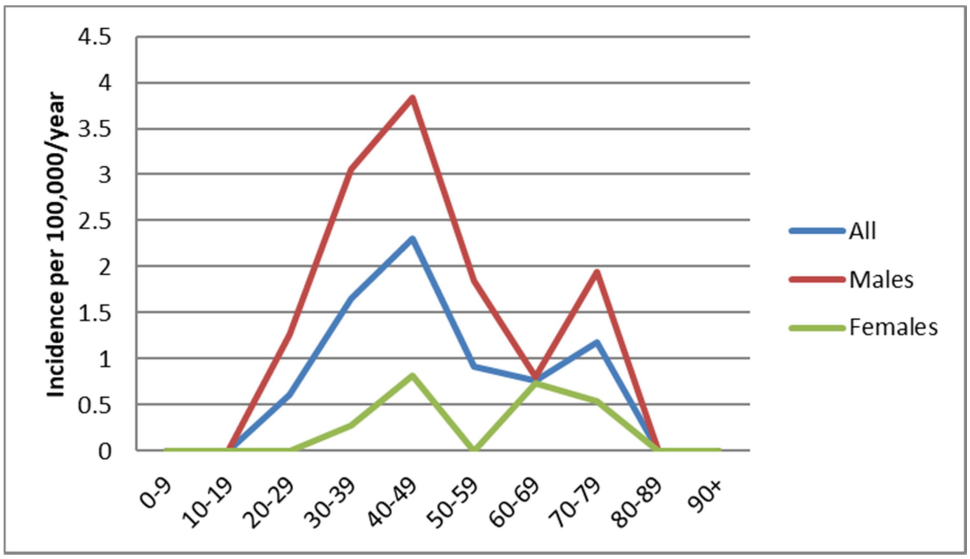


Figure 3.4a. Mean annual incidence of ATRR over the study period in the health-board population by age bracket.

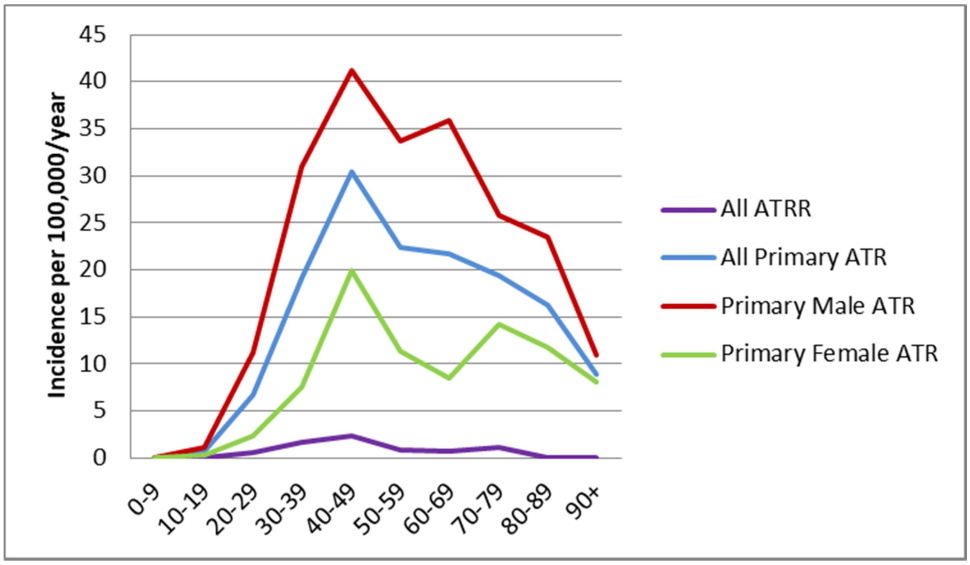


Figure 3.4b. Mean annual incidence of primary ATR over the study period in the health-board population by age bracket. The mean annual incidence by age for ATRR is included in the graph for reference purposes (purple line).

There was a statistically significant relationship between incidence of ATRR and socioeconomic deprivation status, with incidence over the study period being higher in the least deprived population biquintile (33 cases in a population of 425,254) as compared to the most deprived biquintile (11 in a population of 294,239; OR=2.01, 95%CI 1.01-3.97, p=0.04).

ATRR occurred most frequently during the summer months (figures 3.5a and 3.5b) and June was the mode month of injury but there was no statistically demonstrable seasonal variation ($p \geq 0.13$) in incidence of ATRR (Table 3.2).

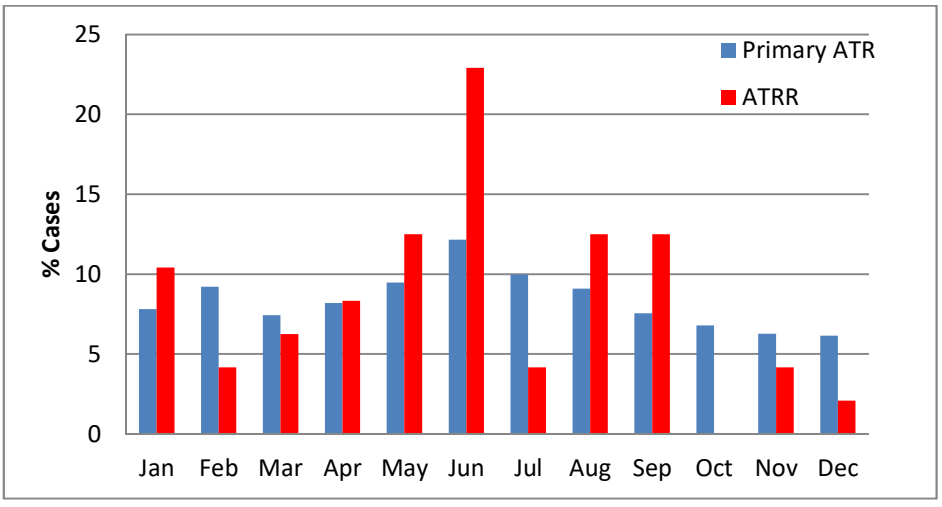
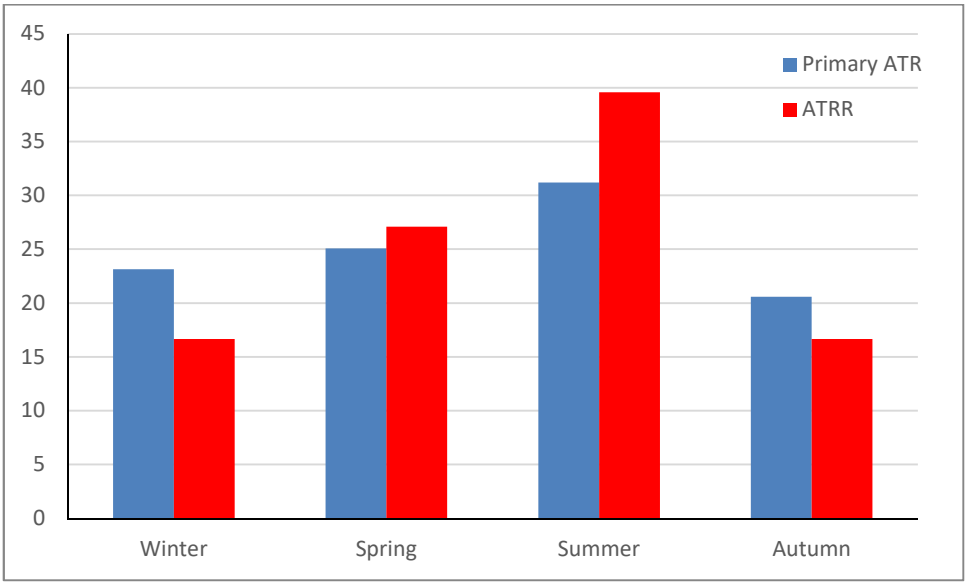


Figure 3.5a. Incidence of primary ATR and ATRR by month.



Figures 3.5b. Incidence of primary ATR and ATRR by season.

	Actual distribution	Expected distribution in the absence of seasonal variation	*p*-value
Autumn	8	12	0.32*
Winter	8	12	0.32*
Spring	13	12	0.82*
Summer	19	12	0.13*
Total	48	48	

Table 3.2. Actual incidence of ATRR per season compared to expected incidence of ATRR in the absence of any seasonal variation. *Chi square test.

The majority of ATRR were low energy injuries, with spontaneous ATRR, injuries while walking and other low energy mechanisms accounting for almost 60% of injuries. Two ATRR (4.2%) occurred while patients were undertaking primary ATR rehabilitation exercises (Table 3.3). By contrast, 60% of primary ATR occurred as a result of sporting or dancing activity.

Treatment of ATRR was surgical in 36 cases (75%) while 5 patients (10.4%) were advised surgical management but declined this. Three patients were treated using the standard casting regime and 3 with a walking boot regime; one patient was lost to follow up after radiological confirmation of re-rupture.

	Primary ATR	ATRR
Sport	388 (49.6%)	3 (6.3%)
Walking	55 (7.0%)	13 (27.1%)
Low Energy*	68 (8.7%)	9 (18.8%)
Fall (>standing height)	17 (2.2%)	1 (2.1%)
Open injury	8 (1%)	0 (0%)
Blunt trauma	10 (1.3%)	1 (2.1%)
Running (non-sports)	20 (2.6%)	1 (2.1%)
Jumping (non-sports)	13 (1.7%)	1 (2.1%)
Dancing	81 (10.3%)	0 (0%)
Pushing/lifting heavy objects	21 (2.7%)	1 (2.1%)
Standing up from sitting/lying	12 (1.5%)	0 (0%)
Stairs/steps	41 (5.2%)	5 (10.4%)
No specific event/Spontaneous	22 (2.8%)	6 (12.5%)
Physiotherapy/rehabilitation exercises	N/A	2 (4.2%)
Other	16 (2.0%)	4 (8.3%)
Unknown	11 (1.4%)	1 (2.1%)
Total	783	48

Table 3.3. Mechanism of injury for primary ATR and ATRR. * Low energy category includes slips, trips, stumbles, ankle inversion injuries and falls from standing height.

3.3.2 Part 2 (Secondary Outcomes): Predictors of re-rupture at time of first presentation

3.3.2.1 Patient Factors

Males presenting with a primary ATR were more likely to sustain ATRR than females (OR=2.97, 95%CI=1.15-7.66, $p<0.001$) and patients who went on to develop ATRR were younger at first presentation than their counterparts who did not ($p=0.019$), however there were no other identifiable demographic differences that were found to be predictive of re-rupture, at the time of first presentation with an ATR (Table 3.4).

	ATRR patients (n=42)	Patients without ATRR (n=737)	*p*-value
Gender			
Male	37 (88.1%)	526 (71.4%)	<0.001*
Female	5 (11.9%)	211 (28.6%)	
Age (median, IQR)	41 (32-47)	48 (40-62)	0.019**
Ethnicity			
White British	33 (78.6%)	625 (84.8%)	
White Other	4 (9.5%)	36 (4.9%)	
Asian	0 (0%)	8 (1.1%)	0.56†
Black	0 (0%)	10 (1.4%)	
Other	0 (0%)	5 (0.6%)	
Unknown	5 (11.9%)	53 (7.2%)	
BMI (median, IQR)	25.56 (23.72-28.42)	26.76 (24.26-30.59)	0.17**
SEDS			
More Deprived¶	9 (21.4%)	183 (24.8%)	0.48*
Less Deprived¶	28 (66.7%)	431 (58.5%)	

Table 3.4. Baseline characteristics for patients according to re-rupture status for 779 patients with primary ATR comprising the cohort in part 2. *Chi Square test; **Independent Samples Mann Whitney U-test. †Fisher's Exact test for proportion of patients who self-identified as White British (including Scottish) compared to all other known ethnicities. ¶Most and least deprived groupings refer to patients falling into quintiles 1 and 2 vs quintiles 4 and 5 of the Scottish Index of Multiple Deprivation respectively. Body mass index (BMI) was determined from height and weight documented at the closest-available time point to primary ATR; this was known for 74.7% of patients (n=582/779).

3.3.2.2 Mechanism and Season of Injury

No particular season at the time of primary ATR conferred an increased risk of ATRR (Table 3.5). No mechanism of primary ATR was shown to be associated with an increased risk of re-rupture, although there was a trend to increased risk of ATRR in patients who sustained their primary injury during sporting activity (p=0.059, Table 3.6).

	Patients with subsequent ATRR	Patients without subsequent ATRR	Odds Ratio (95%CI)	*p*-value
Autumn	7 (16.7%)	152 (20.7%)	0.77 (0.34-1.76)	0.53*
Winter	13 (31%)	168 (22.8%)	1.52 (0.77-2.98)	0.23*
Spring	10 (23.8%)	184 (25%)	0.94 (0.45-1.94)	0.86*
Summer	12 (28.6%)	232 (31.5%)	0.87 (0.44-1.73)	0.69*
Total	42	736		

Table 3.5. Seasonality of primary ATR in patients who did and did not go on to develop ATRR. *Chi square test.

	Whole cohort (n=779)	Patients with subsequent ATRR (n=42)	Patients without subsequent ATRR (n=737)	OR (95%CI)	*p*-value
Sport	385 (49.4%)	27 (64.3%)	358 (48.6%)	1.85 (0.97-3.54)	0.059*
Walking	55 (7.1%)	1 (2.4%)	54 (7.3%)	0.30 (0.04-2.25)	0.35**
Low Energy†	68 (8.7%)	2 (4.8%)	66 (9%)	0.50 (0.12-2.12)	0.57**
Fall (>standing height)	17 (2.2%)	1 (2.4%)	16 (2.2%)	1.08 (0.14-8.36)	1.0**
Open injury	8 (1.0%)	1 (2.4%)	7 (0.9%)		0.36**
Blunt trauma	10 (1.3%)	1 (2.4%)	9 (1.2%)	1.94 (0.24-15.71)	0.43**
Running (non-sports)	20 (2.6%)	2 (4.8%)	18 (2.4%)	1.97 (0.44-8.77)	0.3**
Jumping (non-sports)	12 (1.5%)	0 (0%)	12 (1.6%)	0.94 (0.93-0.96)	1.0**
Dancing	81 (10.4%)	5 (11.9%)	76 (10.3%)	1.16 (0.44-3.03)	0.80**
Pushing/lifting heavy objects	21 (2.7%)	0 (0%)	21 (2.8%)	0.94 (0.93-0.96)	0.62**
Standing up from sitting/lying	12 (1.5%)	0 (0%)	12 (1.6%)	0.94 (0.93-0.96)	1.0**
Stairs/steps	41 (5.3%)	0 (0%)	41 (5.6%)	0.94 (0.93-0.96)	0.16**
No specific event	22 (2.8%)	1 (2.4%)	21 (2.8%)	0.82 (0.11-6.24)	1.0**
Other	16 (2.1%)	1 (2.4%)	15 (2.0%)	1.16 (0.15-8.97)	0.60**
Unknown	11 (1.4%)	0 (0%)	11 (1.5%)	N/A	N/A
Total	779	42	737		

Table 3.6. Mechanism of injury for the primary Achilles tendon rupture in patients who did and did not go on to develop ATRR. *Chi square test. **Fisher's Exact test. † Low energy category includes slips, trips, stumbles, ankle inversion injuries and falls from standing height.

3.3.2.3 Other Potential Predisposing Factors

There was no demonstrable association between medication induced primary ATR, a history of preceding tendinitis at time of primary ATR or a medical history of diabetes or inflammatory arthropathy and the incidence of ATRR (Table 3.7).

	Patients with subsequent ATRR	Patients without subsequent ATRR	Odds Ratio (95%CI)	*p*-value
Diabetes	0	61	1.06 (1.04-1.08)	0.068*
Inflammatory Arthropathy	0	16	1.06 (1.04-1.08)	1.0*
Preceding Achilles tendinitis**	0	56	0.94 (0.93-0.96)	0.065*
Fluoroquinolone use**	0	18	1.06 (1.04-1.08)	0.62*
Steroid use**	1	37	2.17 (0.29-16.24)	0.72*

Table 3.7. Patient factors at time of primary ATR in patients who did and did not go on to develop ATRR. *Fisher's Exact test. **within 6 months prior to primary ATR.

3.3.2.4 Primary ATR Treatment

Immobilising cast treatment of the primary ATR was associated with an increased risk of ATRR (Table 3.8).

	Patients with subsequent ATRR	Patients without subsequent ATRR	Odds ratio (95%CI)	*p*-value
Immobilising cast treatment	34 (6.7%)	470 (93.3%)	2.40 (1.09-5.25)	0.025*
Functional walking boot rehabilitation	6 (3.8%)	153 (96.2%)	0.63 (0.26-1.53)	0.31*
Surgical repair	2 (3.8%)	50 (96.2%)	0.69 (0.16-2.92)	1.0**
Other	0	62	N/A	N/A

Table 3.8. Treatment regime for primary ATR in patients who did and did not go on to develop ATRR. Odds ratios and *p*-values are for the treatment method relative to all other cases. * Chi square test. ** Fisher's Exact test.

3.3.2.5 Regression Model

Patients under the age of 45 years at time of primary ATR and those treated with traditional cast immobilisation were more likely to sustain ATRR (Table 3.9). There was a narrowly insignificant trend towards increased incidence of ATRR in males (p=0.052).

	Adjusted Odds Ratio (95%CI)	*p*-value
Age		
>45 years	Reference	
<45 years	1.96 (1.04-3.71)	0.037
Sex		
Female	Reference	
Male	2.58 (0.994-6.71)	0.052
Cast immobilisation	2.20 (1.0-4.85)	0.050

Table 3.9. Adjusted odds ratios (95%CI) and *p*-values for binary logistic regression model for prediction of ATRR at the time of primary ATR.

3.4 Discussion

This study represents the largest series of ATRR reported to date. The most important finding was the description of the epidemiology of ATRR, which was explored in detail. Known trends such as male predilection for these injuries[223] are confirmed, as is the association with younger age at time of primary ATR, previously alluded to in a single small study with four re-ruptures,[300] while other novel findings are described, including the incidence of a small but significant number of late ATRR, occurring years after the primary injury and a greater incidence of ATRR in patients with lower levels of socioeconomic deprivation. Mechanisms of injury are contrasted between primary ATR and ATRR. Independent relationships between ATRR risk and male sex, younger age and traditional immobilising cast treatment at the time of primary ATR were identified and reported.

3.4.1 Epidemiology of Achilles Tendon Re-rupture

Epidemiological studies of ATRR are lacking, with review of the literature revealing only one brief description of population-level incidence of these injuries in a study that focussed primarily on comparison of patient characteristics between patients who developed either infection or a re-rupture after surgical repair of ATR.[301] Other studies reporting on ATRR seek to compare these patients only to those with primary ATR.[103, 119, 223, 293] This is in contradistinction to the

epidemiology of primary ATR, which is widely documented in population based studies.[32, 33, 36-38, 212, 288] Previous epidemiological studies have shown that primary ATR occur more frequently in males,[32, 33, 36-38, 212] but the only report of male predilection to ATRR is based on comparisons of ATRR relative to a primary ATR cohort rather than on population level data.[223] The current study demonstrated a male predilection to ATRR both at population level (where odds of ATRR were over 7 times those for females) and also relative to primary ATR. Furthermore, age-specific incidence for the population is reported, which, similarly to primary ATR[38] (as detailed in Chapter 2, figure 2.4), demonstrates a bimodal age-related incidence of ATRR, with peak incidence of ATRR in the general population in the 5th decade of life and second peaks in later life for both males and females (although the secondary peaks occurred one decade later for males and earlier for females than those observed for primary ATR in the same population. Unlike primary injuries, where the median age of affliction was the same for both males and females (Chapter 2.3.1), there was a trend towards lower median age of affliction for males with ATRR compared to females, but this did not reach statistical significance.

Patients presenting with ATRR had lower levels of socioeconomic deprivation than the general health-board population. Similar findings were noted with respect to primary ATR (Chapter 2, Figure 2.5) and are the opposite of trends observed for many traumatic injuries[216, 218, 219] and other musculoskeletal[215, 217, 230] and medical[250] conditions, where increasing incidence tends to correlate with increasing levels of socioeconomic deprivation. This finding may be mediated largely through the increased propensity of less deprived individuals to primary ATR, which is a prerequisite for ATRR, since there was no additional demonstrable disparity in re-rupture rates according to SEDS amongst patients who had already sustained a primary ATR.

ATRR were observed most commonly in the summer and more specifically in June, replicating observations of primary ATR incidence in the same population (figures 3.5a and 3.5b). However, the observed incidence of ATRR did not vary significantly by season, when

compared to a homogenous incidence of ATRR across the seasons, which would be expected in the absence of seasonal variation. This would suggest that there is no significant seasonal variation in incidence of ATRR, or possibly that the study was underpowered to detect any seasonal trends in ATRR. The concept of seasonal variation in the incidence of primary ATR is not new although the mode season of affliction for primary ATR is known to exhibit considerable geographic variation.[32, 37, 256, 302, 303] One small study has reported on the effect of season of primary injury on the risk of ATRR[302] but did not give any information on the seasonal incidence of re-ruptures themselves. In fact, seasonal incidence of ATRR does not appear to be a topic of previous study in the existing literature.

ATRR is generally thought to occur early on in the course of rehabilitation, usually within weeks of completing immobilisation.[61, 79, 101, 103, 117, 119, 223, 300] While this study found that the median time to ATRR was 14 weeks after primary injury and that most re-ruptures occurred early, it also found that 1 in 6 ATRR (8 of 48) occurred years after the primary injury, with the reported interval ranging from over 3 years through to 50 years. Studies designed to follow patients prospectively[97, 158, 291] or to retrospectively review patients recently presenting with primary ATR[119, 223, 300] (as was done in part 2 of this study) would be unable to pick up on this phenomenon. Almost all studies on ATR fall into these categories and this may be why this phenomenon (late ATRR) has not previously been recognised or reported. However it has potentially significant implications for studies using re-ruptures as an end-point and also for patients sustaining an ATR, who should not assume that they are 'in the clear' after navigating the early post-injury rehabilitation period uneventfully. Further study of these late ATRR is warranted to determine whether they differ in nature from the traditionally described early ATRR.

The majority of ATRR were low energy injuries, occurring during the course of simple walking, going up or down stairs or even spontaneously with no precipitating event. Two

patients (4.2%) sustained ATRR during rehabilitation exercises for their primary injury. These findings contrast those reported for primary ATR (Table 3.3) where sporting and dancing injuries accounted for the majority of injuries. Reito et al pondered whether the identification of individuals at increased risk of re-rupture would allow for less vigorous rehabilitation to reduce their risk of re-rupture, but ultimately found, in keeping with this study, that most injuries were low-energy injuries and questioned whether a less vigorous rehabilitation regime would have any bearing on these ATRR.[223]

3.4.2 Predictors of ATRR at the time of presentation with primary ATR

The second part of this study sought to determine whether patients at higher risk of ATRR could be identified and distinguished from other patients at the time of presentation with a primary ATR. Early identification of patients at higher risk would facilitate patient counselling and may permit preventive measures to reduce the risk of ATRR, particularly if any of the identified risk factors were modifiable.

To date, only a small number of studies have attempted to identify predictors of ATRR at the time of presentation with a primary ATR[103, 119, 223, 297] and most of these were unable to identify any risk factors for ATRR.[103, 119, 297] This may be the result of type II error, due to relatively small numbers of patients with ATRR in the studies rendering their power inadequate. Male sex is a well-known risk factor for primary ATR[32, 38, 304] (Chapter 2.3.1) but the nature of any association with ATRR has remained poorly understood. In agreement with the results of this study, male sex was found to predict ATRR in patients presenting with a primary ATR in one other study (albeit without correction for confounding factors),[223] but not in other studies.[103, 119, 300] The odds of ATRR in the health-board population in this study were more than seven times greater for males than females. Part of this disparity is explained by the predisposition of males for primary ATR (Chapter 2.3.1), which is a pre-requisite for subsequent ATRR. However, even within the group of patients with primary ATR, there was a clear trend towards increased

incidence of re-rupture in males, with adjusted odds of ATRR being 2.6 times greater in males, a finding which was just outside statistical significance (p=0.052) after adjusting for other confounders in the regression model. This suggests an additional male predisposition to repeat rupture that is independent of that for primary ruptures.

Younger patients presenting with primary ATR were at increased risk of subsequent re-rupture. One other study reported a higher incidence of re-rupture in younger patients, although this was based on a series of only four re-ruptures, in a selected group of athletes undergoing surgical repair of the Achilles tendon and was also unable to demonstrate an association between gender and ATRR, despite all ATRR in that study occurring in males.[300] Due to its size and the highly selected cohort under review, the results of that study cannot be extrapolated to general ATR populations. Another study was not able to demonstrate an association between younger age and overall ATRR risk, despite reporting a younger mean age in patients with ATRR.[223] In the current study, increased odds of ATRR in younger patients were confirmed, even after adjusting for confounding factors.

There was no demonstrable association between season of primary ATR and ATRR risk. This is in contrast to the findings of Saarensilta et al,[302] who reported that patients sustaining primary ATR in summer were more likely to develop ATRR. The reasons for this discrepancy are unknown but may relate to that analysis being based on a very small series of five re-ruptures which may therefore be prone to error, or the authors' decision to use percentages in the place of actual re-rupture numbers in that particular analysis, thereby increasing the cell counts in the cross table analysis artificially and concomitantly inflating the apparent statistical power without increasing patient numbers. As the patients in that study were not a consecutive series but included from amalgamation of previous randomised controlled trials, the seasonal incidence reported may have been affected by logistical issues such as the period of trial recruitment. In

addition, there was no regression analysis to correct for any potentially confounding factors in that analysis.[302]

Mechanism of primary ATR did not predict increased risk of re-rupture although there was a trend towards increased risk with sporting injuries. Pajala et al previously reported that sporting injuries were commoner amongst a cohort of surgically repaired ATR who developed re-rupture as compared to a cohort who developed post-operative infection, but did not compare patients who sustained an ATRR with those who did not develop a re-rupture.[301]

The re-rupture rate after functional non-operative rehabilitation was 3.8%, which is in keeping with the published literature[91, 99] and it was similar to that for surgically treated cases, while after traditional cast immobilisation, it was 6.7%. No difference was demonstrated between operative and other regimes, although this may be related to the small numbers of surgically treated patients in this study and the relative rarity of ATRR. In fact, the majority of individual studies similarly show no difference in this regard, although pooling of data in meta-analyses suggests that there is a small clinical difference in re-rupture rates in favour of surgery.[91] The inclusion of small numbers of surgically treated patients may have resulted in some heterogeneity of the group under study, however it appears that this experience reflects that of other units adopting predominantly non-operative management of ATR, where small numbers of patients continue to undergo surgery[61, 101, 103, 117] and is therefore in keeping with wider practice in the field of orthopaedics. This study provides evidence that traditional immobilising cast regimes are associated with higher re-rupture rates, even after adjusting for confounding variables that may influence re-rupture rate and such regimes should therefore be avoided. This is a belief that is widely held among the medical community and is said to have driven recent trends towards functional rehabilitation,[90, 99] although previous meta-analyses have lamented the paucity of direct evidence in this regard.[99] Despite the strong focus on functional rehabilitation in the published literature, it should not be assumed that cast-based immobilising techniques are no

longer used in the wider clinical community. Indeed, surveys have shown that management of ATR often does not follow the evidence base[132] and that plaster cast immobilisation continued to be employed by many practitioners,[133] even after the publication of studies favouring functional rehabilitation.[62, 90, 95, 97, 305]

Primary ATR is a pre-requisite for ATRR. Factors that appear to influence the incidence of ATRR may therefore be associated directly with ATRR, or may be mediated indirectly, in part or in full, through a propensity for the primary injury. It is therefore unsurprising that some of the characteristics of ATRR observed in the general population, such as the relationship with SEDS, mirror those of primary ATR and were not found to be associated with ATRR specifically in patients who have already sustained a primary ATR. This suggests that some features of ATRR are mediated indirectly, through a propensity for the primary injury. Conversely, other features, such as male sex, showed distinct associations with both primary ATR (Chapter 2.3.1) and ATRR, indicating additive direct and indirect effects on the incidence of ATRR and that ATRR are not simply a random selection of cases from a parent population with primary ATR. The occurrence of ATRR is likely multifactorial and may represent the sum of some features which predispose to primary ATR resulting in a degree of pre-selection, as well as other additional factors which may act independently, or in an additive fashion to these. Furthermore, while some factors that are associated with re-rupture are non-modifiable (e.g. male sex and younger age at the time of primary injury), others (such as choice of treatment regime) are potentially modifiable and may present opportunities for intervention to reduce patients' risk of ATRR.

3.4.3 Limitations

This study does have limitations including its retrospective nature and with this, the possibility of loss to follow up. Despite being by far the largest reported series of ATRR, the potential for type II error remains, particularly for less common variables, although this would relate to the secondary aims of the study and multiple statistically significant relationships have nonetheless

been identified, including on regression analysis. Furthermore, as with all epidemiological studies, individuals who did not seek medical care for their injuries or were misdiagnosed by treating healthcare professionals will have been missed, as may have been others. Strengths of the study design include reporting in two parts with different scope. The first part was able to demonstrate important information about ATRR epidemiology and in particular, late re-ruptures, which would not otherwise be possible. As with all retrospective reviews, a minimum follow up time had to be defined in the second part of the study, although the minimum 1.5 year threshold chosen is longer than that used in other studies on the topic.[119, 223] Additionally, most patients had a significantly longer review period than the minimum defined period and data from part 1 of the study suggests that 80% of ATRR would have occurred within this minimum timeframe. Targeted data collection in this study permitted detailed analysis of all primary ATR and re-ruptures, in contrast to some registry based studies which are limited to the demographic data routinely collected in the registry and may also be unable to differentiate between primary ATR and ATRR.[32]

3.5 Conclusion

This study represents the largest series of ATRR described to date and details the epidemiology of ATRR in a general health-board population. It provides new insight into the demographics of patients and circumstances surrounding these injuries, in comparison to the better known features of primary ATR. Several associations are described, including with male sex, age distribution and lower levels of socioeconomic deprivation, while mechanisms of injury are contrasted between primary ATR and ATRR. The novel finding of a small but significant incidence of delayed ATRR, occurring years after the primary injury, has important implications for both patients and also studies using ATRR as an end-point and has not previously been recognised in the existing literature. A separate secondary analysis of patients presenting with

primary ATR identified male gender, younger age and traditional immobilising cast treatment with prolonged non weight-bearing, as predictors of increased risk of re-rupture and quantified their independent impact on re-rupture risk, providing clinicians with useful data for patient counselling and evidence to support recent management trends which have seen a shift away from traditional immobilising treatment regimes. Traditional immobilising treatment regimes with prolonged periods of non-weight bearing should be avoided.

Chapter 4: Operative versus Non-Operative Management of acute Achilles Tendon Rupture: Long-term follow up of a randomised controlled trial

4.1 Introduction

The frequency of these injuries, as demonstrated in Chapter 2 and in multiple other epidemiological studies, together with the rising incidence of ATR[32, 35-38, 304] ensure that it remains a topical subject in the field of orthopaedic and sports medicine. As previously discussed (Chapter 1), the traditional dilemma for treating surgeons has been between operative and non-operative management, both followed by immobilisation in progressively reducing degrees of equinus. There has been longstanding debate as to whether ATR are best managed operatively or non-operatively[4, 7, 78, 85, 306] and good short term-outcomes have been reported with both modalities.[4, 84, 85] The choice of treatment modality has therefore been controversial,[131] with different authors advocating one or other modality of treatment,[4, 84, 95, 229] although there has been a recent trend towards non-operative management in many countries.[32, 37, 90, 105, 126-128]

Proponents of operative treatment argue that is associated with a lower risk of re-rupture[86, 306] and may give earlier restoration of muscle strength.[57] However, others state that any differences in strength are not clinically significant[95] and that in the short and longer-term, no appreciable differences in muscle volume are seen across the different treatment modalities.[307, 308] Although surgery does appear to result in lower rates of re-rupture when compared to non-operative management of ATR, the differences in re-rupture rate are often not demonstrated in individual

smaller studies,[4, 84, 88, 97, 229] only becoming apparent upon pooling of data in meta-analyses.[85-87, 91, 109, 225, 306, 309] Others state that surgery inevitably carries with it the potential for complications, including infection, wound problems, anaesthetic complications and sural nerve injury.[85-87, 91, 95, 109, 157, 225, 229, 299, 306, 309-312] It is known that the presence of significant complications such as infection, sural nerve injury and re-rupture are associated with worse functional outcomes[311] and outcomes after infection of surgically treated ATR are particularly poor.[301] Proponents of surgery also argue that these additional risks are small and that surgery is therefore justified, on the basis that it may reduce the rate of re-rupture[306] and also that earlier return to work has been observed in some studies,[90, 92] which may additionally justify surgical intervention in certain groups of patients.[313] However, other studies and meta-analyses have not demonstrated statistically significant earlier return to sport or work with surgical treatment.[4, 225] Conversely, advocates of non-operative management argue that re-rupture rates are only marginally higher with non-operative treatment and that the vast majority of patients do well after non-operative management, without being exposed to potentially serious complications of surgery.[90, 95, 119, 229, 314]

As a result of this controversy, various prospective randomised controlled trials (RCT) have been undertaken to assess outcomes after operative and non-operative management of these injuries,[4, 57, 62, 84, 88, 95, 96] with subsequent meta-analyses and systematic reviews collating their results.[85-87, 91, 225, 306] One unifying feature of these prospective randomised studies and review articles is their restriction to short term patient follow up, with outcomes reported at one or occasionally up to two years after injury,[4, 57, 84, 88, 95-97, 315, 316] with only one RCT reporting on outcomes at a mean of 7 years (minimum 5 years; maximum 9 years) post-injury.[60] No assessment of health related quality of life (HRQoL) or satisfaction was made in that study.[60] A small number of non-comparative studies have reported on outcomes in series of patients undergoing either surgical or non-operative treatment for ATR in the medium term, at around 5

years[119, 121, 312, 317] and three non-randomised studies compared operative and non-operative rehabilitation regimes at a mean of 3.6 (minimum 1 year follow up) years[229], 6.5 years (minimum 2 year follow up)[318] and 7.6 years[307] after injury.

In light of the above mentioned short-term studies which demonstrate overall relatively similar outcomes after surgical and non-surgical management, there has been a sustained move away from surgical treatment of ATR in recent years in many places, particularly in Europe and Canada,[32, 36, 37, 105, 128] despite a lack of understanding of the long term implications of these two treatment methods on patient outcome.

Furthermore, as demonstrated in Chapter 2 (as well as in other studies[32, 36, 37]), these injuries occur most frequently (albeit by no means exclusively) in young to middle aged adults who will expect to remain physically and economically active for many years after their injury. It is therefore of particular importance that the longer term implications and outcomes after these injuries are well understood, including after treatment of ATR using these differing modalities (operative and non-operative management). Despite this, there is a distinct lack of data in this regard in the existing medical literature. This is problematic as patients wanting to know about their longer term prognosis and outlook cannot be reliably informed, while medical professionals advising on treatment options have no data about likely outcomes and the long-term implications of treatment choices.

A prospective RCT comparing operative and non-operative management of ATR was undertaken in Edinburgh between 2000 and 2004 and results reported up to one year after injury.[4] Due to the aforementioned lack of available long-term data comparing outcomes between patients treated surgically and non-operatively for ATR, it was decided to undertake a long term follow up study of patients treated in the previous clinical trial.

The primary aim of this study was to compare patient reported outcomes after operative and non-operative treatment of acute ATR. The hypothesis was that surgical treatment of acute ATR

would result in improved patient reported outcomes, as measured by the Short Musculoskeletal Function Assessment (SMFA) dysfunction index, compared to non-operative management. Secondary aims included a comparison of the Achilles Tendon Total Rupture Score (ATRS), HRQoL, satisfaction and complication rates, as well as the long-term net promoter score (NPS) for each treatment modality.

4.2 Methods

Approval for this study was granted by the East Midlands - Leicester Central Research Ethics committee (17/EM/0256). Long term follow up of patients previously recruited into a parallel arm randomised controlled trial that compared operative and non-operative management of Achilles tendon ruptures[4] was undertaken between September 2017 and July 2018.

4.2.1 Patient demographics

Eighty patients (mean age 40.6 years, range 21 to 59) were randomised by a research physiotherapist, to receive operative or non-operative treatment for an acute ATR between 2000 and 2004. All patients with ATR were considered for inclusion. Exclusion criteria were age >60 years at time of injury, presentation >10 days after injury, systemic disease including rheumatoid arthritis, chronic renal failure and steroid treatment or other medication that could influence healing (e.g. chemotherapy).

4.2.2 Intervention

Cards representing the treatment types were placed in unmarked, sealed envelopes and patients were randomised to one arm of the study at first presentation to the orthopaedic outpatient service, through allocation of sequential, sealed envelopes.

Patients presented initially to A&E and were placed into an equinus plaster backslab and referred to the outpatient orthopaedic service, where eligibility for inclusion, consenting and randomisation processes were undertaken by a research physiotherapist.

4.2.2.1 Operative Treatment

Patients randomised to receive surgical treatment were admitted as an urgent case within 7 days of presentation. All patients undergoing surgery did so <14 days from the date of ATR. Surgery was undertaken by a consultant orthopaedic trauma surgeon or an orthopaedic registrar under direct consultant supervision, through a posteromedial longitudinal incision. The paratenon was incised, reflecting full thickness flaps to expose the ruptured tendon. A core Kessler stitch with double stranded 1 PDS suture (Ethicon, Woleuw, Belgium) was used to appose the tendon ends. This was supplemented by interrupted 1 Vicryl (Ethicon, Woleuw, Belgium) circumferential sutures. The paratenon was sutured over the tendon repair using 2,0 Vicryl and the skin closed with interrupted, 3,0 nylon (Ethicon, Woleum, Belgium) mattress sutures. Surgically treated patients were given a single dose of 20mg of enoxaparin on the evening of surgery for venous thromboprophylaxis. Following surgery, the limb was immobilised in a full equinus cast for four weeks, which was then converted to a semi-equinus cast for a further 2 weeks. Following this, the cast was removed and patients were allowed to weight-bear.

4.2.2.2 Non-Operative Treatment

Patients who were treated non-operatively underwent 10 weeks of immobilisation in a below knee plaster cast. For the first four weeks, the ankle was positioned in equinus. Following this, the cast was changed to place the ankle in a semi-equinus position for a further four weeks, after which the plaster cast was changed again to place the ankle in a neutral plantigrade position for a further 2 weeks. Patients were instructed to remain non weight-bearing while in equinus and

semi-equinus positions and were allowed to partially weight-bear whilst in the neutral cast. No venous thromboprophylaxis was administered.

4.2.2.3 Physiotherapy

Following removal of the cast, both groups of patients followed identical physiotherapy regimes, which have been previously described:[4] In the first two weeks patients were instructed to focus on increasing their range of movement and non-weight-bearing dorsiflexion stretches were permitted. Patients were encouraged to commence weight-bearing immediately upon removal of the cast. Between weeks two and week six, ankle range of movement was emphasised using non-weight bearing range-of-movement exercises and weight-bearing stretches. Strengthening of the calf muscle was introduced during this time period using bilateral heel raises and eccentric calf loading, progressing to unilateral heel raises as strength in the injured limb recovered. Proprioception exercises focusing on single-leg balance were also used. Patients were seen by a physiotherapist twice weekly during this period. Between six week and six month time-points, patients in both groups followed a program with increasing functional activity and progressively working on calf muscle strength. Patients were discharged from physiotherapy when the range of movement of the ankle and the pattern of gait were normal, good proprioception was restored, and a single-leg hop on the injured leg matched the normal leg for height and distance. Physiotherapists involved in the programme were provided with guidelines that were identical for both groups.

4.2.3 Long Term Follow Up and Outcome Measures

Patients were contacted and asked to complete postal questionnaires containing SMFA,[168] Achilles Tendon Total Rupture Score (ATRS)[163], EuroQol 5-dimension, 5-level questionnaire (EQ-5D-5L) and EQ-5D health today visual analogue scale (VAS).[177]

The SMFA is a 46 question PROM reported as dysfunction and bother indices.[168] The ATRS is a 10 question PROM, with scores ranging from 0 (most disability due to Achilles tendon) to 100 (least disability).[163] The EQ-5D-5L consists of an EQ-5D index score ranging from -0.59 to +1, calculated from 5 domains (mobility, self-care, usual activities, pain and discomfort, anxiety and depression) and the EQ-5D health today visual analogue score where patients are asked to rate their overall health on a scale between 0 (worst imaginable health) and 100 (best imaginable health). These scores are described in detail in Chapter 1 (section 5.2).

Patients were also asked three questions:

1. How satisfied are you with your treated Achilles tendon?
2. Would you have the same treatment again if it were required on the opposite side?
3. How likely are you to recommend this treatment to friends and family if they needed similar care or treatment?

For question 1, possible answers were very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied or very dissatisfied; For the last two questions, patients could answer extremely likely, likely, neither likely nor unlikely, unlikely, extremely unlikely or don't know.

For calculation of the NPS, patients who said they would be 'very likely' to recommend their treatment to others were considered 'promoters'; those who stated they would be 'likely' to do so were considered 'passives' and those who stated they 'didn't know', were 'unlikely'/'very unlikely' or were 'neither likely nor unlikely' to do so were considered 'detractors'.

Patients who sustained a re-rupture were not excluded from the long-term study and their results were analysed on an intention to treat basis, according to their initial treatment modality at randomization. A repeat analysis, excluding patients sustaining re-ruptures was undertaken, to determine whether the ordeal of re-rupture and its subsequent treatment had altered the principal findings of this study. The results of this repeat analysis are presented separately (see Appendix 4.1).

Of 80 patients originally randomised into the trial, two withdrew from the trial to seek alternative treatment. In total, 64 (33 treated surgically; 31 non-operatively) of the original cohort of 78 patients (82.1%) were followed up at a mean of 15.7 years (13.4 to 17.7) while two were deceased. In addition 12 patients were lost to follow up (Figure 4.1). There was no significant difference in rates of loss to follow up between operative and non-operative cohorts (p=0.405, Fisher's Exact test).

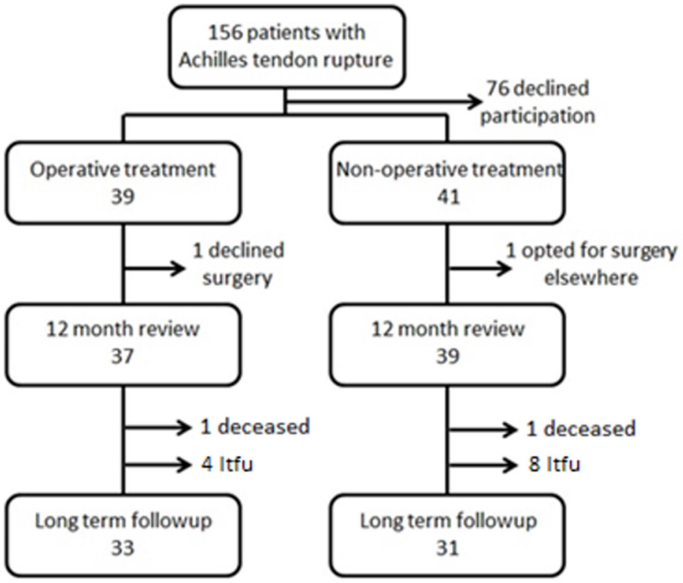


Figure 4.1. CONSORT flow diagram illustrating patient flow through the study.

4.2.4 Statistics

The primary outcome measure was SMFA dysfunction index. A minimum clinical important difference of 7 points has been described for this score[193]. Using a one-tailed non-parametric power analysis with a standard deviation of 10 points, a minimum of 54 patients would be required to achieve power of 80% with an α=0.05.

Data parametricity was assessed using Kolmogorov-Smirnov testing. Non-parametric continuous data was compared between treatment groups using Independent Samples Mann Whitney U-tests. Nominal variables were compared between groups using Fisher's Exact test

(FET). One tailed analyses were used when comparing treatment modalities, with an assumed better outcome in the surgical group, which could justify the potential risks associated with surgery.

Analysis of change in PROM scores within groups over time (non-parametric, continuous data) was with two tailed Related Samples Wilcoxon Signed Rank test, while PROMs data (non-parametric continuous) were correlated with each other using two-tailed Spearman's rank test. A p-value of ≤ 0.05 was considered significant. Power analysis was undertaken using G*Power v3 (Heinrich-Heine Universität, Düsseldorf, Germany). Statistical analysis was undertaken using SPSS v24 (SPSS Inc., Chicago, IL, USA) and GraphPad Prism v8 (GraphPad Software, San Diego, CA, USA).

4.3 Results

4.3.1 Patient Demographics

Sixty four patients (33 treated surgically; 31 treated non operatively) were followed up at a mean of 15.7 years (13.4 to 17.7). The mean age of patients at follow up was 57.6 years (range 37 to 77 years). Patient demographics are summarised in table 4.1.

	Operative	Non-Operative
At Recruitment		
Age in years (range; range)	41.2 (27 to 59)	39.5 (21 to 58)
Gender (male:female)	28:11	32:9
Recruited (n)	39	41
At follow up		
Age in years (mean; range)	55.98 (37 to 75)	59.36 (46 to 77)
Gender (male:female)	22:11	23:8
Followed up (n)	33	31

Table 4.1. Patient demographics and treatment.

4.3.2 Patient Reported Outcome Measures (PROMs) at Short and Long Term Follow Up

There was no statistically significant difference in SMFA dysfunction and bother indices at any time point during short term follow up, up to one year after injury (Table 4.2). At long term follow up, there was no difference in SMFA dysfunction and bother indices (Table 4.2), ATRS (Table 4.2) or SMFA disability category indices (Table 4.3).

	Operative	Non-Operative	*p*-value*
12 weeks			
SMFA Dysfunction	15.47 (12.13 to 19.30)	16.90 (10.13 to 26.45)	0.173
SMFA Bother	16.69 (9.88 to 19.83)	17.75 (8.30 to 29.73)	0.104
16 weeks			
SMFA Dysfunction	7.35 (4.40 to 11.58)	8.45 (5.00 to 15.07)	0.085
SMFA Bother	8.30 (2.63 to 14.60)	9.35 (2.10 to 14.60)	0.382
26 weeks			
SMFA Dysfunction	2.56 (1.56 to 4.40)	3.70 (0.74 to 5.90)	0.369
SMFA Bother	4.17 (0.00 to 6.25)	2.10 (0.00 to 6.25)	0.499
52 weeks			
SMFA Dysfunction	0.00 (0.00 to 1.50)	1.48 (0.00 to 3.68)	0.092
SMFA Bother	0.00 (0.00 to 2.08)	0.00 (0.00 to 4.20)	0.107
Current status			
SMFA Dysfunction	1.56 (0.00 to 5.51)	1.47 (0.00 to 5.15)	0.289
SMFA Bother	2.08 (0.00 to 12.50)	0.00 (0.00 to 6.25)	0.074
ATTRS	94 (86 to 100)	95 (81 to 100)	0.313

Table 4.2. Patient reported outcomes after operative and non-operative management of acute Achilles tendon rupture. Scores between 12 and 52 weeks were collected as part of the previous RCT.[4] Median scores are reported (interquartile range).
*Independent samples Mann Whitney U-tests.

SMFA Disability Category	Operative	Non-Operative	p-value*
Mobility	0.00 (0.00 to 8.33)	0.00 (0.00 to 5.56)	0.471
Daily Activities	0.00 (0.00 to 3.75)	0.00 (0.00 to 2.50)	0.455
Emotional	7.14 (0.00 to 14.29)	3.57 (0.00 to 10.71)	0.164
Hand and arm	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.225

Table 4.3. SMFA disability category scores for patients treated operatively and non-operatively. Median scores are reported (interquartile range). *Independent Samples Mann Whitney U-tests.

4.3.3 Relationship between short term SMFA index scores and Long Term PROMs and outcomes

4.3.3.1 Change in SMFA Indices Between Short and Long-Term Follow Up

There was no significant difference in SMFA dysfunction index (p=0.079, two-tailed Related Samples Wilcoxon Signed Rank test) or SMFA bother index (p=0.130, two-tailed Related Samples Wilcoxon Signed Rank test) between one year post-injury and long-term follow up in the non-operatively treated group. There was a statistically significant decline in SMFA dysfunction (p=0.001, two-tailed Related Samples Wilcoxon Signed Rank test) and bother (p=0.001, two-tailed Related Samples Wilcoxon Signed Rank test) indices for operatively treated patients between one year post-injury and long-term follow up, although the clinical magnitude of these changes was small (Table 4.2).

4.3.3.2 Relationship Between One Year SMFA Dysfunction Index and Long-Term Outcomes

Additional analysis was performed to determine whether there is an association between patient reported outcomes at one year post-injury and longer-term PROMs. There was a statistically significant correlation between SMFA dysfunction index at one year post-injury and

all long-term PROMs, except EuroQol five-dimension five-level questionnaire index (EQ-5D-5L), where there was a narrowly insignificant trend (p = 0.083, Spearman's rank correlation; Figures 4.2 a to e).

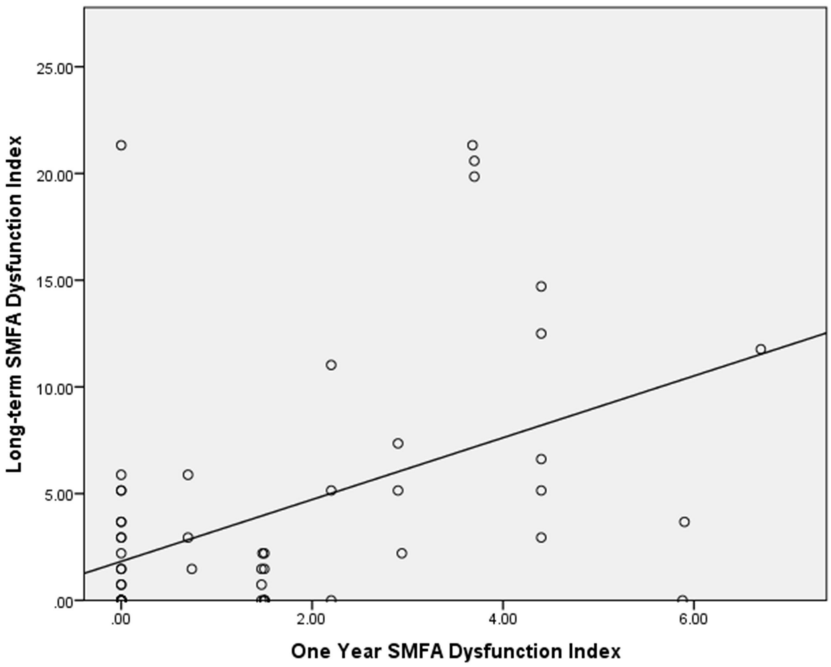


Figure 4.2a. Spearman rank correlation between one year and long-term SMFA dysfunction index (Spearman's r = 0.45, p < 0.001).

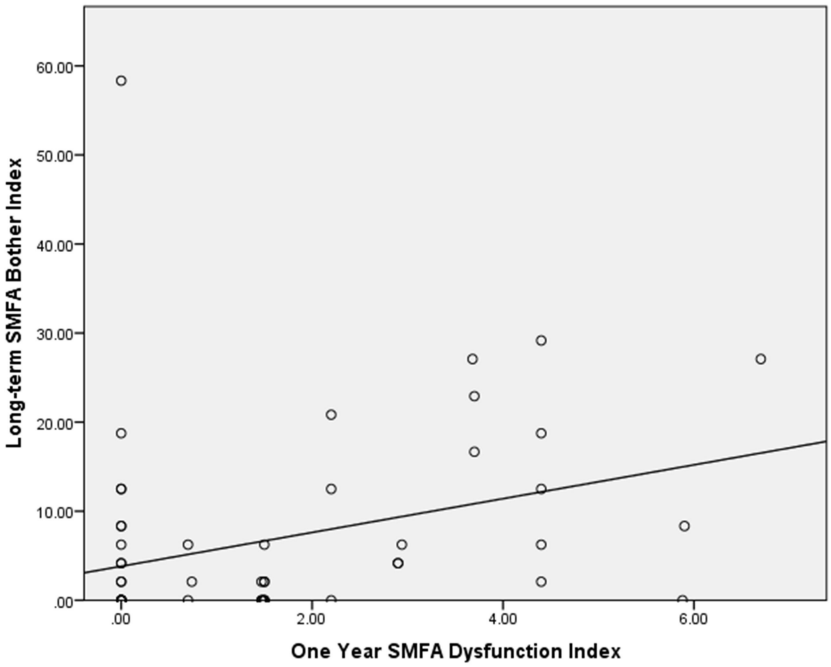


Figure 4.2 b. Spearman rank correlation between one year SMFA dysfunction index and long-term SMFA Bother Index. Spearman's r = 0.65, p < 0.001.

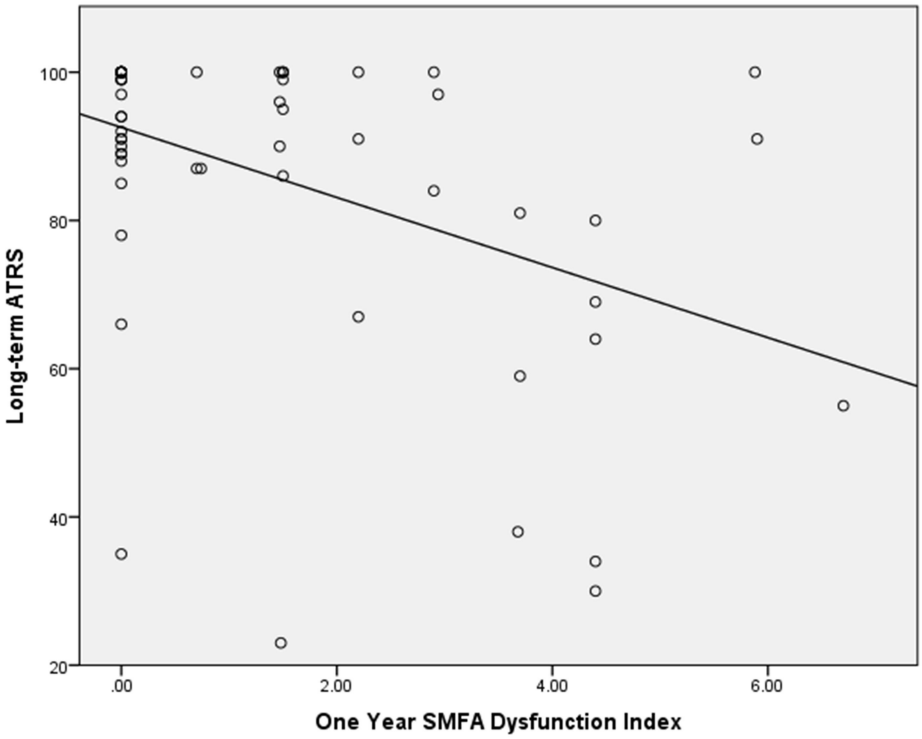


Figure 4.2c. Spearman rank correlation between one year SMFA dysfunction index and long-term ATRS (Spearman's r = -0.36, p = 0.007).

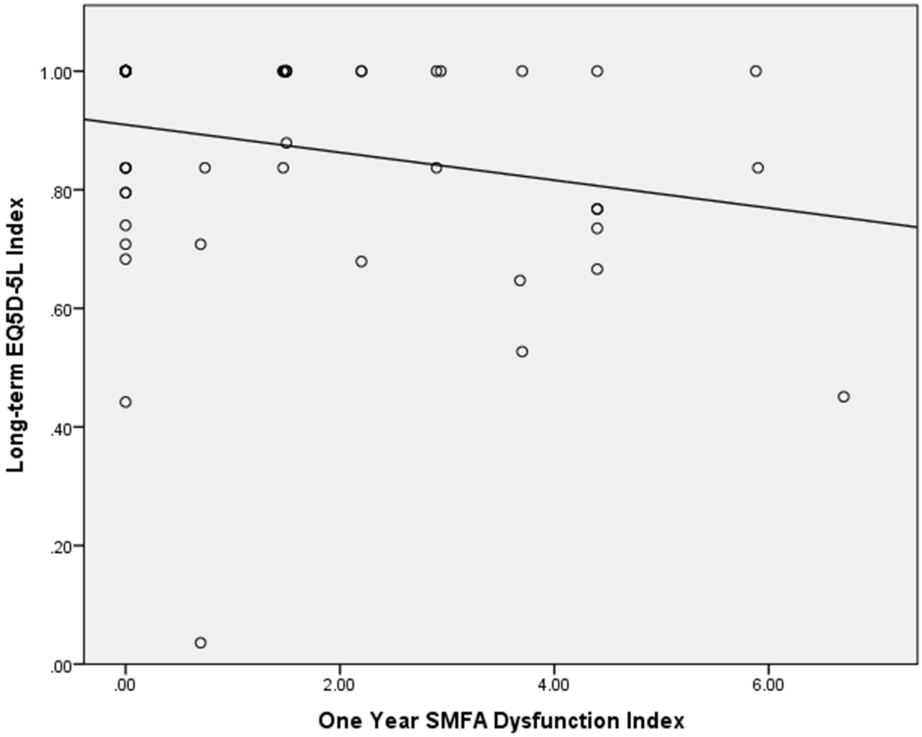


Figure 4.2d. Correlation between one year Short Musculoskeletal Function Assessment (SMFA) dysfunction index and long-term EuroQol five-dimension five-level questionnaire (EQ-5D-5L) index (Spearman's r = -0.23, p = 0.083).

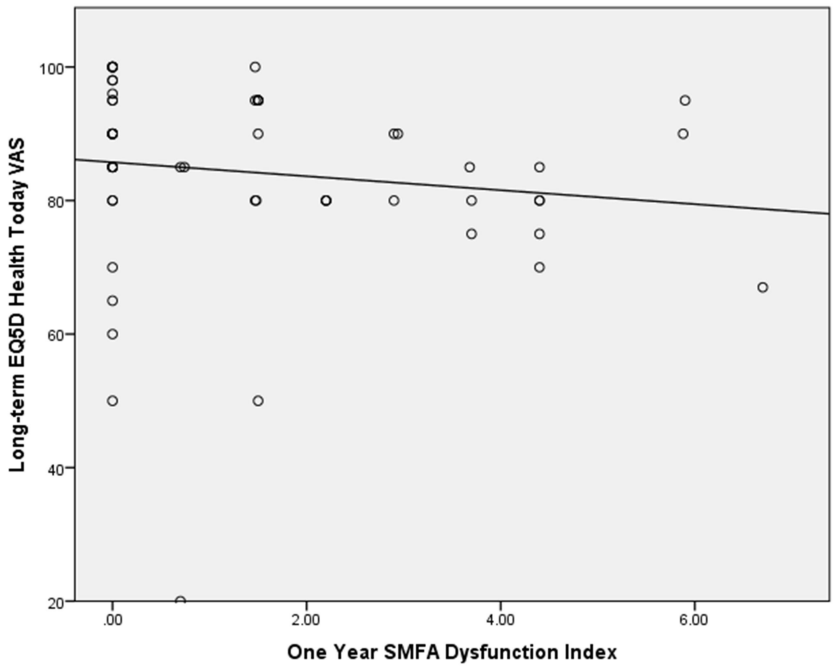


Figure 4.2e. Spearman rank correlation between one year SMFA dysfunction index and long-term EuroQol five-dimension (EQ-5D) health today visual analogue scale (VAS) (Spearman's r = -0.30, p = 0.024).

Additionally, the long-term PROM scores of patients whose SMFA dysfunction index at one year fell into the highest quartile (i.e. most dysfunction as demonstrated by SMFA dysfunction index) were compared to their counterparts in the lower three quartiles at one year (i.e. least dysfunction as demonstrated by SMFA dysfunction index) to determine whether patients who were performing more poorly at one year continued to do so at longer-term follow up. SMFA dysfunction index scores were available for 70 of the 78 patients in the original trial and for all 64 patients with long-term follow up reported in this study. Overall, 57 patients had matched one-year and long-term dysfunction index scores. Patients in the highest quartile at one year reported inferior function across all PROMs at long-term follow up and these findings were statistically significant (Table 4.4).

Long-term PROM	One- year SMFA dysfunction index in highest quartile n=14	One-year SMFA dysfunction index in lowest three quartiles n=43	p-value*
SMFA dysfunction	6.99 (3.49 to 15.99)	0.74 (0.00 to 2.94)	< 0.001
SMFA bother	10.42 (4.17 to 23.96)	0.00 (0.00 to 6.25)	< 0.001
ATRS	74.50 (50.75 to 92.50)	96 (89 to 100)	0.002
EQ-5D-5L index	0.803 (0.66 to 1.00)	1.00 (0.84 to 1.000)	0.030
EQ-5D health today VAS	80 (75 to 90)	90 (80 to 95)	0.046

Table 4.4. Long-term follow up PROM scores for patients with one-year SMFA dysfunction index in the worst-performing quartile compared to the rest of the group. Median scores are presented with interquartile range. *two-tailed Independent Samples Mann Whitney U-test.

4.3.4 Health Related Quality of Life

Patients in both groups reported median EQ-5D-5L Index scores of 1.0 (operative group IQR 0.75 to 1.00; non-operative group IQR 0.84 to 1.00; p=0.137, Independent Samples Mann Whitney U-test) and median EQ-5D health today VAS of 85 (IQR 72.5 to 95 and 80 to 95, respectively; p = 0.367, Independent Samples Mann Whitney U-test).

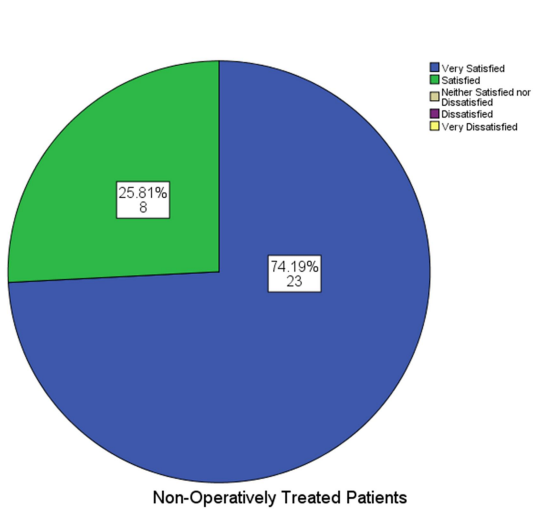
There were no statistically significant differences in the proportion of patients reporting any problems in each of the EQ-5D dimensions between the groups at long-term follow up (Table 4.5).

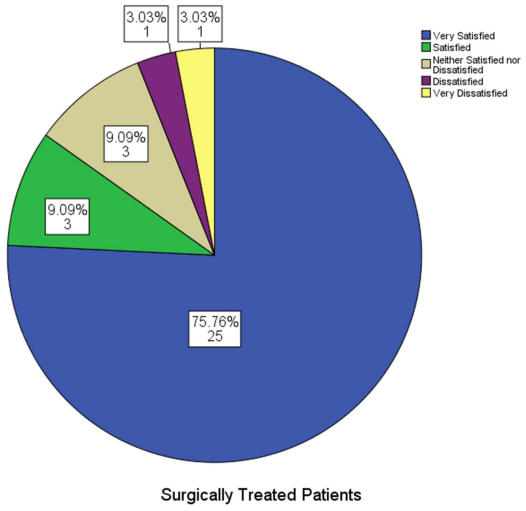
		Operative	Non-Operative	*p*-value*
Mobility	No Problems	24 of 33	26 of 31	0.220
	Problems	9 of 33	5 of 31	
Self-care	No Problems	32 of 33	31 of 31	0.516
	Problems	1 of 33	0 of 31	
Usual Activity	No Problems	25 of 33	27 of 31	0.201
	Problems	8 of 33	4 of 31	
Pain/Discomfort	No Problems	17 of 33	21 of 31	0.143
	Problems	16 of 33	10 of 31	
Anxiety/Depression	No Problems	25 of 33	23 of 31	0.557
	Problems	8 of 33	8 of 31	

Table 4.5. Proportion of patients reporting any degree of problems for each dimension of the EQ-5D-5L score. *Fisher's Exact test.

4.3.5 Satisfaction and Willingness to Undergo Similar Treatment Again

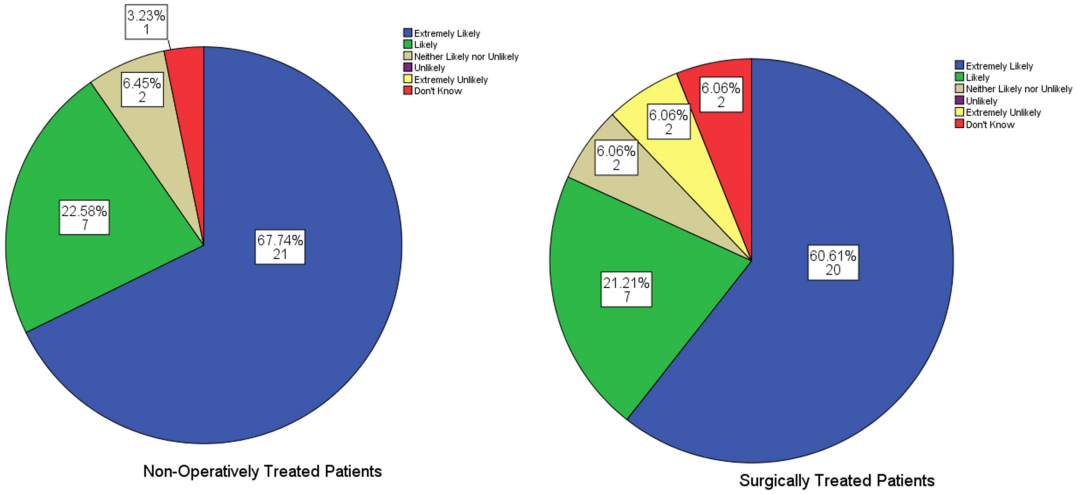
At long-term follow up, 59 of 64 respondents indicated that they were satisfied (92.2%), while 2 (3.1%) were not (figures 4.3a and 4.3b). There was no statistically significant difference in satisfaction rates between treatment groups (p=0.119, FET).





Figures 4.3a and 4.3b. Patients' satisfaction with their treated Achilles tendon.

Patients were also asked whether they would have the same treatment again if it was required on the other side (Figures 4.4a and 4.4b). At long-term follow up, 55 patients (85.94%) indicated that they would be likely to do so, while 2 (3.13%) indicated that they would be unlikely to do so. Comparison of those who stated they were likely (i.e. answered 'extremely likely' or 'likely') and those who were unlikely (i.e. 'extremely unlikely' or 'unlikely') to do so demonstrated no statistically significant difference between treatment groups (p=0.254, FET).



Figures 4.4a and 4.4b. Patient responses for the question 'Would you have the same treatment again if it was required on the other side?'

4.3.6 Net Promoter Scores (NPS)

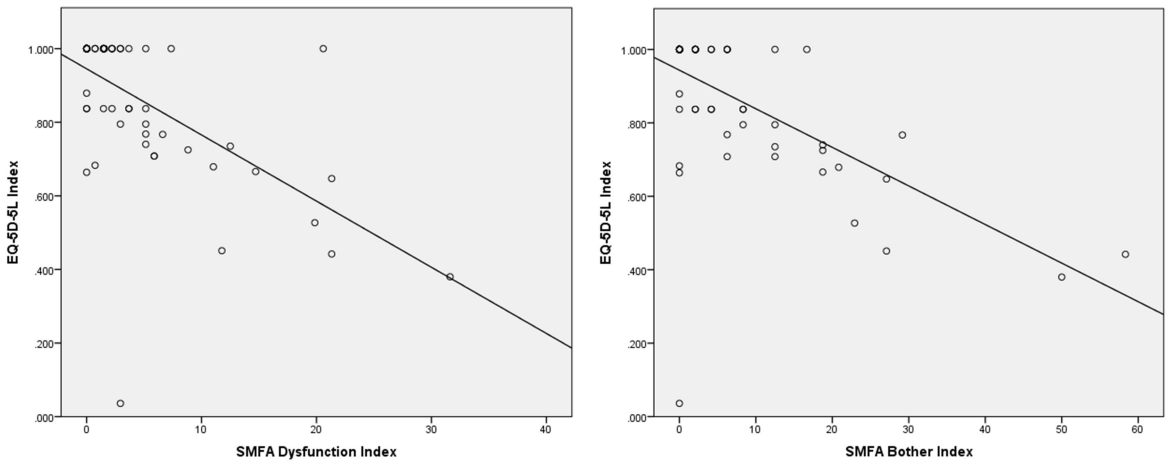
The NPS was 33 for patients treated operatively and 42 for those treated non-operatively. Under the modified NHS FFT reporting guidelines,[186] 78.8% of patients (26 of 33) would recommend operative treatment and 6.1% (2 of 33) would not, while 87.1% (27 of 31) would recommend non-operative treatment and none would not (Table 4.6). Comparison of those who stated they were likely (i.e. those answering 'extremely likely' or 'likely') and those who stated they were unlikely (i.e. 'extremely unlikely' or 'unlikely') to recommend their treatment demonstrated no statistically significant difference between treatment groups (p=0.255, FET).

	Operative	Non-Operative
Extremely likely	18 (54.5%)	17 (54.8%)
Likely	8 (24.2%)	10 (32.3%)
Neither likely nor unlikely	3 (9.1%)	3 (9.7%)
Unlikely	0	0
Extremely unlikely	2 (6.1%)	0
Don't know	2 (6.1%)	1 (3.2%)
Total responses	33	31

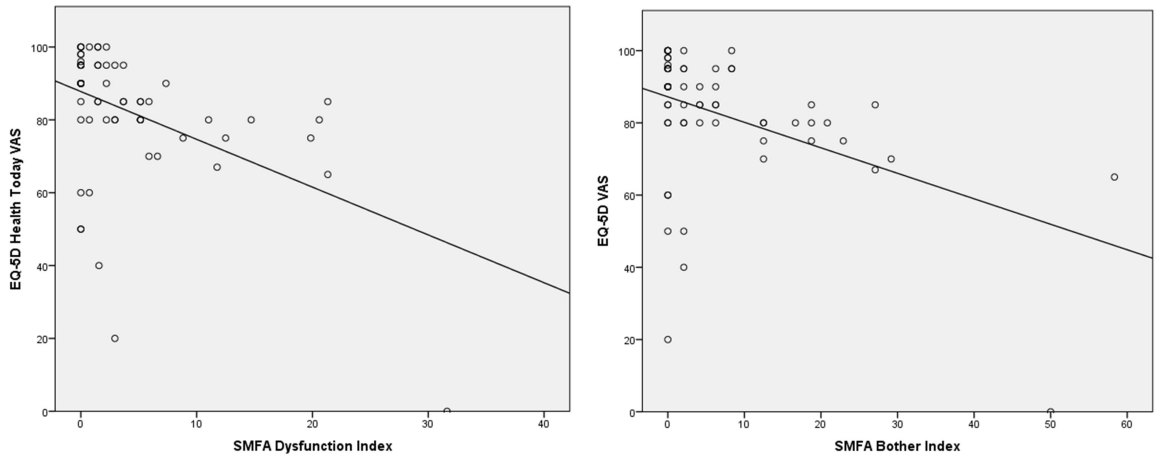
Table 4.6. How likely are you to recommend this treatment to friends and family if they needed similar care or treatment?

4.3.7 Health related Quality of Life (HRQoL) and Musculoskeletal PROMs

Across both groups, there was an association between patients' self-reported HRQoL (as measured by EQ-5D-5L Index and EQ-5D VAS) and their self-reported musculoskeletal health, as measured by the SMFA dysfunction (figures 4.5a and 4.5b) and bother (figures 4.6a and 4.6b) indices and also their Achilles tendon function, as measured by ATRS (figures 4.7a and 4.7b).



Figures 4.5a and 4.5b. Spearman rank correlation between EQ-5D-5L Index and SMFA dysfunction (Spearman's r=-0.627, p<0.001) and bother indices at final follow up (Spearman's r=-0.608, p<0.001).



Figures 4.6a and 4.6b. Spearman rank correlation between EQ-5D-5L health today VAS and SMFA dysfunction (Spearman's r=-0.495, p<0.001) and bother indices (Spearman's r=-0.437, p<0.001) at final follow up.

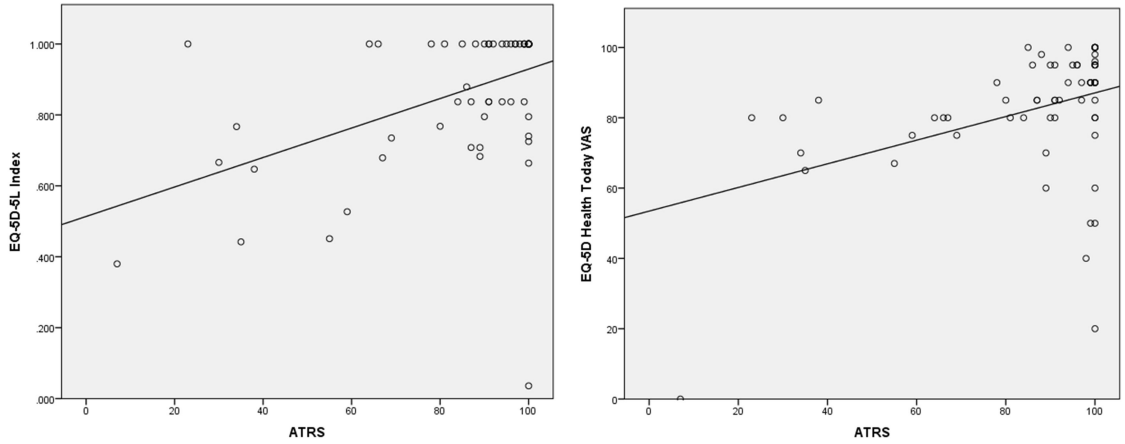


Figure 4.7a and 4.7b. Spearman rank correlation between EQ-5D-5L index (Spearman's r=0.434, p<0.001) and health today VAS (Spearman's r=0.395, p=0.001) and ATRS at final follow up.

4.3.8 Other Complications

The previous study reported venous thromboembolic event (VTE) and re-rupture rates after each treatment modality up to one year post-injury. There were six re-ruptures (4 in the non-operative group and 2 in the operative group; p=0.362, Fisher's Exact test), all of which occurred within 4 months of injury. Re-ruptures were managed surgically in five cases and non-operatively in one, who had previously undergone surgery. All six patients who sustained a re-rupture were either very satisfied (five) or satisfied (one) with their treated Achilles tendon at

long-term follow up. There were 2 deep vein thromboses, both of which occurred in the non-operative group.

All contacted patients were asked if they had sustained a VTE, re-rupture or contralateral rupture at any point. No additional VTE or re-ruptures were identified, but 5 of 64 patients included in this study (7.81%) had sustained a contralateral Achilles tendon rupture.

4.3.9 Additional Analyses

Analyses were repeated for patients in this study, excluding those who sustained a re-rupture (n=6), leaving 58 patients who did not sustain a re-rupture. There were no significant variations in reported outcome measures or findings. The full results and statistical analyses are included in Appendix 4.1.

4.4 Discussion

This study demonstrated no significant differences in long term patient reported functional outcomes after management of Achilles tendon ruptures with surgery or non-operative management, at a mean of 15.73 years post-injury. Patients reported similar general musculoskeletal PROMs (SMFA), Achilles tendon-specific scores (ATRS), and health-related quality of life (EQ-5D-5L index and 'health today' visual analogue score) at long-term follow up. This may indicate that the potential risks of surgery are not offset by improved outcomes. There has been a trend away from surgical treatment of ATR in recent years, spurred by reports of comparable short-term outcomes after non-operative management.[32, 36, 37] This study corroborates these reports in the longer-term, providing further justification for non-operative

management of ATR. No further re-ruptures were encountered beyond 16 weeks after injury, but almost 8% of patients reported that they had sustained a contralateral Achilles tendon rupture in the intervening period.

Older studies tended to focus mainly on binary outcomes such as the presence or absence of complications.[84, 87] While this information is important, it does not relate the presence of such complications to patient function or give any information about outcomes in the (majority of) patients who do not develop complications. In recent years, there has been a shift away from simply reporting binary outcomes. Increasing importance is given to the patients' perspective of outcome[138] and this has resulted in the development and reporting of various PROMs and more recently, exploration and reporting of patient satisfaction and other measures of patient sentiment and experience. These are used both in research[154, 176, 182, 207] and also to assess healthcare delivery on a wider scale.[185, 186, 319] Many registries in the field of orthopaedics now routinely collect PROM scores,[320-322] and the NHS Outcomes Framework for England identifies measures of patient experience as key performance assessment domains and the results are publically available.[185, 186] PROMs data has been routinely collected by NHS England in recent years, for all patients undergoing total hip and knee replacements.[184] Proponents of PROMs argue that they reflect and quantify patients' own perception of their outcome,[138] which is ultimately one of the most important measures of outcome when assessing the efficacy of treatments designed to restore function.

This study does report on complications encountered, but also on a range of modern patient reported outcome measures, incorporating generic musculoskeletal PROMs, injury specific PROMs and health related quality of life PROMs as well as patient satisfaction and recommendation questionnaires which are used to gauge patient sentiment and calculate a net promoter score, thereby giving a broad picture of patient reported function and sentiment in the

long term after surgical or non-operative treatment for ATR, in the context of a randomised study.

4.4.1 Patient Reported Outcome Measures (PROMs)

SMFA scores were collected at short-term follow up, up to one year after injury, in the previous RCT,[4] thereby facilitating direct comparison with long-term outcomes using the same scoring system. Patients in both groups reported low SMFA dysfunction and bother indices one year post-injury and at long-term follow up. There was no clinically or statistically significant difference in SMFA dysfunction indices between the two groups at any time-point. At a mean of 15.73 years after their injury, there was a statistically insignificant difference of 0.09 points in the median SMFA dysfunction index, this difference being markedly less than the minimum clinical important difference.[193] Apart from being statistically insignificant, such a difference would therefore be imperceptible to patients and so clinically unimportant. Similarly, there were no statistically significant differences in SMFA bother index between the groups at any time point. The SMFA dysfunction index is designed to measure patients' own perception of their function while the bother index quantifies how much patients are bothered by problems in broad functional areas.[168] Additionally, there was no significant difference in any of the SMFA dysfunction category indices at long-term follow up. These categories within the global SMFA dysfunction index question set focus on specific areas of function and allow more targeted assessment of outcomes using this general musculoskeletal PROM. Two of these SMFA dysfunction categories are of particular interest in patients who have sustained an ATR – the 'mobility' and 'daily activities' categories and the median score for both groups was 0 in both of these categories, indicating that the majority of patients report low levels of lower limb dysfunction and difficulty undertaking daily activities, at long-term follow up.

Patients in both groups reported very low SMFA dysfunction and bother indices at one year post-injury and also at long-term follow up, suggesting good function and low levels of self-reported disability at both these time-points.

Patients in the non-operatively treated group exhibited no clinical or statistically significant change in SMFA bother or dysfunction indices between follow up one year after their injury and long-term follow up. Those in the surgically treated group exhibited a small but statistically significant deterioration in reported SMFA dysfunction and bother indices between follow up at one year and long term follow up, however, the magnitude of change in median SMFA dysfunction index in the surgical group was of 1.56 points, which is significantly less than the previously described minimum clinical important difference.[193] Therefore, neither group experienced any perceptible clinical change in their musculoskeletal function between one year after their injury and long-term follow up at a mean of 15.73 years. These results demonstrate that on the whole, patients can expect to maintain the good levels of function that are attained after the first year, in the longer term.

However, worse SMFA dysfunction index scores at one year were associated with inferior long-term PROMs, with correlations demonstrated between SMFA dysfunction index at one year and all longer term PROMs (except EQ-5D-5L Index, where there was a narrowly insignificant trend), suggesting that patients reporting poorer outcomes one year after injury are more likely to continue to do so in the long-term. This is an important finding that has not been previously described in the literature and emphasizes the importance of effective initial management of these injuries to achieve the best possible early outcome, since these results show that patients who do poorly in the first year after injury are not likely to report significant improvements later on.

The ATRS is a modern, injury specific score that was introduced after the original study.[163] It is commonly used to measure outcome after Achilles tendon rupture and a systematic review concluded that despite some limitations, it is a valid tool and is presently the most appropriate

PROM for evaluating management of Achilles tendon ruptures,[169] however, having been described relatively recently, it has largely only been used for short[62] to medium-term[60, 318] follow up to date. Reporting of ATRS facilitates comparison of outcomes with other recent studies in this field. Brorsson et al[60] reported very similar ATRS at medium-term follow up of a RCT comparing operative and non-operative management of ATR (median score 96), to those reported in this study at long term follow up (median score 94-95). They found that despite some persistent clinical muscle deficits, patients reported only minor levels of symptoms and relatively high levels of activity and also concluded that there was no change in functional status between assessment two years after injury and assessment at medium term follow up at a mean of 7 years after injury, in their study. These findings would appear to corroborate the findings in this study, i.e. that PROM measures (SMFA indices in this study) did not change appreciably between one year review and long term follow up at a mean of 15.7 years, while the similarity in reported ATRS at medium and long-term follow up in the two studies also demonstrates agreement. Furthermore, these authors[60] and others[4, 95, 318] who compared patient reported outcomes after surgical and non-operative treatment of Achilles tendon rupture have reported no difference at short and medium term follow up and this study demonstrates similar findings for the first time at long term follow up.

4.4.2 Health Related Quality of Life (HRQoL)

Both groups reported median EQ-5D index scores of 1, indicating that the majority of patients reported excellent health related quality of life. While this may raise concerns of a ceiling effect, it has previously been demonstrated that the EQ-5D-5L score, unlike its predecessor (EQ-5D-3L), does not suffer significantly from this phenomenon.[178] There was no statistically significant difference in self-reported HRQoL between groups.

Patients in the cast group reported lower rates of problems with pain, self-care, mobility and usual activities than respondents in a large random sample representative of the general population in England.[178] Those treated surgically reported marginally higher rates of problems in the mobility, usual activities and pain dimensions of the EQ-5D-5L questionnaire, as compared to respondents in the aforementioned general population study.[178] Overall, median scores for both EQ-5D index and VAS scores compared favourably with those of the general population.[178]

At long-term follow up, patients treated for acute Achilles tendon rupture in a cast reported general health related quality of life outcomes that are at least similar to those of the general population, supporting the conclusions that patients with these injuries can expect good functional outcomes in the longer term.

4.4.3 The Relationship Between HRQoL and Musculoskeletal PROMs

This study demonstrated significant correlations between self-reported Achilles tendon (ATRS) and musculoskeletal (SMFA) function with HRQoL at long term follow up in patients in this study, indicating that although most patients report good functional outcomes at long term follow up, any remaining functional deficits correlate with a corresponding reduction in health related quality of life. Similar relationships have been reported in other conditions in the field of sports medicine (e.g. femoroacetabular impingement)[181] and orthopaedic trauma (e.g. talar fractures)[205] and in keeping with findings reported in both those contexts, PROM scores correlated slightly more strongly with the EQ-5D index scores than the EQ-5D health today VAS scores, although both relationships were statistically significant. The EQ-5D indices have been confirmed to correlate with Achilles-specific function as measured by the ATRS.[323]

4.4.4 Satisfaction, Net Promoter Scores (NPS) and Other Measures of Patient Sentiment

The findings of this study suggest that the vast majority of patients can expect to be satisfied with their Achilles tendon in the long term, whether treated surgically or non-operatively. Although a slightly greater proportion of respondents expressed satisfaction in the non-operative group, this finding was not statistically significant. Reported satisfaction rates compare favourably with treatment for other traumatic and degenerative conditions of the foot and ankle,[324, 325] although there is a paucity of data pertaining to satisfaction rates after treatment for Achilles tendon rupture, with one RCT showing no difference[88] and others favouring operative[96] or non-operative[81] management. There are no reports of patient satisfaction after treatment for ATR at long-term follow up, and it is unknown whether long-term satisfaction correlates with short-term satisfaction.

Other measures of patient sentiment were also assessed in this study. The majority of patients stated that they would undergo similar treatment again on the other side if it were indicated. Patients treated non-operatively were slightly more likely to report that they would be likely to consider undergoing the same treatment again and also to recommend similar treatment to friends or relatives, although these differences were not statistically significant. Positive NPS are generally well regarded in industry. Reported NPS for both groups in this study compared favourably with scores for market leaders in non-medical fields,[180] but were lower than those reported for elective procedures.[180, 181] However, traumatic injuries differ to planned elective orthopaedic surgery and direct comparison may not be appropriate.

The FFT was originally reported in the same format as the NPS,[187] however, subsequent NHS FFT reporting guidelines[186] recommended reporting of simple percentage points for the proportion of patients who would recommend a service. Analysis of results in this format

revealed that a large majority of patients in both groups would recommend their treatment modality to others, while only two of 64 patients surveyed (both in the surgical group) would not. Interestingly, self-reported satisfaction rates were slightly higher than recommendation rates, indicating that some patients who are satisfied with their treated Achilles tendon may not necessarily recommend their treatment to others.

4.4.5 Complications

No additional re-ruptures were noted beyond the early post-operative period previously reported in the original study. This finding corroborates other reports that re-rupture mainly tends to occur early in the recovery process[117, 223] and should reassure patients that they can expect outcomes reported at one year to persist in the longer term. These findings, however, should be qualified by the findings of the study on re-ruptures of the Achilles tendon in Chapter 3 which did show a small incidence of late re-rupture occurring many years after primary ATR.[326] Thus, at long-term follow up, as at short-term follow up, there was no statistically significant difference in re-rupture rates between the two groups in this study. This is in keeping with the results of several individual prospective randomised studies comparing operative and non-operative treatment regimes for Achilles tendon rupture[95, 97] although some large meta-analyses[85, 91, 109, 112-114, 225, 226] have reported statistically significant differences in re-rupture rates when pooling data from several studies. It is therefore possible that this study, like other individual RCTs,[111] may be underpowered to detect a statistically significant difference in tendon re-rupture rates between the groups. However, this was not the primary outcome measure for this study and additionally, the clinical significance of such differences may be questionable if it is consistently small enough to only be noted in pooled analyses.[109] The re-rupture rates reported in this study are higher than those reported in one recent meta-analysis,[91] although not dissimilar from those

reported in another.[226] The reasons for this are unknown, but may relate to the relatively small sample size or variation in which studies were included in the meta-analyses.

The incidence of contralateral ATR at long term follow up was just under 8% and this is significantly higher than the rate of ATR reported in the general population[31, 32, 36, 37] and also slightly higher than the rate of ipsilateral re-ruptures in patients in this study. Patients who sustain an ATR are at significantly increased risk of contralateral ATR and this risk is similar to, or possibly slightly greater than, that of ipsilateral re-rupture, despite the latter being possibly more well known and feared among clinicians and patients. Patients should be warned of this risk during counselling. Additionally, this is an area that requires further study as the literature is replete with studies focusing on re-rupture, but little is known about contralateral re-rupture rates. The potential for preventative interventions in this regard merits further study.

The previous study reported 3 cases of infection relating to surgery[4] and these findings are in agreement with those of meta-analyses which have shown higher complication rates after surgical treatment for ATR.[85, 225, 299] If these additional risks are to be justified, surgery should be shown to yield superior functional outcomes, however this study has not demonstrated superiority of surgery in this regard which might justify the additional risks associated with surgery.

4.4.6 Limitations

This study has limitations, including the relatively small sample size and some loss to follow up. However, the minimum number of patients identified in the pre-study power analysis was comfortably exceeded. A degree of loss to follow up is inevitable in long-term studies, however 80% of patients recruited to the original study were followed up, indicating low rates of loss to follow up, particularly in the context of a long-term study. Lack of clinical functional assessment may also be considered a limitation. Additionally, although the outcome measures used have been shown to be valid and reliable, they have not been specifically validated for use at such

long-term follow up, although reports of good concordance with other outcome measures have been reported for the SMFA score at medium term follow up.[327]

4.4.7 Clinical Relevance and Future Research

This study is clinically relevant since it is the first long term report of a RCT comparing operative and non-operative management of ATR in the medical literature and therefore provides new insight into expected outcomes after ATR in the longer term following surgical or non-operative management. The findings add important new information to the debate previously discussed in Chapter 1 (Section 1.4) and suggest that surgical management of ATR does not result in superior patient reported outcome (as measured by the SMFA) to non-operative management at long term follow up. Patients and clinicians can be reassured that there was not a high incidence of direct complications in the longer term, although there was a significant incidence of contralateral injuries noted and the findings also suggest that patients who do poorly in the first year after injury retain a poor prognosis in the longer term.

Given the above findings, which provide answers to some questions in one of the longest standing debates in the sphere of ATR management (operative versus non-operative management) and given recent worldwide trends towards both non-operative and functional rehabilitation in the management of ATR in general, the next logical step is to directly compare the traditional non-operative regime described in this chapter with a more modern functional non-operative regime, so as to determine whether a modern functional non-operative regime can provide superior outcomes to those experienced with the traditional non-operative regime, thereby justifying the more recent trend towards functional rehabilitation. This is the basis for the randomised controlled trial in Chapter 5.

4.5 Conclusion

At long-term follow up at a mean of just under 16 years, patients treated both operatively and non-operatively for acute ATR reported good outcomes. Surgically treated patients did not report superior SMFA scores compared to those treated non-operatively. There was no demonstrable difference in assessed outcomes across a range of injury specific, general musculoskeletal and HRQoL PROMs or measures of patient satisfaction and sentiment, for patients treated with either surgery or non-operative management for an acute Achilles tendon rupture. No new delayed complications were identified at long term follow up in either group, although a high rate of contralateral tendon ruptures were observed. Poor patient reported outcome at one year post-injury was a significant predictor of poorer outcomes in the long term. The hypothesis that surgical treatment of the acutely ruptured Achilles tendon would result in improved functional outcomes at long-term follow up (which might offset the potential risks associated with surgery) was therefore rejected. This is the first randomised study to directly compare long term outcomes between these two treatment methods.

Chapter 5: A prospective Randomised Controlled Trial comparing functional and traditional non-operative management of Achilles Tendon Rupture

5.1 Introduction

As previously discussed (Chapters 1 and 4), the management of ATR continues to be controversial with advocates for both operative and non-operative treatment for these injuries.[4, 84, 85, 95, 97, 101, 103, 117, 118, 126, 130, 131, 328-330] There has been a trend towards increasing non-operative management of ATR, despite some persistent geographical variation.[32, 36, 37, 94, 105, 127, 128, 131, 132] This trend may be driven by reported good results with non-operative management in the context of functional rehabilitation.[105] However, it has been noted by some that the studies said to be driving these trends may have reached conclusions that are not supported by their underlying methodological design[99] and that many units employ regimes that are not supported by robust underlying evidence.[131-133, 227]

Studies driving the advent of non-operative functional rehabilitation programmes have been criticised for a number of reasons. Some have compared functional and traditional rehabilitation in the context of surgical repair of the ruptured Achilles tendon[118, 330-332] and demonstrated similar re-rupture rates and equivalent[332] or superior[118] functional outcomes while meta-analyses have reported a higher proportion of subjective 'excellent' results,[224, 328] fewer adverse events,[221] and earlier return to function[224, 331] in functionally rehabilitated surgical patients, without a corresponding increase in re-rupture rates.[221, 224, 328, 331] These findings may suggest that

functional rehabilitation is beneficial in the context of the surgically repaired Achilles tendon but cannot be extrapolated to non-operative management regimes.

Some studies advocating for functional non-operative management were non-comparative studies.[61, 101, 117] Others have compared functional operative and non-operative management and went on to advocate in favour of functional rehabilitation despite not having assessed outcomes in the presence or absence of functional rehabilitation.[62, 95, 97, 99, 126] Another has compared surgical management using functional rehabilitation with immobilising traditional non-operative management,[96] thereby altering two variables simultaneously and precluding any conclusions as to the degree of effect of the functional rehabilitation regime. One other group compared different functional non-operative regimes with each other, despite a lack of preceding evidence to show that functional non-operative treatment was in fact superior to traditional non-operative immobilisation.[157, 290]

Two small studies have previously compared non-operative plaster cast immobilisation with bracing, however both of these utilised old brace prostheses that are no longer in use.[118, 124] One of these studies, undertaken in 2001 reported no significant differences between groups, although it adopted a relatively long 12 week period in the orthosis for the functional group.[118] The other, published in 1992, involved three weeks of non-weight bearing cast immobilisation followed by a prolonged bracing period (usually 7 weeks). The authors of this study reported earlier return to 'comfortable walking' and greater range of dorsiflexion in the splinted group.[124] Both of these studies involved immobilisation regimes that would be considered significantly longer than modern functional rehabilitation regimes and did not report on musculoskeletal PROMs (although one study did report on HRQoL[118]).

A similar multi-centre randomised controlled trial (the UKSTAR trial) comparing non-operative cast treatment with functional bracing was undertaken concurrently with the study that

comprises this chapter of the thesis and was published in the same year and is the only other prospective randomised comparison of the two regimes.[158] The UKSTAR trial showed no difference in ATRS or re-rupture rate at 9 months post-injury, however, unlike the current study, it did not include any assessment of clinically measured parameters. In addition, follow up in that study was for nine months when other authors have described significant ongoing changes in ATRS measured outcome between 6 and 12 months with similar non-operative regimes.[62]

Therefore, despite the increasing prevalence of non-operative functional rehabilitation, there is a distinct lack of studies that directly compare functional non-operative management with traditional non-operative management and this deficit in the existing literature is even more pronounced with respect to modern non-operative functional rehabilitation.[99, 132, 133] Although the previous studies hypothesized that functional rehabilitation plays an important role in reducing complications and improving outcomes, there was no direct comparison of functional non-operative management with traditional non-operative management prior to the current study and the UKSTAR trial and therefore any such conclusions regarding the relative outcomes of functional and traditional non-operative management for acute Achilles tendon rupture were inferred and not due to a prospective, controlled, direct comparison of the two treatment methods and are therefore open to criticism.

The aim of this prospective randomised trial was to compare patient reported outcomes after traditional cast immobilisation with prolonged non-weight bearing (as described in Chapter 4) with functional rehabilitation and early weight-bearing in a walking boot, for adult patients from the general population, treated non-operatively for an ATR. Secondary aims included comparison of additional patient reported outcome measures (PROMs), clinical measurements of outcome, return to work and driving and complication rates.

5.2 Methods

This was a single-centre prospective randomised non-blinded controlled trial (NCT02598843). The study was granted a favourable opinion by the South East Scotland Research Ethics Committee 01. Walking boots were provided without charge by Ossur®, who were not involved in any aspect of trial design, management, data analysis or reporting. Patients were eligible for inclusion if they were aged between 16 and 60 and had sustained an acute Achilles tendon rupture. Exclusion criteria were delayed presentation >2 weeks and patients presenting with a re-rupture of a previously injured Achilles tendon. Latex allergy was added to the list of exclusion criteria in 2017 after notification by the manufacturer that latex was present in the sole of the walking boot. Patients were diagnosed with ATR clinically, with ultrasound only used at the clinician's discretion if in doubt. One hundred and forty patients (Figure 5.1) were randomised to receive traditional non-operative management (n=71) or accelerated functional rehabilitation using a walking boot (n=69). Randomisation was undertaken on a 1:1 basis by a research assistant at first presentation to the orthopaedic outpatient department using a computer generated binary sequence and sealed envelope allocation. Recruitment was undertaken between November 2013 and May 2018 with a pause for 9.5 months, when the boot suppliers ceased production of the in-boot wedges of the required dimensions, but resumed uneventfully once the wedges were available again. Patients were treated as detailed below:

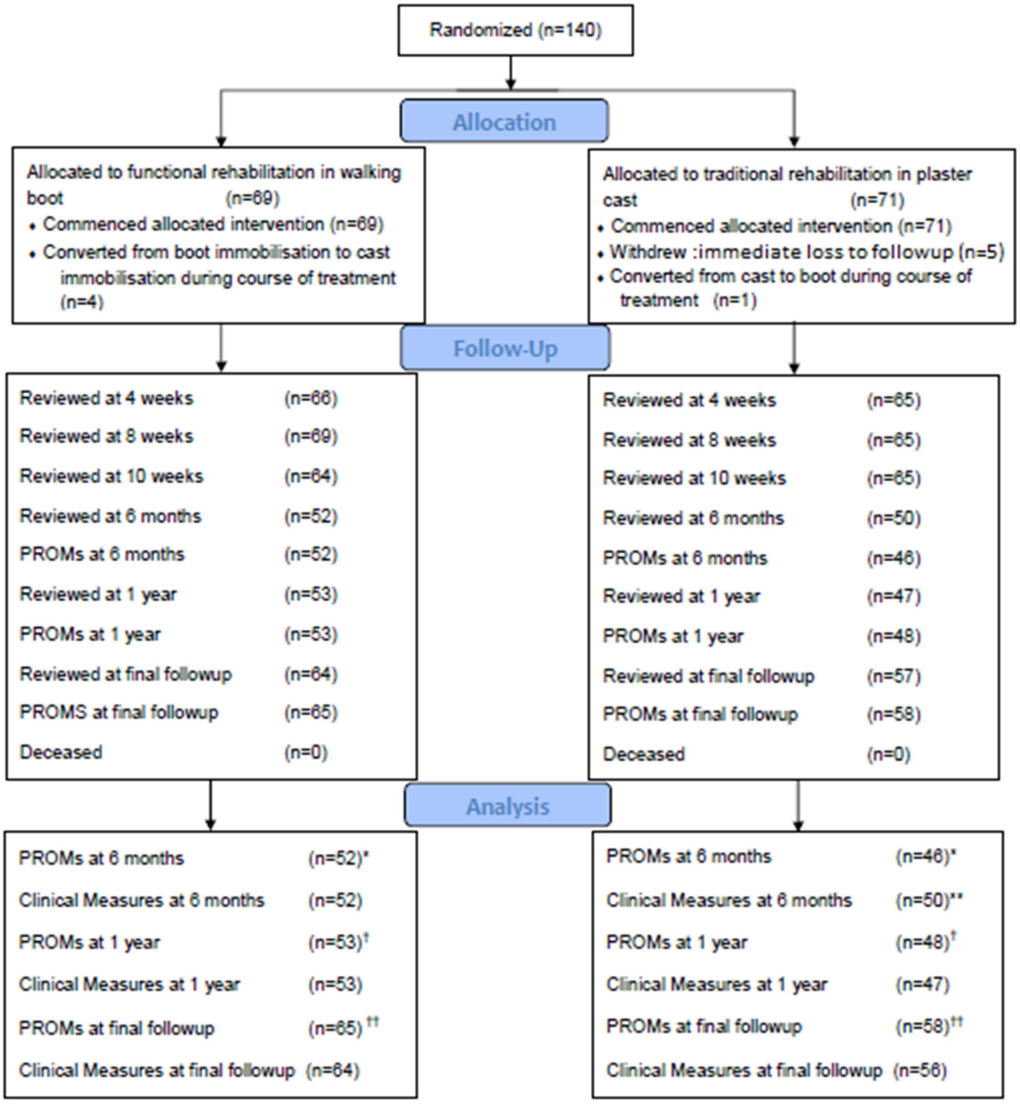


Figure 5.1. CONSORT flow diagram for the study. *applies to all PROMs except ATRS (n=52 and n=47), FAQ core (n=53 and n=45) and FAQ shoe score (n=41 and n=32). ** Except calf circumference and pain score (n=49), †Except FAQ core (n=53 and n=45) and FAQ shoe (n=40 and n=41). ††Except FAQ core (n=65 and n=55) and FAQ shoe (n=48 and n=50).

5.2.1 Treatment Regimes

5.2.1.1 Standard (Traditional) Non-Operative Pathway

Patients were placed into a complete below-knee cast with the ankle in full equinus and instructed to remain non-weight bearing on the affected limb. After 4 weeks, patients were converted into a complete below-knee cast in semi-equinus position for a further 4 weeks and instructed to remain non-weight bearing. Following this, patients were placed into a cast with the

ankle in plantigrade (neutral) position and advised to fully weight bear in this. After 2 weeks, the cast was removed, physiotherapy was commenced as described in Appendix 5.1 and patients could fully weight bear in their normal shoe-wear with an internal 1.5cm heel-raise shoe insert for a further 2 weeks, after which the shoe insert was discarded. Active plantar flexion commenced at 10 weeks.

5.2.1.2 Functional Non-operative pathway

Patients were placed into an Ossur® Rebound (Ossur hk, Reykjavik, Iceland) walking boot (worn continuously, including when in bed) with 3cm internal heel raise and advised to fully weight bear immediately with the aid of crutches for balance as needed. After 4 weeks, the internal heel raise was reduced to 1.5cm for a further 2 weeks. Patients then spent a further 2 weeks in the walking boot in a plantigrade position with no internal heel raise. No range of motion exercises were undertaken while in the boot. The boot was removed after 8 weeks and physiotherapy commenced upon removal of the boot as described in Appendix 5.1. Active plantarflexion commenced at 8 weeks.

5.2.2 Patient Follow up

The primary outcome measure was the Short Musculoskeletal Function Assessment (SMFA) score.[168] Patients were reviewed at their initial visit and then at 4, 6, 8, 10, 26 and 52 or more weeks from the date of injury. At each visit, data regarding complications were recorded, including incidence of venous thromboembolism or tendon re-rupture. Patients were also asked questions pertaining to return to specific activities, including driving and work. At 10, 26 and 52 weeks, additional clinical measurements were taken including calf circumference 11cm below the posterior knee skin crease and active ankle plantar and dorsiflexion, which were measured to the

nearest full degree using a goniometer. Patients were also asked to indicate the subjective level of pain experienced on a scale of 0 (no pain) to 10 (severe pain).

At initial review and at six and twelve months, patients were additionally asked to complete validated PROM questionnaires – the SMFA questionnaire,[168] Achilles Tendon Total Rupture Score[163] (ATRS) and the Foot and Ankle Questionnaire (FAQ).[164] The SMFA is a 46 question PROM derived from the longer Musculoskeletal Function Assessment.[168] Disability and bother indices are calculated. It is valid, reliable and responsive to change in status in patients with musculoskeletal injury. It is therefore reported to be suitable to clinically assess impact of treatment in patients with musculoskeletal injury.[168] The ATRS is a 10 question PROM, shown to be sensitive, valid and reliable in assessment of patients with ATR. The ATRS ranges from 0 (most disability due to Achilles tendon) to 100 (least disability).[163] No questionnaire had more than 2 missing questions and therefore, any missing questions were calculated as a score of 0, in keeping with the methodology employed by the authors who originally described this score.[163] The FAQ is a 25 question PROM developed by the AAOS to measure foot and ankle related disability.[164] It is reported as foot and ankle core and shoe comfort scales.

5.2.3 Statistical Analysis

Power analysis was undertaken using G*Power software (Department of Psychology, Universität Düsseldorf, Düsseldorf, Germany), to determine the number of recruits required. It was based on the primary outcome measure (SMFA questionnaire), for which a minimum clinically important difference of 7 points has previously been described.[193] Using a two-tailed power analysis with a standard deviation of 10 points, a minimum of 110 patients would be required at final follow up to achieve power of 95% with an α=0.05. One hundred and forty patients were recruited to allow for potential loss to follow up.

Statistical analysis was undertaken on an intention to treat basis. Data parametricity was assessed using Kolmogorov-Smirnov testing. Non-parametric continuous data was reported as median with interquartile range (IQR) and compared using Independent Samples Mann Whitney U-tests when unrelated and Related Samples Wilcoxon Signed Rank test (RSWSRT) when related. Parametric data was reported as mean and standard deviation and compared using a two tailed student *t*-test when unrelated and a paired student *t*-test when related. Nominal variables were compared between groups using Chi squared test, except if the expected cell count was <5 in any cell, in which case Fisher's Exact test (FET) was used. Two-tailed analyses were undertaken. A p-value of ≤ 0.05 was considered significant.[242]

5.3 Results

5.3.1 Patient Demographics

One hundred and forty patients (mean age 41 years; range 19-59) were recruited and 123 patients (87.9%) were followed up at the final time point at a median of 385 (IQR 372-419) days post-injury. Five patients crossed over between arms of the study (four converted from boot to cast treatment and one from cast to boot) and five patients (all randomised to the cast group) withdrew from the study. The baseline demographic and PROM data for the two groups was well matched (Table 5.1).

	Functional (Boot) Rehabilitation	Traditional (Cast) Rehabilitation	*p*-value**
Age	41 (33-50.5)	41 (32-49)	0.29
Gender (male:female)	54:15	60:11	0.21
Side of injury (right:left)	28:41	28:43	0.89
Dominant side injured	26 of 69	28 of 71	0.83
BMI*	26.6 (23.8-29.5)	26.4 (24.3-28.9)	0.99
Pre-Injury PROMs			
SMFA Dysfunction Index	0 (0-1.47)	0 (0-1.84)	0.74
SMFA Bother Index	0 (0-0)	0 (0-2.08)	0.87
ATRS	100 (100-100)	100 (100-100)	0.99
FAQ Core Score	100 (100-100)	100 (100-100)	0.32
FAQ Shoe Score	100 (100-100)	100 (100-100)	0.07

Table 5.1. Baseline demographics for patients at enrolment. *BMI = Body Mass Index. Age, BMI and PROMs are provided as median with accompanying interquartile ranges in brackets. **Independent Samples Mann Whitney U-test.

5.3.2 Patient Reported Outcomes (PROMs)

There was a statistically significant difference at 6 month follow up for SMFA, ATRS and Foot and Ankle Questionnaire core scores, but there were no persistent statistically significant differences in either the SMFA or any other PROM at one year or final follow up (Table 5.2). For patients in both boot and cast groups, there was a statistically significant improvement in both SMFA indices, ATRS and FAQ core scores between 6 month and final follow up time points (all $p<0.001$), although changes in FAQ Shoe score were not statistically significant ($p=0.051$ for boot patients and $p=0.093$ for cast patients). At final follow up, a statistically significant difference persisted in both groups for all PROMs, compared to pre-injury scores ($p\leq0.004$), except for FAQ shoe scores in the boot group ($p=0.08$).

		Functional (boot) rehabilitation	Standard (cast) rehabilitation	*p*-value*
6 Months	**SMFA Dysfunction Index**	6.62 (2.21-12.50)	10.66 (4.96-13.42)	**0.050**
	SMFA Bother Index	7.29 (2.08-14.58)	10.42 (5.73-19.27)	**0.04**
	ATRS	71.5 (53.50-84.25)	54.0 (37-76)	**0.01**
	FAQ Core Score	91 (81.89-97.55)	85 (78.25-92.09)	**0.04**
	FAQ Shoe Score	100 (62.50-100)	87.5 (35-100)	0.10
One Year	**SMFA Dysfunction Index**	2.21 (0.74-5.88)	2.94 (1.47-6.62)	0.25
	SMFA Bother Index	2.08 (0-9.38)	5.21 (0.52-11.98)	0.25
	ATRS	92 (72.50-96)	87.5 (66-94.75)	0.21
	FAQ Core Score	97.75 (89.46-99)	95.50 (90.88-97.50)	0.18
	FAQ Shoe Score	100 (81.25-100)	100 (63.33-100)	0.59
Final Follow up	**SMFA Dysfunction Index**	2.21 (0.37-6.25)	2.94 (0.74-7.35)	0.17
	SMFA Bother Index	2.08 (0-9.38)	4.17 (0-13.02)	0.29
	ATRS	92 (74-96)	88 (66-95.25)	0.20
	FAQ Core Score	97.75 (90.38-99)	95.50 (91.25-98.75)	0.21
	FAQ Shoe Score	100 (100-100)	100 (72.92-100)	0.52

Table 5.2 Patient reported functional outcomes for trial patients. Median scores are reported together with interquartile ranges. *Independent Samples Mann Whitney U-test. SMFA = Short Musculoskeletal Function Assessment. ATRS = Achilles Tendon Total Rupture Score. FAQ = Foot and Ankle Questionnaire.

5.3.3 Patient Activities

116 patients stated that they undertook sporting activities prior to their injury while 24 did not. Of these 116 patients, at final follow up, 79 had returned to sport at any level and 28 had not, while sport status was unknown in 9. There was no significant difference in rates of return to sport between patients treated in a walking boot (45 of 57) and those treated with a cast (34 of 50;

p=0.199). There was no difference in median time to first return to sport between the groups (median 26 weeks in both groups, IQR 16-37.5 weeks in boot group and 18.25-33 weeks in cast group; *p*=0.49). Of those who did return to sport (79), 76 provided data regarding the level of return to sports (i.e. normal level of sports or reduced level of sports) – 27 of 43 boot patients and 14 of 33 cast patients returned to their normal levels of sports (*p*=0.08).

125 patients stated that they drove prior to their injury while 15 did not. At one year, driving status was known for 115 (92%) of these, of which 108 patients reported that they could drive without difficulty, 3 stated that they could drive with difficulty and 4 patients were driving but it was not known whether they had any difficulty doing so. One patient who used to drive pre-injury stated that they were unable to drive. Time to return to driving was known for 113 of the 115 patients whose driving status was known at 1 year. Patients treated in a boot (n=59) returned to driving at a median of 12 weeks (IQR 10-14), whereas those treated in a cast (n=54) returned to driving at a median of 13 weeks (IQR 11-16; *p*=0.045).

130 patients were in paid employment at the time of enrolment into the study and of these, employment status was known at 1 year for 127 (97.7%). One patient retired and did not return to work after their injury, while one changed their job from a builder to taxi driving as a result of their Achilles tendon injury. The remaining 125 patients had returned to their previous job within one year of their injury. Median time to initial return to work was 4 weeks (IQR 1-12, range 0-40 weeks) for patients treated in the boot and 2 weeks (IQR 0-12, range 0-26) weeks for patients treated in cast (*p*=0.51) while return to full duties at work was at a median of 10 weeks in both groups (IQR 1-16, range 0 to 52 weeks for boot patients and IQR 0.88-14, range 0 to 30 weeks; *p*=0.48).

5.3.4 Clinical Measures

5.3.4.1 Calf Circumference

Calf circumference was significantly less in the injured than the uninjured leg at all time points across both treatment groups (Table 5.3). The percentage deficit in calf circumference between injured and uninjured legs was greater in the cast group than the boot group at 10 weeks post-injury (5.8% vs 2.8%, $p<0.001$) but there was no significant difference at 6 months ($p=0.82$), one year ($p=0.68$) and at final review ($p=0.68$). Between initial and final calf measurements, calf circumference did not change significantly for the uninjured leg in either boot (p=0.27) or cast (p=0.58) groups, while in the injured leg, calf circumference did significantly increase in both boot (p=0.025) and cast (p<0.001) groups, but, despite this, a significant deficit in circumference persisted at final follow up in both groups.

		Injured	Uninjured	*p*-value*	Injured calf circumference Deficit
10 weeks	Boot	37.00 (34.63-39.88)	38.75 (36-40.50)	<0.001	2.80% (0.29-5.73)
	Cast	36.50 (34-38.38)	39.00 (36-41)	<0.001	5.80% (4.08-8.51)
Six Months	Boot	37.25 (35-40.38)	39.00 (36.13-41.78)	<0.001	2.99% (1.33-5.02)
	Cast	38.00 (36-40.50)	40.00 (37-42)	<0.001	3.33% (1.23-5.76)
One Year	Boot	37.00 (35.25-40.50)	39.19 (37-42)	<0.001	2.44% (1.16-5.16)
	Cast	38.00 (35.50-40)	39.00 (36-41)	<0.001	2.38% (1.14-4.76)
Final Follow up	Boot	37.00 (35-40)	38.85 (36.63-41)	<0.001	2.47% (0.27-5.10)
	Cast	37.75 (35.63-40)	38.75 (36.50-40.93)	<0.001	2.38% (0.28-4.57)

Table 5.3. Calf circumference for injured and uninjured legs. Mean calf circumference in cm, at a point 11cm below the popliteal crease, is reported together with standard deviation. The deficit is reported as the median % difference in calf circumference between injured and uninjured legs, with interquartile range. *p-values refer to two tailed paired *t*-test reported for difference in mean circumference between injured and uninjured legs.

5.3.4.2 Active ankle range of motion

Deficits of plantarflexion and dorsiflexion (Table 5.4) were observed between the injured and uninjured limbs for patients in both boot and cast groups at 10 weeks but the deficit was greater in the cast group for both plantarflexion (p<0.001) and dorsiflexion (p=0.001). At six months (p<0.001 for both), one year (p=0.019 for boot and p=0.003 for cast) and at final follow up (p=0.004 for boot and p=0.001 for cast), there were persistent but clinically small deficits in plantar flexion in both boot and cast groups, however there was no significant difference in the magnitude of this deficit between groups (p>0.38).

At six months, one year and at final follow up, there was no clinical difference in median range of dorsiflexion in both groups.

		Injured		Uninjured		Median Deficit	
		Plantarflexion	Dorsiflexion	Plantarflexion	Dorsiflexion	Plantarflexion	Dorsiflexion
10 weeks	Boot	35° (30-40)	5.5° (5-10)	40° (40-45)	10° (10-15)	6° (0-10)	5° (0-10)
	Cast	30° (20-30)	5° (0-5)	40° (35-50)	10° (10-15)	15° (10-20)	10° (5-10)
Six Months	Boot	43° (40-45)	10° (5.50-15)	45° (40-50)	10° (10-15)	0° (0-5)	0° (0-3.75)
	Cast	40° (33.75-45)	10° (5-14.25)	45° (40-50)	10° (10-15)	0° (0-5)	0° (0-5)
One Year	Boot	40° (40-49)	10° (5.50-14.50)	45° (40-50)	10° (9-15)	0° (0-2)	0° (0-1)
	Cast	40° (40-45)	10° (5-12)	41° (40-50)	10° (10-11)	0° (0-5)	0° (0-0)
Final Follow up	Boot	40° (40-47.25)	10° (6-14.75)	45° (40-50)	10° (10-15)	0° (0-3.75)	0° (0-3)
	Cast	40° (35-45)	10° (10-10.75)	41° (40-50)	10° (10-14.25)	0° (0-5)	0° (0-0)

Table 5.4. Ankle range of motion in degrees (°) reported as the median and interquartile range. The deficit columns represent the median deficit in degrees between the injured and uninjured ankles.

5.3.4.3 Single and Double Heel raise

There was no significant difference in ability to undertake single or double heel raise at 6 months, one year, or final follow up (Table 5.5).

		Functional (boot) rehabilitation	Standard (cast) rehabilitation	*p*-value
Six Months	**Double heel raise**	52 of 52	48 of 50	0.24*
	Single heel raise	32 of 52	35 of 50	0.37**
One Year	**Double heel raise**	53 of 53	48 of 48	N/A
	Single heel raise	28 of 44	30 of 42	0.44**
Final Follow up	**Double heel raise**	64 of 64	57 of 57	N/A
	Single heel raise	56 of 64	55 of 57	0.10*

Table 5.5. Proportion of patients able to complete heel raise. *FET, **Chi-square test.

5.3.4.4 Pain

Most patients reported low levels of pain. There was a small but significant difference in patient reported pain scores noted between the two groups at 8 weeks, but not at any other time-point (Table 5.6). At final follow up, 17.2% (11 of 64) of boot patients and 31.6% (18 of 57) of cast patients reported experiencing any degree of pain (p=0.064).

	Functional (boot) rehabilitation	Standard (cast) rehabilitation	*p*-value*
4 Week Pain Score	0 (0-2)	1 (0-2)	0.22
8 Week Pain Score	0 (0-0)	1 (0-2.5)	**<0.001**
10 Week Pain Score	0 (0-2)	0 (0-1)	0.86
Six Month Pain Score	0 (0-1)	0 (0-2)	0.07
One Year Pain Score	0 (0-0)	0 (0-1)	0.22
Final Follow up Pain Score	0 (0-0)	0 (0-1)	0.07

Table 5.6. Median self-reported pain score for patients (interquartile range presented in brackets). * Independent Samples Mann Whitney U-test.

5.3.5 Complications

5.3.5.1 Re-ruptures

Of 125 patients whose status was known at one year, 16 had sustained a re-rupture (12.8%) at a mean of 13.99 weeks (±3.34 weeks) after the initial injury, of which 11 (of 60, 18.3%) were in cast patients and 5 (of 65, 7.7%) were in boot patients (risk ratio 0.885, 95% CI 0.770 to 1.017, p=0.075). All re-ruptures occurred within 21 weeks of the original injury. Thirteen patients were treated surgically, two were managed in a boot and one patient had a concomitant DVT and was therefore anticoagulated and managed non-operatively. He went on to heal with tendon elongation and underwent delayed surgery for this.

5.3.5.2 Venous Thromboembolism

Five patients (three treated in cast and two in boot; p=0.67) developed symptomatic VTE at a median of 7.28 weeks (IQR 1.79-11.79). Of these, 2 had an isolated DVT, 2 had a DVT and PE confirmed on imaging studies and one had an isolated PE. All were managed with anticoagulation (warfarin in 3 cases and rivaroxaban in two cases).

5.3.5.3 Minor Skin Issues

Fifteen patients, all treated in the boot arm of the trial, developed superficial skin breakdown, maceration or localised blistering during the course of treatment for their primary injury. Two patients were converted to cast treatment on account of this, while the remainder were treated with simple dressings. All skin lesions healed uneventfully with no long-term sequelae. No patients in the cast arm of the trial developed skin lesions ($p<0.001$).

5.4 Discussion

This study compares traditional immobilising cast management with modern functional rehabilitation and early weight bearing in a walking boot, for non-operative management of acute ATR in the setting of a RCT. Improved early function was demonstrated for patients in the boot group with regards to PROMs, time to return to driving, ankle range of motion and calf circumference. However, none of these differences persisted at one year or beyond. This study provides evidence that functional rehabilitation is safe, giving equivalent outcomes to traditional immobilising management at or beyond one year and that it also appears to give superior early outcomes, albeit with a higher incidence of transient minor skin complications.

It has been postulated that the increased use of non-operative management may be due to good outcomes reported with functional rehabilitation,[32, 99] although there is a lack of evidence to support this claim.[99, 132, 133] Similarly, a meta-analysis comparing functional and traditional treatment for ATR also found that the trend towards functional management was not supported by robust evidence, despite multiple authors advocating such protocols.[99] The authors suggested that functional surgical and non-surgical treatment protocols should be distinguished from one another and highlighted the need for randomised studies that directly compare traditional and

functional rehabilitation.[99] If functional rehabilitation is to become and remain the gold-standard treatment for these injuries in modern practice, where non-operative management is increasingly favoured, then it must be shown to provide outcomes that are at least equal to those obtained with traditional non-operative management.

5.4.1 Patient Reported Outcomes (PROMs)

This study reports on a variety of patient reported outcome measures (PROMs), including injury specific,[163] joint specific[164] and general musculoskeletal[168] PROMs, thereby giving a broad overview of patient perceived outcome. Advocates of PROMs argue that they represent patients' subjective opinion of their outcome and that this is important as improvement in patients' health status is the ultimate goal of most health services.[138, 333] There was a statistically significant difference across the range of PROM scores used at 6 month follow up, with better scores consistently reported by patients treated with functional rehabilitation. The MCID for the ATRS has not been scientifically defined, although some authors have suggested a value of 10 points[157] and others 8 points,[158] while the minimum detectable change has been reported to be 6.8 points.[197] Differences in ATRS demonstrated at 6 month follow up comfortably exceeded these, suggesting that patients experienced a noticeable difference in Achilles tendon function after treatment using these two techniques. However, although statistically significant, the difference in SMFA dysfunction index was less than the previously reported MCID for this score.[168] Olsson et al, using a very similar functional rehabilitation regime, reported similar ATRS scores to the functionally rehabilitated group in the current study at six (median 73 points) and twelve (median 90 points) months as well as a significant improvement in ATRS between 6 and 12 months, but with a persistent deficit at final follow up,[62] thereby corroborating the results of the current study. However, they did not compare this regime with traditional non-operative treatment. Costa et al, in their RCT published in the same year as the current study, reported no difference in ATRS

between cast and functional brace groups at 6 or 9 months, but they did report a statistically significant difference in ATRS in favour of the functional brace group at 8 weeks.[158] Taken together, the findings of the UKSTAR and the current RCT suggest that there is a likely early benefit to patients from weight bearing functional rehabilitation but that this does not persist in the longer term.

These differences between treatment groups did not persist at final follow up, indicating that the benefits of accelerated functional rehabilitation are most obvious to patients earlier on in the course of their recovery but that longer-term patient reported outcomes are similar. Both groups exhibited significant improvements between 6 month follow up and final follow up but their final scores remained lower than their pre-injury scores, indicating that some deficit persists after these injuries and these findings are in agreement with other studies of outcomes after ATR.[62, 97]

5.4.2 Patient Activities

Patients treated with functional rehabilitation in a walking boot returned to driving at a median of 1 week earlier than those treated in a cast. This would be consistent with the shortened period of immobilisation in this group that may facilitate an earlier return to some routine activities. However, there was no significant difference in the time to return to work or sports between the groups. Rates of return to sports after ATR in the current study were slightly higher than those reported in a previous meta-analysis.[226] A recent meta-analysis comparing functional rehabilitation with immobilisation also reported no difference in time to return to work between the two modalities.[99] There are no randomised controlled comparisons of return to sporting activity or driving after modern non-operative functional rehabilitation and traditional non-operative immobilisation. One small study did compare return to work in this fashion, utilising an old bracing system for functional rehabilitation and it reported no difference in time to return to work or sports between the two groups.[118] Similarly, the recent UKSTAR trial reported an

overall period of approximately 3 weeks off work for all participants, with no demonstrable significant difference between traditional cast and walking boot groups.[158] These findings are similar to the those of the current study. However, the convenience of early weight bearing has also been acknowledged.[99, 118, 158]

5.4.3 Clinical Measures of Outcome

Calf circumference of the uninjured legs remained unchanged throughout the period of study in both groups. The deficit in injured leg calf circumference was greatest at first measurement at 10 weeks post-injury for both groups and gradually diminished with the passage of time, however at final follow up there was a persistent residual deficit. Other authors have similarly reported that a deficit in calf circumference of the injured leg persists beyond one year post-injury.[61, 229] The observed deficit was greater in the group managed with cast at 10 weeks, suggesting that functionally rehabilitated patients who continue to weight bear throughout their course of treatment lose less muscle bulk initially than those managed in a non-weight bearing cast. However, there was no persistent significant difference between treatment groups at longer term follow up, although a deficit between injured and uninjured legs did persist in both groups. Recent studies using modern non-operative, early weight-bearing functional rehabilitation regimes[61, 95] have reported very similar findings to those in the current study, with a small but persistent deficit in calf circumference noted at one to two years,[61] thereby corroborating the results.

Similarly, patients in both groups exhibited a significant deficit in plantar and dorsiflexion compared to their uninjured limb at 10 weeks post-injury but this deficit was greater in the cast group. With the passage of time, patients in both groups demonstrated improvements in range of motion and there was no difference between the groups at final follow up. A majority of patients in both groups regained a full range of dorsiflexion compared to their uninjured limb but there

was a small persistent active plantarflexion deficit, possibly relating to tendon lengthening. These findings are also in keeping with previously reported outcomes after non-operative management of ATR.[4]

Both groups reported low levels of pain after these injuries and these findings are in keeping with reports by others.[4, 88] There was a statistically significant difference in median pain score between groups at 8 week follow up, in favour of the functionally rehabilitated group, although this was clinically small. At final follow up, median pain scores were 0 in both groups, however, almost one third of patients treated in a cast, as compared to almost one fifth rehabilitated functionally, complained of some degree of persisting pain, indicating that although most patients report good PROM scores and function, a degree of discomfort may persist in a notable minority of patients. The proportion of patients who reported some degree of persistent pain in the functionally rehabilitated group at final follow up was virtually identical to that reported in a non-comparative study reporting on a functional rehabilitation regime allowing early weight bearing but not early motion, thereby supporting these results.[117]

All tested patients in both groups were able to complete a double heel raise at final follow up, however around 8.3% could not complete a single heel-raise on the injured leg. There was no difference between groups. Deficits in heel-raise ability are a recognised sequela of ATR.[334]

5.4.4 Complications

There was a trend towards a lower risk of re-rupture in functionally rehabilitated patients (p=0.075). Re-rupture rates in the cast group were more than double those in the functionally rehabilitated group, which may be a clinically important finding despite not reaching statistical significance. This may be due to the study being underpowered to detect differences in re-rupture rate, which was a secondary outcome measure and is a feature of many RCTs in the field of ATR, where differences in re-rupture rate are often not detected in individual studies[57, 95, 97] but

become apparent when data is pooled into meta-analyses.[91, 226] A *post hoc* power calculation was performed according to the re-rupture rates observed between the groups, using an alpha of 0.05, which confirmed the current study to be underpowered (43%) to demonstrate a statistical difference in re-rupture rates and this may have resulted in a type II error. It has been postulated that functional rehabilitation may significantly reduce the rate of tendon re-rupture,[90] however this conclusion has been criticised as it was not based on direct comparison of re-rupture rates in functional and traditional rehabilitation regimes.[99] The current study facilitates direct comparison of these regimes. The re-rupture rate in functionally rehabilitated patients compares favourably with other functional regimes, where reported rates range from 6.6% to 12%,[62, 88, 117, 229] although it is slightly higher than those reported in some functional surgical regimes.[62, 229] All observed re-ruptures occurred within 21 weeks of the injury and this finding is in keeping with other reports that tendon re-rupture tends to occur early on in the process of recovery.[117, 223]

Minor skin issues were frequent in the group treated in a walking boot. Other authors have reported similarly high rates of minor skin issues when patients are treated in a walking boot,[62, 88] while the authors of one recently published functional rehabilitation programme did not report on these complications[61] although they described a 10% incidence of skin problems in their patients at an oral presentation on their treatment protocol.[335] It is unclear whether the skin issues are the result of treatment in a boot or early weight bearing, but it appears that they occur with increased frequency in patients managed with early weight bearing functional rehabilitation regimes and clinicians and patients should be aware of this. None of the patients who developed these complications in the current study had any long term sequelae although in two cases, the skin issues were significant enough to warrant conversion to cast treatment.

5.4.5 Limitations

This study does have limitations. Some patients did not attend for scheduled one year review appointments on time. However, results of those presenting more than 3 months after the one year mark were not included in the one year analysis and are only presented in the final follow up cohort, which includes results from the last review at or beyond one year after injury. Median time to final follow up for the final review cohort was 393 days (IQR 372.5-429.5; range 360-1151) for patients treated in the boot and 382 days (IQR 372-406; range 357-1126) for patients treated in cast and there was no significant difference (p=0.32) in time to final follow up between groups, suggesting that the groups remained comparable at this time point. Lack of muscle strength assessment using a dynamometer may also be considered a limitation and was initially planned as the primary outcome measure for this study but could not be undertaken due to logistical constraints. This study only assessed functional rehabilitation with early weight bearing but did not assess the impact of combining this with early range of motion exercises commencing at 4 weeks and weaning of the boot from 6 weeks, which was envisaged in the original protocol for the trial. The authors of recent meta-analyses stated that both early weight bearing and/or early range of motion are considered to constitute functional rehabilitation regimes and suggested that these should be distinguished from each other for analysis.[99, 107] Lack of blinding of physiotherapists to the treatment modality may also be considered a limitation as it may have subconsciously altered their confidence with progressing early exercises, while inability to blind patients to their treatment method may have caused assessment bias. Additionally, lack of 2 year follow up in the study design and a higher amount of loss to follow up in the cast group (which may result in bias) could also be considered limitations. Strengths of the study include a large and highly powered sample size and low rates of loss to follow up at the study endpoint.

5.4.6 Clinical Relevance and Future Research

This study follows on from the study described in the previous chapter and seeks to compare the traditional non-operative regime described in Chapter 4 and shown to give outcomes comparable to surgical management, with a modern functional non-operative regime. Together with the UKSTAR trial published in the same year, it represents the only direct randomised controlled data to support the use of functional non-operative management of ATR over traditional non-operative management of these injuries with an immobilising cast. A meta-analysis published after the RCT that comprises this Chapter of the thesis similarly concluded that functional rehabilitation after ATR results in better early outcomes and equivalent functional outcomes in the longer term and on this basis concluded that such regimes are safe,[336] thereby corroborating the findings of this study.

The findings of this study are of clinical importance since the data justifies the uptake of functional non-operative management regimes, whose use has increased markedly in recent years, despite a previous lack of direct data to support their use. Clinicians and patients can now utilise similar regimes with increased understanding of the expected outcomes across a range of clinical and patient reported measures. Further studies should now aim to give increased understanding of the described regime and also to compare different iterations of functional rehabilitation with each other.

Functional non-operative rehabilitation in a weight bearing boot has been shown to be a safe and effective treatment for ATR which was associated with better short term clinical and patient reported outcomes and equivalent outcomes at and beyond one year post-injury, without any demonstrable increase in major complications. If this regime is to be employed in wider mainstream practice, then it is important that clinicians have a detailed understanding, not only of

the patient reported and clinical outcomes that can be expected when utilising this regime, but also of the physiological processes that underpin it. It is desirable to understand how parameters related to Achilles tendon function change over time when treating ATR using this regime and how these parameters and changes within them relate to both clinical and patient reported outcome measures. The study in Chapter 6 seeks to give a comprehensive understanding of patient recovery after the functional non-operative regime described in this chapter, by recording changes in pedobarographic parameters in the months after ATR treated with the functional non-operative regime described in Chapter 5 and relating these temporal changes to various clinically measured and patient reported outcomes as well as to clinical measures of tendon length (e.g. the Achilles tendon resting measure and resting angle).

5.5 Conclusion

Following an ATR, functional rehabilitation with early weight bearing is a safe alternative to traditional cast immobilisation with prolonged periods of non-weight bearing. It has demonstrated multiple early benefits in the functionally rehabilitated group across a range of outcome measures including patient reported outcomes and clinical measurements. Improved patient reported outcomes in the functionally rehabilitated group did not persist at or beyond one year. It is also associated with a higher incidence of minor skin complications that had no long-term sequelae. The rate of tendon re-rupture was less than half that in the traditionally rehabilitated group, but this finding did not reach statistical significance. On the basis of these results, the use of this treatment regime is recommended in preference to traditional cast immobilisation.

Chapter 6: Standing Plantar Pressures, Clinical and Patient Reported Outcomes after Achilles Tendon Rupture Treated using a Functional Non-operative Early Weight Bearing Rehabilitation Regime: A Case Control Study

6.1 Introduction

Functional rehabilitation has become an increasingly popular form of management for acute ATR in recent years and has been credited with driving recent trends towards non-operative management of ATR by many authors.[32, 37, 105, 127, 227] Despite this, some have lamented a lack of direct comparative data to justify adoption of these techniques[99] and it is only recently that high level evidence has begun to emerge in the form of randomised controlled studies directly comparing functional non-operative management of ATR with other established treatment modalities,[110, 158, 291] including the randomised study in Chapter 5 of this thesis.[291]

While functional non-operative rehabilitation for ATR has now been shown to be effective compared to other regimes,[110, 158, 291] most studies to date have largely focussed on PROMs and questionnaire data,[61, 101, 110, 158] although others have collected some basic clinical data.[157, 290] In recent years, novel clinical measurement tools have been described which were not available for use in earlier studies[337, 338] and there has also been a focus more generally in orthopaedics not just on PROMs but also on health related quality of life and measures of patient sentiment and satisfaction.[151, 180, 182, 339-342]

Pedobarographic studies of plantar force and pressure distribution have long been used in the field of diabetes, with large studies suggesting an association between increased relative forefoot pressure and diabetic ulceration[343] and other studies exploring the utility of orthopaedic interventions (e.g. Achilles tendon lengthening) in offloading forefoot pressure in this patient population.[344-346] Authors in other fields, including orthopaedic surgery, have also shown interest in the study of plantar forces and pressures in both static standing and walking scenarios, primarily but not exclusively relating to foot and ankle pathology.[347-356] The concept of comparison of relative forefoot and hindfoot loading is well established and found in both diabetic[343] and non-diabetic pedobarographic studies.[347, 352-354] Achilles tendon function is postulated to be a major determinant of active plantarflexion[357] and consequently pressure distribution[344] under the foot. Surgical lengthening of the Achilles tendon has been shown to reduce relative forefoot loading in the context of patients with diabetic foot ulceration. ATR is also known to result in tendon lengthening[358] and could theoretically therefore result in similar reductions in forefoot loading.

The efficacy of functional non-operative treatment for ATR has now been established, through the work in Chapter 5 of this thesis[291] and that of other authors[158] and we understand functional non-operative rehabilitation to be a safe and effective treatment option for ATR. However, understanding of the specific processes and changes that patients go through as they recover during these programmes is limited and it is evident that there is a paucity of clinically measured data that can be correlated with PROMs, patient sentiment and other outcome measures over multiple time points in the months after ATR. Therefore, there is a need for studies that bring all the above measures together to give practitioners a holistic and detailed overview of patient progress through the functional non-operative rehabilitation programme over time. This may help to identify what makes the regime successful or identify areas that could be targeted for improvement.

The main aim of this study was to report peak plantar pressures and forces acting on the feet during static stance as a forefoot to rearfoot (FFRF) ratio after ATR and to describe changes in the FFRF ratios over time up to 9 months post-injury. Secondary aims included assessment of patient reported outcomes, health related quality of life, clinically measured parameters and self-reported pain scores, both at absolute standardised time points and with respect to changes over time in the months after ATR. Other secondary outcomes included comparison of measured parameters with a group of healthy control subjects, correlation of FFRF ratios with patient reported outcome measures and health related quality of life and assessment of patient sentiment after completing treatment for ATR with a functional non-operative rehabilitation regime.

6.2 Methods

This study was a prospective case control study comparing patients treated for ATR with weight bearing functional rehabilitation in a walking boot with normal control subjects. The study was granted a favourable opinion by the South Berkshire research ethics committee (18/SC/0699).

Patients were eligible for inclusion in the study if they were aged between 16 and 75 years and sustained an acute ATR. Exclusion criteria included a history of foot or ankle surgery or pathology; individuals residing out with the hospital catchment area who would find it difficult to attend for follow up; individuals presenting with a re-rupture of the Achilles tendon; previous major hip or knee surgery; symptomatic hip or knee arthritis, diabetes or any form of peripheral neuropathy.

Twenty-five age and sex matched control subjects were also recruited according to the same inclusion and exclusion criteria, except for the requirement of an acute ATR. Control subjects were recruited from attendees at the orthopaedic outpatient department including staff and visitors.

Patients were diagnosed with ATR clinically, with ultrasound only used for confirmation of the diagnosis at the clinician's discretion in the event of diagnostic doubt.

Recruitment was undertaken between May 2019 and September 2021 with disruption to recruitment and follow up in the intervening period due to the COVID-19 global pandemic which mandated a moratorium on both recruitment and clinical follow up of patients for research purposes. Recruitment was paused in March 2020 and resumed in June 2021, as a result of COVID-19 restrictions. Any patient missing two or more follow up appointments as a result was excluded and permission was granted by the REC by way of an amendment to recruit replacement patients. One patient was excluded from the study and replaced with a new recruit after developing a tendon re-rupture in the early days after boot removal. Twenty-five patients were included in the study.

6.2.1 Recruitment and Treatment Regime including Physiotherapy

Patients were placed into an equinus backslab in the emergency department at first presentation and referred to the virtual trauma clinic from which they were triaged into the trauma clinic. At first presentation to the trauma clinic, prospective patients were identified and informed of the study. Informed consent was taken for inclusion in the study if the patient indicated a desire to be included. Patients were asked to complete their baseline PROMs data for both immediately pre- and post-injury. This method has been used in other large studies to collect pre-injury data.[110, 291] then placed into an Ossur® Rebound (Ossur hk, Reykjavik, Iceland) walking boot (worn continuously, including when in bed) with 3cm internal heel raise and advised to fully weight bear immediately with the aid of crutches for balance as needed. Four weeks after injury, patients were reviewed in clinic and the internal heel raise was reduced to 1.5cm for a further 2 weeks, at which point patients were again reviewed in clinic for removal of the remaining heel raise. Patients then spent a further 2 weeks in the walking boot in a

plantigrade position with no internal heel raise and were reviewed in clinic once again at the 8 week post-injury mark for boot removal and commencement of physiotherapy as per the protocol (Appendix 6.1). No range of motion exercises were undertaken while in the boot. Active plantarflexion was commenced at 8 weeks after injury upon boot removal.

6.2.2 Matching of Controls

Patients included in the study were matched for age (+/- 2 years) and sex with control subjects in a ratio of 1:1. For the purposes of statistical analysis, further matching was undertaken of the control subjects' limbs, whereby patients' injured and uninjured limb were matched with the relevant ipsilateral limb of the control.

6.2.3 Patient Follow up and Outcome Measures

Patients were reviewed for collection of study data at 2 months (boot removal), 3 months, 6 months and 9 months after their ATR. Controls were assessed on one occasion and the full data set (pedobarographic data, PROMs and clinical measurements) collected for patients was also collected for controls, with the exception of satisfaction and patient sentiment data for their treatment, which was not applicable to control subjects. PROMs data was collected by post while physical reviews were paused due to COVID-19 restrictions.

At each visit, a wide range of data was collected:

Plantar force and peak pressure data during static stance were collected by asking patients to stand on a footmat (SB Mat, Tekscan Inc, Boston, MA, USA) for 130 seconds. Prior to standing on the mat, all shoe wear and socks were removed and any baggy trousers rolled up to prevent any contact with the mat surface. Patients were instructed to look straight ahead during the period of assessment. Data was collected from both feet simultaneously at a rate of 100 frames per second (i.e. one frame every 0.01 second) using Tekscan Pressure Measurement System,

FootMat Research ver. 7.10-13 (Tekscan Inc., Boston, MA, USA). Thus there were 13,000 frames per 130 second recording. The sole of the foot was bisected longitudinally into two equal portions between the posterior-most point of heel contact and the distal most point of metatarsal contact. Toe contact was highly variable and minor in comparison and thus not used in this division but any toe contact was included with the forefoot readings. In this way, four quadrants were defined, comprising the left forefoot and rearfoot and the right forefoot and rearfoot. The software records data visually using colour coded pressure maps and can also generate graphs showing variation in the variables of interest over time (figure 6.15a and b). For the purposes of data analysis, this data was exported numerically as total force (Newtons) and peak pressure (Newtons per cm^2, N/cm^2) for each quadrant as defined above and for each frame. Data collected during the first 45 seconds was not analysed, to allow patients to equilibrate during static stance. Data analysis was then performed on data collected between 45 and 120 seconds. Data for total force in each quadrant as well as the peak pressure recorded over a $1cm^2$ area in each quadrant was collected over 13,000 frames during each episode. This was used to calculate the forefoot to rearfoot (FFRF) force ratio and the FFRF peak pressure (PP) ratio for each foot. Sampling of twenty random data samples from patients indicated non-parametric distribution for this data in all cases and therefore median values for the ratios were calculated. Forefoot to rearfoot ratios can be used to understand load distribution in the foot in the axis of Achilles tendon function (i.e. longitudinal) and also facilitates comparison of loading patterns between patients of varying mass. Ratios were compared between injured and uninjured feet and between ATR patients and healthy controls.

Patient Reported Outcome Measures. Multiple PROMs datasets were collected for patients and controls. The Short Musculoskeletal Form Assessment is a general musculoskeletal PROM comprising of a 46 question questionnaire completed by patients, from which a dysfunction index and a bother index are calculated with possible values ranging from 0 to 100 and lower scores

indicating better function. It has been shown to be valid, reliable and responsive to change in status in patients with musculoskeletal injury.[168] The Achilles Tendon Total Rupture Score is an injury specific 10 question PROM, designed specifically to measure patient reported function and outcomes after ATR. Possible scores range between 0 (most disability due to the injured Achilles tendon) and 100 (least disability due to the injured Achilles tendon).[163] The EQ-5D-5L PROM assess health related quality of life and consists of the EQ-5D Index ranging from -0.59 to +1 and calculated from patient responses to 5 questions in the domains of mobility, self-care, usual activities, pain and discomfort, anxiety and depression; and the EQ-5D visual analogue scale (VAS) where patients are asked to rate their overall health on a scale between 0 (worst imaginable health) and 100 (best imaginable health).[177] Full details on all PROM scores used in this study can be found in Chapter 1 (section 5.2).

Clinical Measures. Various clinical assessments were undertaken on patients and controls. Active plantar and dorsi flexion range were measured with the patient lying supine. Using a marker pen, the fibular head, the distal-most tip of the fibula and the centre of the 5th metatarsal head and base were marked on the lateral border of the limb. The patient was then instructed to maximally plantarflex or dorsiflex the foot and a long-arm goniometer used, centred over the marked tip of the fibula and with one arm aligned along the fibula and the other arm placed parallel to the dots along the long axis of the 5th metatarsal bone. Measurements were made to the nearest degree relative to the plantigrade position. Negative measurements signified inability to reach the plantigrade position in the direction being measured. The Achilles Tendon Resting Angle (ATRA) is a measure of the neutral resting angle of the ankle. It is calculated as the angle between the long axis of the fibula and a line between the tip of the fibula and the centre of the 5th metatarsal head on the lateral border of the foot.[337] It has been shown to correlate with absolute tendon length.[359, 360] The ATRA was measured with the patient prone and the knee flexed to 90°, in the fashion described by Carmont et al[337] with minor modifications as described by Hansen et

al[338] including the marking of reference points on the skin using a skin marker and use of a long arm goniometer with 1 degree increments. The relative ATRA was calculated by subtracting the injured side absolute ATRA from the uninjured side ATRA. Negative values indicate relative dorsiflexion of the injured limb.[337] The Achilles Tendon Length Measure (ATLM) was measured with the patient in the prone position as described by Hansen et al.[338] The relative ATLM was calculated by subtracting the injured side absolute ATLM from the uninjured side ATLM. A positive relative ATLM indicates that the injured foot is in relative dorsiflexion. Calf circumference was measured to the nearest millimetre using a measuring tape placed 10cm below the proximal-most palpable tip of the tibial tuberosity. The presence or absence of callosities over the forefoot sole, hindfoot sole, posterior border of the heel or 'other' region of the foot was recorded as a nominal variable.

Pain Visual Analogue Scales. Patients were asked to complete a pain visual analogue scale detailing the amount of pain on the day of assessment in three regions of each foot – the forefoot sole, the hindfoot sole and the posterior heel region (Appendix 6.2).

Measures of Patient Sentiment. Patients were asked the following three questions:

1. How satisfied are you with your treated Achilles tendon?

2. Would you have the same treatment again if it were required on the opposite side?

3. How likely are you to recommend this treatment to friends and family if they needed similar care or treatment?

For question 1, possible answers were very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied or very dissatisfied; For the last two questions, patients could answer extremely likely, likely, neither likely nor unlikely, unlikely, extremely unlikely or don't know. The last question was used to calculate the Net Promoter Score (NPS),[180, 208] a single question metric that quantifies individual's likeliness to recommend a good or service to others (see Chapter 1, section 5.2.5). For calculation of the NPS, patients who said they would be 'very likely' to

recommend their treatment to others were considered ‘promoters’; those who stated they would be ‘likely’ to do so were considered ‘passives’ and those who stated they ‘didn’t know’, were ‘unlikely’/’very unlikely’ or were ‘neither likely nor unlikely’ to do so were considered ‘detractors’. This data was also presented in the format of the NHS England Friends and Family Test.[209]

Twenty one of 25 patients (84%) were followed up to completion of the study at 9 months. Of those completing the study, five had missed one earlier review (at 6 months) but had full data at all other time points. Of the 4 patients not seen at 9 months (all due to COVID restrictions), all had full follow up at all other time points. Thus the lowest follow up rate for the primary outcome measure was 20 of 25 (80%) at 6 months while it was 21 of 25 (84%) at 9 months (figure 6.1). No patient included in the study missed more than one of their scheduled follow up reviews. PROMs data was collected by post while physical reviews were paused due to COVID-19 restrictions.

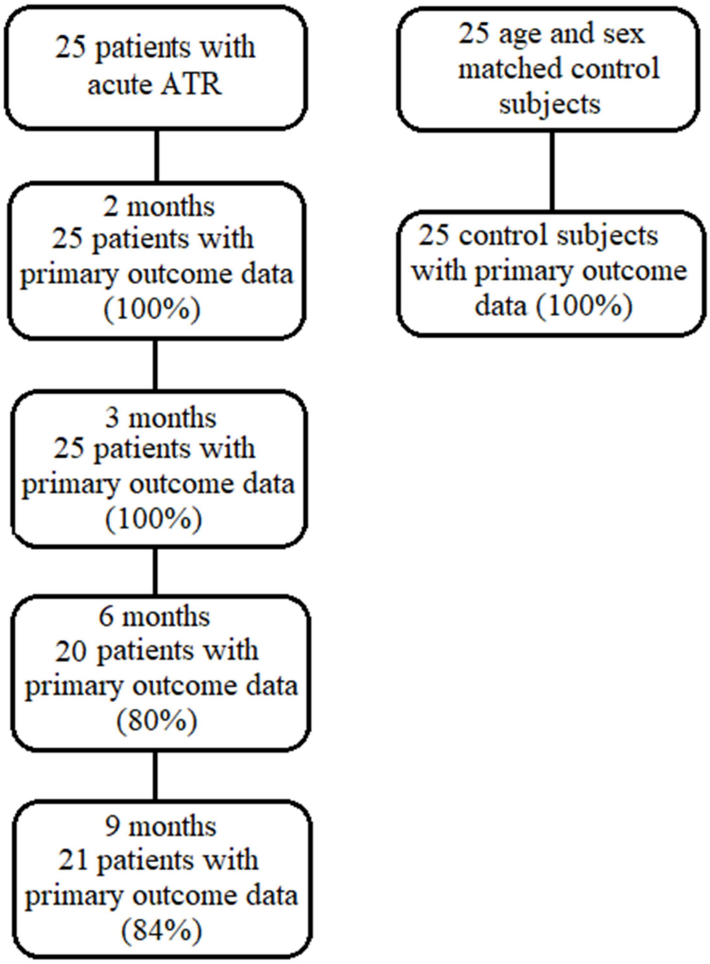


Figure 6.1 Diagram illustrating patient flow through the study.

6.2.4 Statistical Analysis

The primary outcome measure was the forefoot to rearfoot ratio of peak pressure under the foot. There were no previous studies of static plantar pressures after treatment for ATR with modern functional rehabilitation regimes, nor any studies detailing a minimum clinically important difference in forefoot to rearfoot ratio in the context of Achilles tendon rupture in the published medical literature.

Power analysis was performed for the primary outcome: change in the forefoot to rearfoot peak pressure ratio between 2 and 9 months after injury. Using an effect size of 0.7 and an alpha 0.05 with a power of 80% and a two tailed analysis using a Wilcoxon signed rank test for

matched pairs it was determined that 20 patients would need to be recruited. A moderate effect size was chosen (0.7) to assess the change in forefoot/hindfoot pressure ratio based on dynamic data from Maluf et al who found a similar effect size when assessing change in forefoot pressure for diabetic patients undergoing surgical tendoachilles lengthening between 3 weeks and 9 months.

Data was tested for parametricity using the Kolmogorov-Smirnov test. Where the data was found to be non-parametric at one or more time-points, non-parametric statistical tests were employed for that variable at all time-points. Continuous parametric data was reported as the mean with standard deviation and unpaired parametric data was assessed using the student *t*-test. Non-parametric continuous data was presented as the median with interquartile range. Unpaired non-parametric continuous data was compared using the independent samples Mann Whitney U test while paired non-parametric data was compared using the related samples Wilcoxon signed rank test. Continuous variables (all non-parametric) were correlated using Spearman's rank correlation. A p-value of ≤ 0.05 was considered statistically significant.

6.3 Results

6.3.1 Patient and Control Group Demographics

The mean age for patients in the study was 43.8 years (±12.2) while that for controls was 43.9 (±12.3). There were 19 males and 6 females in each group. 10 patients sustained left sided injuries and 15 sustained right sided injuries.

	Patients	Controls	*p*-value
Age	43.80 (±12.22)	43.88 (±12.31)	0.98
BMI	27.47 (25.25 - 29.44)	26.20 (23.35 - 28.55)	0.15
Pre-Injury SMFA Disability Index	4.41 (0.37-11.77)	0 (0-1.84)	**0.001**
Pre-Injury SMFA Bother Index	0 (0 - 6.25)	0 (0-2.08)	0.57
Pre-Injury ATTRS	100 (94.50 – 100)	100 (100 - 100)	0.07
Pre-Injury EQ5D Index	1 (94.50 – 100)	1 (1 – 1)	0.39
Pre-Injury EQ5D VAS	90 (77.50 – 98.50)	90 (85-98)	0.27

Table 6.1 Pre-Injury patient characteristics and control patient characteristics. Age is presented as mean with standard deviation (two tailed student t-test), whereas all other variables were non-parametric and are presented as median with interquartile range (Independent samples Mann Whitney U test).

6.3.2 Forefoot to Rearfoot Force ratio

Patients recovering from ATR exhibited a significantly reduced forefoot to rearfoot force ratio in the injured leg as compared to the uninjured leg at all time points (figure 6.2 blue lines, table 6.2). Through the course of the follow up period, the FFRF force ratio increased significantly in both the injured (median 0.083 at 2 months post-injury and 0.31 at 9 months post-injury; $p<0.001$, related samples Wilcoxon Signed rank test) and uninjured (median 0.66 at 2 months and 1.04 at 9 months; $p=0.01$) legs (table 6.2, figure 6.3), indicating progressively greater relative loading of the forefoot as compared to the hindfoot in both feet with the passage of time after

ATR, however the difference between injured and uninjured leg still remained significant at last measurement.

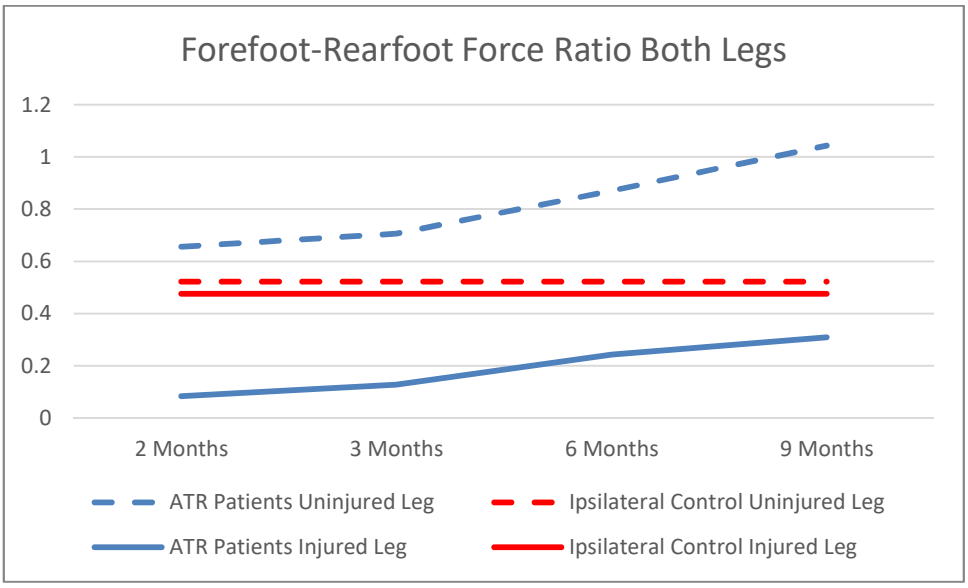


Figure 6.2 Median forefoot to rearfoot force ratio for patients' injured and uninjured legs (blue lines) at each time point between 2 and 9 months after ATR. Note: The control data is not time-point specific but is shown as red horizontal reference lines.

Figure 6.3 Median forefoot and rearfoot force distribution in percentage terms for the injured, uninjured and control feet.

Assessment Timepoint	Injured Leg	Uninjured Leg	p-value*
2 months	0.083 (0.069 – 0.14)	0.66 (0.41 – 0.92)	<0.001
3 months	0.13 (0.09 – 0.18)	0.71 (0.42 – 0.92)	<0.001
6 months	0.24 (0.14 – 0.35)	0.87 (0.60 – 1.08)	<0.001
9 months	0.31 (0.22 – 0.47)	1.04 (0.54 – 1.48)	<0.001
Controls	0.48 (0.41 – 0.77)	0.52 (0.33 – 0.74)	0.88

Table 6.2 Forefoot to rearfoot force ratio for injured and uninjured legs at sequential time points after Achilles tendon rupture. Control feet were matched to the ipsilateral patient leg for injury status. * Related samples Wilcoxon signed rank test.

Controls subjects, unlike patients exhibited no significant difference in FFRF force ratios between their matched control legs (table 6.2). There was a statistically significant difference in median force ratio between injured legs after ATR at all time points during the follow up period when compared to the control readings for matched ipsilateral legs ($p \leq 0.023$). The injured foot exhibited a very low relative forefoot load at initial review 2 months after injury and despite a steady increase in relative forefoot loading over time, had not reached the levels of forefoot loading seen in control subjects at the time of last follow up 9 months after injury (figures 6.2 and 6.3). The uninjured foot exhibited no statistically significant difference in forefoot:rearfoot force compared to control subjects at initial measurement 2 months after ATR ($p=0.20$), however there was progressive increased relative forefoot loading in the uninjured foot with the passage of time, such that the measurements taken on patients uninjured foot at 3, 6 and 9 months after injury were significantly different from control measurements ($p \leq 0.045$).

6.3.3 Forefoot to Rearfoot Peak Pressure Ratio

Patients recovering from ATR exhibited a significantly reduced forefoot to rearfoot peak pressure ratio in the injured leg as compared to the uninjured leg at all time points (figure 6.4 blue lines, table 6.3). Over the course of the follow up period, the FFRF PP ratio (table 6.3) increased significantly in the injured leg (median 0.13 at 2 months post-injury and 0.28 at 9 months post-injury; $p<0.001$). While the FFRF PP ratio also increased in the uninjured leg (median 0.47 at 2 months and 0.83 at 9 months; $p=0.15$), this change did not reach statistical significance.

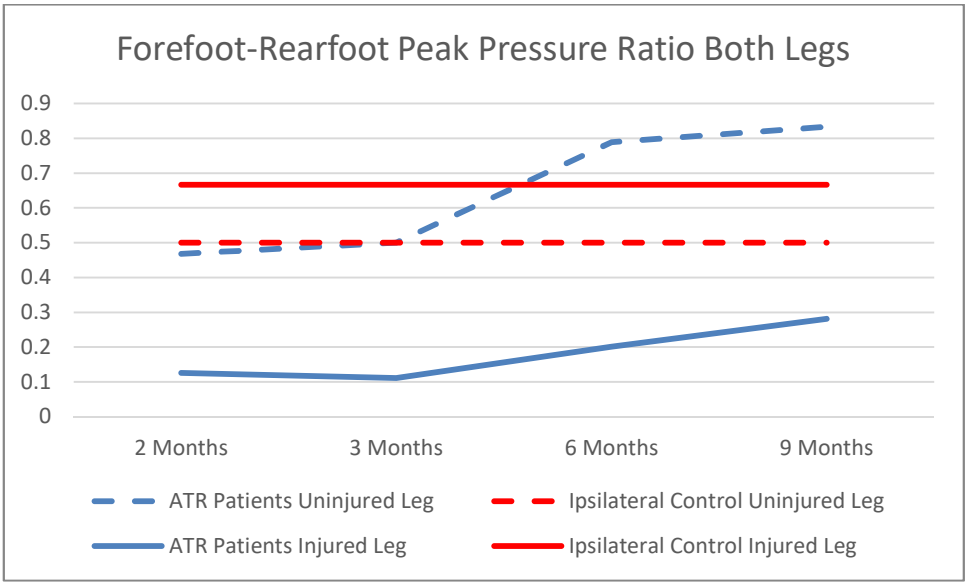


Figure 6.4. Median forefoot to rearfoot peak pressure ratio for patients' injured and uninjured legs (blue lines) at each time point between 2 and 9 months after ATR. Note: The control data is not time-point specific but is shown as red horizontal reference lines.

Assessment Timepoint	Injured Leg	Uninjured Leg	*p*-value*
2 months	0.13 (0.07 – 0.18)	0.47 (0.33 – 0.90)	<0.001
3 months	0.11 (0.07 – 0.18)	0.50 (0.33 – 0.76)	<0.001
6 months	0.20 (0.13 – 0.27)	0.79 (0.51 – 1.00)	<0.001
9 months	0.28 (0.18 – 0.53)	0.83 (0.43 – 1.06)	<0.001
Controls	0.67 (0.40 – 0.89)	0.50 (0.29 – 0.65)	0.03

Table 6.3 Forefoot to rearfoot peak pressure ratios for injured and uninjured legs at sequential time points after ATR. Control feet were matched to the ipsilateral patient leg for injury status. *Related samples Wilcoxon signed rank test.

Controls also exhibited a statistically significant difference in FFRF PP ratio between matched control legs, having been matched to the same side as injured and uninjured patient legs (p=0.03).

There was a statistically significant difference in median FFRF PP ratio between injured legs after ATR (table 6.3) at all time points during the follow up period when compared to the control readings for matched ipsilateral legs ($p \leq 0.008$). Conversely, the FFRF PP ratios for the uninjured leg were not significantly different from the control reading at any time point ($p > 0.12$), although there was a narrowly insignificant trend to higher FFRF PP ratio in the uninjured foot at 9 months as compared to the control reading (p=0.063).

6.3.4 Patient Reported Outcome Measures and Health Related Quality of Life

All PROMs were significantly negatively impacted by Achilles tendon rupture (figures 6.5a and b; figures 6.6a and b) and exhibited a statistically significant subsequent improvement over the ensuing 9 months (table 6.4; Appendix 6.3 table 1). All measures except the SMFA Dysfunction Index exhibited progressive improvement up to the last follow up time point. The SMFA dysfunction index exhibited a slight worsening in median scores between follow up at 6 and 9 months post-injury, however while this change was statistically significant (p=0.008), the change in median score was of 5.15 points, which is lower than the minimum clinical important difference for the SMFA score[168] and is therefore not considered clinically significant. At 9 months post-injury, median SMFA dysfunction index, ATRS and EQ-5D-5L Index scores remained lower than patient reported pre-injury scores (table 6.4; Appendix 6.3 table 1).

The final scores for SMFA dysfunction index (p<0.001), ATRS (<0.001) and EQ-5D Index (p=0.004) were inferior at 9 months after injury to the control readings. However, there was no difference between SMFA Bother Index (p=0.065) and EQ-5D VAS (p=0.132) at 9 months for patients compared with control readings. Full data is presented in table form in Appendix 6.3.

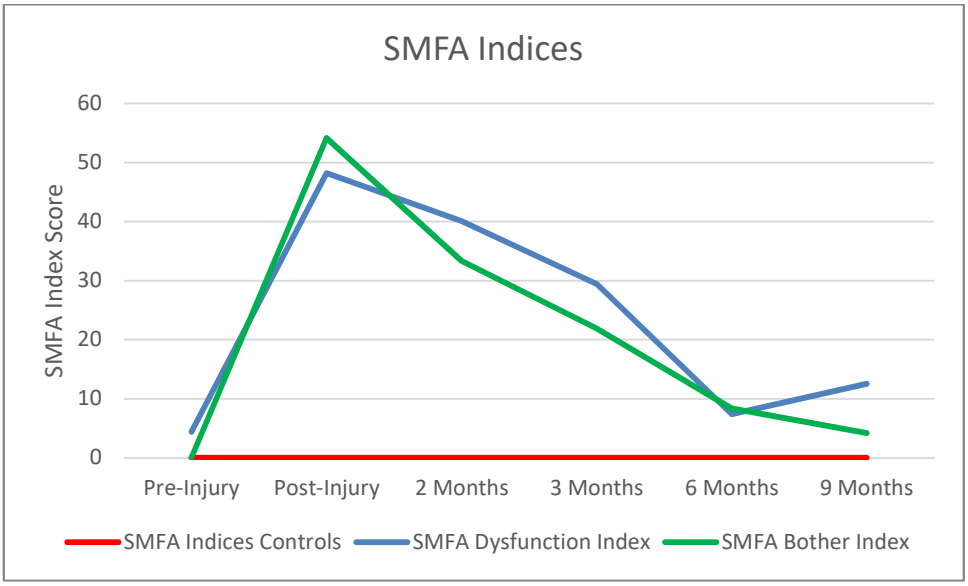


Fig 6.5a Change in SMFA Dysfunction and Bother Indices for Achilles tendon rupture patients over time. Note: The control data is not time-point specific but is shown as a red horizontal reference line.

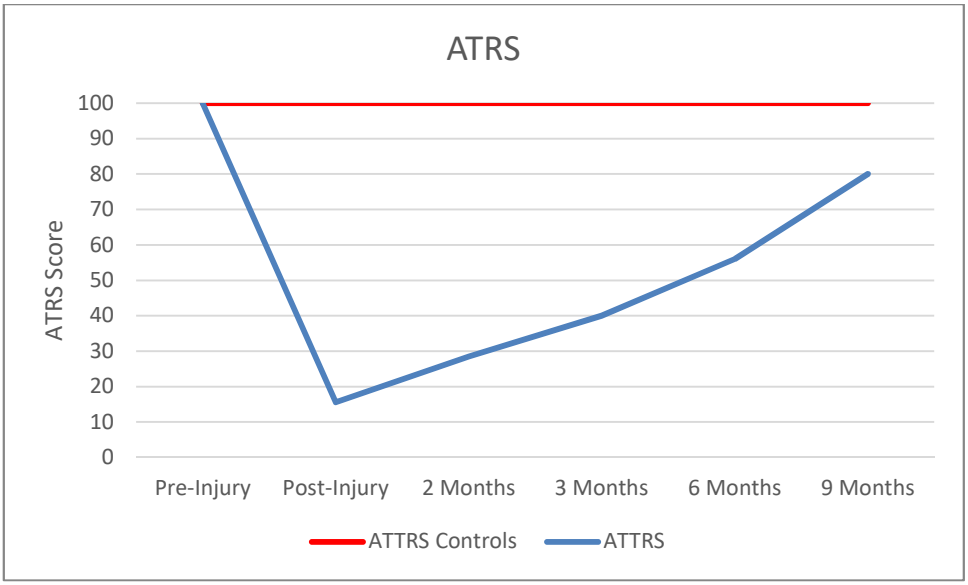


Fig 6.5b Change in Achilles Tendon Total Rupture Score (ATRS) for Achilles tendon rupture patients over time. Note: The control data is not time-point specific but is shown as a red horizontal reference line.

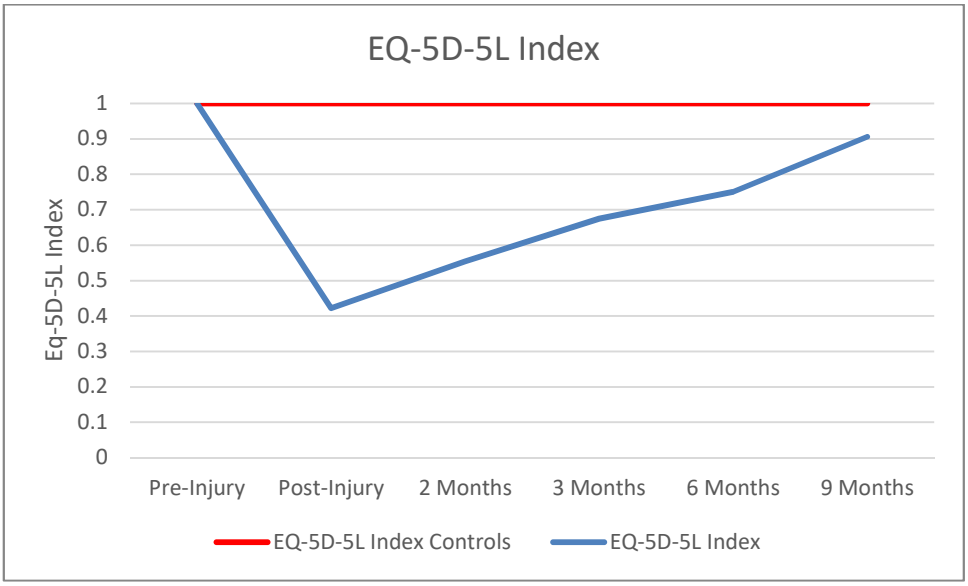


Figure 6.6a Change in EQ-5D-5L Index for Achilles tendon rupture patients over time. Note: The control data is not time-point specific but is shown as a red horizontal reference line.

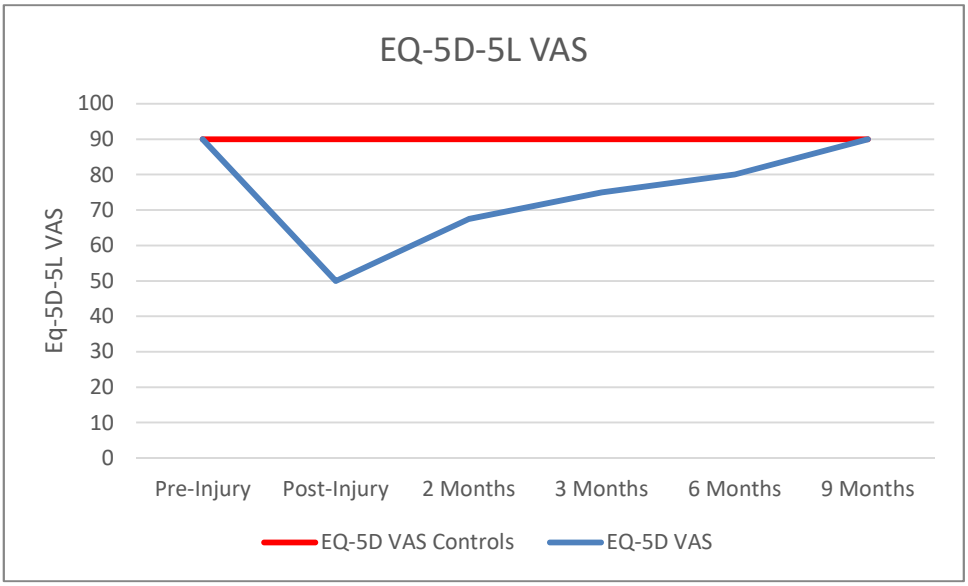


Figure 6.6b Change in EQ-5D VAS for Achilles tendon rupture patients over time. Note: The control data is not time-point specific but is shown as a red horizontal reference line.

PROM	Patients Pre-Injury to Immediate Post-Injury	Patients Immediate Post-Injury to 9 Months Post-Injury	Patients 9 Months Post Injury vs Pre-Injury
SMFA Dysfunction Index	**<0.001***	**<0.001***	**<0.001**
SMFA Bother Index	**<0.001***	**<0.001***	0.206
ATRS	**<0.001***	**<0.001***	**<0.001**
EQ-5D Index	**<0.001***	**<0.001***	**0.02**
EQ-5D VAS	**<0.001***	**<0.001***	0.584

Table 6.4 PROM score comparison after injury and at end of follow up. The *p*-values for comparison of the median scores reported in figures 6.5 and 6.6 are reported in this table. For further information regarding precise median scores at each time point, see graphs in figures 6.5 and 6.6 or Appendix 6.3 table 1. *Related Samples Wilcoxon Signed Rank Test for paired variables.

6.3.5 Clinical Measures

6.3.5.1 Active Plantarflexion and Dorsiflexion

At first measurement upon removal of the immobilising walking boot 2 months after ATR, patients exhibited significant deficits of active plantarflexion and dorsiflexion compared to the uninjured side (table 6.5). The difference in median active plantarflexion between injured and uninjured sides was of a magnitude of 20° while that of median active dorsiflexion was of 5°. During the course of follow up to 9 months post-injury (table 6.5), patients exhibited a statistically significant increase in both active plantarflexion (figure 6.7a, p=0.02, related samples Wilcoxon signed rank test) and active dorsiflexion (figure 6.7b, p<0.001) range and at 9 months post-injury, there was no statistically significant persisting deficit of dorsiflexion, while there was a persisting statistically significant deficit of active plantarflexion, but was clinically very small (difference in median plantarflexion between injured and uninjured sides of 1 degree).

Control subjects exhibited no difference in either active plantar or dorsiflexion between legs (table 6.5 $p \geq 0.94$). Patients with ATR had a statistically significant deficit of plantarflexion at first assessment 2 months post-ATR compared to matched sided control legs but there was no significant difference in active plantarflexion between these groups when patients were reassessed 9 months after injury ($p=0.06$). Conversely, the uninjured legs exhibited no difference in measurements at 2 ($p=0.24$) or 9 months ($p=1.0$) when compared to plantarflexion in their matched sided control legs. Dorsiflexion was reduced in both the injured ($p=0.001$) and uninjured legs ($p=0.01$) of ATR patients at first review 2 months after ATR compared to controls, although the latter was of a small magnitude (difference in median dorsiflexion 3 degrees). AT 9 months post-ATR, there was no significant difference in dorsiflexion range for either injured ($p=0.13$) or uninjured ($p=0.92$) legs in comparison to the control group.

	Injured Leg	Uninjured Leg	p-value
Active dorsiflexion (°)			
2 Months	-3.00 (-6 - 6)	2.00 (-0.50 – 6.50)	**0.032**
3 Months	4.00 (-1.50 – 7.00)	6.00 (2.50 – 8.00)	**0.03**
6 Months	5.00 (2.00 – 12.00)	5.00 (2.00 -8.00)	0.18
9 Months	10.00 (5.50 – 13.50)	7.00 (4.00 -9.50)	0.073
Control	5.00 (2.00 – 10.00)	5.00 (2.00 – 10.00)	0.94
Active plantarflexion (°)			
2 Months	30.00 (24.50 – 47.50)	50 (41.50 – 55.00)	**0.015**
3 Months	40.00 (33.50 – 48.50)	50.00 (43.50 – 54.00)	**0.003**
6 Months	47.00 (41.00 – 51.00)	52.00 (45.00 – 59.00)	**0.003**
9 Months	49.00 (39.00 – 51.50)	50.00 (47.50 – 59.00)	**0.005**
Control	52.00 (46.00 – 59.00)	52.00 (45.50 – 61.00)	1.00
ATRA (°)			
2 Months	64 (61.50 – 68.00)	48.00 (45.00 – 53.50)	**<0.001**
3 Months	61.00 (56.00 – 66.00)	48.00 (41.50 – 51.50)	**<0.001**
6 Months	61.00 (50.00 – 66.00)	48.00 (45.00 – 57.00)	**0.013**
9 Months	60.00 (55.50 – 67.00)	50.00 (44.50 -55.50)	**<0.001**
Control	46.00 (37.50 – 51.50)	50.00 (42.50 – 52.50)	0.08
ATLM (cm)			
2 Months	52.50 (50.40 – 54.45)	55.40 (54.10 – 58.25)	**<0.001**
3 Months	53.80 (50.60 – 55.35)	55.70 (54.50 – 58.15)	**<0.001**
6 Months	53.10 (51.00 – 55.50)	54.60 (52.90 – 59.50)	**0.001**
9 Months	53.90 (50.85 – 55.65)	55.30 (55.30 – 57.45)	**0.004**
Control	54.00 (47.00 – 58.10)	53.00 (47.00 – 57.45)	0.87
Calf circumference (cm)			
2 Months	35 (32.65 – 36.75)	36.40 (34.95 – 39.00)	**<0.001**
3 Months	37.00 (34.65 – 39.50)	37.50 (32.50 – 39.70)	0.106
6 Months	37.00 (34.00 – 38.00)	38.00 (35.10 – 39.70)	**0.001**
9 Months	36.40 (33.90 – 38.75)	38.10 (35.50 – 40.00)	**<0.001**
Control	36.00 (34.60 – 39.55)	36.80 (34.45 – 40.05)	0.63

Table 6.5 Clinically measured parameters for the injured and uninjured legs for patients at each time point and for matched ipsilateral control legs. Related samples Wilcoxon signed rank test used for all analyses.

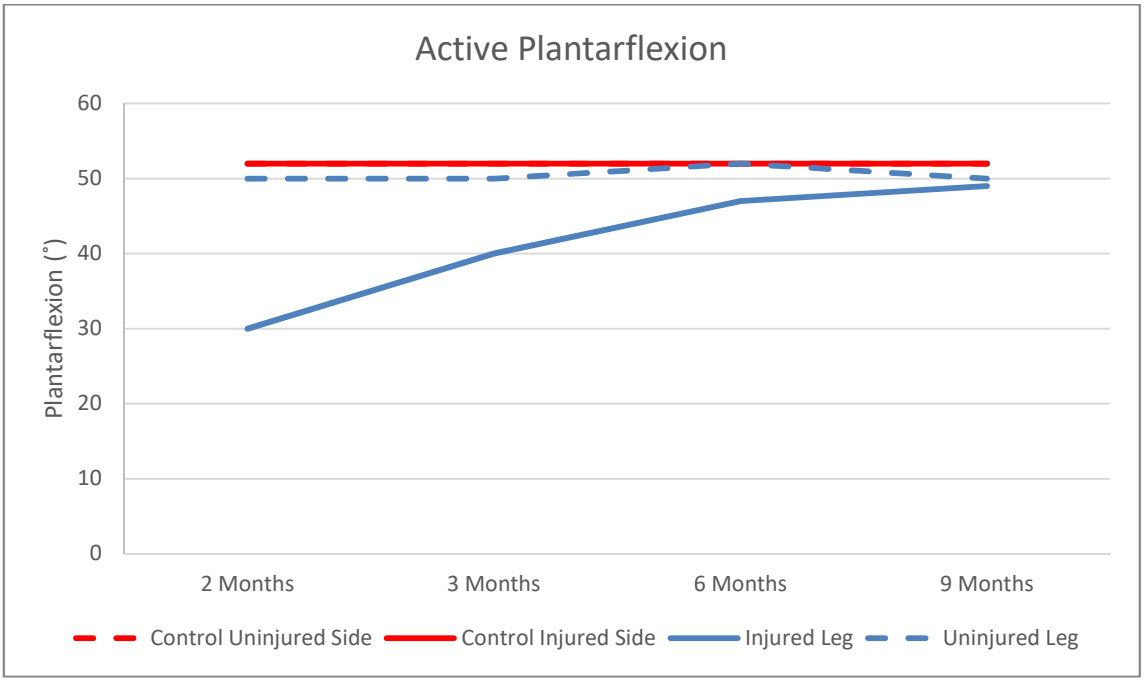


Figure 6.7a. Change in median active plantar flexion in injured and uninjured legs over time. Note: The control data is not time-point specific but is shown as a red horizontal reference line. There was no difference between control uninjured and injured side legs and their lines are superimposed.

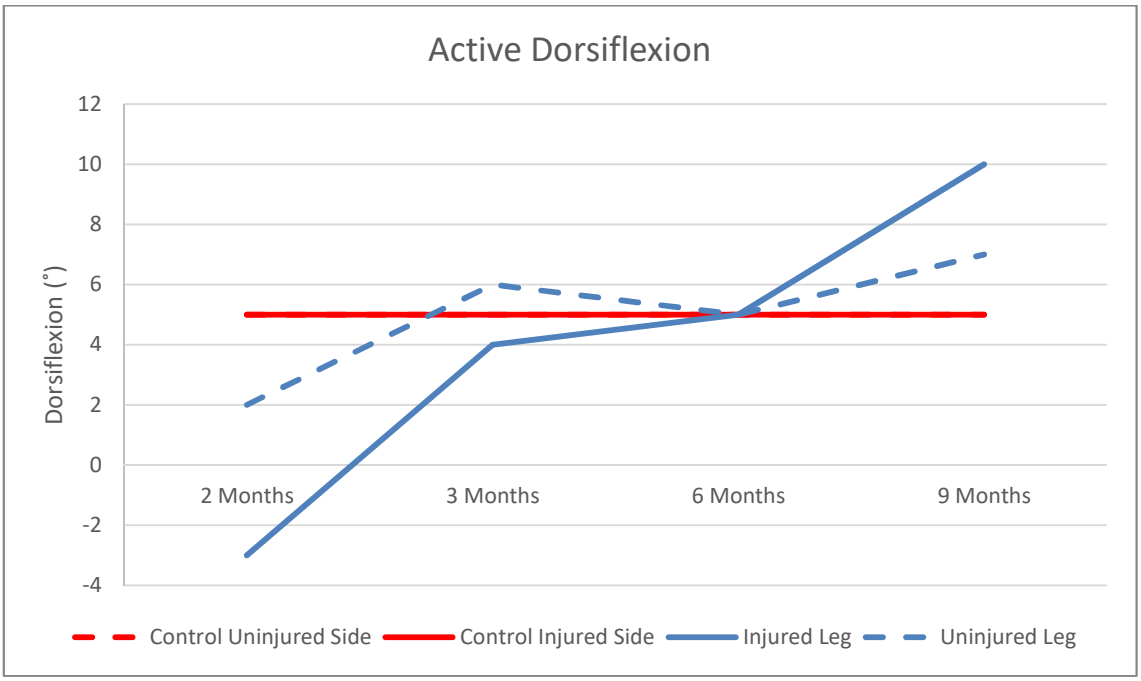


Figure 6.7b. Change in median active dorsiflexion in injured and uninjured legs over time. Note: The control data is not time-point specific but is shown as a red horizontal reference line. There was no difference between control uninjured and injured side legs and their lines are superimposed.

6.3.5.2 Calf Circumference

Patients exhibited a statistically significant deficit in calf circumference of 4.86% on the injured side, at first assessment 2 months after ATR when their walking boot was removed (table

6.5). During the course of follow up between 2 and 9 months post-ATR, there was a statistically significant increase in calf muscle circumference on the injured side (p=0.03, related samples Wilcoxon signed rank test) but no statistically significant change on the uninjured side (p=0.07). At 9 months post-injury, a statistically significant difference in calf circumference of 3.03% persisted between injured and uninjured legs (p<0.001).

When compared to controls, there was a statistically significant difference in median calf circumference at initial assessment 2 months after injury (p=0.021, related samples Wilcoxon signed rank test), while at final follow up, the difference was no longer statistically significant (p=0.85). There was no difference between control leg and the uninjured patient leg median circumference at either initial (p=0.91) or final (p=0.21) follow up points.

6.3.5.3 Achilles Tendon Resting Angle and Achilles Tendon Length Measure

Absolute ATRA in the injured leg was significantly higher at all time points than in the uninjured leg (p≤0.013, table 6.5 and figure 6.8) and was also lower than the matched sided leg control readings (p<0.001). Conversely, the uninjured legs in ATR patients showed no statistically significant variation in ATRA at any assessed time point when compared to the matched sided control leg reading (p≥0.26). Absolute ATLM in the injured leg was similarly reduced at all time points between 2 and 9 months post-injury when compared to the uninjured leg (p≤0.004, table 6.5).

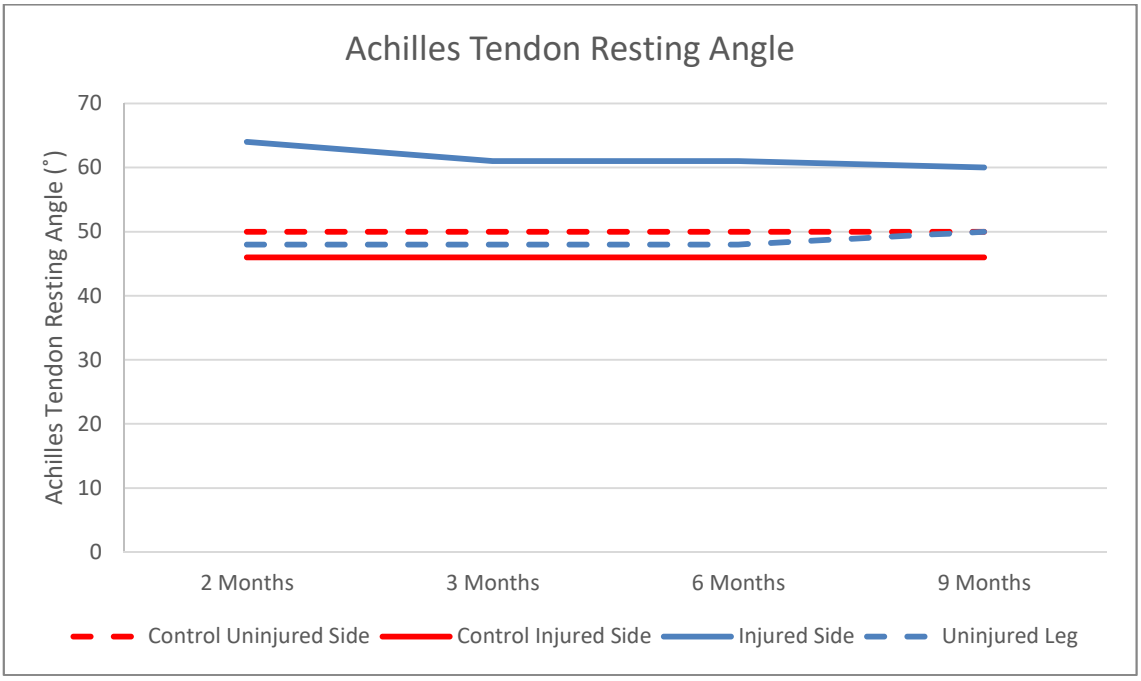


Figure 6.8. Achilles tendon resting ankle in injured and uninjured legs of patients with ATR at sequential time point. Note: The control data is not time-point specific but is shown as red horizontal reference lines.

The relative ATRA was negative at 2 months post-ATR and remained so throughout the course of follow up until 9 months (figure 6.9a). During this period, the median relative ATRA increased from -17° at first assessment to -12° at final assessment (p=0.02). The relative ATLM was positive at 2 months post-ATR and remained so throughout the course of follow up until 9 months (figure 6.9b). During this period, the median relative ATLM decreased from 3.5cm to 1.9cm (p=0.03).

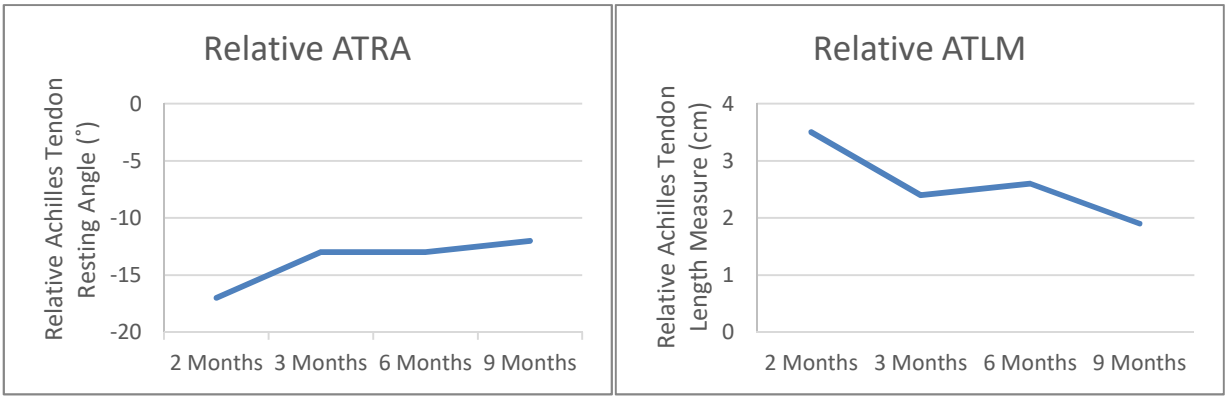


Fig. 6.9 a and b. Relative Achilles Tendon Resting Angle and Achilles Tendon Length Measure.

The median relative ATRA for side matched control subjects was 2° (-1° to 5.5°). Relative ATRA for patients with Achilles tendon rupture (figure 6.9a) was significantly lower at all tested time points, than the control group reading ($p \leq 0.016$). The median relative ATLM for side matched control subjects was -2cm (-10.1cm to 8.45cm). Relative ATLM for patients with ATR (figure 6.9b) was not significantly different from the control group reading ($p \geq 0.14$).

There was no demonstrable correlation between ATRA and either FFRF force or peak pressure ratios ($p > 0.19$). There was no correlation between ATLM and FFRF peak pressure ratio ($p = 0.15$), however there was a weak correlation between ATLM and FFRF force ratio ($r = 0.22$, $p = 0.04$).

6.3.5.4 Pain Visual Analogue Scales

Most patients reported low levels of pain intensity (table 6.6). Pain was most notable in the injured foot at 3 months post-injury, where the median VAS pain score was 3/10 in the hindfoot region and 4/10 in the region of the Achilles tendon. Twenty of 24 patients (83.3%) completing the pain VAS at 2 months post-injury complained of pain, whereas 22 of 23 (95.7%) completing the VAS at 3 months, 15 of 21 at 6 months (71.4%) and 12 of 23 at 9 months (52.2%) described an ongoing degree of pain.

	Injured Leg	Uninjured Leg	*p*-value*
Forefoot Pain VAS			
2 Months	0.50 (0.00 - 2.00)	0.00 (0.00 – 0.00)	**0.002**
3 Months	0.00 (0.00 - 1.00)	0.00 (0.00 – 0.00)	**0.005**
6 Months	0.00 (0.00 – 1.50)	0.00 (0.00 – 0.00)	**0.026**
9 Months	0.00 (0.00 – 0.00)	0.00 (0.00 – 0.00)	0.56
Hindfoot Pain VAS			
2 Months	1.00 (0.00 – 3.00)	0.00 (0.00 – 0.00)	**<0.001**
3 Months	3.00 (1.00 – 5.00)	0.00 (0.00 – 0.00)	**<0.001**
6 Months	0.00 (0.00 – 2.00)	0.00 (0.00 – 0.00)	0.056
9 Months	0.00 (0.00 – 2.00)	0.00 (0.00 – 0.00)	0.23
Achilles Region VAS			
2 Months	1.50 (0.00 – 3.75)	0.00 (0.00 – 2.00)	**0.048**
3 Months	4.00 (2.00 – 6.00)	0.00 (0.00 – 1.00)	**<0.001**
6 Months	1.00 (0.00 – 3.00)	0.00 (0.00 – 0.00)	**0.008**
9 Months	0.00 (0.00 – 2.00)	0.00 (0.00 – 0.00)	**0.028**
Controls			
Forefoot VAS	0.00 (0.00 – 0.00)	0.00 (0.00 – 0.00)	1.00
Hindfoot VAS	0.00 (0.00 – 0.00)	0.00 (0.00 – 0.00)	1.00
Achilles Region VAS	0.00 (0.00 – 0.00)	0.00 (0.00 – 0.00)	0.33

Table 6.6 Pain visual analogue scale data for patients and controls. Data are presented as median scores with IQR. *Related samples Wilcoxon signed rank test.

6.3.5.5 Foot Callosities

Callosities did not occur more frequently in the injured legs (table 6.7).

	Injured Leg	Uninjured Leg
Forefoot Callosities		
2 Months	10 of 25	7 of 25
3 Months	11 of 25	9 of 25
6 Months	5 of 19	5 of 19
9 Months	7 of 21	8 of 21
Hindfoot Callosities		
2 Months	9 of 25	5 of 25
3 Months	6 of 25	7 of 25
6 Months	8 of 19	6 of 19
9 Months	11 of 21	11 of 21
Achilles Region Callosities		
2 Months	1 of 25	3 of 25
3 Months	2 of 25	2 of 25
6 Months	1 of 19	2 of 19
9 Months	2 of 21	1 of 21
Other Callosity		
2 months	10 of 25	7 of 25
3 months	10 of 25	11 of 25
6 months	2 of 19	4 of 19
9 months	6 of 21	6 of 21
Controls		
Forefoot VAS	9 of 25	8 of 25
Hindfoot VAS	4 of 25	4 of 25
Achilles Region VAS	0 of 25	0 of 25
Other Callosity	1 of 25	2 of 25

Table 6.7 Incidence of callosities in the various foot regions for patients and controls.

6.3.6 Satisfaction, Net Promoter Score and Other Measures of Patient Sentiment

At 9 months after ATR, 22 of 23 patients (95.7%) responding stated that they were satisfied or extremely satisfied with their treated Achilles tendon, while one patient was dissatisfied (figure 6.10).

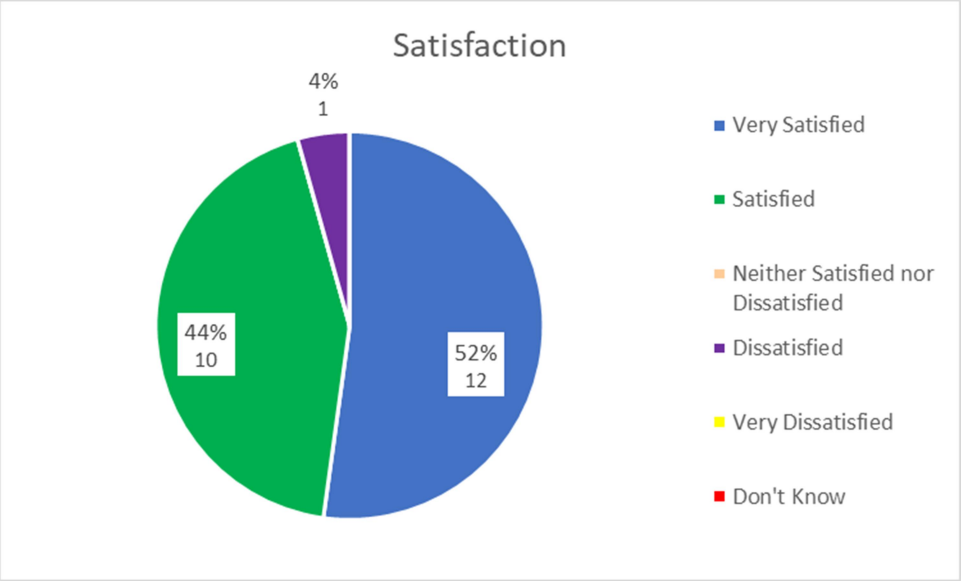


Figure 6.10. Patient responses to the question 'How satisfied are you with your treated Achilles tendon?' which was posed as a Likert scale.

At 9 months after injury, 19 of 23 (82.6%) patients responding stated that they would be likely or extremely likely to undergo the same treatment again if they had a contralateral ATR, while 3 (13%) stated that they would be neither likely nor unlikely to do so and one patient said they would be extremely unlikely to have the same treatment again (figure 6.11). Of note, the patient who stated they would be extremely unlikely to undergo the same treatment again if they had a contralateral rupture stated that they were satisfied with their treated Achilles tendon.

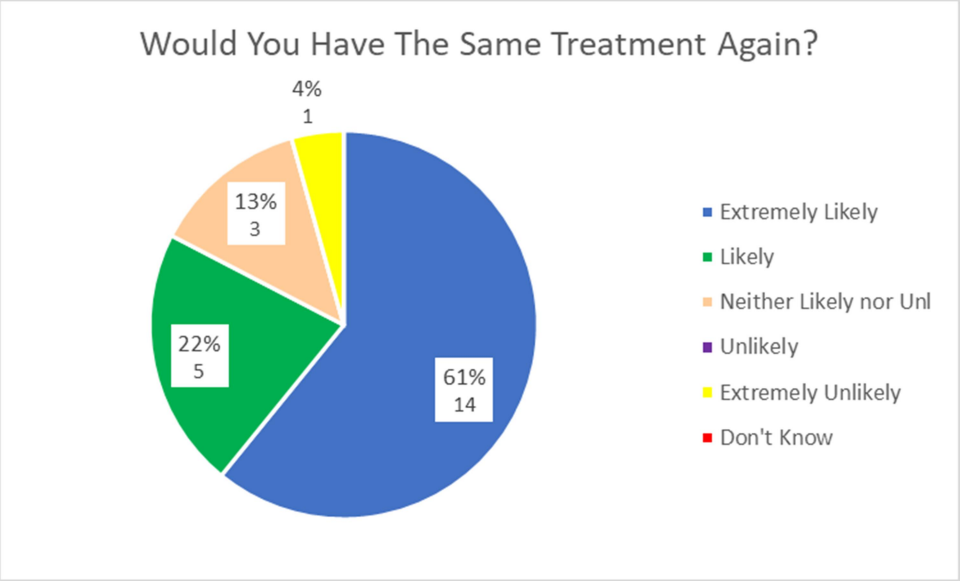


Figure 6.11. Patient responses to the question 'Would you have the same treatment again if it were required on the opposite side?' which was posed as a Likert scale.

The NPS for patients treated for ATR with functional weight bearing rehabilitation in a walking boot was 52.17. Under the modified NHS FFT reporting guidelines,[209] 86.96% of patients (20 of 23) would recommend this treatment to friends and family, while 4.35% (1 of 23) would not (table 6.8).

Patient Response	Number of responses (%)
Extremely Likely	15 (65.2%)
Likely	5 (21.7%)
Neither Likely nor Unlikely	1 (4.35%)
Unlikely	0
Extremely Unlikely	1 (4.35%)
Don't Know	1 (4.35%)

Table 6.8. Responses to the question 'How likely are you to recommend this treatment to friends and family if they needed similar care or treatment?'

6.3.7 Relationship Between FFRF Ratios and PROMs

Statistically significant correlations between the FFRF Force ratio in the injured patient leg and the SMFA disability (figure 6.12a) and bother (figure 6.12b) indices, ATRS score (figure

6.13), EQ5D Index and VAS scores (figures 6.14 a and b) were observed (all $p \leq 0.001$, Spearman's rank correlation). The FFRF Peak pressure ratio also exhibited statistically significant correlations with SMFA disability index (Spearman's r=-0.49, p<0.001), SMFA bother index (r=-0.40, p<0.001), ATRS (r=0.41, p<0.001), EQ-5D-5L Index (r=0.41, p<0.001) and EQ-5D VAS (r=0.28, p=0.008).

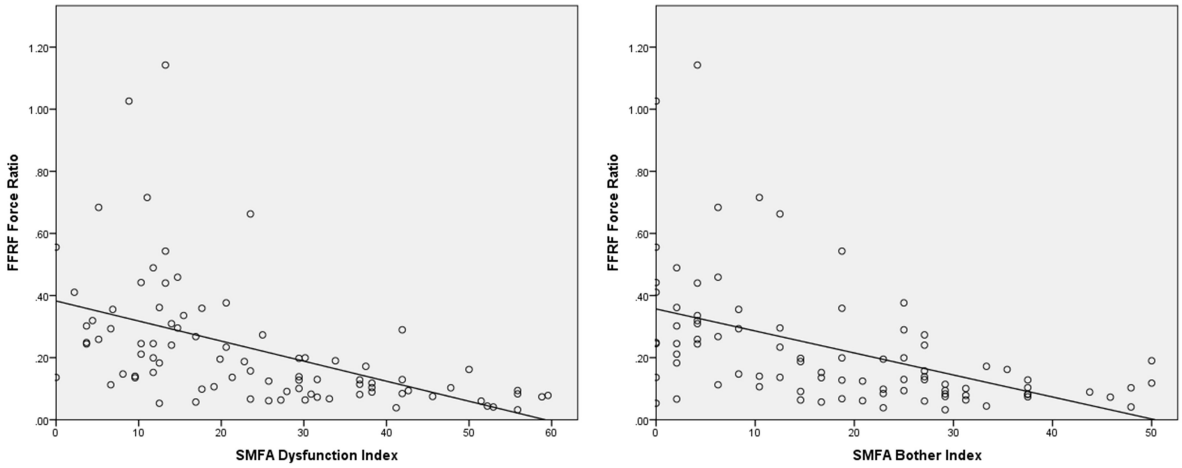


Figure 6.12 a and b. Spearman rank correlation between FFRF Force ratio and SMFA Dysfunction (Spearman's r=-0.66, p<0.001) and Bother (Spearman's r=-0.57, p<0.001) indices.

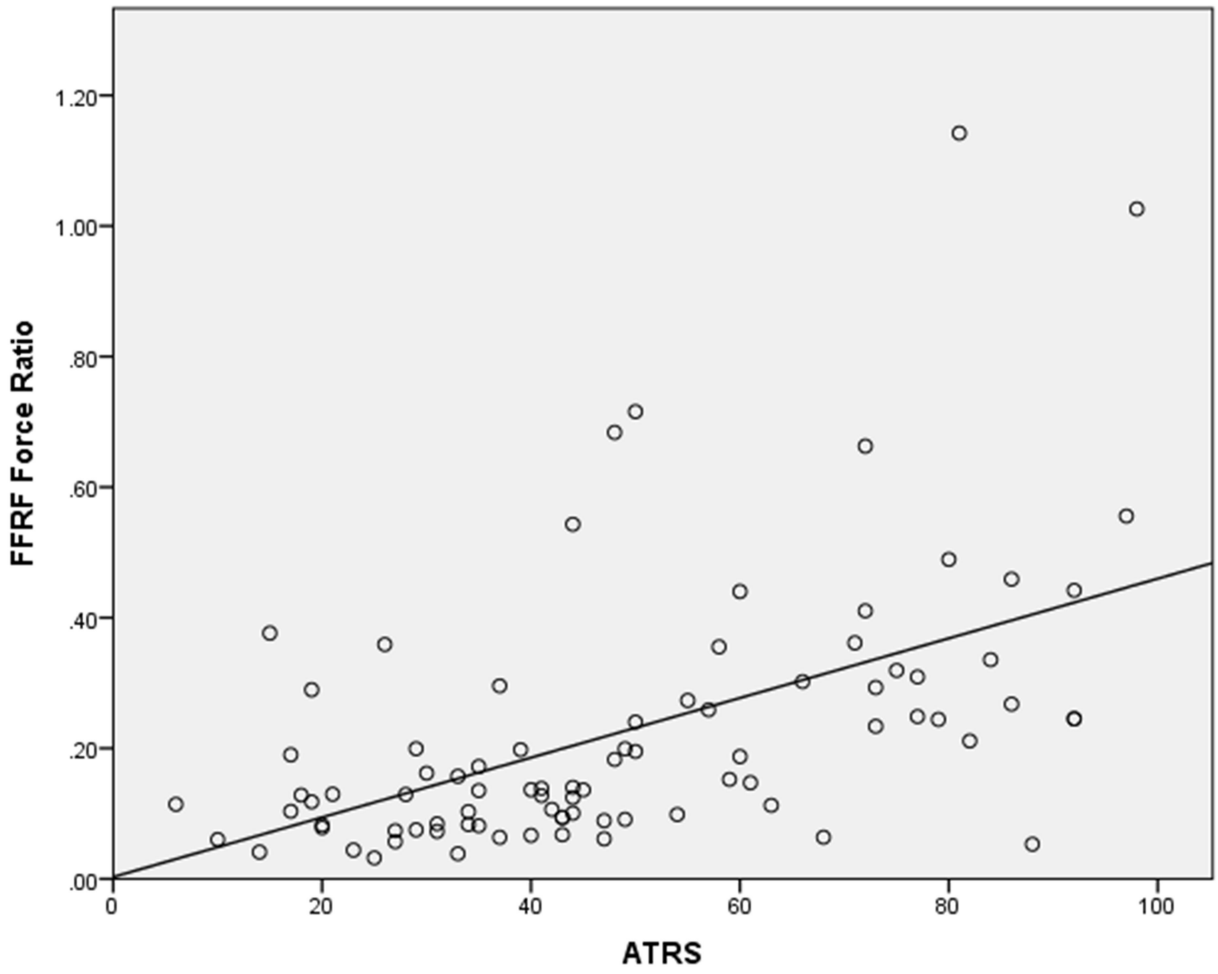


Figure 6.13. Spearman rank correlation between FFRF Force ratio and ATRS (Spearman's r=-0.56, p<0.001).

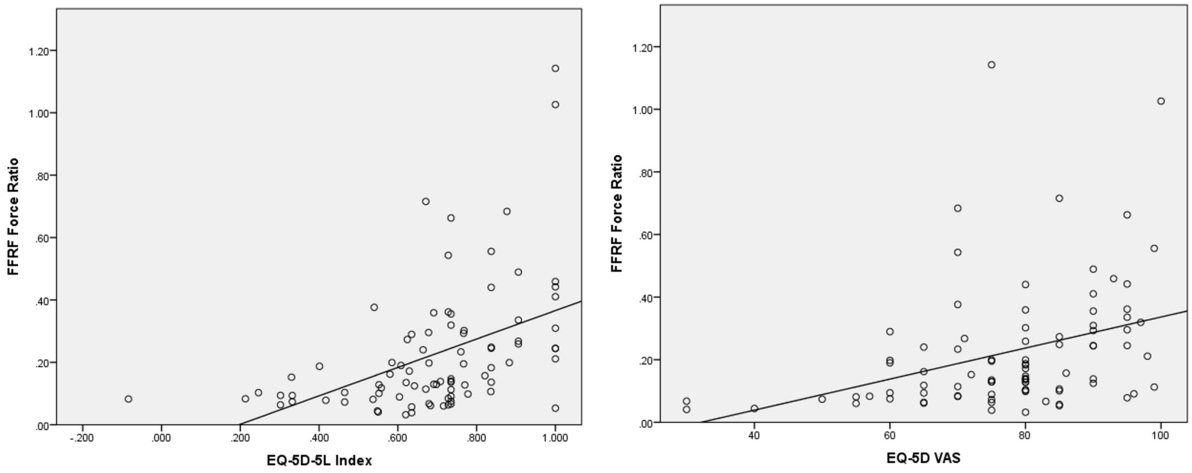


Figure 6.14 a and b. Spearman rank correlation between FFRF Force ratio and EQ-5D-5L Index (Spearman's r=0.53, p<0.001) and EQ-5D VAS (Spearman's r=0.44, p<0.001) indices.

6.4 Discussion

The most important finding of this study was a significant reduction in the forefoot to rearfoot force and peak pressure ratios of the injured limb relative to the uninjured limb, occurring after ATR. This indicates a significant relative reduction in forefoot load and forefoot peak pressures in the injured limb. Reduced relative FFRF ratios in the injured limbs improved gradually over the period of follow up between 2 and 9 months after injury, indicating progressive re-loading of the forefoot with the passage of time, however, statistically significant differences persisted as compared to the uninjured limb throughout the study period. When compared to matched healthy control subjects' legs, the deficits in both force and PP forefoot to rearfoot ratios persisted at 9 months post-injury. A number of other interesting observations were made and are also discussed.

Functional non-operative rehabilitation has been demonstrated in high quality randomised studies,[110, 158, 291] including that in Chapter 5, to give outcomes at least equivalent to other mainstream methods of management for ATR. It has become increasingly popular and widely adopted in mainstream use.[32] Accordingly, it becomes ever more important to have a detailed understanding of how the treatment works and how various physical and patient reported parameters progress over time when patients are treated using these modern regimes, in addition to the simple reporting of final outcomes after treatment.

Patients were matched to a control subject of the same sex and age (+/- 2 years). Distribution of these characteristics was similar to that described in large epidemiological studies of ATR,[32, 37, 42, 304] suggesting that they should be representative of wider ATR populations. Subsequent analysis showed that patient and control baseline characteristics were comparable, with no differences in BMI or patient reported function across all measures used in this study, other than a statistically significant difference in pre-injury SMFA dysfunction index of 4 points, which is

well below the minimum clinically important difference for the SMFA score[168] and is therefore not felt to be of any clinical significance.

6.4.1 Forefoot to Rearfoot Force and Peak Pressure Ratios

Patients experienced a significant reduction in both ratios in their injured limbs, indicating relative increased rearfoot and reduced forefoot forces and peak pressures in the limb after an ipsilateral ATR. Of note, these changes were marked and persisted throughout the period of study, despite a slight increase in the FFRF ratios between 2 and 9 months after injury, which indicates a partial re-loading of the injured forefoot with the passage of time (figures 6.2, 6.3 and 6.4). At the end of follow up 9 months post-injury the FFRF ratios had not yet normalised in comparison to either the uninjured leg or control subjects, indicating persisting abnormal load patterns in the injured foot, although the abnormalities were not as severe as they had been at the first reading 2 months post-injury. The above is clearly illustrated in the sample images below, featuring a single frame from the pedobarographic recordings of one control subject (figure 6.15a) and one patient who had a right Achilles tendon rupture 2 months prior (figure 6.15b). Accompanying each frame is the graph showing force vs time for the full sequence of 13000 frames (130 seconds). The forefoot and rearfoot for each side have dedicated lines on the graph. The graphs illustrate that the vertical distance between forefoot and rearfoot force lines (see image captions for legend) is similar for both feet in the control patient (indicating relatively similar FFRF ratios between the two feet), whereas for the ATR patient, the injured side forefoot force line lies very low while its corresponding rearfoot force line is elevated. This results in a low forefoot to rearfoot ratio and is also evident pictorially in the foot map showing intense red and magenta colours in the right heel signifying high load and dark blue colours in the right forefoot indicating low load. By contrast the patient's uninjured left foot shows a more even distribution of colour coding in rearfoot and forefoot regions (figure 6.15b). Reduced forefoot and increased rearfoot loading may be due to a deficit in the musculotendinous unit that provides

plantarflexion torque to the ankle. Multiple factors might contribute to this phenomenon, including tendon lengthening, muscle wasting or pain inhibition.

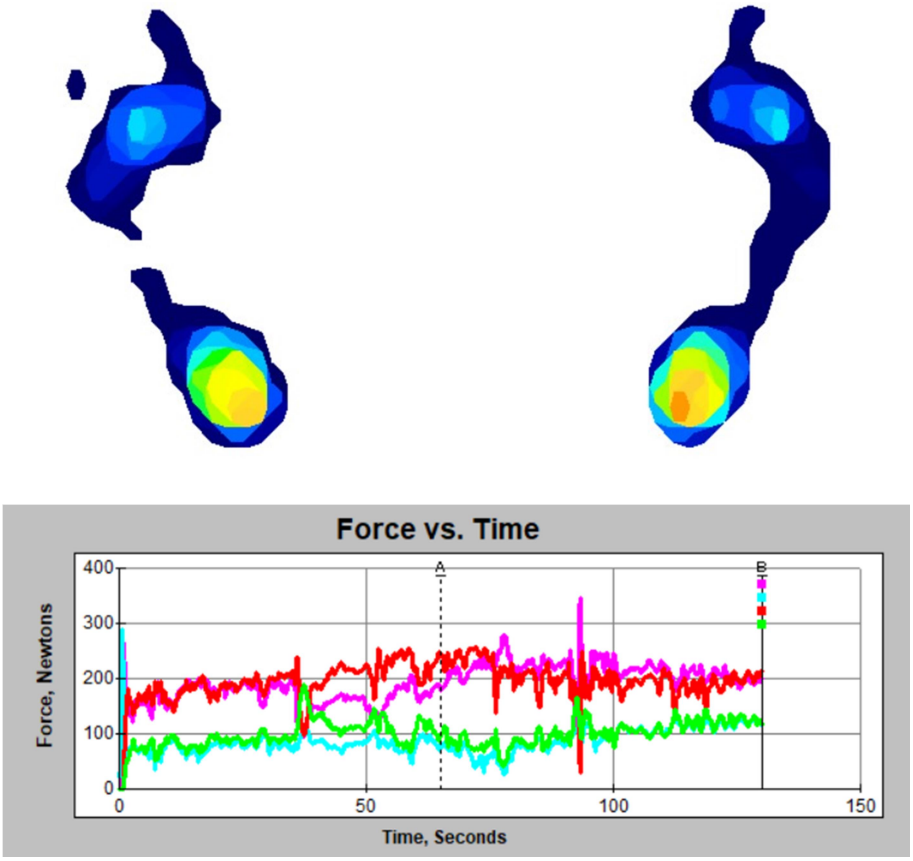


Figure 6.15a Control patient foot map still frame. Below this is the Force vs time graph for the same patient showing force in right and left forefeet and rearfeet over the course of 130 seconds (data from 13000 frames included in the graph). The red line represents left rearfoot force, the green line represents left forefoot force. The magenta line represents right rearfoot force and the cyan line represents right forefoot force. The forefoot to rearfoot ratio for each foot (for force in this example) is calculated by establishing the median value of each force line and then creating the relevant ratio. Thus the values for the green line divided by the red line would give the left foot FFRF force ratio whereas the values for the cyan line divided by the magenta line would give the right foot FFRF force ratio. Note how the vertical distance between forefoot and rearfoot lines for right and left feet is similar, indicating comparable FFRF ratios.

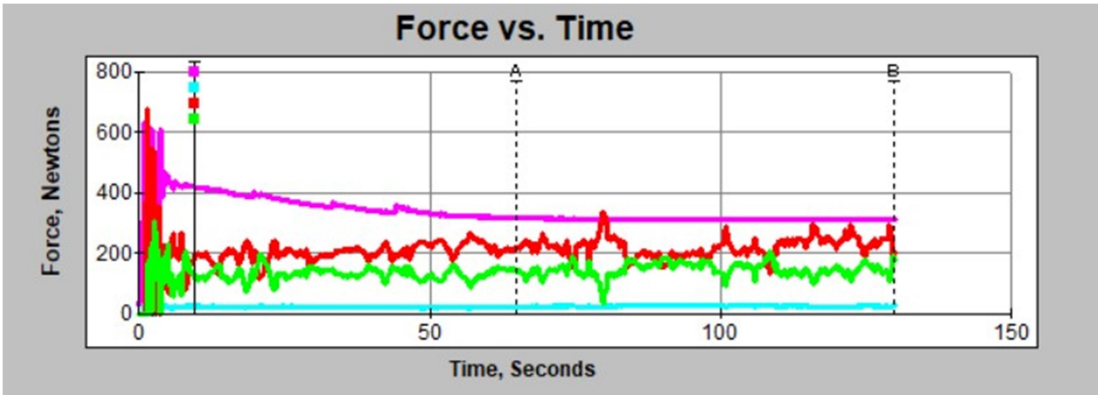


Figure 6.15b ATR patient foot map still frame from a force recording taken 2 months after right Achilles tendon rupture. Below this is the Force vs time graph for the same patient showing force in right and left forefeet and rearfeet over the course of 130 seconds (data from 13000 frames included in the graph). The red line represents left rearfoot force, the green line represents left forefoot force. The magenta line represents right rearfoot force and the cyan line represents right forefoot force. The forefoot to rearfoot ratio for each foot (for force in this example) is calculated by establishing the median value of each force line and then creating the relevant ratio. Thus the values for the green line divided by the red line would give the left foot FFRF force ratio whereas the values for the cyan line divided by the magenta line would give the right foot FFRF force ratio. Note how the vertical distance between forefoot and rearfoot lines for right foot are much further apart than those for the uninjured left foot. The forefoot line for the right foot (cyan) is low and the rear foot force line for the right foot (magenta) is high, resulting in a very low forefoot to rearfoot ratio compared to the ratio calculated from the green and red lines pertaining to the uninjured foot. Note also how the first few seconds show very variable readings while the patient equilibrate, which are not representative of the situation during stable stance. Hence the first 45 seconds of recordings were not included in the analyses of any patient or control subject.

One unexpected finding of interest was that while both the FFRF ratios (force and PP) in the *uninjured* limb were found to be statistically similar to the control readings at 2 months, they then appeared to progressively *increase* over time (blue dotted lines, figures 6.2 and 6.4). This finding

did not reach statistical significance for the FFRF PP ratio of the uninjured limb but it was statistically significant for the FFRF force ratio of the uninjured limb. Thus, while the FFRF force ratio in the injured limb gradually increased from its initial pathologically low value in what one might term 'recovery' towards the control value, the ratio for the contralateral uninjured limb appeared to increase in tandem and diverge *away* from its matched control reading (figure 6.3). In addition, the 9 month FFRF peak pressure ratio for uninjured limbs exhibited a narrowly insignificant trend (p=0.063) towards being greater than the control reading. Although no firm conclusions can be drawn in this regard, it is therefore possible that the peak pressure ratio exhibited a similar trend to the force ratio but that the study was not adequately powered to robustly identify this.

These findings appear to suggest, at least in terms of force, that after an Achilles tendon rupture, the forefoot to rearfoot load distribution is altered not only in the injured limb, but also possibly in the *uninjured* limb, which develops progressively increasing amounts of relative forefoot loading. Furthermore, the increasing FFRF ratio for the uninjured limb depicted in figure 6.1 (progressively moving *away* from the control reading) did not appear to have plateaued by 9 months. It is unknown whether this 'sympathetic' phenomenon of altered forefoot/rearfoot loading in the uninjured foot would persist or gradually revert towards control levels if patients were followed for a longer period. However, this finding has very important implications on study design in the field of pedobarography and Achilles tendon ruptures in general, since it illustrates that one cannot rely exclusively on the uninjured leg for comparative or control data. Whilst comparison between injured and uninjured legs is important and indeed desirable, it is essential to also include healthy controls in such studies, otherwise there is the potential to 'miss' important pathological findings if the two feet progress in tandem with an abnormal loading pattern.

Pedobarographic studies can broadly be divided into static and dynamic studies. Multiple studies have shown that under physiological conditions more load is transferred through the rearfoot than the forefoot in static stance and the split of loading in controls in this study (figure 6.3) was very similar to that reported in a large population based reference study of healthy subjects[352] as well as in other research studies utilising healthy subjects,[353] suggesting that the control group is representative of more general populations with respect to the main variable of interest. Pedobarographic studies have been used extensively and for a number of years in the study of diabetic ulceration,[343, 344, 346] where increased forefoot loading as demonstrated by an increased forefoot to rearfoot ratio has been postulated to increase the risk of plantar ulceration.[343] Others have demonstrated that surgical lengthening of the Achilles tendon in diabetic patients with a history of ulceration leads to reduced forefoot plantar pressures and increased dorsiflexion range.[344, 346]

Although the context varies, with diabetic tendon lengthening studies being undertaken in a different patient population undergoing elective surgical tendon lengthening (as opposed to traumatic rupture with lengthening) and only in a dynamic fashion, there are some interesting parallels with the results of the current study. Lengthening of the tendon in diabetic patients resulted in increased dorsiflexion and reduced forefoot peak pressures in the short term.[344, 346, 361] Both Mueller et al and Maluf et al reported that the reduction in forefoot peak pressures had disappeared 7 to 8 months after surgery.[346, 361] Salsich et al demonstrated early reduced peak plantarflexion torque after tendoachilles lengthening in diabetic patients but a return to baseline by 8 months, however they did not undertake pedobarography.[357] The patients in the current study also exhibited gradually normalising forefoot to rearfoot load patterns in the injured foot in the months after injury, however these had not yet normalised completely by 9 months after injury suggesting that traumatic ATR patients may either take longer than elective AT lengthening patients to restore normal mechanics, or may never do so. Longer term studies will

be required to answer this question. Exploration of the reasons for the differing timescales observed in the normalisation of plantar pressures after ATR and planned surgical lengthening in diabetic patients was beyond the scope of this study. However, these differences may relate to the nature of the underlying tendon, with ATR occurring in a traumatic setting and almost universally through histologically abnormal tendon,[29] while surgical lengthening is undertaken through an otherwise 'normal' tendon.

In recent years, pedobarography has increasingly been applied in the field of orthopaedics, particularly in relation to foot and ankle pathology.[354, 356, 362, 363] Only a handful of studies have assessed pedobarographic parameters after ATR to date and these have focused exclusively on dynamic pedobarography,[98, 355, 364, 365] have been small[98, 355, 364] and only assessed pedobarographic parameters at a single time point[98, 365, 366] or lacked control comparator groups.[366] As a result, there is a very poor understanding of the evolution of plantar forces and pressures in the months after ATR. Studies undertaken as single time point analyses in the medium term have detected no significant differences between patient and control groups[98] or between different treatment regimes.[365] While these findings would be in agreement with the studies on diabetic tendon lengthening suggesting eventual normalisation of forefoot pedobarographic parameters,[346, 361] such a study design does not account for the marked changes that occur early on in the recovery process, which are demonstrated in the current study. Ozkan et al, in a small study of 15 surgically treated patients, compared mean and maximum heel and forefoot pressures during gait between injured and uninjured feet one year after ATR and reported no difference but did not include a control group and would therefore be unable to detect the phenomenon described in the current study whereby injured and uninjured feet pressure changes occur in tandem.[366] Costa et al, reported on a heterogeneous group of ATR patients treated both surgically (n=8) and non-operatively (n=6) using traditional immobilising regimes and found that during walking, there was a relative increase in rearfoot pressure and decrease in

forefoot pressure on the affected side 2 weeks after cast removal and although only eleven patients were available for pedobarographic measurements at 6 months post-injury, these changes appeared to persist.[355] These findings would be consistent with the findings of the current study, albeit in a heterogeneous group with traditional rehabilitation methods and with only two readings at approximately 3 and 6 months taken. Karaaslan et al, in another small study with heterogeneous treatments, reported that ATR patients had higher peak heel pressures than controls but did not relate this to forefoot pressures.[364] Ramakanth et al have described increases in relative forefoot pressures and reduction in relative rearfoot pressures after FHL augmented reconstruction for chronic ATR.[363] These findings would appear to support the main findings of the current study, which clearly demonstrate early reduced forefoot loading and increased rearfoot loading in the injured foot and the described subsequent changes over time, in a relatively large cohort of patients treated with a modern functional non-operative treatment regime and with a control group for comparison.

In summary, a small number of studies focusing exclusively on dynamic pedobarographic parameters have been undertaken and the phenomenon of early decreased forefoot loading and concomitant increased rearfoot loading after acute ATR was noted in one.[355] None have undertaken multiple measurements throughout the early recovery period. This study is the first study of modern functional non-operative rehabilitation regimes for ATR to describe changes in relative forefoot and rearfoot loading in the months after injury in detail. While the findings are in keeping with earlier reports of relative decreased forefoot loading in the months after ATR and elective Achilles tendon lengthening, greater detail is provided and a number of novel findings are reported.

6.4.2 PROMs and Health Related Quality of Life

As with the studies in Chapters 4 and 5, this study reports on a number of PROMs incorporating general musculoskeletal (SMFA) and Achilles tendon specific (ATRS) functional outcomes. All PROMs and health related quality of life were significantly negatively impacted by ATR and subsequently exhibited a gradual improvement over the ensuing months (figures 6.5 and 6.6). At final follow up, median SMFA dysfunction index, ATRS and EQ-5D-5L Index were inferior to the patient reported pre-injury scores and to control subjects, indicating persisting disability at 9 months after injury.

The difference in median SMFA dysfunction index between patients at final follow up and both their pre-injury scores and control subjects' scores was greater than the minimal clinical important difference and therefore likely to be perceptible to patients.[168] Reporting of SMFA indices for patients in this study facilitates comparison with patient outcomes in the other clinical studies in this thesis (Chapters 4 and 5) and provides an indication of patient reported outcome from a general musculoskeletal perspective, allowing comparison with outcomes after other lower limb injuries,[367, 368] which is not possible using the Achilles tendon specific ATRS score. The majority of pre-injury patients and controls in this study reported very low levels of dysfunction and bother as evidenced by their SMFA index scores, both of which were close to the ceiling score, with a difference less than that of MCID for the SMFA Score. After injury, both indices were adversely affected and subsequently exhibited gradual improvement. The SMFA Indices at 6 months, the common time point of assessment with the study in Chapter 5, are very similar, suggesting that both studies are representative of a similar population and treatment outcome, as would be expected given that the same rehabilitation regime was utilised. This does reassure that conditions were similar in both studies. A deficit in general musculoskeletal patient reported outcome, as evidenced by the final SMFA dysfunction index,

persisted at 9 months after injury. However, the SMFA bother index at 9 months post-injury was below the MCID as compared to both controls and patient pre-injury scores, implying that while dysfunction as a result of ATR was still noticeable to patients at 9 months, this may not cause high levels of bother to patients.

The ATRS is a more recently described injury specific PROM and has become the most widely used PROM in the study of ATR.[195] Incorporation of this PROM therefore gives information on Achilles specific patient reported outcome and also facilitates comparison of outcomes with other studies in the field. While the MCID for the English language ATRS has not been scientifically defined, it has been suggested that it may be around 8 points, representing the difference in score between a healthy patient and a patient with a minor disability.[158, 172] Others have assumed a MCID of 10 points,[157] while it has been suggested that the MCID for the Dutch version of the ATRS is at least 13.5 points.[369] The difference in median score between patients and controls and also for patients pre-injury and post-injury scores was of over 80 points immediately post-injury, implying a very significant deterioration in Achilles-specific patient reported function in the early stages after ATR. The functional non-operative treatment regime employed in this study was associated with statistically significant improvements in ATRS over the course of follow up, such that at final follow up 9 months after injury, the median ATRS score for patients had improved to 80 points. The deficit between this score and pre-injury and control subject scores is greater than the suggested MCID for the ATRS, suggesting a likely significant and noticeable persisting deficit in Achilles-specific function to patients at this time point. This, coupled with the deficit in SMFA dysfunction index reported at 9 months after injury, therefore implies that patients felt that Achilles-specific and consequently general musculoskeletal function had not yet fully recovered 9 months after ATR.

The reported changes in ATRS after ATR are similar to those reported by others at the same time points after injury[157, 158, 197, 229] and are also in agreement with the findings for patients treated with the same functional non-operative rehabilitation regime in the study in Chapter 5 of this thesis at slightly longer follow up,[291] where patients demonstrated further improvement along a similar trajectory at one year post-injury.

Overall HRQoL, like other PROMs measures pertaining to musculoskeletal and Achilles-specific function, was negatively impacted by ATR. Patients reported a significant decline in their HRQoL after ATR such that both the EQ-5D-5L Index and VAS were markedly lower than their pre-injury levels and those of control subjects. It has been shown that self-reported HRQoL correlates with injury-specific PROMs after various types of lower limb injury,[181, 205] including ATR (Chapter 4). This suggests that any residual functional deficits pertaining to lower limb injuries, including ATR, may negatively impact patients' perception of their HRQoL. EQ-5D VAS scores were similar to pre-injury and control levels at final follow up 9 months after ATR, while the EQ-5D index had not reached pre-injury or control levels. The MCID for the EQ-5D has been reported across a range of conditions to be as little as 0.051,[370-372] suggesting that the residual deficit in HRQoL for patients at 9 months was clinically relevant.

The findings of the study in Chapter 4 have suggested that short term patient reported outcome, for patients treated for ATR, specifically as determined by the SMFA indices at one year, is a significant predictor of outcomes at long term follow up. The patients in that study were treated with traditional immobilising techniques and short term scores were analysed at one year after injury (as opposed to nine months post-injury in the current study) and the findings cannot therefore be directly extrapolated to the current study. However, this does emphasize the potential importance of a thorough understanding of short term outcomes with modern treatment regimes for ATR, including the current non-operative functional rehabilitation regime. If the

causes of short term dysfunction and poorer patient reported outcome can be further defined through future studies, this may provide opportunities for targeted intervention to attempt to remedy these in the hope of improving longer term outcomes.

6.4.3 Clinical Measures

Injured legs exhibited a deficit in calf circumference compared to the uninjured leg at all time points. This was largest at initial review after boot removal and progressively reduced in size over the course of follow up, however a deficit persisted at the final follow up time point nine months after ATR. These findings are very similar to those described for patients treated with functional rehabilitation in a walking boot in Chapter 5. Other authors have similarly reported that deficits in calf circumference persist at one and two years post-operatively[61, 95, 229] and also in the longer term after ATR.[307, 358] Calf circumference has been shown to correlate with radiologically measured muscle volume after ATR[307, 373] and also with plantarflexion strength.[373]

While a significant deficit in calf circumference persisted between injured and uninjured legs in ATR patients at all time points, the relative deficit between injured legs in ATR patients and matched control subject legs was statistically significant for patient measurements taken at 2 months after injury but did not remain so at 9 months after injury. This apparent contrast in findings relative to the uninjured legs and control subjects' legs may be explained by an increase in calf circumference in the *uninjured* leg of ATR patients in the months after injury, that was just outside statistical significance (p=0.07). As with the findings with respect to FFRF ratios, this could imply that compensatory changes also occur in the uninjured leg of ATR patients in tandem with those of the injured leg during recovery and once again highlights the importance of comparison not only with the uninjured leg but also with uninjured control subjects to provide a comprehensive account of changes over time during recovery after ATR.

Both active plantar and dorsiflexion were significantly reduced in the injured leg at first measurement two months after ATR. The deficit in active plantar flexion was particularly marked and is likely to be accounted for in part by significantly reduced gastroc-soleus-Achilles plantarflexion function. This theory would also be supported by the very low FFRF force and peak pressure ratios observed at this time point. Reduced ability to actively plantarflex the foot would be consistent with reduced forefoot loading during stance. There was also a statistically significant deficit in active dorsiflexion at early time points. The range of plantar and dorsiflexion would also be influenced by the degree of ankle stiffness, which is expected to be more pronounced immediately after a period of prolonged immobilisation.[374, 375] With the passage of time, active plantarflexion range was restored both with respect to the uninjured side (where a statistically significant but clinically insignificant difference of 1 degree persisted at 9 months after ATR) and the control subjects (where there was no statistically significant difference).

ATRA in the injured leg was lower than that in the uninjured leg at all time points, resulting in a negative relative ATRA which suggests possible tendon elongation. Similarly, the relative ATLM was positive throughout the period of follow up. Both measures demonstrated convergence towards those of the contralateral uninjured limb during the course of follow up, in keeping with other clinically measured parameters. Convergence of the ATRA and ATLM may suggest that after initial lengthening of the injured tendon there was a relative shortening over time but the injured leg values did not reach those of the uninjured side 9 months after ATR. These findings are supported by those of another study which reported increasing relative ATRA and decreasing relative ATLM between assessments at 2 and 4 months after ATR which had been treated non-operatively.[338] Other studies have confirmed that Achilles tendon lengthening persists in the longer term after ATR.[307, 358] While the reported findings appear to make logical sense and to be similar to those of others, it must be noted that the ATRA and ATLM are indirect

measures of tendon length. The ATRA has been shown to correlate with radiologically measured tendon length[359, 360] and is known to be a reliable measure.[337] It has been used in research into outcomes after ATR as an indirect measure of tendon elongation.[376] However, correlations with tendon length are only moderate in the early months after ATR,[359, 360] while they are notably stronger beyond one year after ATR[359] and ATRA may be effected by variables other than tendon length, for example oedema and muscle tightness.[373] Other authors have suggested that the ATRA should consequently not be used in isolation as a measure of tendon length.[360] Variables other than tendon length, such as plantarflexion torque or strength may also influence FFRF loading ratios.[365]

Taken together, these findings suggest a residual calf circumference, ATRA and ATLM deficit with normalisation of plantar flexion range in the months after ATR. Kastoft et al, in a recent study reviewing patients treated with functional non-operative rehabilitation at a single time point an average of 4.5 years after ATR, reported persisting tendon elongation and calf circumference deficit as well as a marginal increase in dorsiflexion in the injured leg. However, they could not demonstrate any correlation between tendon length and forefoot or rearfoot peak pressures during gait. These results support those in the current study. They are very similar and are complementary, since their study gave no information on trends over time, nor on early outcomes occurring after ATR in the first year.[365]

ATR is generally considered to be associated with low levels of pain intensity[4, 88] and this was confirmed in both the current study and the RCT in Chapter 5. Despite the relatively low overall median VAS pain scores, a large number of patients described experiencing some degree of pain in the injured foot and although the proportion of patients experiencing pain fell with each passing time point, more than half of patients continued to experience some degree of pain at final follow up nine months after ATR. The study in Chapter 5 found the proportion of patients

suffering from ongoing pain at final follow up after functional rehabilitation in a walking boot to be lower than that in patients treated with traditional cast immobilisation. Despite this, patients and clinicians should be aware that even after modern functional rehabilitation for ATR, a degree of pain can be expected to persist for several months.

6.4.4 Satisfaction, Net Promoter Scores and Other Measures of Patient Sentiment

Patient satisfaction rates after treatment for ATR with the modern non-operative early weight bearing functional rehabilitation regime were very high (96%). Patients and clinicians can be reassured that the vast majority of patients treated using this regime can expect to be satisfied nine months after their injury. The reported satisfaction rates were similar to those reported in Chapter 4 for the traditional immobilising non-operative treatment regime (albeit at different time points after injury) and also similar to satisfaction rates after another described early weight bearing functional rehabilitation regime,[377] while they were slightly higher than those reported in a recent meta-analysis of surgically treated patients.[378] Satisfaction rates also compared favourably with treatments for other isolated ankle injuries[325, 379] and degenerative conditions.[324]

The vast majority of patients stated that they would be 'likely' or 'extremely likely' to undergo similar treatment again in the future if it were required for a contralateral injury. Three patients stated they would be 'neither likely nor unlikely' to do so and of these, two stated that they were satisfied with their treated Achilles tendon, while one was dissatisfied. Additionally, one satisfied patient stated that they would be 'extremely unlikely' to undergo similar treatment again. These findings demonstrate a degree of incongruence between patient reported satisfaction with the outcome of treatment and willingness to undergo similar treatment in the future, suggesting that factors other than the final outcome may also significantly impact on patient sentiment and decisions regarding their treatment.

Similarly, while the vast majority of patients stated that they would be 'likely' or 'extremely likely' to recommend similar treatment to friends and family, one patient stated that they were likely to recommend the treatment to friends and family despite being 'neither likely nor unlikely' to accept similar treatment in the future themselves. One patient, who was satisfied with their treated AT stated that they would be extremely unlikely to either undergo similar treatment themselves or recommend similar treatment to friends and family. Despite these isolated findings, overall congruence between satisfaction and willingness to undergo similar treatments and recommend these to loved ones were high, with the vast majority of patients expressing positive sentiments towards the functional non-operative treatment regime.

The reported NPS for functional non-operative treatment with early weight bearing (52) was notably higher than those reported for both traditional operative and non-operative management of ATR (Chapter 4) and also slightly higher than that reported for total knee replacement[180] although lower than the NPS reported for elective hip procedures.[180, 181] NPS of greater than 50 are generally regarded as being indicative of good performance in industry, where the score was first described.[187] Corresponding recommendation rates using the NHS FFT model were very high for treatment of ATR with functional non-operative rehabilitation.

6.4.5 Correlation between FFRF Ratios and PROMS

Both the FFRF Force and FFRF peak pressure ratios for the injured foot correlated with all PROM measures. The correlation with force ratio was stronger than that with peak pressure ratio for all PROMs. These findings suggest an association between loading patterns under the foot and patient reported outcomes after ATR, with abnormal FFRF ratios which signify relative rearfoot overload and reduced forefoot load being associated with worse patient reported outcomes across a range of PROM measures covering general musculoskeletal function, Achilles tendon specific function and health related quality of life. Schepers et al reported increased

rearfoot loading and reduced forefoot loading after Lisfranc injuries of the foot but could not demonstrate any correlation between measured plantar pressures and HRQoL or PROM measures. They did not report on loading ratios.

Other authors have discussed the need for a better understanding of rehabilitation regimes and how physically measured parameters translate to patient experienced outcomes and it has been suggested that targeting these areas during rehabilitation may lead to improved outcomes[355] but there has not been any attempt to determine the direct relationship between foot loading and patient reported outcomes after ATR previously.

6.4.6 Strengths and Limitations

Strengths of this study include the sample size, which is relatively large for a pedobarographic study[98, 355, 364-366] and with 50 participants is the largest in the published literature. Other strengths include the utilisation of matched controls and the serial measurements for patient parameters at various time points, giving an overview of patient progression through the recovery process over time. The main limitations of this study are the use of single time point measures for control subjects and a small amount of missing data due to COVID-19 related disruption to the study. Despite this, follow up rates at each time point were high. Furthermore, COVID-19 lockdown-related disruptions were mitigated by continued collection of patient reported outcome measures by post during the lockdown and only patients missing a maximum of one scheduled review were included in the study.

6.4.7 Clinical Relevance and Future Research

The main finding of this study is a marked decrease in forefoot to rearfoot force and peak pressure ratios in the months after ATR, treated using a modern, functional non-operative regime. The ratio gradually increases with time but does not reach the level of either the uninjured limb or

control limbs by nine months after injury. Forefoot to rearfoot ratios correlated with general musculoskeletal (SMFA), Achilles tendon specific (ATRS) and HRQoL (EQ-5D) PROMs, suggesting that altered loading biomechanics with reduced forefoot loading are associated with worse patient perceived outcomes. Patient reported outcomes had not returned to pre-injury levels or the levels reported by matched controls, nine months after injury. Despite this, patients reported high levels of satisfaction with their treated ATR and the vast majority would readily recommend similar treatment to friends and family and also undergo similar treatment again in the future themselves, should it be required, suggesting that the treatment regime is acceptable to patients.

Simultaneously, decreased ATRA and increased ATLM were observed. These are purported to be indirect measures of tendon length and suggest initial tendon lengthening followed by gradual shortening in the months after ATR. Neither the relative ATRA nor the relative ATLM reached zero during the period of follow up, which could suggest persistent lengthening and there was a persisting deficit in calf circumference, in keeping with the findings of others.[365]

In addition, progressive changes in the loading patterns of the uninjured foot were also noted in the months after injury, which has important implications both clinically and also in the field of research, since this implies that use of the uninjured leg as the only control measure may not be appropriate and studies should assess both the uninjured foot and matched healthy control subjects to fully understand the changes that occur after ATR.

This is the first published report of static standing plantar plantar pressures after ATR and is the largest published study to date reporting pedobarographic parameters after ATR. Serial measures of pedobarographic, clinical and patient reported outcome measures give a holistic overview of patient recovery after ATR treated with a modern functional non-operative rehabilitation regime, understanding of which is essential for physicians who are increasingly adopting such regimes in the management of ATR and must counsel patients when making

decisions on treatment.[32, 131] The reported PROMs data gives information on patient perceived outcomes, which are important not only for clinicians but also for patients, as this can aide with expectation setting and discussion of expected outcomes from a perspective that is particularly meaningful to the patient, during the early stages of decision making and treatment.

Future studies should look to confirm these findings on larger patient cohorts and continue to follow patients over a longer time period to determine whether and at what point the FFRF ratios of the injured limb normalise if followed for prolonged periods and whether the progressive forefoot loading that was noted to occur in the uninjured limb persists or self-corrects.

6.5 Conclusion

After acute ATR treated with a modern early weight bearing, functional non-operative rehabilitation regime patients demonstrated reduced forefoot loading and peak pressures and increased rearfoot loading and peak pressures in the injured foot whilst standing, resulting in reduced forefoot to rearfoot force and pressure ratios. Over the ensuing months after treatment in a walking boot, the ratio gradually increases but does not reach that of the uninjured limb or healthy matched control subjects within the first nine months after injury. FFRF ratios in the uninjured feet are also effected by contralateral ATR and exhibit progressive changes in the months after injury. While no clinically relevant deficit of active range of motion persisted 9 months after injury, deficits of calf circumference and indirect measures of tendon length (ATRA, ATLM) persisted, as did deficits in patient reported outcomes including the ATRS and SMFA scores and HRQoL as measured by the EQ-5D. Despite this, patients generally expressed high levels of satisfaction with their treated ATR and stated that they would readily recommend similar treatment to others.

Chapter 7 – Summary and Conclusions

7.1 Summary and Discussion of the Main Findings

Acute Achilles tendon rupture is a common soft tissue injury with incidence reported to be rising across various geographical regions.[32-37, 39, 102, 228, 380] This, coupled with ongoing controversies as to the best approach to management,[91, 99] makes it a highly topical area of study in the orthopaedic community. Despite an abundance of studies of varying quality in this field, there are some surprising gaps in the existing literature and studies have shown that clinicians frequently adopt practices which are not evidence based.[59, 131-133]

One of the first challenges to be addressed in any field of study is to define the scale of the problem at hand. Hence it was appropriate to undertake an epidemiological study to better understand the population at risk of these injuries. The primary aim of the study in Chapter 2 of this thesis was to describe the epidemiology of these injuries in a defined health-care board region and furthermore to determine whether there was any association between the incidence of ATR and socioeconomic deprivation status.[304] The secondary aim of the study was to determine whether there were variations in previously described risk factors and features of ATR between more and less socioeconomically deprived individuals with ATR. The findings confirmed several already-known associations of ATR observed in other populations (for example male preponderance, seasonal variation and a bimodal age distribution with a peak incidence in the 5th decade of life),[32, 36] suggesting that they reflect the wider incidence of ATR in general populations elsewhere. The most important novel finding of the study in Chapter 2 was that of an *increased* incidence of ATR in patients with lower levels of socioeconomic deprivation. This is an unusual finding in medical science, where the vast majority of pathologies that exhibit an

association with socioeconomic deprivation status are found to occur more frequently in individuals with higher levels of socioeconomic deprivation.[215-219, 230-233, 249-251] This finding is relevant both in terms of healthcare planning and resource allocation (since SEDS is known to exhibit very marked geographic variation) and also in clinical terms. From a clinical perspective, a better understanding of the nature, circumstances of these injuries and the population at risk may increase clinician awareness of these injuries, which are known to be frequently missed at first presentation.[54, 56, 68] This is important since delayed treatment has been associated with worse patient outcomes.[70, 71] In addition, identification of particular sub-populations at risk of ATR should facilitate the design and implementation of targeted preventative and educational interventions.

Once an association between the incidence of ATR and SEDS was identified, the study sought to undertake a detailed analysis of differences in the more and less deprived patient cohorts with ATR in order to better understand the observed variations in incidence of ATR across these groups. Patient age, seasonal incidence of ATR, mechanism of injury and incidence of preceding symptomatic Achilles tendinopathy were found to vary with SEDS. This suggests that ATR are not a homogenous group of injuries.

This study not only re-affirmed various well known characteristics of ATR epidemiology but also identified a novel association between the incidence of ATR and socioeconomic deprivation status and then analysed the differences in more and less deprived cohorts to identify a number of differences in these cohorts which give a better understanding of variations in the nature and circumstances of ATR across patients of varying SEDS. This lays the foundations for a new direction of research in the field of ATR and it is hoped that others will now confirm this association and use this information to attempt to improve patient experience and outcomes, for example through the design and assessment of targeted preventive and educational programmes.

The most well-known and feared complication of ATR is tendon re-rupture. Outcomes after ATRR are known to be inferior to those of primary ATR and ATRR often necessitates surgery and further prolonged periods of immobilisation and rehabilitation for patients.[289] As a result, almost all clinical studies in the field of ATR report on re-rupture rates and it is frequently chosen as the primary outcome measure for studies.[87, 91, 336] Therefore, a detailed understanding of the risk factors associated with re-rupture is essential for clinicians treating these injuries, both to inform clinical decision making and also with respect to patient counselling. Despite this, there is surprisingly little in the existing medical literature to guide clinicians and ATRR remain poorly understood, unlike primary ATR, whose epidemiology and risk factors have been extensively studied.[31-34, 36-38, 245] Only four prior studies had attempted to determine the risk factors for ATRR. Three of these[103, 119, 297] were unable to identify any risk factors while one identified male sex as a predisposing factor for ATRR.[223] All studies were relatively small and the inability to identify factors associated with ATRR likely relates to the fact that ATRR is a relatively uncommon complication afflicting a small minority of patients with ATR. Smaller studies may therefore be underpowered to identify risk factors for ATRR. This phenomenon is the likely reason that most randomised controlled studies comparing operative and non-operative management of primary ATR have reported no significant differences in re-rupture rates,[4, 95, 97] while pooled data in meta-analyses has shown a small but statistically significant difference in re-rupture rates in this setting.[91, 381] Complications such as ATRR can therefore be more effectively studied using retrospective cohort studies, which, unlike RCTs, facilitate larger patient numbers and are not limited to comparison of two groups with one single changed variable.

The study in Chapter 3 of this thesis therefore aimed to describe the epidemiology of ATRR and to identify factors associated with increased risk of ATRR at the time of presentation with a primary ATR. This study represents the largest series of ATRR reported in the medical literature to date.

ATRR were found to occur most frequently in males. Age-specific incidence was bimodal with peak incidence in the fifth decade of life mirroring that in primary ATR and a second peak in older patients. Also in keeping with the observations in Chapter 2 for primary injuries, patients presenting with re-rupture had lower levels of socioeconomic deprivation than the general health-board population. Mechanism of injury was found to vary between primary ATR and re-ruptures. The former occurred during sporting or dancing activity in the majority of cases, while re-ruptures tended to be lower-energy injuries, with many occurring spontaneously or when walking or on stairs. Patients are often fearful of re-rupture occurring during the course of post-ATR physiotherapy or rehabilitation exercises but only a small minority of injuries (2 of 48, 4.2%) occurred in this way.

ATRR is generally considered to be an early complication, occurring within weeks of ATR.[61, 79, 101, 103, 117, 119, 223, 300] The study in Chapter 3 confirmed that most ATRR occurred early on in the course of rehabilitation, with the median time to re-rupture being 14 weeks from primary ATR. However 1 in 6 ATRR were late re-ruptures, occurring between 3 and 50 years after the primary injury. This phenomenon has not been previously described and has important implications for patients, clinicians and researchers. Awareness of the risk of ATRR in the first weeks after completion of immobilisation is high but these new findings suggest that patients cannot assume that they are 'safe' from ATRR after navigating the initial high-risk period. In addition, studies following patients for one or two years and reporting on re-rupture as an outcome measure or end point may underestimate the true incidence of re-rupture by excluding late re-ruptures.

A secondary analysis has shown that among patients presenting with a primary ATR, male patients, younger patients and those treated with traditional immobilising regimes were at higher risk of re-rupture after correcting for confounding factors in a multiple regression analysis and has quantified the additional risk that each of these variables independently imparts on re-rupture.

While male sex and younger age at the time of primary injury are non-modifiable risk factors, the treatment regime employed is a potentially modifiable risk factor and presents clinicians with an opportunity to reduce the risk of re-rupture. This study provides clinicians with data for patient counselling and evidence to support recent trends in the management of ATR which have seen a shift away from traditional immobilising regimes and towards functional rehabilitation, despite a lack of direct comparative evidence previously being available to support this shift.[99] Traditional immobilising treatment regimes with prolonged periods of non-weight bearing should be avoided on the basis of these results.

This study complements the study in Chapter 2 and together they provide a comprehensive overview of the epidemiology, circumstances and features of primary ATR and ATRR, which form the basis of the topics under study in the remaining chapters of the thesis. These chapters define the scale and nature of these pathologies and the population at risk of developing these injuries.

There has been considerable debate amongst surgeons as to the best treatment for ATR over recent decades and a large number of prospective randomised controlled trials have compared outcomes after operative and non-operative treatment of these injuries.[4, 57, 88, 95-97, 315, 316] As demonstrated in Chapter 2, ATR tends to effect mainly middle-aged adults who will expect to remain physically and economically active for many years after their initial injury. It is therefore imperative to understand the long term implications and outcomes of treatment for ATR. Despite this and the robust debate around operative and non-operative treatment of these injuries spanning decades, all RCTs published in the medical literature have reported on outcomes at one to two years after ATR[4, 57, 62, 84, 88, 95, 96] and only one report of outcomes in the medium term at a mean of 7 years after injury is found in the published literature.[60] One such RCT, undertaken in Edinburgh between 2000 and 2004, concluded that there was no significant difference in outcome after operative or non-operative treatment of ATR one year after injury.[4] The study in Chapter 4

is a long-term follow up of patients enrolled in this RCT at a mean of 15.7 years (13.4 to 17.7) and is the first long term data from a randomised controlled trial comparing operative and non-operative management of ATR to be published. The primary aim of the study was to compare patient reported outcomes after operative and non-operative treatment of acute ATR at long-term follow up. The hypothesis was that surgical treatment for acute ATR would result in improved patient reported outcomes, as measured by the Short Musculoskeletal Function Assessment (SMFA) dysfunction index, compared to non-operative management, which might in turn justify the increased risks[91, 114] known to be associated with surgical treatment. Secondary aims included a comparison of the Achilles Tendon Total Rupture Score (ATRS), HRQoL, satisfaction and complication rates, as well as the long-term net promoter score (NPS) for each treatment modality.

At long-term follow up after ATR treated both operatively and non-operatively, patients reported low levels of dysfunction and bother as recorded by the SMFA score dysfunction and bother indices and also the category indices for daily activities and mobility, indicating low levels of lower limb dysfunction and difficulty undertaking daily activities at long term follow up. There was no perceptible change in SMFA indices between one year and long term follow up, suggesting that patients can expect to maintain the generally good levels of function attained one year after ATR in the longer term. Surgically treated patients did not report superior PROM scores at any time point. Others have reported similar outcomes between surgically and non-operatively treated patients in the short[4, 95, 318] and medium term[60] and these findings suggest that they can be expected to persist in the longer term and provide further evidence to support the non-operative management of ATR.

Three other important novel findings of this study were the high rate of contralateral ruptures sustained by patients in the years after their initial ATR (8%), the finding that short term outcomes at one year were predictive of longer term outcomes at a mean of over 15 years after

injury and the high satisfaction rates with treated ATR reported by patients at long term follow up.

Worse SMFA dysfunction index scores at one year after injury correlated with long-term patient reported outcomes, suggesting that patients reporting poorer outcomes one year after injury are more likely to continue to do so in the longer term and highlighting the importance of early effective treatment of these injuries, since patients reporting poorer initial outcomes at one year are unlikely to make significant improvements later on.

Significant correlations were also noted between patients' general musculoskeletal (SMFA) and Achilles tendon specific (ATRS) self-reported outcomes and health related quality of life, suggesting that while most patients report good function at long term follow up, those patients who did have persisting functional deficits due to their Achilles tendon were more likely to report a poorer health related quality of life. Patient satisfaction and more recently other measures of patient sentiment are relatively new outcomes of interest in the field of orthopaedics. This study is the first to report on long term patient satisfaction, net promoter scores and friends and family test outcomes in the field of ATR. The vast majority of patients in both surgical and non-operative groups were satisfied with their treated Achilles tendon in the long term and stated that they would have the same treatment again on the other side if it were required and recommend similar treatment to friends and family if they had a similar injury. Both of these treatments therefore appear to be acceptable to patients and associated with high levels of patient satisfaction with the treated Achilles tendon.

Re-rupture is a well known and much feared complication of ATR, however there is little awareness of the increased risk of contralateral rupture in patients with ATR. Most studies of ATR involve relatively short periods of follow up and would therefore be unable to identify this phenomenon, which effected 8% of patients at long term follow up.

The study in Chapter 4 provides new insight into expected long term functional outcomes after treatment for ATR. These findings are important both for patients, who will benefit from a better understanding of their long term prognosis, as well as clinicians who must counsel patients through treatment decisions in the early stages after injury. The findings indicate that surgical management of ATR does not result in superior patient reported outcome at long term follow up and indicate that the potential risks of surgery are not offset by improved outcomes in the longer term. The hypothesis was therefore rejected.

The study in Chapter 5 follows on from that in Chapter 4. It aimed to compare the traditional non-operative regime described in Chapter 4 and shown to give outcomes comparable to surgical management in the long term, with a modern functional non-operative rehabilitation regime. Given the above findings, which provide answers to some questions in one of the longest standing debates in the sphere of ATR management (operative versus non-operative management) and given recent worldwide trends towards both non-operative and functional rehabilitation in the management of ATR in general, the next logical step is to directly compare the traditional non-operative regime described in Chapter 4 with a more modern functional non-operative regime, to determine whether a modern functional non-operative regime can provide equivalent or superior outcomes to those experienced with the traditional non-operative regime, thereby justifying the more recent trend[32, 36, 94, 105, 127, 128, 131, 132, 223] towards functional rehabilitation, which had been noted to lack a robust underlying evidence base.[59, 99, 131, 132] There were no prior direct comparisons of modern functional non-operative rehabilitation with traditional immobilising non-operative rehabilitation.[99]

The aim of this prospective randomised trial was to compare patient reported outcomes after traditional cast immobilisation with prolonged non-weight bearing (as described in Chapter 4) with functional rehabilitation and early weight-bearing in a walking boot, for adult patients from the general population, treated non-operatively for an ATR. Secondary aims included

comparison of additional patient reported outcome measures (PROMs), clinical measurements of outcome, return to work and driving and complication rates.

Functional non-operative rehabilitation after acute ATR was found to be a safe alternative to a traditional immobilising non-operative regime with prolonged periods of non-weight bearing. Equivalent outcomes were reported for both groups at or beyond one year post-injury. Multiple early benefits were observed in the functionally rehabilitated group, including improved PROMs, shorter time to return to driving (but not sport or work), improved ankle range of motion and less calf circumference deficit but these did not persist at or beyond one year, where there was no difference in outcomes observed between groups. Achilles specific function (as measured by the ATRS) improved between six and twelve months after injury but a small persistent deficit remained at one year after ATR. These findings are corroborated by the findings of others who reported similar ATRS at these time points.[62] Functional rehabilitation was associated with a statistically significant higher incidence of minor skin complications. Re-rupture rates in the functionally rehabilitated group were less than half those observed in the traditionally rehabilitated group but these findings were just outside statistical significance. This is likely to be because the study was underpowered to identify this phenomenon, which is a common feature of prospective randomised studies in the field of ATR,[95, 97, 102] where differences in re-rupture rate are frequently only identified in pooled data from meta-analyses.[91, 292]

The findings of the study in Chapter 5 are in agreement with those reported in the UKSTAR randomised study undertaken simultaneously.[158] Taken together, these studies suggest that there is a likely early benefit to patients from weight bearing functional rehabilitation but that this does not persist in the longer term. On the basis of these results, the use of this functional non-operative treatment regime is recommended in preference to traditional cast immobilising non-operative regimes as it has been shown to have early benefits and equivalent longer term

outcomes with the added convenience to patients of being able to weight bear from the early stages of treatment.

Given the findings in Chapter 5 and the increasing prevalence of functional non-operative rehabilitation in mainstream practice, a more detailed understanding of the underlying physiological processes, clinical changes and patient reported outcome measures in the months after ATR treated with functional non-operative rehabilitation is required. The study in Chapter 6 is the largest study to date reporting on pedobarographic parameters after ATR and is the first report of static standing pedobarographic data. It was designed to give a holistic overview of changes in these variables that occur in the months after ATR when patients undergo functional non-operative rehabilitation.

The main aim of the study in Chapter 6 was to report peak plantar pressures and forces acting on the feet during static stance as a forefoot to rearfoot ratio after ATR and to describe changes in the FFRF ratios over time up to 9 months post-injury. Secondary outcomes included assessment of patient reported outcomes, health related quality of life, clinically measured parameters and self-reported pain scores, both at standardised time points and with respect to changes over time in the months after Achilles tendon rupture. Other secondary outcomes included comparison of measured parameters with a group of healthy control subjects, correlation of FFRF ratios with patient reported outcome measures and health related quality of life and assessment of patient sentiment after completing treatment for ATR with the functional non-operative rehabilitation regime.

The most important finding of this study was a significant reduction in the forefoot to rearfoot force and peak pressure ratios of the injured limb relative to the uninjured limb, occurring after ATR treated using a modern functional non-operative regime. This indicates a significant relative reduction in forefoot load and forefoot peak pressures in the injured limb. The ratio gradually increases with time, indicating progressive re-loading of the forefoot with the passage

of time but does not reach the level of either the uninjured limb or control limbs by nine months after injury. Forefoot to rearfoot ratios correlated with general musculoskeletal (SMFA), Achilles tendon specific (ATRS) and HRQoL (EQ-5D) PROMs, suggesting that altered loading biomechanics with reduced forefoot loading are associated with worse patient perceived outcomes. In addition, progressive changes in the loading patterns of the uninjured foot were also noted in the months after injury. The clinical implications of changes occurring in the uninjured foot after ATR merit further investigation and there are also important implications for research design, where the uninjured foot is frequently assumed to be 'normal' and unaffected by the injury and thus used as the only control in studies.

Similar reductions in clinical measures such as calf circumference to those reported in Chapter 5 were observed, corroborating the results. Muscle wasting, as measured by calf circumference, was most marked at first assessment after boot removal and gradually improved thereafter. Similarly, both the relative ATRA and ATLM, which are indirect measures of tendon elongation, were of highest magnitude at the time of first follow up and gradually improved over time. None of the above clinical measures had normalised relative to the uninjured leg or matched control legs at last follow up 9 months after injury. Other authors have similarly reported persisting deficits in calf circumference and tendon elongation after ATR.[365] In keeping with the findings in Chapter 5 and those of other authors,[110, 158] PROMs exhibited progressive improvement with the passage of time but had not reached pre-injury levels or those of matched control subjects 9 months after ATR. Ninety six percent of patients treated with the functional non-operative regime stated that they were satisfied or very satisfied with their treated ATR 9 months after injury. Satisfaction levels were similar to those reported at long-term follow up for traditional non-operative management of ATR in Chapter 4, supporting the findings in Chapter 5 that suggest similar ultimate outcomes after traditional and functional non-operative management. The Net Promoter Score for functional non-operative management of ATR with the early weight

bearing regime was higher than that reported in the long term for both traditional non-operative and operative treatments (Chapter 4).

7.2 Summary of Main Novel Findings

Below is a summary in list form of the most important novel findings from the studies that comprise this thesis:

- ATR occurs more frequently in those with lower levels of socioeconomic deprivation. The circumstances and nature of ATR vary with SEDS.
- The largest reported series of ATRR permits detailed analysis of the circumstances and features of ATRR. Regression analysis confirmed the independent effects of age, male sex and traditional immobilising management of primary ATR on re-rupture risk.
- ATRR, like primary ATR, occurred more frequently in patients with lower levels of socioeconomic deprivation.
- There is a small but significant incidence of late ATRR, occurring many years after the primary injury, which was not previously recognised.
- Surgical treatment of ATR was not found to be give superior patient reported outcomes at long term follow up.
- Patients generally reported low levels of dysfunction, good health related quality of life and high levels of satisfaction with their treated Achilles tendon at long term follow up after both surgical and non-operative treatment.
- Poor short term outcome at one year was predictive of persisting poor outcome at long term follow up.
- At long term follow up, patient reported Achilles and musculoskeletal function correlated with patient reported health related quality of life.

- A significant incidence (8%) of contralateral ATR was noted at long term follow up.
- Together with the UKSTAR trial published in the same year, the study in Chapter 5 represents the only direct randomised controlled data to support the use of functional non-operative management of ATR over traditional non-operative management of these injuries with an immobilising cast.
- This study provides evidence that functional rehabilitation is safe, giving equivalent outcomes to traditional immobilising management at or beyond one year and that it also appears to give superior early outcomes, albeit with a higher incidence of transient minor skin complications.
- The study in Chapter 6 demonstrated a significant reduction in the forefoot to rearfoot force and peak pressure ratios of the injured limb relative to the uninjured limb, occurring after ATR. Reduced FFRF force and pressure ratios were most marked at the first post-injury follow up time point 2 months after ATR and improved with the passage of time but remained significantly lower than those in the uninjured leg and those of healthy control subjects throughout the study period.
- Progressive changes in the FFRF force ratios were observed in the uninjured leg after ATR and this finding has important implications on the use of the uninjured leg as the sole control comparator in studies on ATR.
- There was a direct correlation between ATRS score and both the EQ-5D Index and EQ-5D VAS, showing that Achilles specific function is directly related to patient perceived HRQoL.
- There was a statistically significant correlation between FFRF force and peak pressure ratios and all PROMs, demonstrating that abnormal loading patterns are associated with poorer patient reported outcome.

7.3 Future Research

The studies that comprise this thesis have given a better understanding of the epidemiology of primary ATR, in particular from the novel perspective of socioeconomic deprivation status, which has been shown to influence the incidence of a multitude of pathologies but whose role in the incidence of ATR was previously unexplored. Further studies in this field should now seek not only to confirm these findings, but to determine whether the enhanced understanding of variation in the incidence of ATR can be used to develop targeted preventive tools for different at-risk populations and subsequently test the efficacy of any such tools.

The study on ATRR represents the largest in the published literature in this field and provides new insight into the epidemiology of these injuries, contrasting this with the much better known features of primary ATR epidemiology. Several novel findings were reported, among them the identification of a significant group of delayed re-ruptures occurring many years after the primary injury. This has important implications for patients and clinicians and also for researchers planning studies that utilise re-rupture as an end-point and where it was previously assumed that re-rupture is exclusively an early complication of ATR. Further studies are required to determine whether delayed re-ruptures differ from the typical early re-ruptures in both their nature and in clinical outcomes. In addition, the study identified risk factors for ATRR at the time of primary presentation and further studies should now seek to use this information to target higher risk patients and explore whether the increased risk can be mitigated.

The clinical studies in Chapters 4, 5 and 6 advance current knowledge on the management of ATR and seek to provide answers to questions that have dominated the debate around the management of ATR for many years. In the first randomised controlled long term data addressing the perennial debate on operative or non-operative management of these injuries, surgical management with traditional rehabilitation was not shown to give superior outcomes to non-operative management. Short term outcomes were shown to be predictive of long-term

outcomes. If the causes of short term dysfunction and poorer patient reported outcome can be further defined through future studies, this may provide opportunities for targeted intervention to attempt to remedy these in the hope of improving longer term outcomes after ATR. The study in Chapter 5 sought to advance on the finding that surgery did not give superior long term outcomes to traditional non-operative management, by comparing the traditional non-operative management regime with a modern non-operative functional rehabilitation regime. This study, together with that in Chapter 3, also provides data to support the recent trend towards increasing mainstream use of functional rehabilitation programmes, which have been widely adopted in recent years despite a reported lack of data to support their use.[59, 99, 131-133] The study in Chapter 6 subsequently sought to give a deeper understanding of the described functional non-operative rehabilitation regime. Further studies should now aim to compare the described regime with different iterations of functional rehabilitation regimes, to determine whether outcomes can be further improved and to analyse the described regime in larger cohorts and over longer term follow up to confirm the findings and determine whether and if so when, pedobarographic parameters normalise after treatment for ATR using this regime.

7.4 Conclusions

ATR are common soft tissue injuries and occur more frequently in males and less socioeconomically deprived individuals. ATR exhibit seasonal variation in incidence and a bimodal age distribution. SEDS is also associated with variations in patient age, seasonality, mechanism of injury and incidence of pre-operative symptomatic tendinopathy. Known trends with respect to Achilles tendon re-rupture (e.g. male preponderance) were confirmed, while other novel findings were described, including incidence of a small but significant number of late re-ruptures, occurring years after the primary injury and an increased incidence of re-rupture in less

socioeconomically deprived patients. Younger age and traditional immobilising cast treatment of primary Achilles tendon rupture were independently associated with Achilles tendon re-rupture.

At long term follow up at a mean of 15.7 years, surgically treated patients did not report superior SMFA scores to non-operatively treated patients. There was no demonstrable difference in assessed outcomes across a range of PROMs or patient sentiment. The SMFA at one year after injury predicted longer term outcomes and there was no significant change in SMFA score between one year post-injury and long-term follow up. At long-term follow up there was a direct correlation between Achilles specific and general musculoskeletal PROMs and HRQoL, indicating that any persisting deficits in these areas impacted on HRQoL. There was a high incidence of contralateral tendon rupture in the years after primary ATR.

Functional non-operative rehabilitation with early weight-bearing is a safe alternative to traditional cast immobilisation. Multiple early benefits in clinical and PROM outcomes were noted in the functionally rehabilitated group at early follow-up but none persisted at one year. There was a higher incidence of minor skin complications in the functionally rehabilitated group. Re-rupture rates in the traditionally rehabilitated group were double those in the walking boot group but this finding was not statistically significant. On the basis of these results the use of this regime is recommended in preference to traditional immobilising rehabilitation using a cast.

Patients undergoing functional rehabilitation demonstrated a significant reduction in forefoot to rearfoot force and peak pressure ratios after injury. Over the ensuing months, FFRF ratios gradually increased but did not match those of either controls or the uninjured foot at final follow up. The uninjured foot also exhibited progressive forefoot loading in the months after injury. FFRF loading ratios in the injured foot correlated with PROMs. Deficits of calf circumference, ATRA and ATLM were most marked at boot removal and gradually reduced with time but did not normalise by the

time of final follow-up. Despite this, patients generally reported high rates of satisfaction with their functionally rehabilitated Achilles tendon.

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Appendix 1 – Supplementary Material for PROMs

The SMFA, ATRS, EQ-5D and satisfaction questionnaires are attached in the following pages. The Net Promoter Score is calculated from question 3 in the Satisfaction questionnaires sheet.

Appendix 1.1 – Short Musculoskeletal Function Assessment (SMFA) Additional Information

The following formula is applied to calculate each index in the SMFA score:

$$\text{Standardised Index} = \left(\frac{(\text{actual raw score}) - (\text{lowest possible raw score})}{\text{possible raw score range}} \right) \times 100$$

The following questions are used for calculation of each index:

SMFA dysfunction index: questions 1-34

SMFA bother index: questions 35-46

SMFA dysfunction categories:

- Mobility: questions 1, 4, 6, 8, 12, 13, 19, 26, 28
- Daily activities: questions 3, 14, 15, 20, 21, 22, 23, 24, 25, 33
- Emotional: questions 7, 27, 29, 30, 31, 32, 34
- Arm & hand: questions 2, 5, 9, 10, 11, 16, 17, 18

Short Musculoskeletal Function Assessment (SMFA)

We are interested in finding out how you are managing with your previously injured ankle. We would like to know about any problems you may be having with your daily activities because of your previous injury.
Please answer each question by putting a tick in the box corresponding to the choice that best describes you.

These questions are about how much difficulty you may be having <u>this week</u> with your daily activities <u>because of your previous injury.</u>

	Not at All Difficult	A Little Difficult	Moderately Difficult	Very Difficult	Unable To Do
1. How difficult is it for you to get in or out of a low chair?	1☐	2☐	3☐	4☐	5☐
2. How difficult is it for you to open medicine bottles or jars?	1☐	2☐	3☐	4☐	5☐
3. How difficult is it for you to shop for groceries or other things?	1☐	2☐	3☐	4☐	5☐
4. How difficult is it for you to climb stairs?	1☐	2☐	3☐	4☐	5☐
5. How difficult is it for you to make a tight fist?	1☐	2☐	3☐	4☐	5☐
6. How difficult is it for you to get in or out of the bathtub or shower?	1☐	2☐	3☐	4☐	5☐
7. How difficult is it for you to get comfortable to sleep?	1☐	2☐	3☐	4☐	5☐
8. How difficult is it for you to bend or kneel down?	1☐	2☐	3☐	4☐	5☐
9. How difficult is it for you to use buttons, snaps, hooks or zippers?	1☐	2☐	3☐	4☐	5☐
10. How difficult is it for you to cut your own fingernails?	1☐	2☐	3☐	4☐	5☐
11. How difficult is it for you to dress yourself?	1☐	2☐	3☐	4☐	5☐
12. How difficult is it for you to walk?	1☐	2☐	3☐	4☐	5☐
13. How difficult is it for you to get moving after you have been sitting or lying down?	1☐	2☐	3☐	4☐	5☐
14. How difficult is it for you to go out by yourself?	1☐	2☐	3☐	4☐	5☐
15. How difficult is it for you to drive?	1☐	2☐	3☐	4☐	5☐
16. How difficult is it for you to clean yourself after going to the bathroom?	1☐	2☐	3☐	4☐	5☐
17. How difficult is it for you to turn knobs or levers (for example, to open doors or to roll down car windows)?	1☐	2☐	3☐	4☐	5☐
18. How difficult is it for you to write or type?	1☐	2☐	3☐	4☐	5☐
19. How difficult is it for you to pivot?	1☐	2☐	3☐	4☐	5☐

	Not at All Difficult	A Little Difficult	Moderately Difficult	Very Difficult	Unable To Do
20. How difficult is it for you to do your usual physical recreational activities, such as bicycling, jogging or walking?	1☐	2☐	3☐	4☐	5☐
21. How difficult is it for you to do your usual leisure activities, such as hobbies, crafts, gardening, card playing or going out with friends?	1☐	2☐	3☐	4☐	5☐
22. How much difficulty are you having with sexual activity?	1☐	2☐	3☐	4☐	5☐
23. How difficult is it for you to do light housework or yard work, such as dusting, washing dishes or watering plants?	1☐	2☐	3☐	4☐	5☐
24. How difficult is it for you to do heavy housework or yard work, such as washing floors, vacuuming or mowing lawns?	1☐	2☐	3☐	4☐	5☐
25. How difficult is it for you to do your usual work, such as a paid job, housework or volunteer activities?	1☐	2☐	3☐	4☐	5☐

These next questions ask how often you are experiencing problems <u>this week</u> because of your injury.

	None of the Time	A Little of the Time	Some of the Time	Most of the Time	All of the Time
26. How often do you walk with a limp?	1☐	2☐	3☐	4☐	5☐
27. How often do you avoid using your painful limb?	1☐	2☐	3☐	4☐	5☐
28. How often does your leg lock or give way?	1☐	2☐	3☐	4☐	5☐
29. How often do you have problems with concentration?	1☐	2☐	3☐	4☐	5☐
30. How often does doing too much in one day affect what you do the next day?	1☐	2☐	3☐	4☐	5☐
31. How often do you act irritable toward those around you (for example, snap at people, give sharp answers or criticise easily)?	1☐	2☐	3☐	4☐	5☐
32. How often are you tired?	1☐	2☐	3☐	4☐	5☐
33. How often do you feel disabled?	1☐	2☐	3☐	4☐	5☐
34. How often do you feel angry or frustrated that you have this injury?	1☐	2☐	3☐	4☐	5☐

These questions are about how much you are bothered by problems you are having <u>this week</u> because of your injury.

	Not at All Bothered	A Little Bothered	Moderately Bothered	Very Bothered	Extremely Bothered
35. How much are you bothered by problems using your hands, arms or legs?	1☐	2☐	3☐	4☐	5☐
36. How much are you bothered by problems using your back?	1☐	2☐	3☐	4☐	5☐
37. How much are you bothered by problems doing work around your home?	1☐	2☐	3☐	4☐	5☐
38. How much are you bothered by problems with bathing, dressing, toileting or other personal care?	1☐	2☐	3☐	4☐	5☐
39. How much are you bothered by problems with sleep and rest?	1☐	2☐	3☐	4☐	5☐
40. How much are you bothered by problems with leisure or recreational activities?	1☐	2☐	3☐	4☐	5☐
41. How much are you bothered by problems with your friends, family or other important people in your life?	1☐	2☐	3☐	4☐	5☐
42. How much are you bothered by problems with thinking, concentrating or remembering?	1☐	2☐	3☐	4☐	5☐
43. How much are you bothered by problems adjusting or coping with your injury?	1☐	2☐	3☐	4☐	5☐
44. How much are you bothered by problems doing your usual work?	1☐	2☐	3☐	4☐	5☐
45. How much are you bothered by problems with feeling dependent on others?	1☐	2☐	3☐	4☐	5☐
46. How much are you bothered by problems with stiffness and pain?	1☐	2☐	3☐	4☐	5☐

FOR OFFICE USE ONLY:

DYSFUNCTION RAW SCORE		**DYSFUNCTION INDEX**	
BOTHER RAW SCORE		**BOTHER INDEX**	
SMFA RAW SCORE		**OVERALL SMFA SCORE**	

Appendix 1.2 – Achilles Tendon Total Rupture Score (ATRS)

All questions refer to your limitations/difficulties related to your previously injured Achilles tendon.
0 refers to major limitations (poor function), whilst 10 refers to no limitations (good function). Please select ONE answer for each question.

Note that a higher number denotes a better outcome.

MAJOR LIMITATION ←----------→ NO LIMITATION

1. Are you limited due to decreased strength in the calf/Achilles tendon/foot?

0☐ 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐ 9☐ 10☐

2. Are you limited due to fatigue in the calf/Achilles tendon/foot?

0☐ 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐ 9☐ 10☐

3. Are you limited due to stiffness in the calf/Achilles tendon/foot?

0☐ 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐ 9☐ 10☐

4. Are you limited due to pain in the calf/Achilles tendon/foot?

0☐ 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐ 9☐ 10☐

5. Are you limited during activities of daily living?

0☐ 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐ 9☐ 10☐

6. Are you limited when walking on uneven surfaces?

0☐ 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐ 9☐ 10☐

7. Are you limited when walking quickly up the stairs or up a hill?

0☐ 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐ 9☐ 10☐

8. Are you limited during activities that include running?

0☐ 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐ 9☐ 10☐

9. Are you limited during activities that include jumping?

0☐ 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐ 9☐ 10☐

10. Are you limited in performing hard physical labour?

0☐ 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐ 9☐ 10☐

TOTAL SCORE (for office use only)

Appendix 1.3 - Foot and Ankle Questionnaire

Thank you for completing this questionnaire!

This questionnaire will help us to better understand your general health and any problems related to bone and muscle conditions.

Your completion of this questionnaire is completely voluntary and your responses will be held in the strictest confidence.

Please answer every question. Some questions may look like others, but each one is different.

There are no right or wrong answers. If you are not sure how to answer a question, just give the best answer you can. You can make comments in the margin. We do read all your comments, so feel free to make as many as you wish.

Instructions

Please answer the following questions for the foot/ankle being treated or followed up. If it is BOTH feet/ankles, please answer the questions for your **worse** side. All questions are about how you have felt, on average, during the **past week**. If you are being treated for an injury that happened less than one week ago, please answer for the period since your injury.

1. During the **past week**, how **stiff** was your foot/ankle? (Circle one response.)

1 Not at all 2 Mildly 3 Moderately 4 Very 5 Extremely

2. During the **past week**, how **swollen** was your foot/ankle? (Circle one response.)

1 Not at all 2 Mildly 3 Moderately 4 Very 5 Extremely

During the **past week**, please tell us about how painful your foot/ankle was during the following activities. (Circle ONE response on each line that best describes your average ability.)

	Not painful	Mildly painful	Moderately painful	Very painful	Extremely painful	Could not do because of foot/ankle pain	Could not do for other reasons
3. Walking on **uneven** surfaces?	1	2	3	4	5	6	7
4. Walking on **flat** surfaces?	1	2	3	4	5	6	7
5. Going up or down stairs?	1	2	3	4	5	6	7
6. Lying in bed at night?	1	2	3	4	5	6	7

During the **past week**, did your foot/ankle **give way** during the following activities. (Circle ONE response on each line that best describes you for each activity level.)

	Did not give way at all	Partially gave way, but I did not fall	Completely gave way, so that I fell	Could not do the activity because of foot/ankle giving way	Could not do for other reasons
7. Strenuous activity, such as heavy physical work, skiing, tennis?	1	2	3	4	5
8. Moderate activity, such as moderate physical work, jogging, running?	1	2	3	4	5
9. Light activity, such as walking, house work, yard work?	1	2	3	4	5

10. Which of the following statements **best** describes your ability to get around most of the time during the **past week**? (Circle one response.)

1 I did not need support or assistance at all.
2 I mostly walked without support or assistance.
3 I mostly used one cane or crutch to help me get around
4 I mostly used two canes, two crutches or a walker to help me get around.
5 I used a wheelchair.
6 I mostly used other supports or someone else had to help me get around.
7 I was unable to get around at all.

11. How much trouble did you have with balance during the **past week**? (Circle one response.)

1 No trouble at all
2 A little bit of trouble
3 A moderate amount of trouble
4 Quite a bit of trouble
5 A great amount of trouble
6 I cannot balance on my feet at all

12. How difficult was it for you to put on or take off socks/stockings during the **past week**? (Circle one response.)

1 Not at all difficult 2 A little bit difficult 3 Moderately difficult 4 Very difficult 5 Extremely difficult 6 Cannot do it at all

All questions are about how you have felt on average **during the past week**.

During the **past week**, please tell us about how **painful** your **foot or ankle** was when you were performing the following activities. (Circle ONE response on each line that best describes your average ability.)

	No pain	Mild pain	Moderate pain	Severe pain	Extreme pain	Could not do because of foot/ankle pain	Could not do for other reasons
13. Strenuous activity, such as heavy physical work, skiing, tennis	1	2	3	4	5	6	7
14. Moderate activity, such as moderate physical work, jogging, running	1	2	3	4	5	6	7
15. Light activity, such as walking, house work, yard work	1	2	3	4	5	6	7
16. Standing for an hour	1	2	3	4	5	6	7
17. Standing for a few minutes	1	2	3	4	5	6	7

18. How much difficulty do you have walking on uneven surfaces (eg., small stones, rocks, sloping ground)? (Circle one response.)

1 No difficulty
2 Mild difficulty
3 Moderate difficulty
4 Severe difficulty
5 Extreme difficulty
6 Cannot do because of foot/ankle
7 Cannot do for other reasons

What types of shoes can you wear comfortably?
(Circle one response on each line.)

	Yes	No	Not applicable
19. Any women's shoe (including high heels) OR any men's shoe (including fancy dress shoes)	1	2	3
20. Most women's dress shoes (except high heels) OR most means dress shoes	1	2	3
21. Sneakers, walking, or casual shoes	1	2	3
22. Orthopaedic or prescription shoes	1	2	3
23. All shoes	1	2	3

24. How much did your foot or ankle problem interfere with your normal work, including work both outside the home and house work? (Circle one response.)

1 Not at all 2 A little bit 3 Moderately 4 Quite a bit 5 Extremely 6 Unable to work due to foot and ankle problems

25. How much did your foot or ankle problem interfere with your life and your ability to do what you want? (Circle one response.)

1 Not at all 2 A little bit 3 Moderately 4 Quite a bit 5 Extremely 6 It ruins everything

Appendix 1.4 - EQ-5D Index and VAS Score Questionnaires

EQ5D

Under each heading, please tick the ONE box that best describes your health at present

MOBILITY

I have no problems in walking about ☐
I have slight problems in walking about ☐
I have moderate problems in walking about ☐
I have severe problems in walking about ☐
I am unable to walk about ☐

SELF-CARE

I have no problems washing or dressing myself ☐
I have slight problems washing or dressing myself ☐
I have moderate problems washing or dressing myself ☐
I have severe problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

USUAL ACTIVITIES (eg. work, study, housework, family or leisure activities)

I have no problems doing my usual activities ☐
I have slight problems doing my usual activities ☐
I have moderate problems doing my usual activities ☐
I have severe problems doing my usual activities ☐
I am unable to do my usual activities ☐

PAIN/DISCOMFORT

I have no pain or discomfort ☐
I have slight pain or discomfort ☐
I have moderate pain or discomfort ☐
I have severe pain or discomfort ☐
I have extreme pain or discomfort ☐

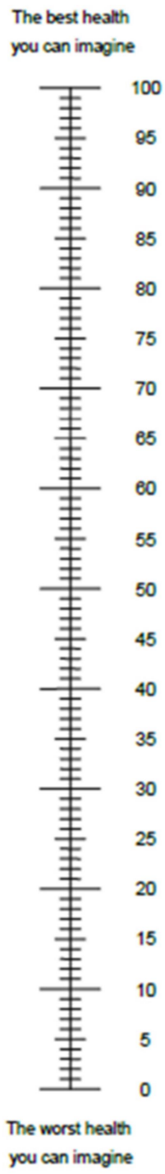
ANXIETY/DEPRESSION

I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
I am severely anxious or depressed ☐
I am extremely anxious or depressed ☐

We would like to know how good or bad your health is at present.
This scale is numbered from 0 to 100.
100 means the <u>best</u> health you can imagine.
0 means the <u>worst</u> health you can imagine.
Mark an X on the scale to indicate how your health is at present.

Now, please write the number you marked on the scale in the box below:

Your health = ☐



Appendix 1.5 – Patient Satisfaction, Sentiment, NPS and FFT

Patients were asked to complete the below questionnaire to gauge satisfaction and sentiment. The NPS and NHS FFT data was calculated from the third question

1. How satisfied are you with your treated Achilles tendon?

Very Satisfied	Satisfied	Neither Satisfied or Dissatisfied	Dissatisfied	Very Dissatisfied
☐	☐	☐	☐	☐

2. Would you have the same treatment again if it was required on the other side?

Extremely Likely	Likely	Neither likely nor unlikely	Unlikely	Extremely unlikely	Don't know
☐	☐	☐	☐	☐	☐

3. How likely are you to recommend this treatment to friends and family if they needed similar care or treatment?

Extremely Likely	Likely	Neither likely nor unlikely	Unlikely	Extremely unlikely	Don't know
☐	☐	☐	☐	☐	☐

The NPS was calculated from the third question - 'How likely are you to recommend this treatment to friends and family if they needed similar care or treatment?'

For calculation of the NPS, patients who said they would be 'very likely' to recommend their treatment to others were considered 'promoters'; those who stated they would be 'likely' to do so were considered 'passives' and those who stated they 'didn't know', were 'unlikely'/'very unlikely' or were 'neither likely nor unlikely' to do so were considered 'detractors'.

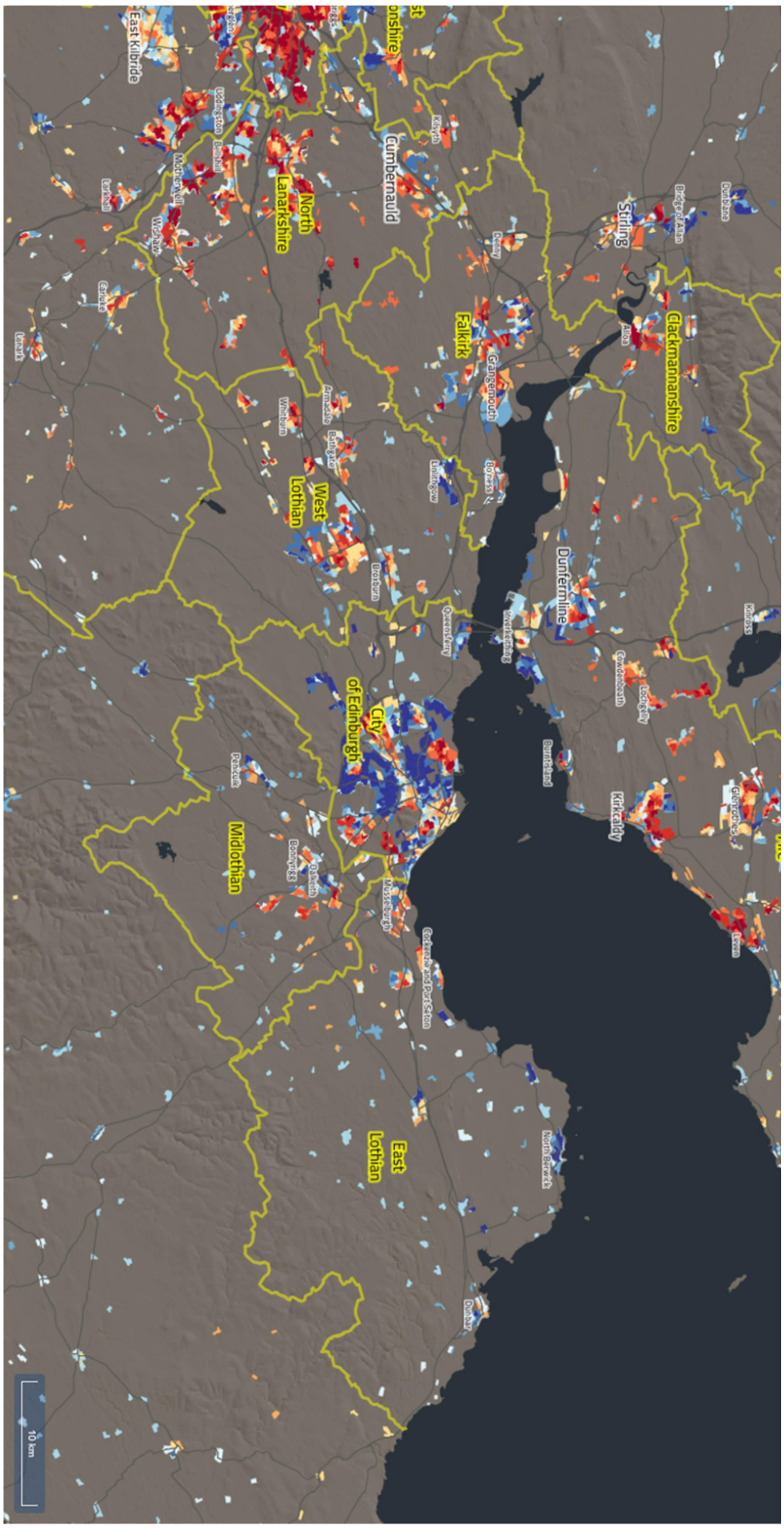
The following algorithm was then used to calculate the NPS:

$$NPS = \left(\frac{[\text{Promoters (n)}] - [\text{Detractors (n)}]}{[\text{Total Responders (n)}]} \right) x100$$

The NHS FFT data was reported as the % patients who were likely/very likely to recommend their treatment to others.

Appendix 2 – Supplementary Material Chapter 2

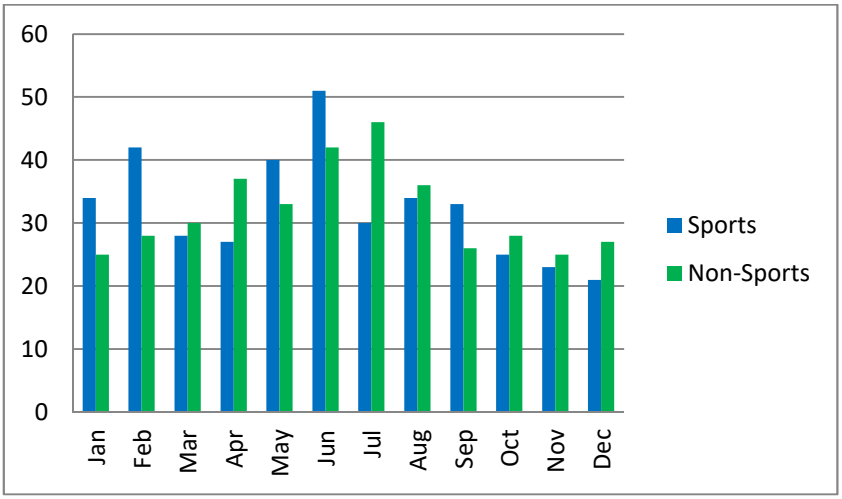
Appendix 2.1 – Geographic Map of Socioeconomic deprivation status



Appendix 2 Figure 1. Colour coded socioeconomic deprivation status map of the Lothians, using SIMD-16 data. Reference: https://simd.scot/#/simd2016/BTTTFTT/9/-4.0000/55.9000/

Last accessed on 05/06/2023.

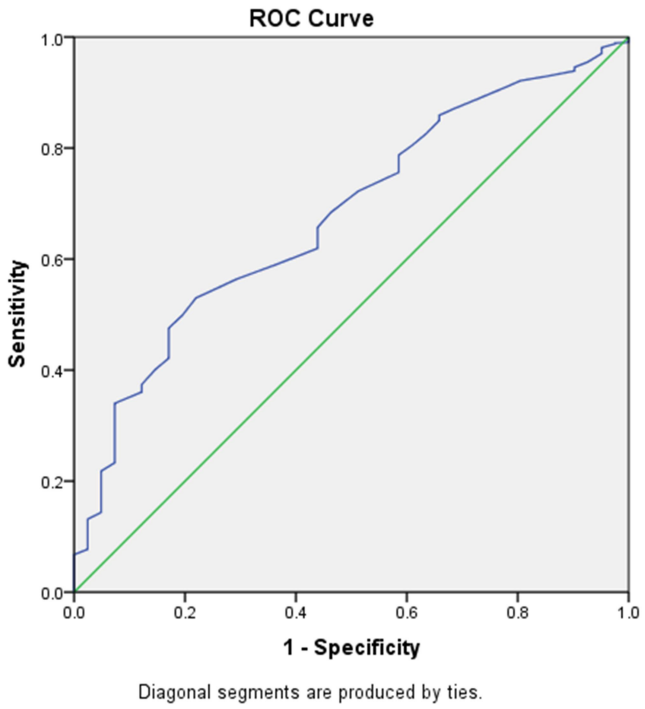
Appendix 2.2 – Seasonal Variation in Sporting and Non-Sporting Injuries



Appendix 2 Figure 2. Month of injury for sporting and non-sporting related ATR.

Appendix 3 – Supplementary Material Chapter 3

Appendix 3.1 – Receiver Operator Characteristic (ROC) Curve for determination of age threshold for prediction of ATRR



Appendix 3 Figure 1. Receiver operator characteristic curve for determination of age threshold for prediction of ATRR.

Age	Sensitivity	1-Specificity
40.5	0.722	0.512
41.5	0.684	0.463
42.5	0.657	0.439
43.5	0.642	0.439
44.5	0.619	0.439
45.5	0.591	0.366
46.5	0.564	0.293
47.5	0.530	0.220
48.5	0.499	0.195
49.5	0.476	0.171
50.5	0.449	0.171

Appendix 3 Table 1. Sensitivity and 1-Specificity data for ROC curve.

Appendix 4 – Supplementary Material Chapter 4

Appendix 4.1 - Repeat Analysis of Outcomes Excluding Patients who Sustained a Re-rupture

Analyses were repeated on the remaining 58 patients, after excluding the 6 patients who had sustained a tendon re-rupture. There was no significant difference identified in any patient-reported outcome measure (PROM) between operative and non-operatively treated groups at long-term follow up (Appendix 4 Table 1).

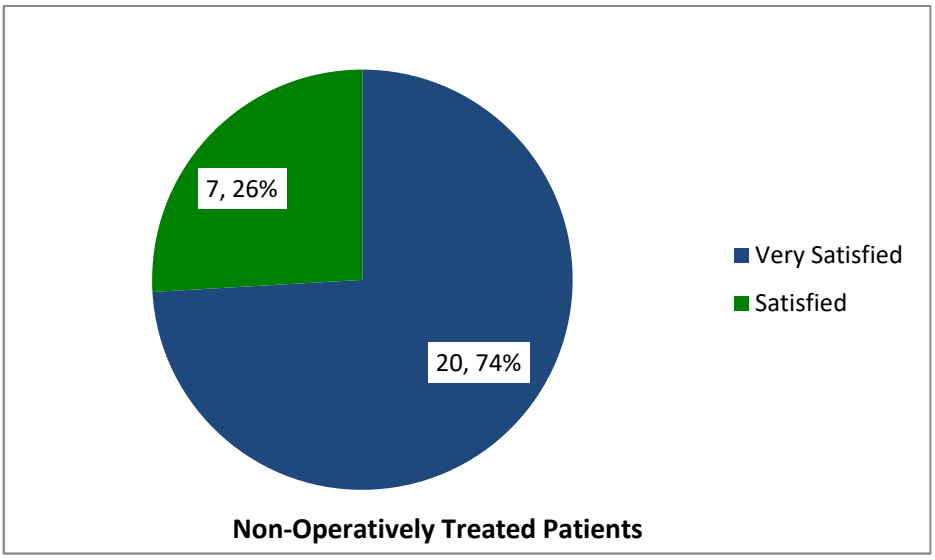
PROM	Median operative score (IQR) n=31	Median non-operative score (IQR) n=27	p-value*
SMFA dysfunction	1.56 (0.00 to 5.88)	1.47 (0.00 to 5.15)	0.291
SMFA bother	2.08 (0.00 to 12.50)	0 (0.00 to 6.25)	0.116
ATRS	92 (85 to 100)	91 (78 to 100)	0.461
EQ-5D-5L index	0.84 (0.74 to 1.00)	1 (0.84 to 1.00)	0.064
EQ-5D VAS	85 (70 to 95)	85 (80 to 95)	0.296

Appendix 4 Table 1. PROM scores for 58 patients treated for Achilles tendon rupture who did not sustain a re-rupture of their tendon. * Mann Whitney U-test.

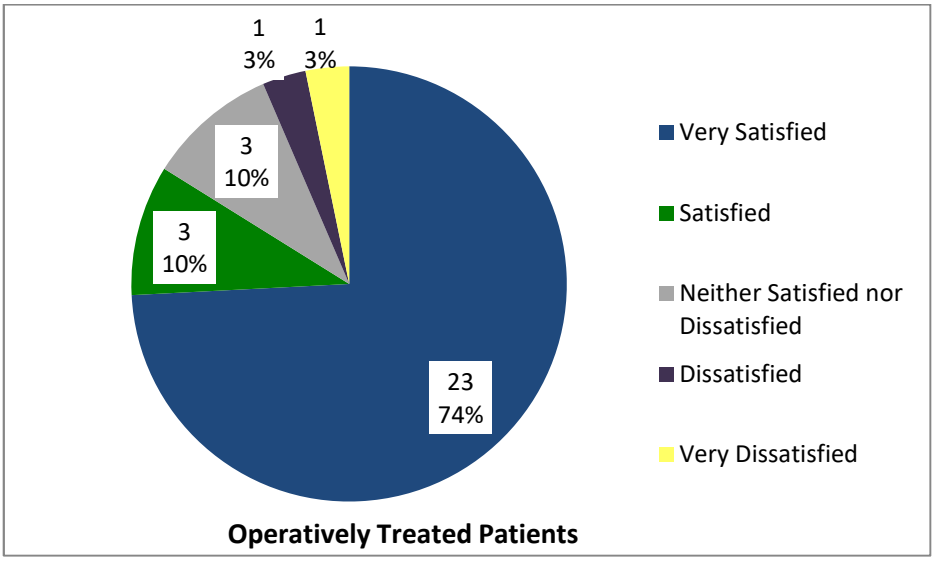
Additionally, there was no significant difference identified in any of the SMFA dysfunction categories between operatively and non-operatively treated groups at long-term follow up (Appendix 4 Table 2) and no significant difference in satisfaction rates (Appendix 4, Figures 1a and 1b) between treatment groups (p=0.255, Fisher's exact test).

SMFA Disability Category	Median operative score (IQR) n=31	Median non-operative score (IQR) n=27	p-value*
Mobility	0 (0.00 to 8.33)	0 (0.00 to 5.56)	0.491
Daily activities	0 (0.00 to 5.00)	0 (0.00 to 5.00)	0.461
Emotional	7.14 (0.00 to 14.29)	3.57 (0.00 to 10.71)	0.157
Hand and arm	0 (0.00 to 0.00)	0 (0.00 to 0.00)	0.330

Appendix 4 Table 2. Median (IQR) SMFA disability category scores for patients treated operatively and non-operatively. * Independent Samples Mann Whitney U-test.



Appendix 4 Figure 1a. Patient satisfaction with their non-operatively treated Achilles tendon.



Appendix 4 Figure 1b. Patient satisfaction with their operatively treated Achilles tendon.

Patients were also asked whether they would have the same treatment again if it was required on the other side (Appendix 4 Table 3). Comparison of those who stated they were likely (i.e. answered 'extremely likely' or 'likely') and those who were unlikely (i.e. 'extremely unlikely' or 'unlikely') to do so demonstrated no significant difference between treatment groups (p=0.75, Fisher's Exact Test).

	Operative	Non-Operative
Extremely Likely	18	17
Likely	7	7
Neither Likely nor Unlikely	2	2
Unlikely	0	0
Extremely Unlikely	2	0
Don't Know	2	1
Total Responses	31	27

Appendix 4 Table 3. Would you have the same treatment again if it were required on the opposite side?

The net promoter score was 32 for patients treated operatively and 37 for patients treated non-operatively. Under current NHS FFT reporting guidelines, 77.4% of patients would recommend operative treatment and 6.5% would not, while 85.2% would recommend non-operative treatment and none would not (Appendix 4 table 4). Comparison of those who stated they were likely (i.e. those answering 'extremely likely' or 'likely') and those who were unlikely (i.e. 'extremely unlikely' or 'unlikely') to recommend demonstrated no significant difference between treatment groups (p = 0.276, Fisher's exact test).

	Operative	Non-Operative
Extremely Likely	17	14
Likely	7	9
Neither Likely nor Unlikely	3	3
Unlikely	0	0
Extremely Unlikely	2	0
Don't Know	2	1
Total Responses	31	27

Appendix 4 Table 4. How likely are you to recommend this treatment to friends and family if they needed similar care or treatment?

Appendix 4.2 – REC Favourable Opinion

NHS
Health Research Authority

East Midlands - Leicester Central Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

11 July 2017

Mr John Keating
Consultant Orthopaedic Surgeon
NHS Lothian
Royal Infirmary of Edinburgh
51, Little France Crescent
Edinburgh
EH16 4SA

Dear Mr Keating

Study title:	**Operative versus Non-Operative Treatment for Achilles Tendon Rupture: Long Term Followup of Patients in a Previous Randomised Controlled Trial.**
REC reference:	**17/EM/0256**
Protocol number:	**AC17034**
IRAS project ID:	**224857**

The Proportionate Review Sub-committee of the East Midlands - Leicester Central Research Ethics Committee reviewed the above application on 07 July 2017.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Covering letter on headed paper [Covering Letter]	1.0	23 June 2017
Participant information sheet (PIS) [Patient Information Sheet]	1.3	10 April 2017

REC Application Form [REC_Form_21062017]		21 June 2017
Research protocol or project proposal [Project Protocol v1.3]	1.3	09 April 2017
Summary CV for Chief Investigator (CI) [Chief Investigator CV (J Keating)]	1.0	24 April 2017
Summary CV for student [Student CV (J Maempel)]	1.0	23 April 2017
Summary CV for supervisor (student research) [Student Supervisor CV (N Clement)]	1.0	25 April 2017
Validated questionnaire [Questionnaire Booklet]	1.1	

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

17/EM/0256	Please quote this number on all correspondence

Yours sincerely

pp. S. O'Neil

Mr Ken Willis
Chair

Email: nrescommittee.eastmidlands-leicestercentral@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Mr Kenneth Scott, NHS Lothian*

East Midlands - Leicester Central Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting on 07 July 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Alan Cudworth	Retired Senior Lecturer	Yes	
Mr Michael Jones	Medical Statistician	Yes	
Mr Ken Willis	Medical Devices Manager - retired	Yes	Chair

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Joanne O'Neil	REC Assistant

Appendix 5 – Supplementary Material Chapter 5

Appendix 5.1 – Physiotherapy Regime

Patients in both groups followed similar physiotherapy regimes, but these were commenced at different time-points. Patients treated in a cast began physiotherapy when the cast was removed at the 10 week time-point, whereas those treated in a walking boot commenced physiotherapy when the walking boot was discarded at the 8 week time-point. Further details can be found in Appendix 6.1.

Physiotherapy progressed as follows:

Initial Physiotherapy (commencing at 8 weeks for boot patients and 10 weeks for cast patients):

Patients were referred to supervised physiotherapy, with a focus on gait re-education, maintaining quadriceps and hamstring function, strengthening all lower limb muscle groups, increasing neuromuscular control and ankle range of motion. All patients were warned of common complications, including their signs and symptoms. Isotonic and isometric hamstring and quadriceps exercises were undertaken. Non-weight bearing active range of motion ankle exercises were commenced. Concentric and eccentric heel raises were commenced, through the available range (but eccentric load not allowed to exceed concentric load). Full weight bearing stretching of the tendon was avoided. Balance exercises were undertaken, commencing with single leg static exercises, then progressing as able. Slow dorsiflexion stretching.

Physiotherapy was then progressed, building on the above exercises and focusing on restoration of full tendon extensibility, with weight bearing calf stretches off a step and

increase of strength through the full active range of motion. Continued eccentric calf exercises, progressing to loads that exceeded concentric ability.

Late physiotherapy (24 weeks+):

Work towards restoration of full occupational and sporting function. Occupational and sport specific rehabilitation, including return to running. Early plyometric training commenced (e.g. skipping, double leg bounding), followed by progression of plyometric exercises. Restoration of optimal calf strength with progressive concentric and eccentric exercises. Full sports-specific training and end-stage sports rehabilitation. Aim for return to contact sports at 6 months.

Additional note: The original trial physiotherapy protocol envisaged commencement of early supervised range of motion exercises below neutral position from 4 weeks and weaning of the boot between 6 and 8 weeks for boot patients, however, during the trial, a slightly more conservative regime was adopted with all boot patients remaining in the walking boot at all times for 8 weeks and then removing it abruptly. Physiotherapy and range of motion exercises were commenced upon boot removal. This was notified to the trial sponsor and REC.

Appendix 5.2 – REC Favourable Opinion

Lothian NHS Board

South East Scotland Research Ethics Committee 01

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 536 9000
Fax 0131 465 5789

www.nhslothian.scot.nhs.uk

Date 13 February 2013
Your Ref
Our Ref

Enquiries to: Sandra Wyllie
Extension: 35679
Direct Line: 0131 465 5679
Email: Sandra.Wyllie@nhslothian.scot.nhs.uk

Ms Leela Biant
Consultant Orthopaedic Surgeon
Lothian Universities Healthcare Trust
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
EH16 4SA

Dear Ms Biant

Study title:	**Functional outcomes after conservative management of the acutely ruptured achilles tendon in the under 60 age group. A randomised controlled trial comparing standard conservative management with accelerated rehabilitation using a moonboot.**
REC reference:	**13/SS/0002**
Protocol number:	**Awaited**
IRAS project ID:	**89061**

Thank you for your letter of 12 February 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mrs Sandra Wyllie, Sandra.Wyllie@nhslothian.scot.nhs.uk.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study:

- Replace the phrase "non-surgical accelerated rehabilitation programme" with a less technical phrase.
- Although the PIS has been amended to "A summary of the results in lay terms will be freely available for participants once they study is completed" it still does not state how they will actually obtain the information. Will they be sent it, will it be available on a website etc? Please detail.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You must notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations

NHS Lothian

to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
GP/Consultant Information Sheets	Version 1.2	08 February 2013
Interview Schedules/Topic Guides	Version 1	18 December 2012
Other: Data Collection Tool - Achilles Tendon Total Rupture Score		
Other: Data Collection Tool - Foot and Ankle Outcome Score (FAOS) Sheet		
Other: Data Collection Tool - Short Musculoskeletal Function Assessment		
Other: Data Collection Tool	Version 1.3	
Participant Consent Form	Version 1.3	08 February 2013
Participant Information Sheet	Version1.11	08 February 2013
Protocol	Version 1.12	17 November 2012
REC application		20 December 2012
Response to Request for Further Information		12 February 2013

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

NHS
Lothian

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

13/SS/0002	Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

pp
Dr Janet Andrews
Chair

Email:Sandra.Wyllie@nhslothian.scot.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Ms Karen Maitland, NHS Lothian Research & Development Office*

NHS Lothian

South East Scotland Research Ethics Committee 01

Attendance at Sub-Committee of the REC

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Lindsay Murray	Health & Safety Manager	Yes	
Dr Kevin Smith	Biochemist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Sandra Wyllie	Committee Co-ordinator

Appendix 6 – Supplementary Material Chapter 6

Appendix 6.1 – Physiotherapy Regime

ACHILLES TENDON PLANTAR PRESSURES STUDY

ACCELERATED REHABILITATION PATIENTS

Total time in boot - 8 weeks

Physiotherapy/Rehabilitation Guidelines

Note: All timescales are relative to the date of initiation of treatment with equinus plaster in A&E

Boot Protocol

0-4 weeks. Patient is seen in A&E and placed into an equinus cast and referred to clinic. At clinic, diagnosis is confirmed, eligibility for study confirmed against inclusion/exclusion criteria and the patient is placed into an Ossur Rebound walking boot with 3x 1cm heel raises (i.e. total 3cms).

- The boot is to be worn continuously including when in bed.
- WBAT / FWB once in boot - crutches for balance.
- Note: time spent in equinus backslab from A&E is included in this 4 week period so for example, if a patient presents to clinic in an equinus cast 7 days after review in A&E, they are placed into a boot with 3cm wedges for a further 3 weeks, totalling 4 weeks in full equinus.

4-6 weeks (i.e. total time of 2 weeks) in Ossur Rebound walking boot with 1x1cm Ossur heel raise and 1x0.5cm additional heel raise BENEATH the Ossur heel raise (i.e. total of 1.5cms).

- The boot is worn continuously including when in bed.
- WBAT / FWB - crutches for balance.

6-8 weeks: 2 weeks Ossur Rebound walking boot with foot in neutral position.

- FWB.

Physiotherapy regime

0-8 weeks: No physiotherapy.

- Ensure patient is mobilising safely with crutches
    - gait re-education
    - FWB/ WBAT
- Ensure patient is aware of common complications
    - educate patient regarding signs & symptoms

8 weeks: Remove boot.

- Give Ankle Exercises Instruction & Leaflet
    - NWB active plantar / dorsiflexion to neutral
    - NWB active inversion / eversion below neutral
    - Reinforce **NO** stretching
- Knee/Hip exercises with no ankle involvement (e.g. leg lifts from sitting, prone, side-lying).

Precautions 8 - 12 weeks

- **Avoid** Full weight bearing stretching of tendon
- **Avoid** using eccentric loads which exceed the concentric ability
- **8 weeks Onwards:** Out of boot.
    - Refer to supervised physiotherapy
    - Increase Range of Motion of the ankle
        - active range of motion exercises for the ankle
        - functional mobilisation
    - Increase Strength
        - concentric / eccentric heel raising through available range
          (eccentric load = concentric load only)
        - strengthen all lower limb muscle groups as indicated:
          open / closed chain gluteal, hamstring & quadriceps exercises
    - Increase Neuromuscular Control
        - balance exercises – initially single leg static and progress as able
        - dorsiflexion stretching, slowly.
        - graduated resistance exercises
        - open and closed kinetic chain as well as functional activities.
        - proprioceptive and gait retraining.
- **10+ weeks:** Continue to progress ROM, strength.

Precautions 12-24 weeks

- No Max Isokinetic testing until 24 weeks
- Restore full tendon extensibility
    - weight bearing calf stretches off step
- Increase Strength Through Range
    - continue to strengthen through full active range

- Improve Eccentric capacity

  - eccentric calf exercises with loads that exceed concentric ability

24 weeks post injury +

- Restore Full Occupational & Sporting Function
  - occupation and sport specific rehab including return to running (when patient's calf strength 80% or greater than Involved)
  - commence early plyometric training e.g. skipping, double leg bounding (when patient's calf strength 80% or greater than uninvolved)
- Restore Optimal Calf Strength Concentrically & Eccentrically
  - Isokinetic testing (NB expect strength deficit of15%)
    Full Sports Specific training and Return to competitive Sport
  - end stage sports specific rehabilitation
- Patients are expected to return to full function including contact sports at 6 months.

Please contact the SORT-iT office in the Orthopaedic Outpatients Department at the Royal Infirmary of Edinburgh on 01312423545 if you have any questions or queries about this physiotherapy regime

Physiotherapy Guidelines following Lothian Physiotherapy Guidelines; Achilles Tendon Rupture – Surgical Repair Version 3 updated 19/9/2013

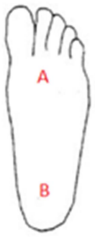
Appendix 6.2 – Pain Visual Analogue Scales

DATE: __/__/____ TIMEPOINT: _____

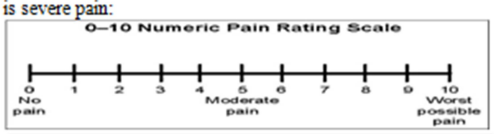
Foot Pain Scales

FOR YOUR INJURED FOOT:

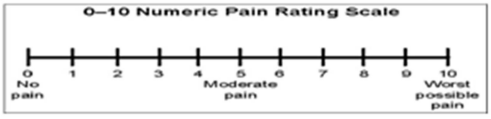
How much pain do you have today in the following areas? Please indicate the amount of pain on the scale below with an 'X', where 0 is no pain and 10 is severe pain:



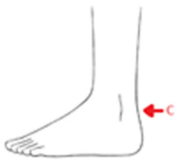
Area A: Forefoot sole

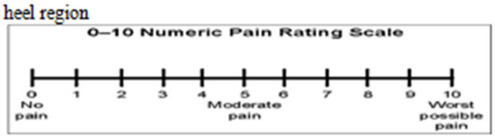


Area B: Hindfoot sole



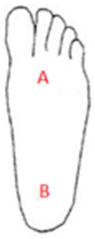
Area C: Posterior heel region



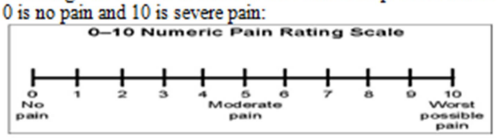


FOR YOUR UNINJURED FOOT:

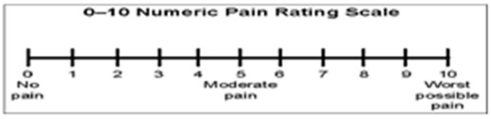
How much pain do you have today in the following areas? Please indicate the amount of pain on the scale below with an 'X', where 0 is no pain and 10 is severe pain:



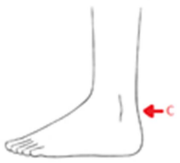
Area A: Forefoot sole

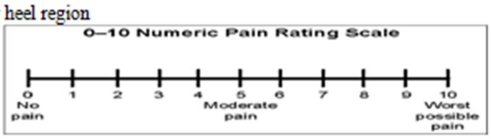


Area B: Hindfoot sole



Area C: Posterior heel region





Appendix 6.3 – PROMs Data

	SMFA Dysfunction Index	SMFA Bother Index	ATRS	EQ-5D-5L Index	EQ-5D VAS
Pre-Injury	4.41 (0.37 – 11.77)	0.00 (0.00 – 6.25)	100 (94.50 – 100)	1.000 (0.940-1.000)	90 (77.50-98.50)
Post-Injury	48.16 (43.38 – 57.91)	54.17 (42.71 – 63.54)	15.50 (8.25 – 25)	0.422 (0.205 – 0.543)	50 (40 – 67.50)
2 Months	40.08 (31.62 – 55.15)	33.33 (27.08 – 39.06)	28.50 (20.00 – 35.00)	0.554 (0.353-0.682)	67.50 (57.75 – 80)
3 Months	29.41 (21.87 – 36.76)	21.88 (14.58 – 27.08)	40.00 (30.00 – 44.00)	0.675 (0.590 – 0.735)	75.00 (70.00 – 85.00)
6 Months	7.36 (4.23 – 17.10)	8.33 (4.17 – 19.80)	56.00 (47.25 – 67.25)	0.751 (0.684 – 0.877)	80.00 (78.75 – 90.00)
9 Months	12.50 (10.29 – 16.91)	4.17 (2.08 – 10.42)	80.00 (60.00 – 86.00)	1.000 (0.906 – 1.000)	90.00 (80.00 – 95.00)
Controls	0.00 (0.00 – 1.84)	0.00 (0.00 – 2.08)	100.00 (100.00 - 100.00)	1.000 (1.000 – 1.000)	90.00 (85.00 – 98.00)

Appendix 6.3 Table 1. PROMs data for patients and controls at all time points.

Appendix 6.4 - REC Favourable Opinion Letter

NHS
Health Research Authority
South Central - Berkshire B Research Ethics Committee
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: 0207 104 8059

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

29 January 2019

Mr Nicholas Clement
Royal Infirmary of Edinburgh
51, Little France Crescent
Edinburgh
EH4 1NR

Dear Mr Clement

Study title:	**Plantar pressures after non-operative management of Achilles tendon rupture**
REC reference:	**18/SC/0699**
Protocol number:	**AC18128**
IRAS project ID:	**250756**

Thank you for your letter of 28 January 2019, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Advertising Poster]	1.0	25 November 2018
Covering letter on headed paper [Covering Letter]		06 December 2018
GP/consultant information sheets or letters [GP Information Sheet]	1.0	25 November 2018
Interview schedules or topic guides for participants [Patient Schedule]	1.0	06 December 2018
IRAS Application Form [IRAS_Form_11122018]		11 December 2018
IRAS Application Form XML file [IRAS_Form_11122018]		11 December 2018
IRAS Checklist XML [Checklist_24122018]		24 December 2018
IRAS Checklist XML [Checklist_18012019]		18 January 2019
IRAS Checklist XML [Checklist_28012019]		28 January 2019
Non-validated questionnaire [Foot Pain Scores]	1.0	06 December 2018
Non-validated questionnaire [Satisfaction and Recommendation Questionnaires]	1.0	06 December 2018
Other [Response to REC]	N/A	11 January 2019
Participant consent form [Consent form]	1.1	09 January 2019
Participant consent form [Consent form]	1.1	09 January 2019

Participant consent form [Consent form]	1.1	09 January 2019
Participant information sheet (PIS) [PIS]	1.1	09 January 2019
Participant information sheet (PIS) [PIS]	1.1	09 January 2019
Participant information sheet (PIS) [PIS]	1.1	09 January 2019
Research protocol or project proposal [Protocol v1.1]	1.1	09 January 2019
Research protocol or project proposal [Protocol v1.1]	1.1	09 January 2019
Summary CV for Chief Investigator (CI) [Nick Clement CV]		25 November 2018
Summary CV for student [Julian Maempel CV]		25 December 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Protocol Flowchart]	1.0	06 December 2018
Validated questionnaire [ATRS Questionnaire]		
Validated questionnaire [EQ 5D Questionnaire]		
Validated questionnaire [SMFA Questionnaire]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our RES Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

18/SC/0699	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

PP
Miss Elena Villarreal
Vice-Chair

Appendix 7 – Additional Supplementary Material

Appendix 7.1 Publications Arising from this Thesis

February 2023 - Socioeconomic deprivation status predicts both the incidence and nature of Achilles tendon rupture. Maempel JF, Clement ND, Mackenzie SP, McCann C, White TO. *Knee Surgery, Sports, Traumatology, Arthroscopy Journal* (official journal of the European Society of Sports, Traumatology, Knee Surgery and Arthroscopy) 2023 Feb;31(2):691-700. PubMed ID: 36066575.

July 2022 - The Epidemiology of Achilles Tendon Re-Rupture and Associated Risk Factors: Male gender, younger age and traditional immobilising rehabilitation are risk factors. Maempel JF, White TO, Mackenzie SP, McCann C, Clement ND. *Knee Surgery, Sports, Traumatology, Arthroscopy Journal* (official journal of the European Society of Sports, Traumatology, Knee Surgery and Arthroscopy) 2022 Jul;30(7):2457-2469. PubMed ID: 35018477.

September 2020 – A randomised controlled trial comparing traditional plaster cast rehabilitation with functional walking boot rehabilitation for acute Achilles tendon ruptures. Maempel JF, Clement ND, Duckworth AD, Keenan OJ, White TO, Biant LC. *American Journal of Sports Medicine*. 2020 Sep;48(11):2755-2764. PMID: 32816521.

July 2020 – Operative repair of acute Achilles tendon rupture does not give superior patient reported outcomes to non-operative management: results of a randomized controlled trial at a minimum of 13 years follow up. Maempel JF, Clement ND, Wickramasinghe NR, Duckworth AD, Keating JF. *Bone and Joint Journal*. 2020 Jul;102-B(7):933-940. PMID: 32600149.

Knee Surgery, Sports Traumatology, Arthroscopy
https://doi.org/10.1007/s00167-022-07103-2

ANKLE

Socioeconomic deprivation status predicts both the incidence and nature of Achilles tendon rupture

J. F. Maempel[1,2] · N. D. Clement[3] · S. P. Mackenzie[3] · C. McCann[3] · T. O. White[3,4]

Received: 15 September 2021 / Accepted: 3 August 2022

Abstract

Purpose The aim of this study was to describe the epidemiology of Achilles tendon rupture (ATR) and its relationship with socioeconomic deprivation status (SEDS). The hypothesis was that ATR occurs more frequently in socioeconomically deprived patients. Secondary aims were to determine variations in circumstances of injury between more and less deprived patients.

Methods A 6-year retrospective review of consecutive patients presenting with ATR was undertaken. The health-board population was defined using governmental population data and SEDS was defined using the Scottish Index of Multiple Deprivation. The primary outcome was an epidemiological description and comparison of incidence in more and less deprived cohorts. Secondary outcomes included reporting of the relationship between SEDS and patient and injury characteristics with univariate and binary logistic regression analyses.

Results There were 783 patients (567 male; 216 female) with ATR. Mean incidence for adults (≥ 18 years) was 18.75/100,000 per year (range 16.56–23.57) and for all ages was 15.26/100,000 per year (range 13.51 to 19.07). Incidence in the least deprived population quintiles (4th and 5th quintiles; 18.07 per 100,000/year) was higher than that in the most deprived quintiles (1st and 2nd; 11.32/100,000 per year; OR 1.60, 95%CI 1.35–1.89; $p<0.001$).

When adjusting for confounding factors, least deprived patients were more likely to be > 50 years old (OR 1.97; 95%CI 1.24–3.12; $p=0.004$), to sustain ATR playing sports (OR 1.72, 95%CI 1.11–2.67; $p=0.02$) and in the spring (OR 1.65, 95%CI 1.01–2.70; $p=0.045$) and to give a history of preceding tendinitis (OR 4.04, 95%CI 1.49–10.95; $p=0.006$). They were less likely to sustain low-energy injuries (OR 0.44, 95%CI 0.23–0.87; $p=0.02$) and to be obese (OR 0.25–0.41, 95%CI 0.07–0.90; $p\leq 0.03$).

Conclusions The incidence of ATR was higher in less socioeconomically deprived populations and the hypothesis was therefore rejected. Significant variations in patient and predisposing factors, mechanisms of injury and seasonality were demonstrated between most and least deprived groups, suggesting that circumstances and nature of ATR may vary with SEDS and these are not a homogenous group of injuries.

Level of Evidence Prognostic Study Level III.

Keywords Achilles tendon · Tendon, · Rupture · Epidemiology · Socioeconomic deprivation

Abbreviations

ATR	Achilles tendon rupture
SEDS	Socioeconomic deprivation status
LD	Least deprived
MD	Most deprived
NHS	National health service
REC	Regional ethics committee
NRS	National records of Scotland
SIMD	Scottish index of multiple deprivation
IQR	Inter-quartile range
FET	Fisher's exact test

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3 Edinburgh Orthopaedics, Royal Infirmary of Edinburgh, Edinburgh, United Kingdom

4 University of Edinburgh Medical School, Edinburgh, United Kingdom

Published online: 06 September 2022

Introduction

Achilles tendon rupture (ATR) is a common soft-tissue injury and the incidence is rising [16, 19, 30, 36]. ATR occurs most frequently in middle-aged adults and males are most frequently affected [16, 19]. They occur most commonly during sporting activity and seasonal variation in incidence has been described [16, 17, 32, 36].

The epidemiology of ATR has previously been described in general terms [16, 19, 26, 36, 38]; however, the influence of socioeconomic deprivation status (SEDS) on the incidence of ATR is unknown. SEDS has been shown to influence the epidemiology of musculoskeletal pain [41] and various orthopaedic conditions, including carpal tunnel syndrome [21], proximal humeral fractures [11], osteoarthritis of the hand, hip and knee [31] and adult trauma [13] and fractures [15] in general. An improved understanding of the potential influence of SEDS on the epidemiology of ATR may give insight into underlying causes and provide important information about at-risk populations that may aide planning of medical service provision, while detailed analysis of the circumstances of injury will give clinicians more insight into the clinical features of ATR in different population groups, which may provide opportunities for targeted preventive or treatment interventions.

The aim of this study was to describe the incidence and epidemiology of ATR in a defined population and the association with SEDS. The hypothesis was that ATR occurs more frequently in socioeconomically deprived patients. The secondary aim was to determine whether there were variations in previously described risk factors and features of ATR between more and less socioeconomically deprived individuals with ATR.

Materials and methods

This study was part of a departmentally approved service review of ATR which was reviewed by the scientific officer for the regional ethics committee (REC) who advised that REC review was not necessary. A retrospective electronic search of all medical records was undertaken to identify patients treated for ATR between 1st January 2011 and 31st December 2016 at NHS Lothian health-board. The health-board is the only authority overseeing delivery of regional healthcare services and there are no other National Health Service (NHS) providers in this region. Emergency services are provided through three emergency departments and one minor injuries unit; orthopaedic surgery is performed at two locations and outpatient clinics are based at five locations. There are two private hospitals in the region, but none have an emergency department, and therefore, acute presentations

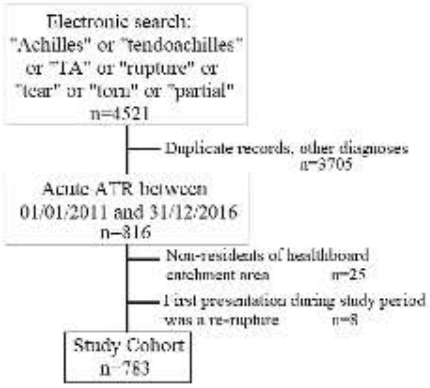

Fig. 1 Flow diagram for the study cohort

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Achilles tendon rupture	Achilles tendinitis without rupture
Date of injury 01/01/2011–31/12/2016	Patients whose first presentation during the study period was a re-rupture of the Achilles tendon
Patients residing within the health-board geographical region as defined by the Scottish Government National Records of Scotland Small Area Population Estimate data zones (i.e., patients residing within the 1089 data zones that make up the health-board catchment area), even if: • They initially presented elsewhere and only returned to the health-board for on-going care • They presented initially to the health-board but subsequently underwent on-going care in the private sector	Patients residing outwith the health-board geographical region as defined by Scottish Government National Records of Scotland Small Area Population Estimate data zones (i.e., patients residing outwith the 1089 data zones that make up the Health-board catchment area)

are rooted through the NHS and should be identified by the search algorithm employed.

All medical records in the health-board are electronically recorded and were screened for the following search terms: "Achilles", "tendoachillies", "TA", "rupture", "tear", and "torn". The search returned 4521 records. Each was screened according to the inclusion and exclusion criteria (Table 1), leaving 783 patients who form the study cohort (Fig. 1).

The health-board population (total, gender-specific and with reference to age brackets) for each year of study was determined using Scottish Government population data from the National Records of Scotland (NRS), who issue annual mid-year population estimates for each health-board [27]. SEDS was determined using the Scottish Index of Multiple Deprivation (SIMD-16) [34], an official Scottish government resource that takes into account employment, income, crime, housing, health, education and access to services to assess and classify population SEDS across 6500 data zones nationwide. Each data zone is ranked by SIMD and placed into the appropriate quintile of the national population. SIMD data are published for each data zone and the health-board population serves a geographic region made up of 1083 data zones. Data for these data zones were combined to determine the socioeconomic deprivation status characteristics of the health-board population. Patients were matched to their corresponding data zone using their postcode. SEDS data were available for all patients. They were categorised into quintiles on an ordinal scale where quintile one represents the most deprived 20% of the national population and quintile 5 represents the least deprived 20%.

A history of preceding tendinitis was defined as preceding pain or a formal diagnosis of tendinitis in the 6 months preceding ATR. Body mass index (BMI) was determined from height and weight documented at the closest-available time-point to injury; this was known for 74.5% of patients ($n = 583/783$). Seasonality was defined according to the meteorological system. Late presentation was defined as presentation ≥ 14 days after injury. Four patients who underwent on-going follow-up for their injury at institutions elsewhere despite initial presentation to the NHS were excluded from analyses pertaining to complications.

Statistical analysis

The primary outcome was an epidemiological description and comparison of incidence in the more and less deprived population cohorts. Secondary outcomes included reporting of the relationship between SIMD and patient and injury characteristics. The annual incidence of ATR per 100,000 was calculated as the number of cases occurring between 1st January and 31st December, divided by the health-board population (or relevant population bracket), as defined in the mid-year population estimate for that year. The resulting figure was multiplied by 100,000. SIMD data are released quadrennially and the SIMD-16 dataset was used. The incidence of ATR in each SIMD quintile per 100,000 population per year was determined by calculating the average annual occurrences in the quintile over the study period and dividing this by the SIMD-16 quintile health-board population, then multiplying the resulting number by 100,000.

The ATR cohort was then subdivided into most deprived (MD; comprising of patients in quintiles 1 and 2) and least deprived (LD; patients in quintiles 4 and 5) subgroups for further analysis. Within this cohort, data parametricity was assessed using Kolmogorov–Smirnov testing. Non-parametric data were compared using independent samples Mann–Whitney *U* tests. Nominal variables were compared using Chi-squared tests (or Fisher's exact test if cell count was < 5 in any cell). Binary logistic regression was undertaken to identify variables that were independently associated with SEDS. Variables were included in the regression analysis if $p \leq 0.1$ on univariate analysis. This lax threshold was chosen, since a relationship that is narrowly statistically insignificant on initial analysis may be found to be statistically significant after adjusting for confounding relationships. A p value of ≤ 0.05 was considered significant [12].

Results

Epidemiology of ATR

Seven hundred and eighty three patients (567 males, 72% and 216 females, 28%) residing in the catchment population sustained a primary ATR during the study period. Median age was 48 years for both females (IQR 41–65) and males (IQR 38–60). Median BMI was 26.6 (IQR 24.2–30.4). Forty-nine patients (6.3%) were 'late presenters'.

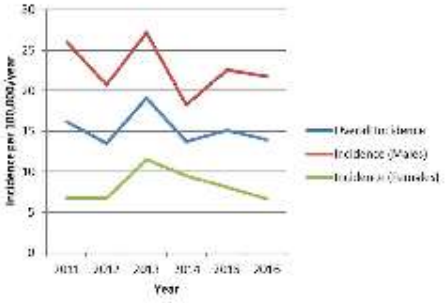

Fig. 2 Annual incidence of Achilles tendon rupture across all age groups

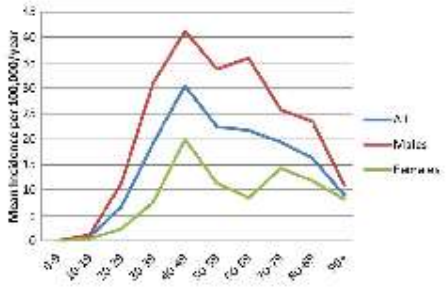

Fig. 3 Mean annual incidence per 100,000 in each 10 year age bracket

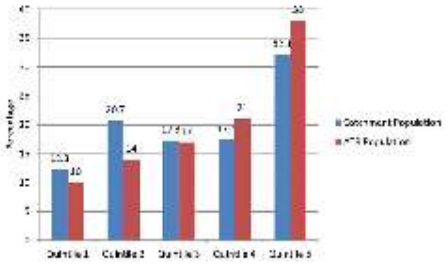

Fig. 4 Percentage of individuals in each SIMD social deprivation quintile for Achilles tendon rupture cases (n = 783) and for the whole population of the health-board area (n = 858,090). The relative incidence is lower in the most deprived quintiles, crossing over around the third quintile, and it is higher in the least deprived quintiles

The mean incidence of ATR for all ages over the study period was 15.26/100,000 per year (range 13.51 to 19.07; Fig. 2) and was higher in males (22.73/100,000 per year, range 18.22–27.12) than females (8.19/100,000 per year, range 6.63–11.45; OR 2.88, 95% CI 1.29–6.43; $p = 0.007$). The mean incidence in adults (≥ 18 years) was 18.75/100,000 per year (range 16.56–23.57). Age-related incidence was bimodal, peaking in the fifth decade for both sexes (Fig. 3).

The incidence of ATR in each SIMD quintile (Fig. 4) of the health-board population is shown in Table 2. There was a statistically significant relationship between SIMD and incidence of ATR, with patients in the least deprived group (4th and 5th national quintiles) demonstrating significantly higher incidence of ATR (18.07/100,000 per year) than those in the most deprived (1st and 2nd quintiles) group (11.32/100,000 per year; OR 1.60, 95%CI 1.35–1.89; $p < 0.001$).

Patient and injury characteristics and variation with SIMD

Patient demographics

There was no significant difference in gender or ethnicity between most and least deprived groups. However, patients in the most deprived group were younger (median age 47, IQR 39–56.5 vs 48, IQR 40–63; $p = 0.05$) and had a higher BMI (27.8, IQR 25.2–33.4 vs 26.04, IQR 23.9–29.2; Table 3).

Seasonality of ATR

ATR occurred most frequently during the summer and June was the mode month of injury for both groups (Fig. 5a, b). However, there were statistically insignificant trends towards relative higher incidence of springtime injuries and lower incidence of summertime injuries in the least deprived group (Table 4).

Table 2 Incidence of Achilles Tendon rupture in the health-board population by social deprivation quintile

	Achilles tendon rupture	Health-board population excluding ATR[a]	Total health-board population[a]	Average incidence/100,000 per year[b]	Odds ratio (95%CI)	*P* value
Quintile 1	81	106,341	106,522	12.70	Reference	
Quintile 2	112	177,816	177,928	10.49	0.83 (0.62–1.10)	ns
Quintile 3	129	148,457	148,586	14.47	1.14 (0.86–1.50)	ns
Quintile 4	163	149,453	149,598	18.38	1.45 (1.11–1.89)	0.0061
Quintile 5	296	275,363	275,656	17.90	1.41 (1.10–1.80)	0.0059
Total	783	857,307	858,090			

[a]Health-board population as per SIMD-16 dataset

[b]Calculated from incidence over six year study period, divided by 6

Table 3 Baseline characteristics for patients, according to social deprivation status

	Most deprived (quintiles 1 and 2)	Least deprived (quintiles 4 and 5)	*P* value
Gender (male/female)			
Male	141 (73.1%)	340 (75.8%)	ns*
Female	52 (26.9%)	121 (26.2%)	
Age (median, IQR)	47 (39–56.5)	48 (40–63)	0.050**
Ethnicity			
White British	162	387	ns†
White Other	11	22	
Asian	3	6	
Black	4	4	
Other	3	5	
Unknown	12	30	
BMI (median, IQR)	27.78 (25.16–33.41)	26.04 (23.87–29.28)	< 0.001**

*Chi Square test; **Independent samples Mann–Whitney *U* test. †Chi-square test for proportion of patients who self-identified as White British (including Scottish) compared to all other known ethnicities

Mechanism of injury

The mechanism of injury was known in 772 (98.6%) cases and sport-related injuries accounted for the majority (388 of 772, 50.3%). Both sporting and non-sporting injuries exhibited temporal variations in incidence through the year, being commonest in summer (Appendix Fig. 6). Patients in the least deprived group were more likely to sustain sporting injuries (55.6% vs 42.3%; $p = 0.002$; OR 1.71, 95%CI 1.21–2.40) and less likely to sustain low-energy injuries (7% vs 12.7%; $p = 0.02$; OR 0.52, 95%CI 0.3–0.91; Table 5). Among sport-related ATR, the type of sport also varied with SEDS (Table 6).

Predisposing events

Less deprived patients were more likely ($p = 0.01$; OR 3.29, 95%CI 1.27–8.50) to give a history of recent symptomatic tendinitis (37 of 460; 8.04%), than their more deprived counterparts (5 of 193; 2.59%). Patients in the most deprived group had a higher incidence of inflammatory arthropathy (3 of 193) than those in the least deprived group (7 of 461; $p = 0.049$; OR 2.81, 95%CI 1.003–7.85); however, there was no detectable difference in recorded use of corticosteroids or fluoroquinolones in the 6 months preceding ATR (n.s.).

Complications

Tendon re-rupture occurred in 42 of 779 patients (5.4%), and there was no difference in incidence between most (9 of 192, 4.7%) and least (28 of 459, 6.1%) deprived groups (OR 1.32, 95%CI 0.61–2.86; n.s.). Symptomatic venous thromboembolism occurred in 27 of 779 patients (3.5%), and there was no difference in incidence between most (5 of 192, 2.6%) and least (17 of 459, 3.7%) deprived groups (OR 1.44, 95%CI 0.52–3.96; n.s.).

Regression model

Binary logistic regression demonstrated independent variations in patient factors, mechanism of injury, and seasonality with SEDS (Table 7). Patients in the least deprived group were more likely to be aged > 50 years (OR 1.97, 95%CI 1.24–3.12; $p = 0.004$), more likely to sustain sport-related injuries (OR 1.72 (95%CI 1.11–2.67; $p = 0.02$), and less likely to suffer low-energy injuries (OR 0.44, 95%CI 0.23–0.87) and also less likely to be obese ($p \leq 0.03$). Spring time injuries were commoner in the least deprived group (OR 1.65, 95%CI 1.01–2.70; $p = 0.045$), as was a history of preceding tendinitis ($p = 0.006$; OR 4.04, 95%CI 1.49–10.95).

Discussion

The most important finding of the present study was a significant variation in the incidence and nature of ATR with socioeconomic deprivation status. This study demonstrated a higher incidence of ATR in patients with lower levels of socioeconomic deprivation and the hypothesis was therefore rejected. In addition, SEDS has been shown to be associated with independent variations in patient factors, mechanisms of injury, and seasonality in patients presenting with ATR, suggesting that the circumstances and nature of ATR may vary with SEDS status. This is the first study to assess the relationship between SEDS and ATR.

Patient demographics in this study were similar to those reported in other large epidemiological studies, suggesting

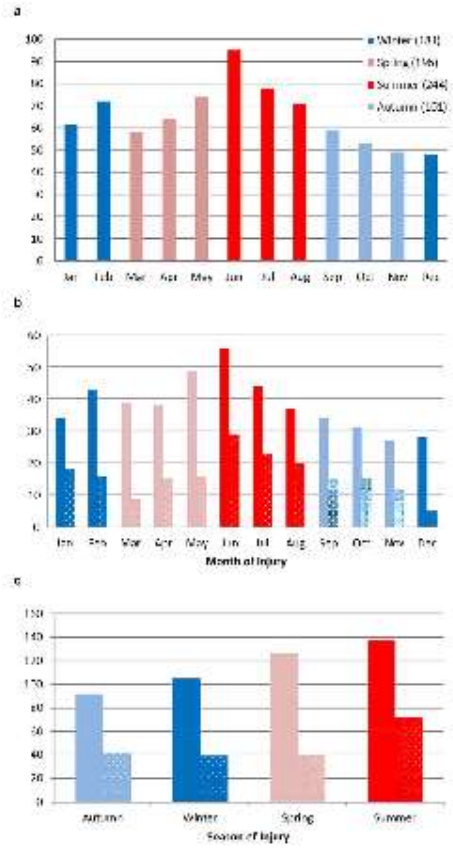

Fig. 5 a Monthly occurrence of Achilles tendon rupture with seasonal colour coding for the whole cohort. b Monthly incidence of ATR in relation to social deprivation status. Solid bars represent the LD cohort and spotted bars represent the MD cohort. c Seasonal incidence of ATR in relation to social deprivation status. Solid bars represent the LD cohort and spotted bars represent the MD cohort

that the study population was representative of general ATR populations encountered elsewhere [16, 19]. This lends credence to the findings and could suggest that the novel findings reported in this study may also mirror those elsewhere; however, this cannot be known until studies assessing the relationship between SIMD and ATR are repeated in other geographical regions. Previous studies have reported wide variation in incidence of ATR [16, 23, 26, 36, 38] and the incidence reported in this study falls centrally within this range. Interestingly, studies reporting a higher incidence of ATR originate largely in Scandinavia, in countries that score very highly on socioeconomic indices, even in comparison to the United Kingdom [18]. This would appear to support the finding of higher incidence of ATR being associated with lower levels of deprivation.

SIMD has been shown to influence the epidemiology of traumatic injuries [11, 13, 15, 42], osteoarthritis [31], musculoskeletal [21, 41], and non-orthopaedic [9] conditions. However, the relationship identified with ATR is the inverse of that seen with respect to all the above, where increasing levels of deprivation are associated with higher rates of incidence [9, 11, 13, 15, 21, 31, 41]. This has important implications for the planning of clinical services and resource allocation in relation to the population served. It is known that individuals with lower levels of deprivation are more active and have higher levels of sports participation [6, 22, 43], potentially predisposing them to ATR. Differing activity profiles may therefore contribute significantly to differences in the incidence of ATR with SIMD.

The male preponderance for ATR observed in this and other studies [1, 16, 19, 24, 45] did not vary with SIMD and is unlikely to be a major driver of the discrepancy in ATR across different SIMD categories. There was a notably higher proportion of patients > 50 years old in the LD group and there may be an association between trends towards increased incidence of ATR in older patients [16, 19] and the higher incidence of ATR in LD individuals. Seasonality is another known predictor of ATR, and others have similarly reported higher incidence in summer and spring [8, 36]. The reasons for these discrepancies are unknown, but may relate to certain injury mechanisms [16], including sporting preferences [38], exhibiting seasonal variation, or other factors, such as SIMD, which has, for the first time, been shown to have an association with seasonality. However, even after adjusting for mechanism of injury and other confounders,

Table 4 Seasonality of injuries in MD and LD groups. Odds ratio (OR) is reported for the least deprived cohort relative to the most deprived cohort

	Most deprived (%)	Least deprived (%)	OR (95% CI)	*P* value
Autumn	42 of 195 (21.5)	92 of 460 (20)	0.90 (0.60–1.36)	ns
Winter	39 of 195 (20.2)	103 of 460 (22.8)	1.17 (0.77–1.77)	ns
Spring	40 of 195 (20.7)	126 of 460 (27.4)	1.44 (0.96–2.16)	0.074
Summer	72 of 195 (37.3)	137 of 460 (29.8)	0.71 (0.50–1.02)	0.059

Table 5 Mechanism of injury for whole cohort and for most and least deprived patients. [a]Patients in the two most deprived national quintiles. [b]Patients in the two least deprived national quintiles. Odds ratio (OR) is reported for the least deprived cohort relative to the most deprived cohort

	Whole cohort	Most deprived[a] (n = 180)	Least deprived[b] (n = 455)	OR (95%CI)	*P* value
Sport	388 (50.3%)	60 (42.3%)	253 (55.6%)	1.71 (1.21–2.40)	0.002
Walking	55 (7.1%)	14 (7.8%)	30 (6.6%)	0.88 (0.46–1.70)	ns
Low energy: slip, trip, stumble, ankle inversion, or fall from standing height	68 (8.8%)	24 (13.3%)	32 (7%)	0.52 (0.3–0.91)	0.02
Fall (> standing height)	17 (2.2%)	5 (2.8%)	9 (2%)	0.74 (0.25–2.25)	ns
Open injury	8 (1%)	4 (2.1%)	2 (0.4%)	0.20 (0.04–1.12)	ns
Blunt trauma	10 (1.3%)	3 (1.6%)	7 (1.5%)	0.97 (0.25–3.79)	ns
Running (non-sports)	20 (2.6%)	7 (3.7%)	9 (2%)	0.53 (0.19–1.45)	ns
Jumping (non-sports)	13 (1.7%)	3 (1.6%)	9 (2%)	1.25 (0.34–4.67)	ns
Dancing	81 (10.5%)	18 (9.5%)	48 (10.5%)	1.12 (0.63 to 1.98)	ns
Pushing/lifting heavy objects	21 (2.7%)	4 (2.1%)	12 (2.6%)	1.25 (0.4–3.84)	ns
Standing up from sitting/lying	13 (1.6%)	4 (2.1%)	5 (1.1%)	0.51 (0.14–1.84)	ns
Stairs/steps	41 (5.3%)	15 (7.9%)	19 (4.2%)	0.51 (0.25–1.02)	0.052
No specific event	23 (3.0%)	4 (2.1%)	12 (2.6%)	1.35 (0.40–3.54)	ns
Other	16 (2.1%)	4 (2.1%)	8 (1.8%)	0.85 (0.23–2.78)	ns
Total	772	199	453		

Table 6 Sport-related ATR and socioeconomic deprivation status.

	Whole cohort	Most deprived[a] (n = 80)	Least deprived[b] (n = 253)	OR (95% CI)	*P* value
Soccer	174	45 (56.2%)	107 (42.3%)	0.57 (0.34–0.95)	0.029
Racket sports	86	11 (13.8%)	63 (24.9%)	2.08 (1.04–4.18)	0.037
Gym/gym class	14	0 (0%)	10 (4.0%)	1.33 (1.25–1.42)	ns
Basketball/Netball	23	7 (8.8%)	11 (4.3%)	0.52 (0.20–1.37)	ns
Running/Jogging	22	5 (6.2%)	13 (5.1%)	0.81 (0.28–2.35)	ns
Rugby	17	3 (3.8%)	12 (4.7%)	1.28 (0.35–4.65)	ns
Other	52	9 (11.2%)	36 (14.2%)	1.31 (0.60–2.85)	ns
Total	388	80	253		

[a]Patients in the two most deprived national quintiles

[b]Patients in the two least deprived national quintiles. Odds ratio (OR) is reported for the least deprived cohort relative to the most deprived cohort

seasonal variation was confirmed, suggesting a degree of independence between these factors and that injury mechanism alone does not explain the differences in seasonal variation observed between deprivation groups.

Mechanism of injury also varied with SEDS. Sporting injuries accounted for the majority of ATR, particularly in the LD group. Socioeconomic deprivation is known to be associated with reduced participation in sports and physical activity [2, 22, 49] and this would support our findings. It may be one reason why ATR, unlike many other medical afflictions, is commoner in less deprived individuals and also supports the finding that incidence of ATR in the study population was lower than that in some Scandinavian studies, since Scandinavian populations are known to be especially active [43]. Racket sports are considered a "textbook" mechanism of injury for ATR. While these were common injuries, soccer accounted for approximately double the number of ATR in this study. Variations in the type of sporting activity engaged in at the time of injury were also observed between SEDS groupings, with soccer being commoner among MD individuals and racket sports being commoner amongst LD individuals. It is known that less deprived individuals are more likely to engage in solo sports and reasons for this may include cost and access to facilities [20]. MD individuals were also more likely to sustain low-energy ATR, which is consistent with higher levels of sedentary lifestyle reported in this demographic group [43].

There is little evidence to support [35] or refute [28] a link between BMI and the incidence of ATR. There is, however, a well-known association between increasing levels

Table 7 Binary logistic regression model for more and less deprived patients

	Adjusted odds ratio (95%CI)	*P* value
Age		
40–60 years	Reference	
< 40 years	0.86 (0.533–1.39)	ns
> 60 years	1.97 (1.24–3.12)	0.004
MOI		
Other	Reference	
Sports	1.72 (1.11–2.67)	0.02
Steps	0.53 (0.24–1.18)	ns
Low energy	0.44 (0.23–0.87)	0.02
Open laceration	0.26 (0.04–1.60)	ns
Season		
Summer	Reference	
Autumn	1.14 (0.69–1.87)	ns
Winter	1.34 (0.81–2.23)	ns
Spring	1.63 (1.01–2.70)	0.045
Preceding Conditions		
Preceding tendinitis	4.04 (1.49–10.93)	0.006
Inflammatory arthropathy	0.33 (0.18–1.03)	0.057
Diabetes mellitus	0.75 (0.37–1.54)	ns
BMI		
< 25	Reference	
25–29.99 (overweight)	0.74 (0.44–1.26)	ns
30–34.99 (class I obesity)	0.41 (0.22–0.76)	0.005
35–39.99 (class II obesity)	0.27 (0.12–0.63)	0.002
> 40 (class III obesity)	0.25 (0.07–0.90)	0.03
BMI Unknown	0.61 (0.36–1.04)	ns

The more deprived group is the reference group and all adjusted odds ratios are reported for the least deprived group relative to the more deprived group. BMI is classified as per WHO categories for the purpose of this model

of social deprivation and increasing BMI [4, 33] and this is likely to explain the increased BMI in the MD group. This may have implications on treatment outcomes for ATR in deprived patients, since both surgical complications [7] and inadequacy of ankle plaster immobilisation [5] are commoner in obese patients.

LD group patients were more likely to give a history of tendinitis prior to ATR. Conversely, a history of inflammatory arthropathy was commoner in the MD group, although this trend was not statistically significant on regression analysis. Inflammatory arthropathies are known to occur more commonly in more deprived individuals [3] and have also been linked to ATR [35]. Although these cases make up only a small proportion of total ATR, the findings do suggest that there are significant variations in patient factors, co-morbidities, and preceding symptoms across SIMD groupings, which may account for some of the variation in incidence observed with SIMD.

Taken together, these findings suggest that the cause of ATR is multifactorial, with differences identified in mechanism of injury, seasonality, and patient factors between more and less deprived groups. Re-rupture [25] and venous thromboembolism [29] are feared complications after VTR, and have been associated with worse outcomes [39, 44], but complication rates did not vary with SIMD.

This study does have limitations, including its retrospective nature and the potential for type II error when analysing some less common variables. In addition, it is possible that patients may have developed complications and been treated for these elsewhere, resulting in an under-estimation of complication rates.

Unlike registry or database epidemiological studies, which are limited by the collection of only basic demographic data [16, 19, 23, 26, 36], this study permitted more detailed analysis of the circumstances surrounding injuries, including the mechanism of injury, co-morbid conditions, and preceding symptoms, giving clinicians a comprehensive picture of the epidemiology and clinical features of ATR at population level. Further research should now seek to compare treatment outcomes and to assess the efficacy of tailored preventive and educational interventions across these groups, using the reported novel information to target interventions.

This study is clinically relevant, since it documents a new association between socioeconomic deprivation status and ATR, which has important implications for health service planning and resource allocation, particularly as socioeconomic deprivation status is known to exhibit marked geographic variation [34]. Furthermore, it has previously been reported that ATR are frequently misdiagnosed or missed on presentation [14, 40] and chronic injuries are often associated with poor outcomes and present a treatment challenge to clinicians [10, 37]. A better understanding of the epidemiology and nature of these injuries will increase clinician awareness and reduce the risk of missed injuries. It should prompt clinicians to consider this diagnosis in situations where it may not otherwise have been the primary differential diagnosis. For example, ATR may not immediately be considered in a patient with a low-energy non-sporting injury, which has been shown to be relatively common, particularly in more socioeconomically deprived patients, in this study. Similarly, older individuals are not traditionally considered to be typical ATR patients. The reporting of a bimodal incidence with a second peak in older patients, more marked in less deprived individuals, should raise awareness

among clinicians that ATR are not exclusively injuries of the young adult, as they are commonly perceived to be.

Conclusion

The incidence of ATR was related to SIMD, being higher in patients with lower levels of deprivation. Furthermore, significant variations in patient and predisposing factors, mechanisms of injury, and seasonality were demonstrated between more and less deprived patients with acute ATR, suggesting that the circumstances and nature of ATR may vary with SIMD status and that these are not a homogenous group of injuries.

Appendix

See Fig. 6.

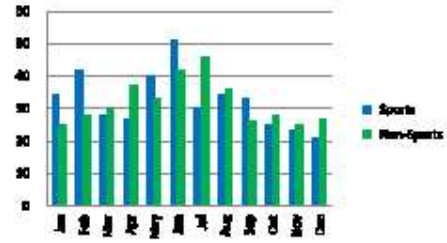

Fig. 6 Month of injury for sporting and non-sporting injuries.

Author contributions JM: concept/idea for study, data collection, review and analysis, drafting of manuscript, and editing of manuscript; NDC: guidance with study design, assistance with statistical analysis, and editing of manuscript; SPM: data collection and manuscript editing; CMcC data collection and manuscript editing; TOW: guidance with study design and manuscript editing.

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Declarations

Conflict of interest The authors have no conflicts of interest to declare.

Ethical approval This study was part of a departmentally approved service review of ATR which was reviewed by the scientific officer for the regional ethics committee (REC) who advised that REC review was not necessary.

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The epidemiology of Achilles tendon re-rupture and associated risk factors: male gender, younger age and traditional immobilising rehabilitation are risk factors

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Abstract

Purpose The aim of this study was to describe the epidemiology of Achilles tendon re-rupture. Secondary aims were to identify factors predisposing to increased Achilles tendon re-rupture risk, at the time of primary Achilles tendon rupture.

Methods A retrospective review of all patients with primary Achilles tendon rupture and Achilles tendon re-rupture was undertaken. Two separate databases were compiled: the first included all Achilles tendon re-rupturespresenting during the study period and described epidemiology, mechanisms and nature of the re-rupture; the second was a case–control study analysing differences between patients with primary Achilles tendon rupture during the study period, who did, or did not, go on to develop re-rupture, with minimum review period of 1.5 years.

Results Seven hundred and eighty-three patients (567 males, 216 females) attended with primary Achilles tendon rupture and 48 patients (41 males, 7 females) with Achilles tendon re-rupture. Median time to re-rupture was 98.5 days (IQR 82–122.5), but 8/48 re-ruptures occurred late (range 3 to 50 years) after primary Achilles tendon rupture. Males were affected more commonly (OR = 7.40, 95% CI 0.91–60.15; $p = 0.034$). Mean Achilles tendon re-rupture incidence was 0.94/100,000/year for all ages and 1.16/100,000/year for adults (≥ 18 years). Age distribution was bimodal for both primary Achilles tendon rupture and re-rupture, peaking in the fifth decade, with secondary peaks in older age. Incidence of re-rupture was higher in less socioeconomically deprived sub-populations (OR = 2.01, 95%CI 1.01–3.97, $p = 0.04$). The majority of re-ruptures were low-energy injuries. Greater risk of re-rupture was noted for patients with primary rupture aged < 45 years [adjusted odds ratio (aOR) 1.96; $p = 0.037$] and those treated with traditional cast immobilisation (aOR 2.20; $p = 0.050$).

Conclusion The epidemiology of Achilles tendon re-rupture is described and known trends (e.g. male predilection) are confirmed, while other novel findings are described, including incidence of a small but significant number of late re-ruptures, occurring years after the primary injury and an increased incidence of re-rupture in less socioeconomically deprived patients. Younger age and traditional immobilising cast treatment of primary Achilles tendon rupture were independently associated with Achilles tendon re-rupture.

Level of evidence III.

Keywords Achilles tendon · Tendon · Rupture · Re-rupture

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Abbreviations

ATR	Achilles tendon rupture
ATRR	Achilles tendon re-rupture
FET	Fisher's exact test
NHS	National Health Service
REC	Regional ethics committee
SEDS	Socioeconomic deprivation status
SIMD	Scottish Index of Multiple Deprivation

Introduction

Primary Achilles tendon ruptures (ATR) are common soft tissue injuries and their incidence is rising [4, 13, 21]. Achilles tendon re-rupture (ATRR) is a much-feared and widely discussed complication of primary ATR [26, 31, 45]. Despite the significant publicity given to ATRR, the rate of which is widely reported in studies on ATR and whose occurrence has been an outcome measure of multiple randomised studies [19, 23] and meta-analyses [26, 31, 34] in the field, studies detailing the epidemiology of ATRR are lacking. This is in contrast to the epidemiology of primary ATR, which is extensively documented and whose incidence is known to have risen in recent decades [13, 21, 40]. This is surprising, given that ATRR is by far the most frequently reported complication of primary ATR [26, 31, 34] and that it is also known to be associated with poorer patient reported and functional outcomes and lower rates of return to sports [27, 45] than uncomplicated primary ATR, while patients who sustain ATRR are subjected to further treatment that oftenrequires additional surgery and further prolonged periods of rehabilitation [25, 30, 45].

It is unclear which patients with primary ATR are at increased risk of ATRR and only a few studies have attempted to identify risk factors for ATRR [15, 17, 35, 44], with most of these unable to identify any [15, 17, 44]. Despite otherwise similar outcomes [10, 12, 24, 31], surgical repair may result in a small reduction in re-rupture rate, although the relative risk reduction is small and often only identifiable when results from individual studies are pooled into meta-analyses [31] and this potential benefit must be weighed against the risk of potential surgical complications [42]. Although it is believed that modern functional rehabilitation regimes for primary ATR may be associated with lower levels of ATRR than traditional immobilising regimes, the authors of a previous meta-analysis indicated a lack of direct evidence in this regard [26]. Subsequent randomised controlled trials comparing traditional and functional rehabilitation have suggested trends towards higher re-rupture rate with traditional immobilising techniques, but these were not statistically significant [8, 22, 23]. A better understanding of the risk factors for ATRR would allow higher risk patients to be identified and counselled accordingly and any modifiable risk factors identified may present opportunities to reduce the risk of ATRR.

The primary aim of this study was to describe the epidemiology of ATRR. The hypothesis was that males would be more commonly affected than females. The secondary aim of this study was to determine whether it is possible to identify factors that predispose patients to increased risk of ATRR at the time of primary ATR.

Materials and methods

This study was part of a departmentally approved service review of ATR which was reviewed by the scientific officer for the regional ethics committee (REC) who advised that REC review was not necessary. A retrospective electronic search of all health-board medical records was undertaken to identify patients treated for primary ATR and ATRR between 1st January 2011 and 31st December 2016. All records in the health board are electronically recorded and were searched for the following search terms: "Achilles", "tendoachilles", "TA", "rupture", "tear", "torn". The search returned 4521 records. Each was screened according to the inclusion and exclusion criteria (Table 1), leaving 791 patients eligible for inclusion in this study. Records were assessed up to the time of study, with a minimum review period of 1.5 years after primary ATR. The nature and

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Any Achilles tendon rupture (primary or re-rupture) within the period 01/01/2011–31/12/2016	Patients residing out with the health-board geographical region
Rupture of any anatomic region of the Achilles tendon	
Patients residing within the health-board geographical region as defined by the Scottish Government National Records of Scotland Small Area Population Estimate data zones (i.e. patients residing within the 1083 data zones that make up the health-board catchment area), even if they initially presented elsewhere and only returned to the health board for ongoing care	For part 2 only: •Patients whose first presentation during the study period was with a re-rupture •Patients who initially presented to the health board with their primary ATR but completed their treatment for this injury elsewhere

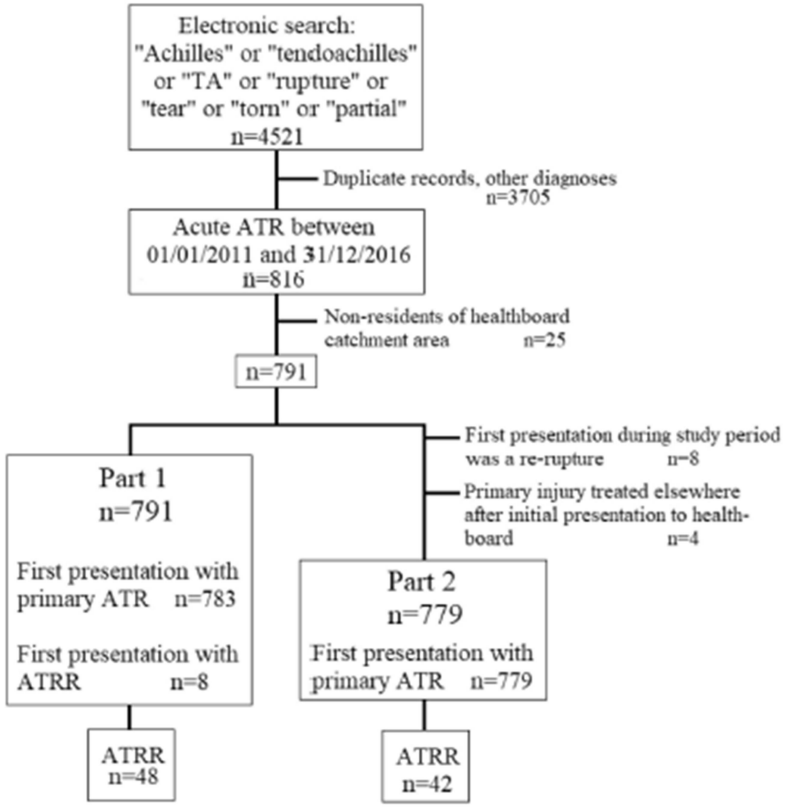

Fig. 1 Flow diagram for the study. Part 1 consists of 791 acutely presenting ATR, including eight patients whose first presentation during the study period was with a re-rupture and 783 who first presented with a primary ATR. Of these 783, 40 developed a subsequent re-rupture between January 2011 and December 2016. Thus, there were 48 ATRR in total, occurring between January 2011 and December 2016. This data was used for epidemiological descriptions relating to ATRR during the study period and for comparison of presenting features of the 48 identified ATRR with those of primary ATR injuries. Part 2 consists of 779 patients presenting with acute primary ATR between January 2011 and December 2016, who completed treatment for the primary injury at the study institution. In this group, there were 42 patients with ATRR, comprising the 40 patients mentioned previously in part 1 and a further 2 patients who had presented with primary ATR before December 2016, but who developed an ATRR during the review period after 1st January 2017. This data was used to compare variables at primary ATR presentation for patients who did and did not go on to develop ATRR to determine whether any risk factors for ATRR at the time of presentation with primary ATR could be identified

circumstances of primary ATR and ATRR were recorded. ATR was diagnosed clinically, with ultrasound used at the discretion of the treating physician if there was doubt as to the diagnosis. Two separate databases were compiled from this data (Fig. 1): the first, consisting of 791 entries, which included any patient presenting with a rupture (either primary ATR or ATRR) between 2011 and 2016, for the epidemiological study of ATRR; the second database, consisting of 779 entries, included only patients presenting with a primary ATR during the study period and completing treatment for this at the study institution and recorded re-ruptures occurring at any subsequent time point (which thereby permitted analysis of factors that might predict ATRR at the time of presentation with primary ATR), with a minimum review period of 1.5 years from the date of primary injury. Seasonality was defined according to the Northern Hemisphere meteorological system.

Setting

The health board is the only authority overseeing delivery of regional healthcare services and there are no other

National Health Service (NHS) providers in this region. Emergency services are provided through three emergency departments and one minor injuries unit; orthopaedic surgery is performed at two locations and outpatient clinics are based at five locations. There are two private hospitals in the region, but none of these have an emergency department and therefore acute presentations are routed through the NHS and should be securely identified by the search algorithm employed.

Population definitions

The health-board population (total, gender specific and with reference to age brackets) for each year of study was determined using Scottish Government population data from the National Records of Scotland, which issues annual mid-year population estimates for each health board [28]. Socioeconomic deprivation status was determined using the Scottish Index of Multiple Deprivation (SIMD-16), an official Scottish government resource that takes into account employment, income, crime, housing, health, education and access to services to assess and classify population socioeconomic deprivation status (SEDS) across 6,500 data zones nationwide. Each data zone is ranked by SEDS and placed into the appropriate quintile of the national population. SEDS data are published for each data zone and the health-board population serves a geographic region made up of 1083 data zones. Data for these data zones were combined to determine the socioeconomic deprivation status characteristics of the health-board population. SIMD data are published quadrennially, unlike the mid-year population estimates and, therefore, for the socioeconomic deprivation analysis only, the SIMD-16 health-board population data was used to determine the size of more and less deprived components of the health-board population, which were assumed to be static during the period of study. Patients were matched to their corresponding data zone using their postcode, and SEDS data was available for all patients. They were categorised into biquintiles, each comprising patients from data zones in the most deprived 40% and least deprived 40% bands of the national population.

Treatment of ATR

Non-operative management is routinely employed at the study institution unless there are specific indications for surgery (e.g. delayed presentation or patient request), and the period of study straddled a move from traditional immobilising cast treatment (with 10 weeks of cast immobilisation comprising 4 weeks in equinus and 4 weeks in semi-equinus, non-weight bearing, followed by 2 weeks in a neutral, weight-bearing cast and then a further 2 weeks with a shoe heel raise) to a modern functional early weight-bearing regime (with immediate weight bearing in a walking boot orthosis and progressive reduction of heel wedges such that the foot was in neutral position by 6 weeks and the boot removed at 8 weeks) as the standard treatment for primary ATR. Surgical treatment, when performed, was by open means. For the purposes of statistical analysis, treatment type was defined as the first commenced definitive treatment after the initial A&E treatment (A&E management usually comprises an equinus backslab).

Statistical analysis

The annual incidence of ATRR per 100,000 was calculated as the number of cases occurring between 1st January and 31st December, divided by the health-board population (or relevant population bracket), as defined in the government mid-year population estimate for that year. The resulting figure was multiplied by 100,000. The occurrence of ATRR was reported in the most and least socioeconomically deprived national biquintiles (40% bands) in the health-board population, over the period of study, as described above.

Data parametricity in the ATR cohorts was assessed using Kolmogorov–Smirnov testing. Non-parametric data was compared using independent samples Mann–Whitney *U* tests. Nominal variables were compared using Chi-squared tests (or Fisher's Exact test if cell count was < 5 in any cell). Binary logistic regression was undertaken to identify variables that were independently associated with ATRR at the time of primary ATR. Variables with a p value of ≤ 0.05 on initial analysis were included in the regression model. The threshold for age used in the regression analysis was determined using a receiver operator characteristic curve to identify the threshold value that predicted ATRR with maximum combined sensitivity and specificity. A p value of ≤ 0.05 was considered significant [6].

Results

Part 1 (primary outcome): epidemiology of re-rupture of the Achilles tendon

Seven hundred and eighty-three patients (567 males, 72.4%; 216 females, 27.6%) residing in the health-board catchment population presented with a primary ATR and 48 patients (41 males, 85.4% and 7 females, 14.6%) with an ATRR between January 2011 and December 2016. Median time between primary ATR and ATRR was 99.5 days (IQR 82.25–130.75), although 8 ATRR (16.7%) occurred late, between 3 and 50 years after the primary injury (Fig. 2). Males (mean 6.83 cases per year, range 2–10; in an average male population of 416,096) were affected more commonly

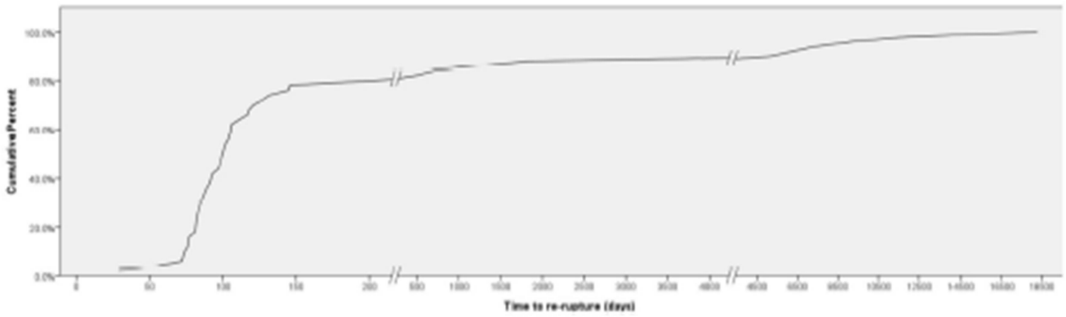

Fig. 2 Cumulative incidence (%) of ATRR over time relative to date of primary ATR. Note the differing scales used on the x-axis in different parts of the graph representing the short, medium and longer term

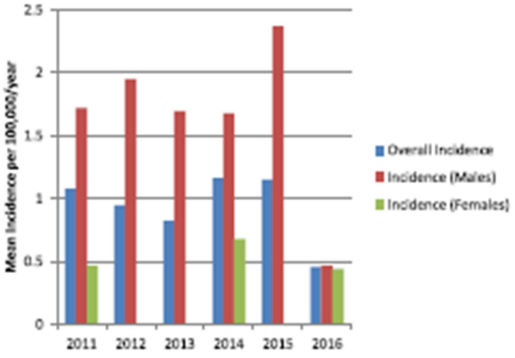

Fig. 3 Incidence of Achilles tendon re-rupture

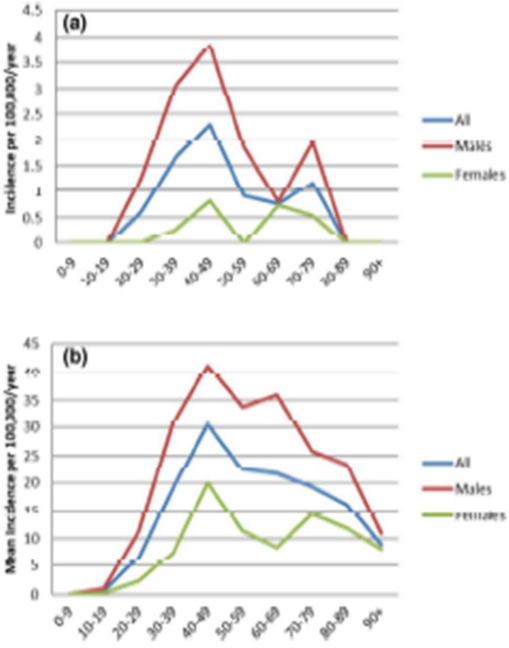

Fig. 4 **a** Mean annual incidence of ATRR over the study period in the health-board population by age bracket. **b** Mean annual incidence of primary ATR over the study period in the health-board population by age bracket

than females (mean 1.17 cases per year, range 0–3; in an average female population of 439,902; $p = 0.034$ FET; OR = 7.40, 95% CI 0.91–60.15).

Median age at the time of ATRR was 44 years (IQR 33–54) and there was a trend trend towards older age in females (median age 47, IQR 42–66 vs 41, IQR 33–52; $p = 0.10$). Male preponderance for ATRR was more pronounced than for primary ATR ($p = 0.048$; OR = 2.23, 95% CI 0.99–5.05).

The mean incidence of ATRR over the study period was 0.94/100,000 per year (range 0.45 to 1.17/100,000 per year) for all ages (Fig. 3) and 1.16/100,000 per year (range 0.56–1.44/100,000 per year) for the adult population (≥ 18 years). This compares to a mean incidence of primary ATR of 15.26/100,000 per year (range 13.51 to 19.07) for all ages and 18.75/100,000 per year (range 16.56–23.57) in adults (≥ 18 years). Peak incidence of both primary ATR and ATRR was in the fifth decade (Fig. 4a, b).

Incidence of ATRR was higher in the least socioeconomically deprived population biquintile (33 cases in a population of 425,254) compared to the most deprived biquintile (11 of 294,239; OR = 2.01, 95% CI 1.01–3.97, $p = 0.04$). ATRR occurred most frequently in summer (Fig. 5a, b), but there was no statistically demonstrable seasonal variation ($p \geq 0.13$; Appendix 1). The majority of ATRR were low-energy injuries and two ATRR (4.2%)

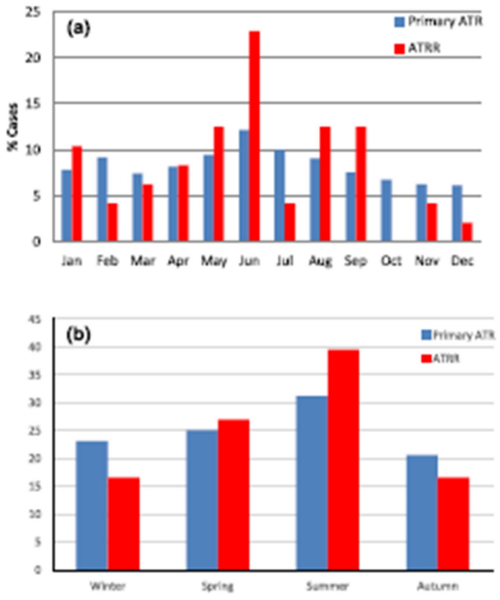

Fig 5 a, b Incidence of primary ATR and ATRR by season

Table 2 Mechanism of injury for primary ATR and ATRR

	Primary ATR	ATRR
Sport	388 (49.6%)	3 (6.3%)
Walking	55 (7.0%)	13 (27.1%)
Low energy: slip, trip, stubbing foot, stumble, ankle inversion or fall from standing height	68 (8.7%)	9 (18.8%)
Fall (> standing height)	17 (2.2%)	1 (2.1%)
Open injury	8 (1%)	0 (0%)
Blunt trauma	10 (1.3%)	1 (2.1%)
Running (non-sports)	20 (2.6%)	1 (2.1%)
Jumping (non-sports)	13 (1.7%)	1 (2.1%)
Dancing	81 (10.3%)	0 (0%)
Pushing/lifting heavy objects	21 (2.7%)	1 (2.1%)
Standing up from sitting/lying	12 (1.5%)	0 (0%)
Stairs/steps	41 (5.2%)	5 (10.4%)
No specific event/spontaneous	22 (2.8%)	6 (12.5%)
Physiotherapy/rehabilitation exercises	N/A	2 (4.2%)
Other	16 (2.0%)	4 (8.3%)
Unknown	11 (1.4%)	1 (2.1%)
Total	783	48

occurred while undertaking primary ATR rehabilitation exercises (Table 2).

Treatment of ATRR was surgical in 36 cases (75%), while 5 patients (10.4%) were advised surgical management but declined. Three patients were treated using the casting regime and three with a walking boot regime; one patient was lost to follow-up after radiological confirmation of re-rupture.

A repeat analysis was undertaken, with ATRR defined as re-rupture occurring ≤ 3 years from primary injury (Appendix 2).

Part 2 (secondary outcomes): predictors of re-rupture at the time of first presentation

Patient factors

Males presenting with primary ATR were more likely to sustain ATRR than females (OR = 2.97, 95% CI 1.15–7.66, $p < 0.001$) and patients who went on to develop ATRR were younger at first presentation than those who did not ($p = 0.019$); however, there were no other demographic differences (Table 3) or other identifiable patient factors (Table 4).

Mechanism and seasonality of injury

No mechanism (Table 5) or season (Table 6) of primary ATR was shown to be associated with increased risk of ATRR.

Primary ATR treatment

Immobilising cast treatment for primary ATR was associated with increased risk of ATRR (Table 7).

Regression model

Patients sustaining a primary ATR under the age of 45 years and those treated with traditional cast immobilisation were more likely to sustain ATRR (Table 8).

Discussion

This most important finding of this study was the description of the epidemiology of ATRR. Risk factors for ATRR are also described. A male predilection for these injuries was confirmed and the hypothesis accepted. An association with younger age at the time of primary ATR, previously alluded to in a single small study with four re-ruptures [36], was confirmed while other, novel findings were described, including the incidence of a small, but significant number of late ATRR, occurring years after the primary injury and a greater incidence of ATRR in patients with lower levels of socioeconomic deprivation. Mechanisms of injury are contrasted between

Table 3 Baseline characteristics for patients according to re-rupture status for 779 patients with primary ATR comprising the cohort in part 2 ****NOTE: for the caption for Table 3 underneath it, you included all the symbols used in the table to explain what they refer to but forgot to put the symbol for more deprived and Less deprived near the sentence explaining their definitions****

	ATRR patients ($n=42$)	Patients without ATRR ($n=737$)	
Gender			< 0.001*
Male	37 (88.1%)	526 (71.4%)	
Female	5 (11.9%)	211 (28.6%)	
Age (median, IQR)	41 (32–47)	48 (40–62)	0.019**
Ethnicity			
White British	33 (78.6%)	625 (84.8%)	ns†
White other	4 (9.5%)	36 (4.9%)	
Asian	0 (0%)	8 (1.1%)	
Black	0 (0%)	10 (1.4%)	
Other	0 (0%)	5 (0.6%)	
Unknown	5 (11.9%)	53 (7.2%)	
BMI (median, IQR)	25.56 (23.72–28.42)	26.76 (24.26–30.59)	ns**
SEDS			ns*
More deprived¶	9 (21.4%)	183 (24.8%)	
Less deprived¶	28 (66.7%)	431 (58.5%)	

*Chi square test; **independent samples Mann–Whitney U test. †Fisher's exact test for proportion of patients who self-identified as White British (including Scottish) compared to all other known ethnicities. ¶Most and least deprived groupings refer to patients falling into quintiles 1 and 2 vs quintiles 4 and 5 of the Scottish Index of Multiple Deprivation, respectively. Body mass index (BMI) was determined from height and weight documented at the closest-available time point to primary ATR; this was known for 74.7% of patients ($n=582/779$)

Table 4 Patient factors at the time of primary ATR in patients who did and did not go on to develop ATRR

	Patients with subsequent ATRR	Patients without subsequent ATRR	Odds ratio (95% CI)	p value
Diabetes	0	61	1.06 (1.04–1.08)	ns*
Inflammatory arthropathy	0	16	1.06 (1.04–1.08)	ns*
Preceding Achilles tendinitis**	0	56	0.94 (0.93–0.96)	ns*
Fluoroquinolone use**	0	18	1.06 (1.04–1.08)	ns*
Steroid use**	1	37	2.17 (0.29–16.24)	ns*

*Fisher's exact test. **Within 6 months prior to primary ATR

primary ATR and ATRR. Associations between ATRR risk and male gender, younger age and traditional immobilising cast treatment at the time of primary ATR were observed.

Epidemiological studies of ATRR are lacking, with only one description of population-level incidence noted on literature review, in a study focussing primarily on comparison of patient characteristics between patients who developed either infection or a re-rupture after surgical repair of ATR [33]. This is in contradistinction to the epidemiology of primary ATR, which is widely documented [13, 21, 40]. Previous epidemiological studies have shown that primary ATR occurs more frequently in males [13, 21], but the only report of male predilection to ATRR is based on comparisons of ATRR relative to a primary ATR cohort [35] and there is no population-level data in this regard. This study demonstrated a male predilection both at population level (OR = 7.40) and also relative to primary ATR. Furthermore, age-specific incidence is reported, which, similarly to primary ATR [21], demonstrates a bimodal age-related incidence of ATRR, with peak incidence in the fifth decade of life.

An original finding of the current study was the increased incidence in those with lower levels of socioeconomic deprivation. These findings are the opposite of trends observed for many traumatic injuries [5, 7, 9] and other musculoskeletal [16, 37, 43] and medical [3] conditions, where increasing incidence correlates with increasing levels of socioeconomic deprivation.

ATRR is generally thought to occur early on in the course of rehabilitation, usually within weeks of completing immobilisation [1, 11, 14, 15, 35, 36, 39, 44]. While this study found that the median time to ATRR was 14 weeks after primary injury and that most re-ruptures occurred early, it also found that 1 in 6 ATRR (8 of 48) occurred years after the primary injury, ranging from over 3 years through to 50 years. Studies designed to follow

Table 5 Mechanism of injury for the primary Achilles tendon rupture in patients who did and did not go on to develop ATRR ****Table 5 - the OR (95%CI) for Open injury is missing: Please add in. The values are: 2.51 (0.30-20.85).****

	Whole cohort ($n=779$)	Patients with subsequent ATRR ($n=42$)	Patients without subsequent ATRR ($n=737$)	OR (95%CI)	p value
Sport	385 (49.4%)	27 (64.3%)	358 (48.6%)	1.85 (0.97–3.54)	ns*
Walking	55 (7.1%)	1 (2.4%)	54 (7.3%)	0.30 (0.04–2.25)	ns**
Low energy: slip, trip, stumble, ankle inversion or fall from standing height	68 (8.7%)	2 (4.8%)	66 (9%)	0.50 (0.12–2.12)	ns**
Fall (> standing height)	17 (2.2%)	1 (2.4%)	16 (2.2%)	1.08 (0.14–8.36)	ns**
Open injury	8 (1.0%)	1 (2.4%)	7 (0.9%)	2.51 (0.30–20.85)	ns**
Blunt trauma	10 (1.3%)	1 (2.4%)	9 (1.2%)	1.94 (0.24–15.71)	ns**
Running (non-sports)	20 (2.6%)	2 (4.8%)	18 (2.4%)	1.97 (0.44–8.77)	ns**
Jumping (non-sports)	12 (1.5%)	0 (0%)	12 (1.6%)	0.94 (0.93–0.96)	ns**
Dancing	81 (10.4%)	5 (11.9%)	76 (10.3%)	1.16 (0.44–3.03)	ns**
Pushing/lifting heavy objects	21 (2.7%)	0 (0%)	21 (2.8%)	0.94 (0.93–0.96)	ns**
Standing up from sitting/lying	12 (1.5%)	0 (0%)	12 (1.6%)	0.94 (0.93–0.96)	ns**
Stairs/steps	41 (5.3%)	0 (0%)	41 (5.6%)	0.94 (0.93–0.96)	ns**
No specific event	22 (2.8%)	1 (2.4%)	21 (2.8%)	0.82 (0.11–6.24)	ns**
Other	16 (2.1%)	1 (2.4%)	15 (2.0%)	1.16 (0.15–8.97)	ns**
Unknown	11 (1.4%)	0 (0%)	11 (1.5%)	N/A	N/A
Total	779	42	737		

*Chi square test. **Fisher's exact test

Table 6 Seasonality of primary ATR in patients who did and did not go on to develop ATRR

	Patients with subsequent ATRR	Patients without subsequent ATRR	Odds ratio (95% CI)	p value
Autumn	7 (16.7%)	152 (20.7%)	0.77 (0.34–1.76)	ns*
Winter	13 (31%)	168 (22.8%)	1.52 (0.77–2.98)	ns*
Spring	10 (23.8%)	184 (25%)	0.94 (0.45–1.94)	ns*
Summer	12 (28.6%)	232 (31.5%)	0.87 (0.44–1.73)	ns*
Total	42	736		

*Chi square test

Table 7 Treatment regime for primary ATR in patients who did and did not go on to develop ATRR

	Patients with subsequent ATRR	Patients without subsequent ATRR	Odds ratio (95%CI)	p value
Immobilising cast treatment	34 (6.7%)	470 (93.3%)	2.40 (1.09–5.25)	0.025*
Functional walking boot rehabilitation	6 (3.8%)	153 (96.2%)	0.63 (0.26–1.53)	ns*
Surgical repair	2 (3.8%)	50 (96.2%)	0.69 (0.16–2.92)	ns**
Other	0	62	N/A	N/A

Odds ratios and p values are for the treatment method relative to all other cases

*Chi square test. **Fisher's exact test

patients prospectively [8, 23, 29] or to retrospectively review patients with primary ATR in recent years [15, 35, 36], would be unable to pick up on this phenomenon and this is probably why it has not been previously recognised. However it has potentially significant implications for studies using re-ruptures as an end point and for patients sustaining an ATR, who should not assume that they are "in the clear" after navigating the early post-injury rehabilitation period uneventfully. It is possible that some authors may consider re-ruptures occurring many years after the primary injury as a new primary injury and we have therefore also presented full epidemiological results defining ATRR as a rupture occurring ≤ 3 years after primary ATR (Appendix 2): similar demographic trends were observed. Further study of 'late' ATRR is

Table 8 Adjusted odds ratios (95%CI) and *p* values for binary logistic regression model for prediction of ATRR at the time of primary ATR

	Adjusted odds ratio (95%CI)	*p* value
Age		
>45 years	Reference	
<45 years	1.96 (1.04–3.71)	0.037
Sex		
Female	Reference	
Male	2.58 (0.994–6.71)	ns
Cast immobilisation	2.20 (1.0–4.85)	0.050

warranted to determine whether they differ in nature from traditionally described 'early' ATRR.

The majority of ATRRs were low-energy injuries, occurring during the course of simple walking, navigating stairs or even spontaneously with no precipitating event. Only two injuries were sustained during rehabilitation exercises. Reito et al. pondered whether the identification of individuals at increased risk of re-rupture would allow for less vigorous rehabilitation to reduce their risk of re-rupture, but ultimately found, in keeping with this study, that most injuries were low-energy injuries and questioned whether less vigorous rehabilitation regimes would have any bearing on these ATRR [35].

To date, only a small number of studies have attempted to identify predictors of ATRR at the time of presentation with a primary ATR [15, 17, 35, 44] and most were unable to identify any risk factors [15, 17, 44]. This may be the result of type II error due to relatively small numbers of ATRR in the studies. Male sex is a well-known risk factor for primary ATR [13, 21], but the nature of any association with ATRR has remained poorly understood—it was found to predict ATRR in patients presenting with a primary ATR in one other study (albeit without correction for confounding factors)[35]. but not in other studies [15, 36, 44]. Part of this disparity is explained by the predisposition of males for primary ATR; which is a pre-requisite for subsequent ATRR, however even within the group of patients with primary ATR, there was a trend towards increased incidence of re-rupture in males, which was just outside statistical significance ($p=0.052$), suggesting an additional predisposition to repeat rupture that is independent of that to primary ruptures.

Younger patients presenting with primary ATR were at increased risk of subsequent re-rupture. One other study reported a higher incidence of re-rupture in younger patients, although this was based on a series of only four ATRR, in a selected group of athletes undergoing surgical repair [36]. Another study was unable to demonstrate an association between younger age and overall ATRR risk, despite reporting a younger mean age in patients with ATRR [35]. In the current study, increased odds of ATRR in younger patients were confirmed, even after adjusting for confounding factors.

There was no demonstrable association between season of primary ATR and ATRR risk. This is in contrast to the findings of Saarensilta et al. [38], who reported that patients sustaining primary ATR in summer were more likely to develop ATRR. The reasons for this discrepancy are unknown but may relate to that analysis being based on a small series of five re-ruptures which may therefore be prone to error, or the authors' decision to use percentages in the place of actual re-rupture numbers in that analysis, thereby increasing the cell counts in the cross table analysis and the apparent statistical power without increasing patient numbers [38].

Re-rupture rate after functional non-operative rehabilitation was 3.8%, which is in keeping with the published literature [26, 31] and it was similar to that for surgically treated cases, while after traditional cast immobilisation, it was 6.7%. It is acknowledged that inclusion of a small number of surgically treated patients may result in some heterogeneity of the group under study, however it appears that our experience reflects that of other units adopting predominantly non-operative management of ATR, where small numbers of patients continue to undergo surgery [1, 11, 14, 44]. No difference was demonstrated between operative and other regimes, although this may be related to the small numbers of surgically treated patients in this study and the relative rarity of ATRR. In fact, the majority of studies similarly show no difference in this regard, although pooling of data in meta-analyses suggests that there is a small clinical difference in re-rupture rates in favour of surgery [31]. This study provides evidence that traditional immobilising cast regimes are associated with higher re-rupture rates, even after adjusting for confounding variables that may influence re-rupture rate and they should therefore be avoided. This is a belief that is widely held among the medical community and is said to have driven recent trends towards functional rehabilitation [26, 41]; however, a previous meta-analysis lamented the paucity of direct evidence in this regard [26]. Surveys have shown that management of ATR often does not follow the evidence base [2] and that plaster cast immobilisation continued to be employed by some practitioners [20], even after the publication of high-quality studies favouring functional rehabilitation [18, 29, 32, 41, 46].

Primary ATR is a pre-requisite for ATRR. Factors that appear to influence incidence of ATRR may therefore be associated directly with ATRR, or mediated indirectly, in part or in full, through a propensity for the primary injury. SEDS appears to be associated with ATRR risk in the general population, but was not found to predict increased re-rupture risk in patients presenting with primary ATR and this effect may therefore be mediated indirectly. Conversely, male sex appears to exert additive risk of re-rupture through direct and indirect means. Furthermore, while some factors that are associated with ATRR are non-modifiable (e.g. younger age at time of primary injury), others (e.g. choice of treatment regime) are potentially modifiable and present opportunities for intervention to reduce patients' risk of ATRR.

This study does have limitations including its retrospective nature and with this, the possibility of loss to follow-up. Despite being a large series of ATRR, the potential for type II error remains, particularly for less common variables, although this would relate to secondary aims of the study and multiple statistically significant relationships have nonetheless been identified. Furthermore, as with all epidemiological studies, individuals who did not seek medical care for their injuries or were misdiagnosed will have been missed, as may have been others. The strengths of the study design include reporting in two parts with different scope. The first part was able to demonstrate important information about ATRR epidemiology and in particular, late re-ruptures, which would not otherwise be possible. As with all retrospective reviews, a minimum follow-up time had to be defined in the second part of the study, although the minimum 1.5 year threshold chosen is longer than that used in other studies on the topic [15, 35]. Additionally, most patients had a significantly longer review period than the minimum period and data from part 1 suggests that over 80% of ATRR would have occurred within this minimum timeframe. Targeted data collection in this study permitted detailed analysis of all primary ATR and re-ruptures, in contrast to some registry-based studies which are limited to the demographic data collected in the registry and may be unable to differentiate between primary ATR and ATRR [13].

Conclusions

The epidemiology of ATRR is described and the hypothesis confirmed. Other novel findings are described, including incidence of a small but significant number of late ATRR, occurring years after the primary injury and increased incidence of ATRR in less socioeconomically deprived patients. Younger age and traditional immobilising cast treatment of primary ATR were independently associated with ATRR. Traditional immobilising rehabilitation regimes should be avoided to reduce re-rupture risk.

Appendix 1

See Table 9.

Table 9 Actual incidence of ATRR per season compared to expected incidence of ATRR in the absence of any seasonal variation *Chi square test

	Actual distribution	Expected distribution in the absence of seasonal variation	
Autumn	8	12	ns*
Winter	8	12	ns*
Spring	13	12	ns*
Summer	19	12	ns*
Total	48	48	

Appendix 2

For the purposes of this sub-analysis, only patients presenting with a second Achilles tendon rupture within 3 years of their primary rupture ($n=40$) were considered to have re-ruptures. All other presenters with ATR ($n=791$) were considered to have primary ruptures. The median time between primary ATR and ATRR was 92.5 days (IQR 82–106). Males (mean 6 cases per year, range 2–9; in an average male population of 416,096) were affected more commonly than females (mean 0.67 cases per year, range 0–3; in an average female population of 439,902; $p=0.063$ FET; OR = 6.34, 95% CI 0.76–52.69).

Median age at the time of ATRR was 41 years (IQR 33–47). Male preponderance for ATRR was more pronounced than for primary ATR ($p=0.014$; OR = 3.43, 95% CI 1.21–9.75). The mean incidence of ATRR over the study period was 0.78/100,000 per year (range 0.34–1.05/100,000 per year) for all ages and 0.96/100,000 per year (range 0.42–1.30/100,000 per year) for the adult population (≥ 18 years). This compares to a mean incidence of primary ATR of 15.41/100,000 per year (range 13.63 to 19.18) for all ages and 19.04/100,000 per year (range 16.86–23.71) in adults (≥ 18 years). Peak incidence of both primary ATR and ATRR was in the fifth decade (Appendix 2, Fig. 6a,

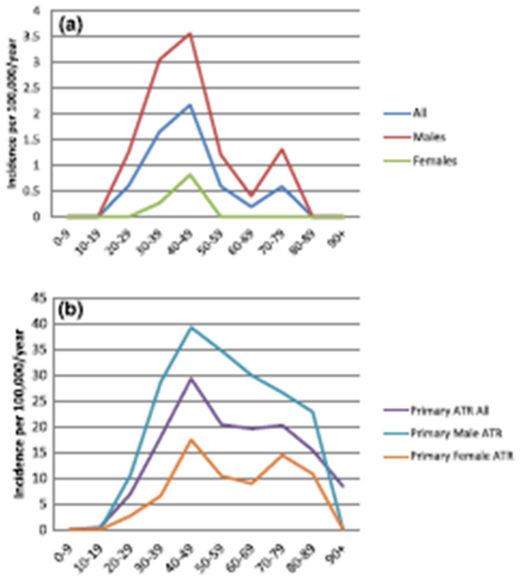

Fig. 6 **a** Mean annual incidence of ATRR over the study period in the health-board population by age bracket. **b** Mean annual incidence of primary ATR over the study period in the health-board population by age bracket

Table 10 Actual incidence of ATRR per season compared to expected incidence of ATRR in the absence of any seasonal variation. *Chi square test

	Actual distribution	Expected distribution in the absence of seasonal variation	*p* value
Autumn	7	10	ns*
Winter	7	10	ns*
Spring	10	10	ns*
Summer	16	10	ns*
Total	40	40	

Table 11 Mechanism of injury for primary ATR and ATRR

	Primary ATR	ATRR
Sport	389 (49.2%)	2 (5%)
Walking	56 (7.08%)	12 (30%)
Low energy: slip, trip, stubbing foot, stumble, ankle inversion or fall from standing height	70 (8.85%)	7 (17.5%)
Fall (> standing height)	17 (2.15%)	1 (2.5%)
Open injury	8 (1.01%)	0 (0%)
Blunt trauma	11 (1.39%)	0 (0%)
Running (non-sports)	20 (2.53%)	1 (2.5%)
Jumping (non-sports)	13 (1.64%)	1 (2.5%)
Dancing	81 (10.24%)	0 (0%)
Pushing/lifting heavy objects	21 (2.65%)	1 (2.5%)
Standing up from sitting/lying	12 (1.52%)	0 (0%)
Stairs/steps	41 (5.18%)	5 (12.5%)
No specific event/spontaneous	25 (3.16%)	3 (7.5%)
Physiotherapy/rehabilitation exercises	N/A	2 (5%)
Other	16 (2.02%)	4 (10%)
Unknown	11 (1.39%)	1 (2.5%)
Total	791	40

b). ****NOTE THE END OF THIS SENTECE...i.e. "6a, b)." should be BEFORE Figure 6, with the beginning of the sentence and not over here***

Incidence of ATRR was higher in the least socioeconomically deprived population biquintile (26 cases in a population of 425,254) compared to the most deprived biquintile (10 of 294,239) but this finding did not reach statistical significance after excluding late re-ruptures (OR = 1.74, 95%CI 0.84–3.60, $p = 0.13$). ATRR occurred most frequently during the summer, but there was no statistically demonstrable seasonal variation ($p \geq 0.15$; Appendix 2, Table ***NOTE that throughout this section, as above with figure 6, the end of the sentence linking to the appropriate figure or table has been separated and inserted after the relevant figure or table.*** 10). The majority of ATRR were low-energy injuries and two ATRR (5%) occurred while undertaking primary ATR rehabilitation exercises (Appendix 2, Table 11).

Author contributions JM—concept/idea for study, data collection, review and statistical analysis, drafting of manuscript and editing of manuscript; TOW—guidance with initial study design and with manuscript; SPM—data collection, manuscript editing; CMcC—data collection, manuscript editing; NDC—guidance with study design, assistance with statistical analysis and editing of manuscript.

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Declarations

Conflict of interest The authors have no conflicts of interest to declare.

Ethical approval This study was part of a departmentally approved service review of ATR which was reviewed by the scientific officer for the regional ethics committee (REC) who advised that REC review was not necessary.

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■ FOOT & ANKLE

Operative repair of acute Achilles tendon rupture does not give superior patient-reported outcomes to nonoperative management

RESULTS OF A RANDOMIZED CONTROLLED TRIAL AT A MINIMUM OF 13 YEARS' FOLLOW-UP

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Aims

The aim was to compare long-term patient-reported outcome measures (PROMs) after operative and nonoperative treatment of acute Achilles tendon rupture in the context of a randomized controlled trial.

Methods

PROMs including the Short Musculoskeletal Function Assessment (SMFA), Achilles Tendon Total Rupture Score (ATRS), EuroQol five-dimension (EQ-5D), satisfaction, net promoter score and data regarding re-rupture, and venous thromboembolic rates were collected for patients randomized to receive either operative or nonoperative treatment for acute Achilles tendon rupture in a previous study. Of the 80 patients originally randomized, 64 (33 treated surgically, 31 nonoperatively) patients were followed up at a mean of 15.7 years (13.4 to 17.7).

Results

There was no statistically significant difference between operatively and nonoperatively treated patients, in SMFA Dysfunction Index (median 1.56 (interquartile range (IQR) 0 to 5.51) vs 1.47 (IQR 0 to 5.15); p = 0.289), SMFA Bother Index (2.08 (IQR 0 to 12.50) vs 0.00 (IQR 0 to 6.25); p = 0.074), ATRS (94 (IQR 86 to 100) vs 95 (IQR 81 to 100); p = 0.313), EQ-5D-5L (1 (IQR 0.75 to 1) vs 1 (IQR 0.84 to 1); p = 0.137) or EQ-5D health today visual analogue score (85 (IQR 72.5 to 95) vs 85 (IQR 8 to 95); p = 0.367). There was no statistically significant difference between operative and nonoperative groups in terms of satisfaction (84% vs 100%; p = 0.119) or willingness to recommend treatment to friends or family (79% vs 87%; p = 0.255). Four nonoperative patients and two in the operative group sustained a re-rupture (p = 0.306).

Conclusion

Both patient groups reported good results at long-term follow-up. The findings give no evidence of superior long-term patient reported outcomes (as measured by the SMFA) for surgical treatment over nonoperative treatment. There was no demonstrable difference in other patient reported outcome measures, satisfaction, or re-rupture rates at long-term follow-up.

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Introduction

Acute Achilles tendon rupture (ATR) is a common soft-tissue injury with a rising incidence.[1,2] Good outcomes are reported with operative and nonoperative management and both have been advocated.[3-6] Various randomized controlled trials (RCT) have compared operative and nonoperative management,[3,5-8] with meta-analyses collating results.[9,10] However, these report short-term outcomes at one[3,8] or two[5-7] years. Proponents of surgery argue that it may reduce risks of re-rupture[6] and give earlier and greater restoration of calf muscle strength,[7] while

Table I. Patient characteristics.

Variable	Operative	Nonoperative
At recruitment		
Mean age, yrs (range)	41.2 (27 to 50)	39.5 (21 to 58)
Sex (male:female)	28:11	32:9
Treatment at randomization, n	39	41
At follow-up		
Mean age, yrs (range)	56.0 (37 to 75)	50.4 (46 to 77)
Sex (male:female)	22:11	23:8
Treatment modality	33	31

nonoperative management has been linked to increased rates of skin issues.[11] Others state that surgery risks complications, including infection, wound problems, anaesthetic complications, and sural nerve injury.[4,5,12]

ATR occurs most commonly in middle-aged individuals,[1,2] who are expected to remain physically active for many years after their injury. It is therefore important to understand the long-term implications and outcomes of treatment. Despite this, there is a paucity of long-term data from RCTs, with only one reporting medium-term outcomes comparing operative and nonoperative treatment at mean follow-up of seven years,[13] while others have compared outcomes with differing rehabilitation regimes after operative[14] or nonoperative[15] management.

The primary aim of this study was to compare long-term patient-reported outcomes after operative and nonoperative treatment of acute ATR. The hypothesis was that surgical treatment would result in improved patient-reported outcomes, as measured by the Short Musculoskeletal Function Assessment (SMFA) score,[16] compared with nonoperative management. Secondary aims included a comparison of Achilles Tendon Total Rupture scores (ATRS),[17] health-related quality of life (HRQoL), satisfaction and complication rates, and long-term net promoter scores(NPS)[18] for each treatment modality.

Methods

Long-term follow-up of patients previously recruited into a RCT[3] comparing operative and nonoperative management of ATR was undertaken between September 2017 and July 2018. In total, 80 patients (mean age 40.6 years; 21 to 59) were randomized to receive operative or nonoperative treatment for ATR between 2000 and 2004. Exclusion criteria were age > 60 years, presentation more than ten days postinjury, systemic disease including rheumatoid arthritis, chronic renal failure, and steroid treatment, or medication that could influence healing (Table I). Randomization was through sealed envelope allocation at first presentation to clinic.

When surgery was assigned, it was undertaken within seven days of presentation to clinic and all patients underwent surgery within 14 days of their injury, utilizing a posteromedial longitudinal incision with double-stranded 1 PDS (Ethicon, Woleuw, Belgium) core Kessler stitch supplemented by interrupted 1-0 Vicryl (Ethicon) circumferential sutures for the repair. The paratenon was sutured over the tendon repair using 2-0 Vicryl and the skin closed with interrupted 3-0 nylon sutures. Following surgery, the limb was immobilised in a full equinus cast for four weeks, then semi-equinus for two weeks. The cast was then removed and weight-bearing commenced.

Patients treated nonoperatively underwent ten weeks of immobilization in a below-knee cast, positioned in equinus (four weeks), then semi-equinus (four weeks), and neutral (two weeks). Patients were non weight-bearing while in equinus and semi-equinus and allowed partial weight-bearing in the neutral cast.

Operatively treated patients received a single subcutaneous 20 mg dose of enoxaparin postoperatively. No other thromboprophylaxis was administered to patients in either group. Following cast removal, both patient groups followed identical physiotherapy regimes, as previously described.[3]

Long-term follow-up. Patients were asked to complete postal questionnaires containing SMFA, ATRS, EuroQol five-dimension five-level questionnaire (EQ-5D-5L), and the EQ-5D health today visual analogue scale (VAS).[19] Patients were also asked three questions: how satisfied are you with your treated Achilles tendon?; would you have the same treatment again if it were required on the opposite side?; and, how likely are you to recommend this treatment to friends and family if they needed similar care or treatment?

For the first question, possible answers were: very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied, or very dissatisfied; For the last two questions, patients could answer: extremely likely, likely, neither likely nor unlikely, unlikely, extremely unlikely, or don't know.

The SMFA is a 46-question patient reported outcome measure (PROM).[16] Dysfunction and bother indices are calculated. Mobility, daily activities, emotional status, and arm/hand category indices can also be calculated. All indices are reported on a scale between zero and 100, where lower scores represent better function. It is valid, reliable, and responsive to change and therefore suitable to clinically assess impact of treatment in patients with musculoskeletal injury.[16] The ATRS is a ten-question PROM, shown to be sensitive, valid, and reliable in assessment of patients with Achilles tendon rupture. The ATRS ranges from zero (most limitation due to Achilles tendon) to 100 (least limitation).[17] The EQ-5D-5L index comprises five domains (mobility, self-care, usual activities, pain and discomfort, and anxiety and depression) used to calculate an index score ranging between -0.59 and +1. The EQ-5D health today visual analogue scale (VAS) asks patients to rate their overall health on a scale between zero (worst) and 100 (best).

The NPS is a single question metric focusing on likeliness of an individual to recommend a good or service to others.[18] It is widely used in industry and the original NHS England Friends and Family test (FFT)[20] was modelled on it. Respondents are classified as 'promoters', 'passives', or 'detractors'. The NPS is calculated by subtracting the number of 'detractors' from 'promoters' and dividing the resulting value by the total number of respondents. Patients who said they would be very likely to recommend their treatment to friends and family were considered 'promoters'; those who said 'likely' were considered 'passives' and all other answers were considered 'detractors'.

Patients who sustained a re-rupture were not excluded from the long-term study and their results were analysed on an intention to treat basis, according to their initial treatment modality at randomization. A repeat analysis, excluding patients sustaining re-ruptures, was undertaken and the results

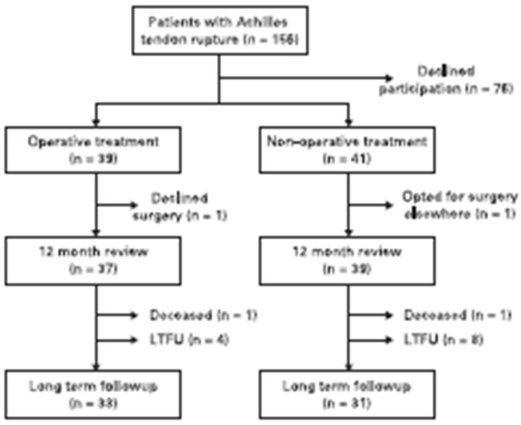

Fig. 1

CONSORT flow diagram illustrating patient flow through the study. Two patients (one operative and one nonoperative) were not reviewed at 12 months, but completed their assigned treatment as per protocol and were subsequently included in the long-term follow-up. LTFU, lost to follow-up.

are presented separately (see Supplementary Material: Analysis of outcomes excluding patients who sustained a tendon re-rupture).

Of 80 patients originally randomized into the trial, two withdrew (Figure 1). In total, 64 (33 treated surgically; 31 nonoperatively) of the original cohort of 78 patients (82.1%) were followed up at a mean of 15.7 years (13.4 to 17.7) while two were deceased. In addition 12 patients were lost to follow-up. The mean age of patients at follow-up was 57.6 years (37 to 77). There was no significant difference in rates of loss to follow-up between operative and nonoperative cohorts (p = 0.405, Fisher's exact test).

Statistical analysis. The primary outcome measure was SMFA dysfunction index. A minimum clinical important difference (MCID) of seven points has been described for this score.[21] Using non-parametric power analysis with a SD of ten, a minimum of 54 patients would be required to achieve power of 80% with $\alpha = 0.05$, using a one-tailed analysis.

Non-parametric continuous data were compared using Mann-Whitney U tests when unrelated and related-samples Wilcoxon signed-rank test when related. Nominal variables were compared between groups using Fisher's exact test. One-tailed analyses were used, with an assumed better outcome in the surgical group, which could justify the potential risks associated with surgery. Non-parametric variables were correlated with Spearman's rank test. A p-value of ≤ 0.05 was considered significant. Power analysis was undertaken using G*Power v. 3 (Heinrich-Heine Universität, Düsseldorf, Germany). Statistical analysis was undertaken using SPSS v. 24 (Chicago, Illinois, USA) and GraphPad Prism v. 8 (GraphPad Software, San Diego, California, USA).

Table II. Patient reported outcomes after surgical and nonoperative management of acute Achilles tendon rupture. Scores between 12 and 52 weeks were collected as part of the previous RCT.*

Timepoint	Median operative score (IQR)	Median nonoperative score (IQR)	p-value*
12 weeks			
SMFA Dysfunction	15.47 (12.13 to 19.30)	16.00 (10.13 to 26.45)	0.173
SMFA Bother	16.69 (9.88 to 19.83)	17.75 (8.30 to 29.73)	0.104
16 weeks			
SMFA Dysfunction	7.35 (4.40 to 11.58)	8.45 (5.00 to 15.07)	0.085
SMFA Bother	8.30 (2.63 to 14.60)	9.35 (2.10 to 14.60)	0.382
26 weeks			
SMFA Dysfunction	2.56 (1.56 to 4.40)	3.70 (0.74 to 5.90)	0.360
SMFA Bother	4.17 (0.00 to 6.25)	2.10 (0.00 to 6.25)	0.400
52 weeks			
SMFA Dysfunction	0.00 (0.00 to 1.50)	1.48 (0.00 to 3.68)	0.092
SMFA Bother	0.00 (0.00 to 2.08)	0.00 (0.00 to 4.20)	0.107
Current status			
SMFA Dysfunction	1.56 (0.00 to 5.51)	1.47 (0.00 to 5.15)	0.289
SMFA Bother	2.08 (0.00 to 12.50)	0.00 (0.00 to 6.25)	0.074
ATRS	94 (86 to 100)	95 (81 to 100)	0.313

*Mann-Whitney U test.
ATRS, Achilles Tendon Rupture Score; SMFA, Short Musculoskeletal Function Assessment.

Table III. Proportion of patients reporting any degree of problems for each dimension of the Euro-Qol five-dimension five-level questionnaire (EQ-5D-5L) score.

Dimension	Operative (n = 33)	Nonoperative (n = 31)	p-value*
Mobility			0.220
No problems	24	26	
Problems	9	5	
Self-care			0.516
No problems	32	31	
Problems	1	0	
Usual Activity			0.201
No problems	25	27	
Problems	8	4	
Pain/Discomfort			0.143
No problems	17	21	
Problems	16	10	
Anxiety/Depression			0.557
No problems	25	23	
Problems	8	8	

*Fisher's exact test.

Results

PROMs. There was no statistically significant difference in SMFA dysfunction and bother indices at any time point (Table II). Additionally, at long term follow-up, there was no statistically significant difference in SMFA dysfunction and bother indices (Table II), SMFA categories (Supplementary Table i), or ATRS (Table II). There was no significant difference in change in SMFA dysfunction index (p = 0.079, related samples Wilcoxon signed-rank test) or SMFA bother index (p = 0.130, related samples Wilcoxon signed-rank test) between

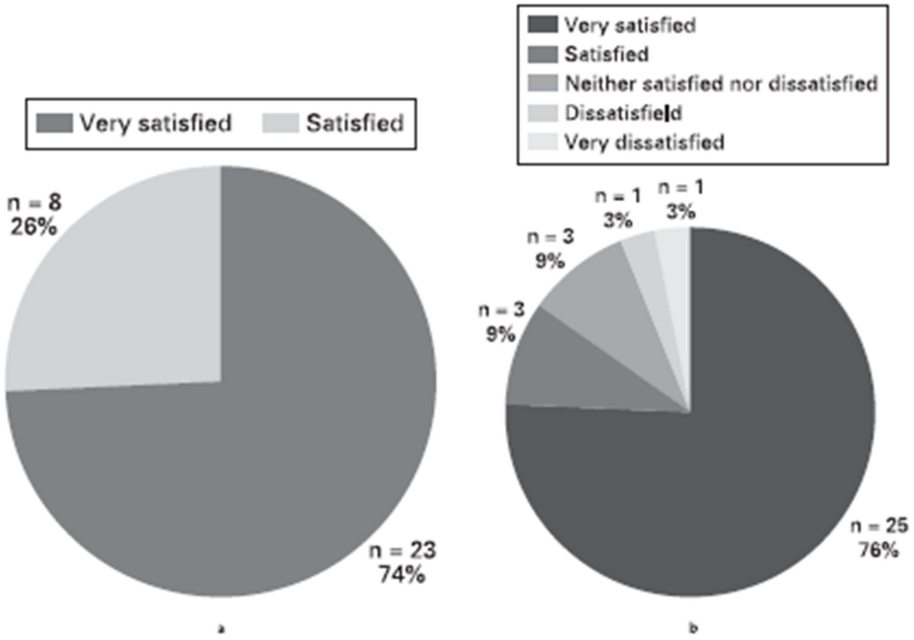

Fig. 2

Patient satisfaction with their treated Achilles tendon in a) nonoperatively treated and b) operatively treated patients.

Table IV. Would you have the same treatment again if it were required on the opposite side?

Response, n (%)	Operative	Nonoperative
Extremely likely	20 (60.61)	21 (67.74)
Likely	7 (21.21)	7 (22.58)
Neither likely nor unlikely	2 (6.06)	2 (6.45)
Unlikely	0	0
Extremely unlikely	2 (6.06)	0
Don't know	2 (6.06)	1 (3.23)
Total responses, n	33	31

Table V. How likely are you to recommend this treatment to friends and family if they needed similar care or treatment?

Response, n (%)	Operative	Nonoperative
Extremely likely	18 (54.5)	17 (54.8)
Likely	8 (24.2)	10 (32.3)
Neither likely nor unlikely	3 (9.1)	3 (9.7)
Unlikely	0	0
Extremely unlikely	2 (6.1)	0
Don't know	2 (6.1)	1 (3.2)
Total responses, n	33	31

one-year post-injury and long-term follow-up in the nonoperative group. There was a statistically significant decline in SMFA dysfunction ($p = 0.001$, related samples Wilcoxon signed-rank test) and bother ($p = 0.001$, related samples Wilcoxon signed-rank test) indices for operatively treated patients between one-year post-injury and long-term follow-up, although the magnitude of these changes was small.

There were significant correlations between one year SMFA dysfunction index and long-term SMFA dysfunction ($r = 0.45$, $p < 0.001$) and bother indices (Spearman's $r = 0.65$, $p < 0.001$), ATRS (Spearman's $r = -0.36$, $p = 0.007$), and EQ-5D VAS (Spearman's $r = -0.3$, $p = 0.024$), while that with EQ-5D index did not reach statistical significance (Spearman's $r = -0.23$, $p = 0.083$). Patients whose SMFA dysfunction index at one year was in the worst quartile reported worse outcomes at long-term follow-up across all PROMs (see Supplementary Material: Relationship between one-year SMFA dysfunction index and long-term outcomes).

HRQoL. Patients in both groups reported median EQ-5D-5L Index scores of 1.0 (operative group IQR 0.75 to 1.00; nonoperative group IQR 0.84 to 1.00; $p = 0.137$, Mann-Whitney U test) and median EQ-5D health today VAS of 85 (IQR 72.5 to 95 and 80 to 95, respectively; $p = 0.367$, Mann-Whitney U test). There were no statistically significant differences in the proportion of patients reporting problems in any of the EQ-5D dimensions between the groups (Table III).

Satisfaction. Overall, 59 patients (92.2%) indicated they were satisfied, while two (3.1%) were not (Figures 2a and 2b). There was no statistically significant difference in satisfaction rates between the groups ($p = 0.119$, Fisher's exact test).

Comparison of those who stated they were likely (i.e. answered 'extremely likely' or 'likely') and those who were unlikely (i.e. 'extremely unlikely' or 'unlikely') to agree to have

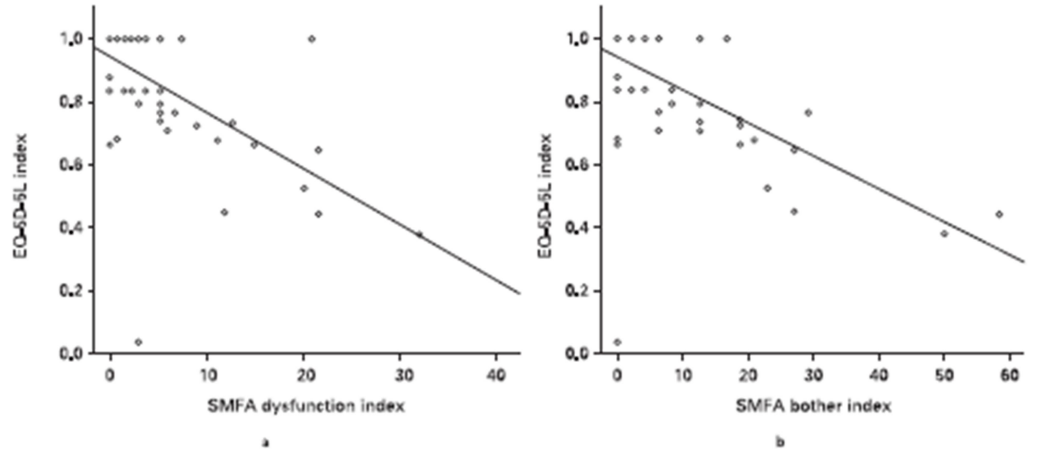

Fig. 3

Spearman rank correlation between EuroQol five-dimension five-level questionnaire (EQ-5D-5L) index and a) Short Musculoskeletal Function Assessment (SMFA) dysfunction ($r = -0.627$; $p < 0.001$) and b) SMFA bother indices at final follow-up ($r = -0.609$; $p < 0.001$).

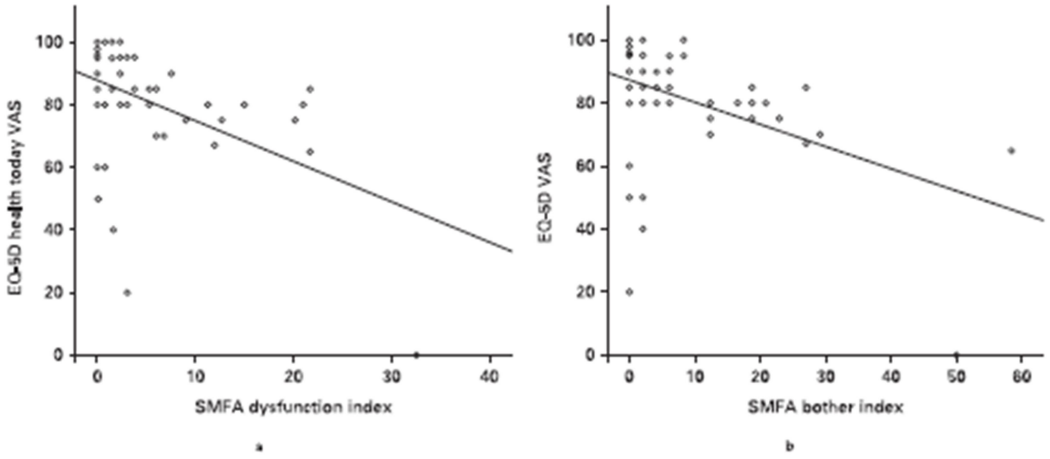

Fig. 4

Spearman rank correlation between EuroQol five-dimension five-level (EQ-5D-5L) health today visual analogue scale (VAS) and a) Short Musculoskeletal Function Assessment (SMFA) dysfunction ($r = -0.495$, $p < 0.001$) and b) SMFA bother indices ($r = -0.437$, $p < 0.001$) at final follow-up.

the same treatment again (Table IV) demonstrated no statistically significant difference between groups ($p = 0.254$, Fisher's exact test).

NPS. The NPS was 33 for patients treated operatively and 42 for those treated nonoperatively. Under current NHS FFT reporting guidelines,[20] 78.8% of patients (26 of 33) would recommend operative treatment and 6.1% (2 of 33) would not, while 87.1% (27 of 31) would recommend nonoperative treatment and none would not (Table V). Comparison of those who stated they were likely and those who were unlikely to recommend their treatment demonstrated no statistically significant difference between groups ($p = 0.255$, Fisher's exact test).

HRQoL and musculoskeletal PROMs. Across both groups, there was an association between self-reported HRQoL (measured by EQ-5D-5L Index and VAS) and self-reported musculoskeletal health, measured by SMFA dysfunction (Figures 3a and 4a) and bother (Figures 3b and 4b) indices and Achilles tendon function, measured by ATRS (Figures 5a and 5b).

Complications. There were two deep vein thromboses (both nonoperative patients), three wound infections (in operative

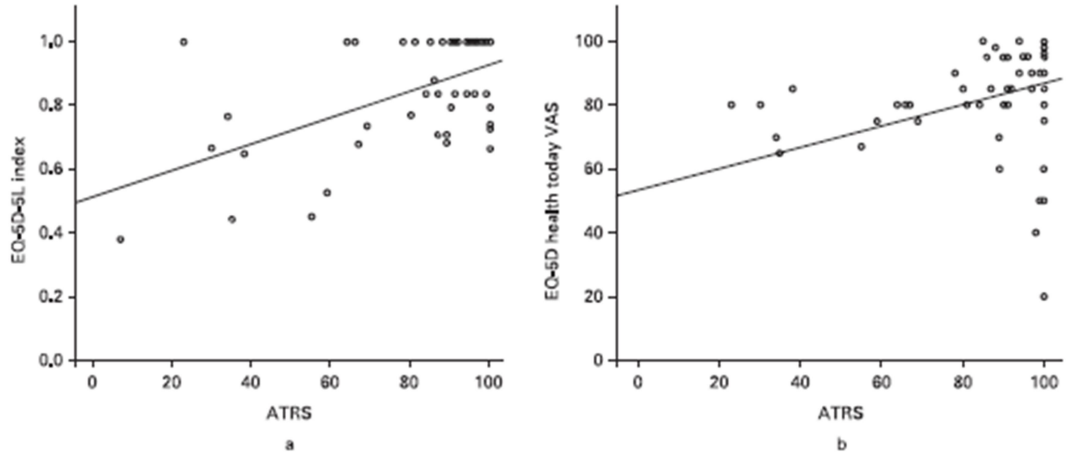

Fig. 5

Spearman rank correlation between a) EuroQol five-dimension five-level (EQ-5D-5L) index (r = 0.434, p < 0.001) and b) EQ-5D-5L health today visual analogue scale (VAS) (r = 0.395, p = 0.001) and Achilles Tendon Total Rupture Score (ATRS) at final follow-up.

patients), and six re-ruptures (four nonoperative, two operative patients; p = 0.306, Fisher's exact test), all of which occurred within four months of injury. Re-ruptures were managed surgically in five cases and nonoperatively in one, who had previously undergone surgery. All six patients who sustained a re-rupture were either very satisfied (five) or satisfied (one) with their treated Achilles tendon at long-term follow-up. All contacted patients were asked if they had sustained a venous thromboembolism (VTE), re-rupture, or contralateral rupture. No additional VTE or re-ruptures were identified, but five of 64 (7.81%) had sustained a contralateral ATR.

Additional analyses. Statistical analyses were repeated, excluding patients who sustained a re-rupture and are reported separately (see Supplementary Material: Analysis of outcomes excluding patients who sustained a tendon re-rupture). There were no statistically significant differences demonstrated between groups in any of the PROMs, satisfaction rates, likeliness to be willing to undergo similar treatment again, or to recommend the treatment to others.

Discussion

This study demonstrated no statistically significant differences in long-term outcomes after operative or nonoperative management of ATR in a group of 64 patients from an initial randomized allocation of 80 patients, at a mean of 15.7 years (13.4 to 17.7) postinjury. Patients reported similar general musculoskeletal PROMs, Achilles tendon-specific scores, and HRQoL. This may indicate that the potential risks of surgery are not offset by improved outcomes. There has been a trend away from surgical treatment of ATR in recent years, spurred by reports of comparable short-term outcomes after nonoperative management.[1,2] This study corroborates these reports in the longer-term, providing further justification for nonoperative management.

SMFA scores were collected in the previous RCT,[3] facilitating direct comparison with long-term outcomes. Patients in both groups reported low SMFA dysfunction and bother indices one year post-injury. Nonoperatively treated patients exhibited no change in median SMFA indices between one year and long-term follow-up, while surgically treated patients exhibited a small but statistically significant deterioration in both indices. However, the change in SMFA dysfunction index was less than the MCID.[21] Therefore, neither group experienced any perceptible change in musculoskeletal function.

Worse SMFA dysfunction index scores at one year were associated with inferior long-term PROMs (see Supplementary Material: Relationship between one-year SMFA dysfunction index and long-term outcomes), suggesting that patients reporting poorer outcomes one year after injury are more likely to continue to do so in the long-term.

The ATRS is a modern, injury-specific score.[17] A systematic review concluded that it is valid and the most appropriate PROM for evaluating ATR management.[22] Reporting of ATRS facilitates comparison of outcomes with other recent studies. Brorsson et al[13] compared operative and nonoperative management, reporting similar medium-term ATRS (median score 96) to our study and noted no change in functional status between assessment two years post-injury and medium-term follow-up, corroborating our finding that PROMs did not change appreciably over time. Others report no difference at short-term follow-up.[3,5] Our study demonstrates similar findings for the first time at long-term follow-up. Interestingly, reported ATRS scores in our nonoperatively treated patients were higher than those reported in an observational study of a more modern functional rehabilitation regime.[23] A recent meta-analysis[24] highlighted a lack of RCTs comparing traditional nonoperative management with more recent functional rehabilitation regimes and this is an area that requires further study. Better

understanding of long-term outcomes attained with traditional rehabilitation techniques will facilitate this comparison, to ensure that modern regimes meet or exceed standards set by traditional regimes.

Both groups reported median EQ-5D index scores of 1, indicating that the majority of patients reported excellent HRQoL. While this may raise concerns of a ceiling effect, it has been demonstrated that the EQ-5D-5L, unlike its predecessor (EQ-5D-3L), does not suffer significantly from this phenomenon.[25] There was no statistically significant difference in HRQoL between groups.

Significant correlations were demonstrated between self-reported musculoskeletal (SMFA) and Achilles tendon (ATRS) function with HRQoL at long-term follow-up, indicating that although most patients report good outcomes, any remaining functional deficits correlate with a corresponding reduction in HRQoL. Similar relationships have been reported in other conditions (e.g. femoroacetabular impingement).[26]

The vast majority of patients were satisfied with longer-term outcomes, whether treated operatively or nonoperatively. Although a slightly greater proportion of respondents expressed satisfaction in the nonoperative group, this finding was not statistically significant. Data pertaining to short-term satisfaction after treatment for ATR is sparse, with one RCT showing no difference[11] and others favouring operative[6] or nonoperative[27] management. There are no long-term reports of satisfaction and it is unknown whether long-term satisfaction correlates with short-term satisfaction.

Patients treated nonoperatively were slightly more likely to consider the same treatment again and recommend similar treatment to others, although these differences were not statistically significant. Positive NPS are generally well regarded in industry. Our reported NPS compared favourably with scores for market leaders in non-medical fields,[28] but were lower than those for elective procedures.[26,28] However, traumatic injuries differ to planned surgery and direct comparison may be inappropriate. The FFT is reported as the proportion of patients who would recommend a service.[29] Scores are affected by multiple variables and critics argue that results are dependent on the precise method of data collection, facilitating comparison of results within an institution but making comparison of FFT results between institutions problematic.[29] A large majority of patients in both groups would recommend their treatment while only two (both surgically treated) would not. Interestingly, self-reported satisfaction rates were slightly higher than recommendation rates, indicating that some satisfied patients may not necessarily recommend their treatment to others.

No additional re-ruptures were noted at long-term follow-up, corroborating reports that re-rupture tends to occur early in the recovery process.[30] There remained no statistically significant difference in re-rupture rates between groups. Our study, like other individual RCTs,[5,31] may be underpowered to detect differences in re-rupture rates favouring surgery, which often only become apparent upon pooling data in meta-analyses.[9,10] Our reported re-rupture rates are higher than those reported in one recent meta-analysis,[10] although not dissimilar from those reported in another.[9] The reasons for this are unknown, but may relate to the relatively small sample size or variation in which studies were included in the meta-analyses.

The incidence of contralateral ATR at long-term follow-up was almost 8%. This is significantly higher than the incidence of ATR in the general population[1,2] and slightly higher than ipsilateral re-rupture rates in this study. Patients with ATR are at increased risk of contralateral ATR and this risk is similar or higher than that of re-rupture, despite re-rupture being possibly more well-known and feared.

This study has limitations, including relatively small size and loss to follow-up. However, the minimum number of patients identified in the power analysis was comfortably exceeded and 80% of patients enrolled in the original study were followed up, indicating low rates of loss to follow-up in the context of long-term follow-up. Lack of clinical functional assessment may also be considered a limitation. Although the outcome measures used have been shown to be valid and reliable, they have not been validated for such long length of follow-up.

At a mean of just under 16 years follow-up, patients treated both operatively and nonoperatively for acute ATR reported good outcomes. Surgically treated patients did not report superior SMFA scores to those treated nonoperatively. There was no demonstrable difference in assessed outcomes across a range of injury specific, general musculoskeletal and HRQoL PROMs, and measures of patient satisfaction and sentiment.

Take home message

- Surgical treatment for acute Achilles tendon rupture did not result in a greater long-term patient reported outcome when compared to nonoperative treatment.

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Supplementary material

Additional analyses have been undertaken and are reported as supplementary material. The individual SMFA disability categories (mobility, daily activities, emotional and hand and arm indices) are reported for the two groups as a whole (n = 64) and no statistically significant differences were noted between the groups. Further analyses were undertaken on the whole group, demonstrating a correlation between SMFA dysfunction index at one year after injury and long-term outcomes, confirming that SMFA dysfunction index at one year after injury is predictive of long term outcomes and that patients scoring poorly at one year are more likely to report poorer PROM scores at long term follow up. Additionally, a repeat analysis, re-reporting the main results of the study for patients in both groups, but excluding patients who sustained a re-rupture was undertaken (n = 58) and there were no material changes to the results previously reported for the group as a whole.

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J. F. Keating: Designed and implemented the original randomized study, Designed the current study, Drafted and edited the manuscript.

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SMFA disability categories for all patients undergoing long-term follow-up

Analysis of individual Short Musculoskeletal Form Assessment (SMFA) disability categories was undertaken for all patients undergoing long-term follow-up. There was no significant difference in any of the individual SMFA disability category scores between patients treated operatively and patients treated nonoperatively (Table i).

Table i. Short Musculoskeletal Functions Assessment (SMFA) disability category scores for patients treated operatively and nonoperatively.

Category	Median operative score (IQR) n=33	Median nonoperative score (IQR) n=31	p-value*
Mobility	0.00 (0.00 to 8.33)	0.00 (0.00 to 5.56)	0.471
Daily Activities	0.00 (0.00 to 3.75)	0.00 (0.00 to 2.50)	0.455
Emotional	7.14 (0.00 to 14.29)	3.57 (0.00 to 10.71)	0.164
Hand and arm	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.225

*Mann-Whitney U test.
IQR, interquartile range.

Relationship between one-year SMFA dysfunction index and long-term outcomes

Additional analysis was performed to determine whether there is an association between patient reported outcomes at one year post-injury and longer-term PROMs. There was a statistically significant correlation between SMFA dysfunction index at one year post-injury and all long-term PROMs, except EuroQol five-dimension five-level questionnaire index (EQ-5D-5L), where there was a narrowly insignificant trend ($p = 0.083$, Spearman's rank correlation; Figures a to e).

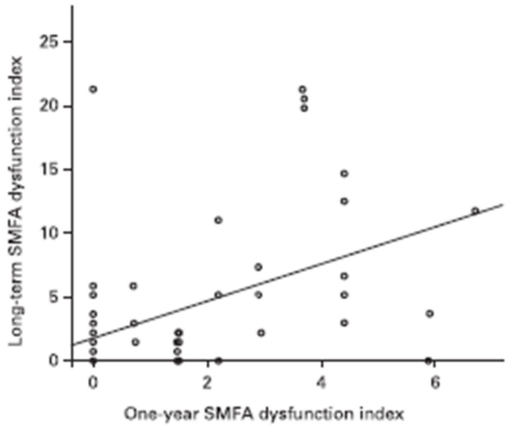

Fig. a

Correlation between one-year and long-term Short Musculoskeletal Function Assessment (SMFA) dysfunction index (Spearman's r = 0.45, p < 0.001).

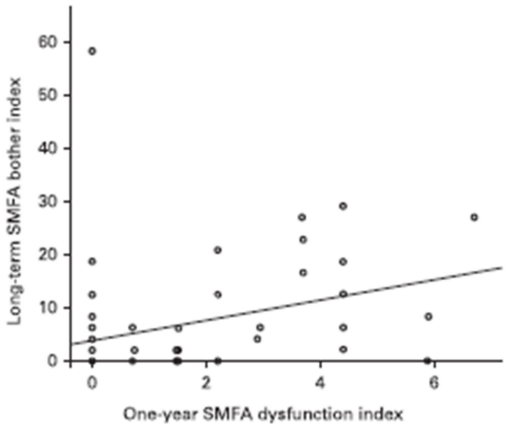

Fig. b

Correlation between one-year Short Musculoskeletal Function Assessment (SMFA) dysfunction index and long-term SMFA Bother Index. Spearman's r = 0.65, p < 0.001.

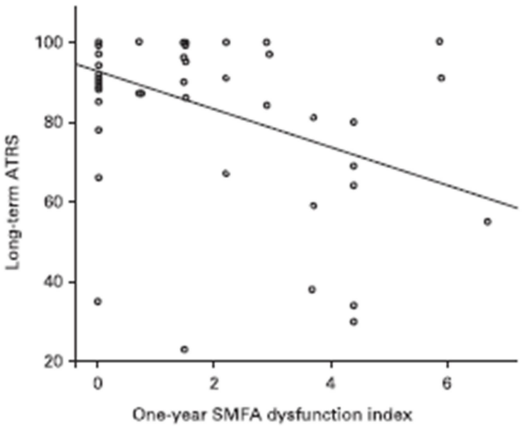

Fig. c

Correlation between one-year Short Musculoskeletal Function Assessment (SMFA) dysfunction index and long-term Achilles Tendon Total Rupture Score (ATRS) (Spearman's r = -0.36, p = 0.007).

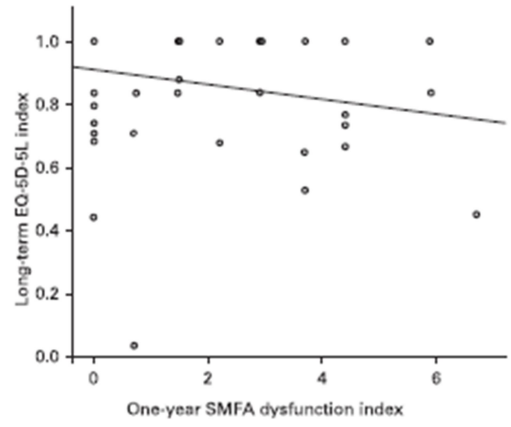

Fig. d

Correlation between one-year Short Musculoskeletal Function Assessment (SMFA) dysfunction index and long-term EuroQol five-dimension five-level questionnaire (EQ-5D-5L) index (Spearman's r = -0.23, p = 0.083).

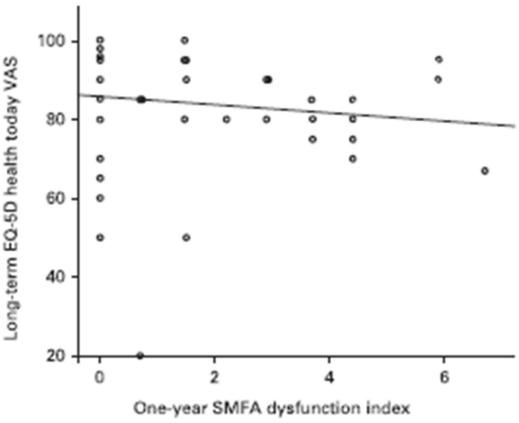

Fig. e

Correlation between one-year Short Musculoskeletal Function Assessment (SMFA) dysfunction index and long-term Euro-Qol five-dimension (EQ-5D) health today visual analogue scale (VAS) (Spearman's r = -0.30, p = 0.024).

Additionally, the long-term PROM scores of patients whose SMFA dysfunction index at one year fell into the highest quartile (i.e. most dysfunction as demonstrated by SMFA dysfunction index) were compared to their counterparts in the lower three quartiles at one year (i.e. least dysfunction as demonstrated by SMFA dysfunction index) to determine whether patients who were performing more poorly at one year continued to do so at longer-term follow-up. SMFA dysfunction index scores were available for 70 of the 78 patients in the original trial and for all 64 patients with long-term follow-up reported in this study. Overall, 57 patients had matched one-year and long-term dysfunction index scores. This test was performed on all patients regardless of their re-rupture status.

Patients in the highest quartile at one year reported inferior function across all PROMs at long-term follow-up and these findings were statistically significant (Table ii).

Table ii. Long-term follow-up patient-reported outcome measure (PROM) scores for patients with one-year Short Musculoskeletal Function Assessment (SMFA) dysfunction index in the worst-performing quartile compared to the rest of the group. Median scores are presented with interquartile range.

Long-term PROM	One- year SMFA dysfunction index in highest quartile (IQR) n=14	One-year SMFA dysfunction index in lowest three quartiles (IQR) n=43	p-value*
SMFA dysfunction	6.99 (3.49 to 15.99)	0.74 (0.00 to 2.94)	< 0.001
SMFA bother	10.42 (4.17 to 23.96)	0.00 (0.00 to 6.25)	< 0.001
ATRS	74.50 (50.75 to 92.50)	96 (89 to 100)	0.002
EQ-5D-5L index	0.803 (0.66 to 1.00)	1.00 (0.84 to 1.000)	0.030
EQ-5D health today VAS	80 (75 to 90)	90 (80 to 95)	0.046

*Mann-Whitney U test.

ARTS, Achilles Tendon Total Rupture Score; EQ-5D-5L, EuroQol five-dimension five-level questionnaire; EQ-5D, EuroQol five-dimension score; IQR, interquartile range; VAS, visual analogue scale.

Analysis of outcomes excluding patients who sustained a tendon re-rupture

Analyses were repeated on the remaining 58 patients, after excluding patients who had sustained a tendon re-rupture. There was no significant difference identified in any patient-reported outcome measure (PROM) between operative and non-operatively treated groups (Table iii). Additionally, there was no significant difference identified in any of the Short Musculoskeletal Function Assessment (SMFA) disability categories between operative and non-operatively treated groups (Table iv). There was no significant difference in satisfaction rates (Figures f and g) between treatment groups (p = 0.255, Fisher's exact test).

Table iii. Patient-reported outcome measure (PROM) scores for 58 patients treated for Achilles tendon rupture who did not sustain a re-rupture of their tendon.

PROM	Median operative score (IQR) n = 31	Median nonoperative score (IQR) n = 27	p-value*
SMFA dysfunction	1.56 (0.00 to 5.88)	1.47 (0.00 to 5.15)	0.291
SMFA bother	2.08 (0.00 to 12.50)	0 (0.00 to 6.25)	0.116
ATRS	92 (85 to 100)	91 (78 to 100)	0.461
EQ-5D-5L index	0.84 (0.74 to 1.00)	1 (0.84 to 1.00)	0.064
EQ-5D VAS	85 (70 to 95)	85 (80 to 95)	0.296

*Mann-Whitney U test.

ATRS, Achilles Tendon Total Rupture Score; EQ-5D-5L, EuroQol five-dimension five-level questionnaire; EQ-5D VAS, EuroQol five-dimension Visual Analogue Scale; IQR, interquartile range; SMFA Short Musculoskeletal Function Assessment.

Table iv. Short Musculoskeletal Function Assessment (SMFA) disability category scores for patients treated operatively and nonoperatively, excluding patients who sustained a re-rupture.

Category	Median operative score (IQR) n=31	Median nonoperative score (IQR) n=27	p-value*
Mobility	0 (0.00 to 8.33)	0 (0.00 to 5.56)	0.491
Daily activities	0 (0.00 to 5.00)	0 (0.00 to 5.00)	0.461
Emotional	7.14 (0.00 to 14.29)	3.57 (0.00 to 10.71)	0.157
Hand and arm	0 (0.00 to 0.00)	0 (0.00 to 0.00)	0.330

*Mann-Whitney U test.
IQR, interquartile range.

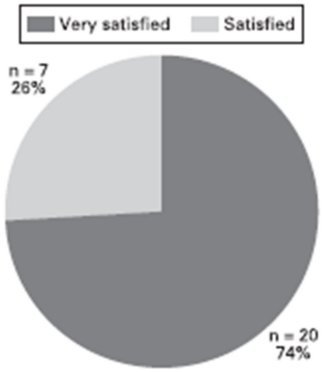

Fig. f

Patient satisfaction with their nonoperatively treated Achilles tendon.

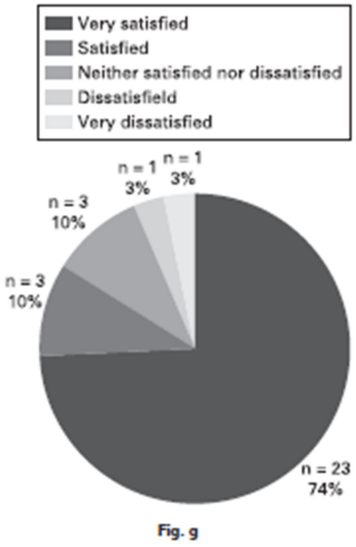

Fig. g

Patient satisfaction with their operatively treated Achilles tendon.

Patients were also asked whether they would have the same treatment again if it was required on the other side (Table v). Comparison of those who stated they were likely (i.e. answered 'extremely likely' or 'likely') and those who were unlikely (i.e. 'extremely unlikely' or 'unlikely') to do so demonstrated no significant difference between treatment groups (p = 0.275, Fisher's exact test).

Table v. Would you have the same treatment again if it were required on the opposite side?

Responses, n	Operative	Nonoperative
Extremely likely	18	17
Likely	7	7
Neither likely nor unlikely	2	2
Unlikely	0	0
Extremely unlikely	2	0
Don't know	2	1
Total responses	31	27

The net promoter score was 32 for patients treated operatively and 37 for patients treated nonoperatively. Under current NHS Friends and Family test (FFT) reporting guidelines, 77.4% of patients would recommend operative treatment and 6.5% would not, while 85.2% would recommend nonoperative treatment and none would not (Table vi). Comparison of those who stated they were likely (i.e. those answering 'extremely likely' or 'likely') and those who were unlikely (i.e. 'extremely unlikely' or 'unlikely') to recommend their treatment demonstrated no significant difference between treatment groups (p = 0.276, Fisher's exact test).

Table vi. How likely are you to recommend this treatment to friends and family if they needed similar care or treatment?

Response, n	Operative	Nonoperative
Extremely likely	17	14
Likely	7	9
Neither likely nor unlikely	3	3
Unlikely	0	0
Extremely unlikely	2	0
Don't know	2	1
Total responses	31	27

A Randomized Controlled Trial Comparing Traditional Plaster Cast Rehabilitation With Functional Walking Boot Rehabilitation for Acute Achilles Tendon Ruptures

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Background: There has been a shift toward functional nonoperative rehabilitation in the treatment of Achilles tendon rupture (ATR) despite a shortage of studies directly comparing nonoperative functional rehabilitation with traditional nonoperative immobilization.

Purpose: To compare patient-reported outcome measures and functional outcomes for nonoperatively treated ATR with traditional cast immobilization or functional rehabilitation in a walking boot.

Study Design: Randomized controlled clinical trial; Level of evidence, 2.

Methods: In a single-center nonblinded study, 140 patients were randomized to compare treatment for acute ATR in (1) an immobilizing cast in reducing degrees of equinus over a 10-week period with 8 weeks of nonweightbearing mobilization or (2) a walking boot for 8 weeks with reducing equinus and immediate full weightbearing. Exclusion criteria were delayed presentation >2 weeks after injury, tendon reruptures, and latex allergy. Analysis was undertaken on an intention-to-treat basis.

Results: A total of 69 patients (median age, 41 years [interquartile range, 33-50.5 years]) were randomized to walking boot treatment and 71 patients (41 [32-49]) to cast treatment. At 6 months, patients treated in a walking boot reported better Short Musculoskeletal Function Assessment (SMFA) dysfunction index (6.62 [2.21-12.50] vs 10.66 [4.96-13.42]; $P = .050$), SMFA bother index (7.29 [2.08-14.58] vs 10.42 [5.73-19.27]; $P = .04$), Achilles Tendon Total Rupture Score (71.5 [53.50-84.25] vs 54.0 [37-76]; $P = .01$), and Foot and Ankle Questionnaire core score (91 [81.89-97.55] vs 85 [78.25-92.09]; $P = .04$). At 1 year, there was no difference in SMFA dysfunction index (2.21 [0.74-5.88] vs 2.94 [1.47-6.62]; $P = .25$), SMFA bother index (2.08 [0-9.38] vs 5.21 [0.52-11.98]; $P = .25$), Achilles Tendon Total Rupture Score (92 [72.50-96] vs 87.5 [66.0-94.75]; $P = .21$), or Foot and Ankle Questionnaire core score (97.75 [89.46-99.00] vs 95.50 [90.88-97.50]; $P = .18$). Rerupture occurred in 5 and 11 patients ($P = .075$) and venous thromboembolism in 2 and 3 patients ($P = .67$) in the boot and cast groups, respectively. Fifteen patients in the boot group but none in the cast group had skin problems ($P < .001$). Patients treated in a boot returned to driving at a median 12 weeks (vs 13 weeks for cast; $P = .045$), but there was no difference in time to return to work ($P = .48$).

Conclusion: Functional rehabilitation with early weightbearing is a safe alternative to traditional immobilizing treatment for ATR, giving better early functional outcomes, albeit with a higher incidence of transient minor skin complications.

Registration: NCT02598843 (ClinicalTrials.gov identifier).

Keywords: Achilles tendon; rupture; clinical assessment; ankle

Achilles tendon ruptures (ATRs) are common injuries, and the incidence is rising.[13,24] Traditionally, when one is faced with an acute ATR, the choice is between operative or nonoperative management, followed by prolonged periods of immobilization without weightbearing in progressively reducing degrees of equinus.[9,16,19] In recent years, good outcomes have been reported with functional rehabilitation programs allowing early weightbearing, controlled motion exercises, or both[22] in the context of operative or nonoperative treatment.**

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**References 11, 12, 14, 18, 26, 31, 36, 39-41.

There has been a trend toward increasing nonoperative management of these injuries, despite some persistent geographical variation.[3,13,15,23,34] This trend may be driven by reported good results with nonoperative management in the context of functional rehabilitation.[23] However, studies driving the advent of functional rehabilitation programs have tended to be in the context of operative treatment for ATR[6] or have compared operative with nonoperative management, but they have not directly assessed outcomes of nonoperative management in the presence or absence of functional rehabilitation.[22,25,26,30,35,39,41] One study undertaken between 2001 and 2003 did compare nonoperative functional weightbearing and traditional cast management and reported no significant differences between groups, although it was small and adopted a relatively long period in the orthosis (12 weeks) for the functional group, with an orthosis not commonly used in modern regimens.[11] There are minimal data comparing functional nonoperative rehabilitation with traditional nonoperative rehabilitation, despite a clear drive toward the former in mainstream practice.[3,22]

The aim of this prospective randomized trial was to compare patient-reported outcomes after traditional cast immobilization with prolonged nonweightbearing versus functional rehabilitation and early weightbearing in a walking boot for adult patients from the general population who were treated nonoperatively for an ATR. Secondary aims included comparison of additional patient-reported outcome measures (PROMs), clinical measurements of outcome, return to work and driving, and complication rates.

METHODS

This was a prospective randomized nonblinded controlled trial (ClinicalTrials.gov NCT02598843). The single-center study was granted a favorable opinion by the South East Scotland Research Ethics Committee 01. Walking boots were provided without charge by Ossur, which was not involved in any aspect of trial design, management, data analysis, or reporting. Patients were eligible for inclusion if they were aged between 16 and 60 years and had sustained an acute ATR. Exclusion criteria were delayed presentation >2 weeks and presentation with a rerupture of a previously injured Achilles tendon. Latex allergy was added to the list of exclusion criteria in 2017 after notification by the manufacturer that latex was present in the sole of the walking boot. ATR was diagnosed clinically, with ultrasound used only at the discretion of the clinician, if in doubt. A total of 140 patients (Figure 1) were randomized to receive traditional nonoperative management (n = 71) or accelerated functional rehabilitation with a walking boot (n = 69). Randomization was undertaken on a 1:1 basis by a research assistant at first presentation to the orthopaedic outpatient department per a computer-generated binary sequence and sealed envelope allocation. Recruitment was undertaken between November 2013 and May 2018 with a pause for 9.5 months, when the boot suppliers ceased production of the in-boot wedges of the required dimensions but resumed once the wedges were available.

Patients were treated as follows.

Standard Nonoperative Pathway

The patient's limb was placed into a complete below-knee cast with the ankle in full equinus and he or she was instructed to remain nonweightbearing on the affected limb. After 4 weeks, patients underwent conversion into a complete below-knee cast in a semiequinus position for a further 4 weeks and were instructed to remain nonweightbearing. After this, the limb was placed into a cast with the ankle in a plantigrade (neutral) position and the patient was advised to fully bear weight in this. After 2 weeks, the cast was removed; physical therapy was commenced as described in Appendix A (available in the online version of this article); and patients could fully bear weight in their normal shoe wear with an internal 1.5-cm heel-raise shoe insert for 2 weeks, after which the shoe insert was discarded. Active plantarflexion commenced at 10 weeks.

Functional Nonoperative Pathway

The patient's limb was placed into an Ossur Rebound (Ossur hk) walking boot (worn continuously, including when in bed) with a 3-cm internal heel raise and he or she was advised to immediately bear full weight with the aid of crutches for balance as needed. After 4 weeks, the internal heel raise was reduced to 1.5 cm for 2 weeks. Patients then spent 2 weeks with the walking boot in a plantigrade position with no internal heel raise. No range

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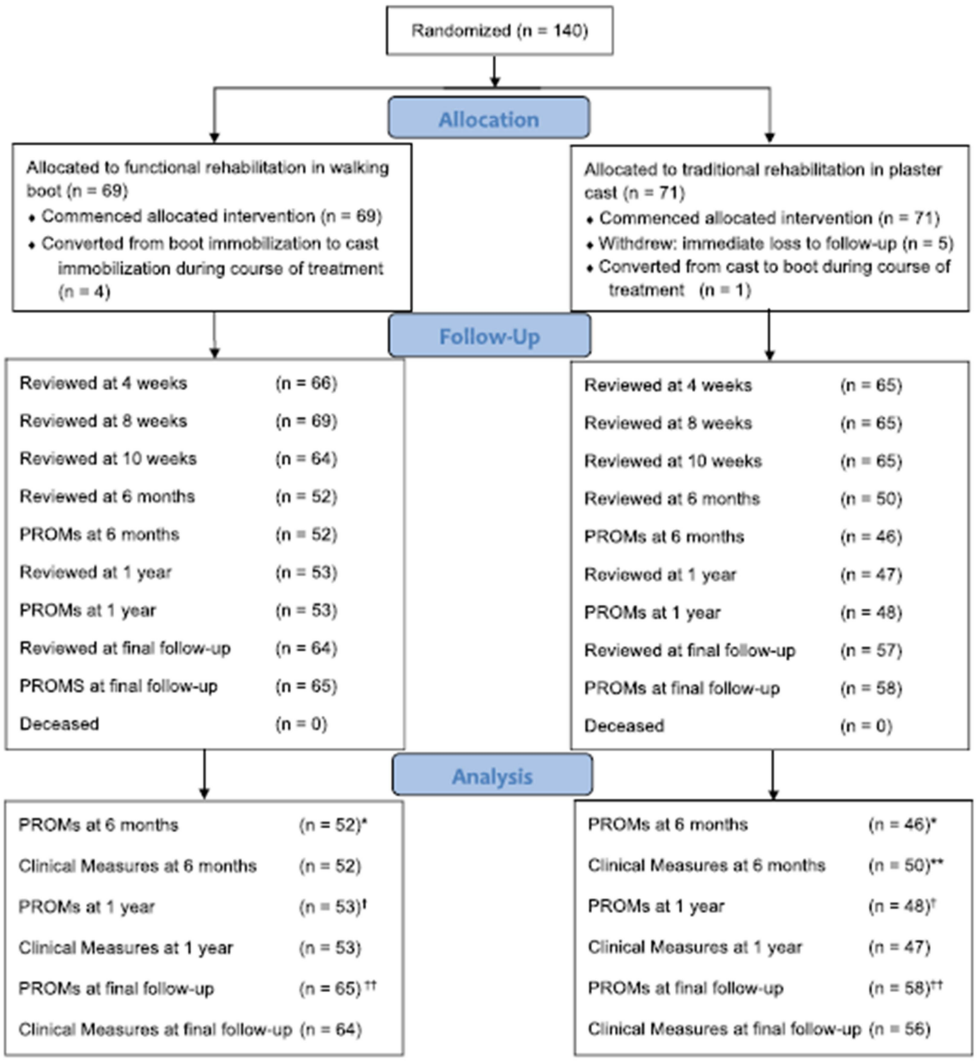

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram for the study. *Applies to all PROMs except ATRS (n = 52 and n = 47), FAQ core (n = 53 and n = 45), and FAQ shoe (n = 41 and n = 32). **Except calf circumference and pain score (n = 49). †Except FAQ core (n = 53 and n = 45) and FAQ shoe (n = 40 and n = 41). ††Except FAQ core (n = 65 and n = 55) and FAQ shoe (n = 48 and n = 50). ATRS, Achilles Tendon Total Rupture Score; FAQ, Foot and Ankle Questionnaire; PROM, patient-reported outcome measure.

of motion exercises were undertaken while in the boot. The boot was removed after 8 weeks, and physical therapy commenced upon removal of the boot, as described in Appendix A (available online). Active plantarflexion was commenced at 8 weeks.

Patient Follow-up

The primary outcome measure was the Short Musculoskeletal Function Assessment (SMFA) score.[37] Patients were reviewed at their initial visit and then at 4, 6, 8, 10, 26,

and ≥52 weeks from the date of injury. At each visit, data regarding complications were recorded, including the incidence of venous thromboembolism or tendon rerupture. Patients were also asked questions pertaining to return to specific activities, including driving and work. At 10, 26, and 52 weeks, additional clinical measurements were taken, including calf circumference 11 cm below the posterior knee skin crease and active ankle plantar- and dorsiflexion range of motion, which were measured to the nearest full degree with a goniometer. Patients were also asked to indicate the subjective level of pain experienced on a scale of 0 (no pain) to 10 (severe pain).

At initial review and at 6 and 12 months, patients were additionally asked to complete validated PROMs—the SMFA questionnaire,[37] Achilles Tendon Total Rupture Score[27] (ATRS), and the Foot and Ankle Questionnaire (FAQ).[17] The SMFA is a 46-question PROM derived from the longer Musculoskeletal Function Assessment.[37] Dysfunction and bother indices were calculated. It is valid, reliable, and responsive to change in status in patients with musculoskeletal injury. It is therefore reported to be suitable to clinically assess the effect of treatment in patients with musculoskeletal injury.[37] The ATRS is a 10-question PROM that was shown to be sensitive, valid, and reliable in assessment of patients with ATR. The ATRS ranges from 0 (most disability attributed to Achilles tendon) to 100 (least disability).[27] No questionnaire had >2 missing questions; as such, any missing questions were calculated as a score of 0, in keeping with the methodology employed by the authors who originally described this score.[26] The FAQ is a 25-question PROM developed by the American Academy of Orthopaedic Surgeons to measure foot and ankle–related disability.[17] It is reported as core and shoe comfort scales.

Power Analysis

Power analysis was undertaken with G*Power software (Department of Psychology; Universität Düsseldorf) to determine the number of recruits required. It was based on the primary outcome measure (SMFA questionnaire), for which a minimum clinically important difference of 7 points was previously described.[7] With a 2-tailed power analysis and an SD of 10 points, a minimum of 110 patients would be required at final follow-up to achieve power of 95% with an $\alpha = .05$. In total, 140 patients were recruited to allow for potential loss to follow-up.

Statistical Analysis

Statistical analysis was undertaken on an intention-to-treat basis. Data parametricity was assessed with Kolmogorov-Smirnov testing. Nonparametric continuous data were reported as median with interquartile range (IQR) and compared with independent-samples Mann-Whitney *U* tests when unrelated and with related-samples Wilcoxon signed rank test when related. Parametric data were reported as mean and standard deviation and compared with a 2-tailed Student *t* test when unrelated and with a paired Student *t* test when related. Nominal variables were compared between groups with a chi-square test, except if the expected cell count was <5 in any cell, in which case a Fisher exact test was used. Two-tailed analyses were undertaken. A *P* value ≤.05 was considered significant.[10]

RESULTS

A total of 140 patients (mean age, 41 years; range, 19-59 years) were recruited, and 123 (87.9%) were followed up at the final time point at a median 385 days (IQR, 372-419) after injury. Five patients crossed over between arms of the study (4 converted from boot to cast treatment and 1 from cast to boot), and 5 patients (all randomized to the cast group) withdrew from the study. The baseline demographic and PROM data for the 2 groups were well-matched (Table 1). Median time to final follow-up for the final review cohort was 393 days (IQR, 372.5-429.5; range, 360-1151) for patients treated in the boot and 382 days (IQR, 372-406; range, 357-1126) for patients treated in the cast ($P = .32$).

Patient-Reported Outcomes

There was a statistically significant difference at 6-month follow-up for SMFA, ATRS, and FAQ core scores but no persistent statistically significant differences in the SMFA or any other PROM at 1 year or final follow-up (Table 2).

For patients in the boot and cast groups, there was a statistically significant improvement in both SMFA indices, ATRS, and FAQ core scores between 6 months and final follow-up (all $P < .001$), although changes in FAQ shoe score were not statistically significant ($P = .051$ for boot and $P = .093$ for cast). At final follow-up, a statistically significant difference persisted in both groups for all PROMs as compared with preinjury scores ($P \leq .003$), except for FAQ shoe scores in the boot group ($P = .08$).

Patient Activities

In sum, 125 patients stated that they drove before their injury, while 15 did not. At 1 year, driving status was known for 116 of these patients (93%), of which 108 reported that they could drive without difficulty, 3 could drive with difficulty, and 4 were driving but whether they had any difficulty was unknown. One patient who drove preinjury indicated an inability to drive. Time to return to driving was known for 113 of the 116 patients whose driving status was known at 1 year. Patients treated in a boot (n = 59) returned to driving at a median 12 weeks (IQR, 10-14), whereas those treated in a cast (n = 54) returned to driving at a median 13 weeks (IQR, 11-16; $P = .045$).

A total of 130 patients were in paid employment at the time of enrollment, and of these, employment status was known at 1 year for 127 (97.7%). One patient retired and did not return to work after injury, while 1 changed jobs from a builder to a taxi driver as a result of the Achilles tendon injury. The remaining 125 patients returned to

TABLE 1
Baseline Demographics for Patients at Enrollment[a]

	Rehabilitation, No. or Median (IQR)		
	Functional: Boot	Standard: Cast	*P* Value
Age, y	41 (33-50.5)	41 (32-49)	.29
Sex, male:female	54:15	60:11	.21
Side of injury, right:left	28:41	28:43	.89
Dominant side injured	26 of 69	28 of 71	.83
Body mass index	26.6 (23.8-29.5)	26.4 (24.3-28.9)	.99
Preinjury PROMs			
SMFA dysfunction index	0 (0-1.47)	0 (0-1.84)	.74
SMFA bother index	0 (0-0)	0 (0-2.08)	.87
ATRS	100 (100-100)	100 (100-100)	.99
FAQ core score	100 (100-100)	100 (100-100)	.32
FAQ shoe score	100 (100-100)	100 (100-100)	.07

[a]ATRS, Achilles Tendon Total Rupture Score; FAQ, Foot and Ankle Questionnaire; IQR, interquartile range; PROM, patient-reported outcome measure; SMFA, Short Musculoskeletal Function Assessment.

TABLE 2
Patient-Reported Functional Outcomes for Trial Patients[a]

	Rehabilitation, Median (IQR)		
	Functional: Boot	Standard: Cast	*P* Value[b]
6 mo			
SMFA dysfunction index	6.62 (2.21-12.50)	10.66 (4.96-13.42)	**.050**
SMFA bother index	7.29 (2.08-14.58)	10.42 (5.73-19.27)	**.04**
ATRS	71.5 (53.50-84.25)	54.0 (37-76)	**.01**
FAQ core score	91 (81.89-97.55)	85 (78.25-92.09)	**.04**
FAQ shoe score	100 (62.50-100)	87.5 (35-100)	.10
1 y			
SMFA dysfunction index	2.21 (0.74-5.88)	2.94 (1.47-6.62)	.25
SMFA bother index	2.08 (0-9.38)	5.21 (0.52-11.98)	.25
ATRS	92 (72.50-96)	87.5 (66-94.75)	.21
FAQ core score	97.75 (89.46-99)	95.50 (90.88-97.50)	.18
FAQ shoe score	100 (81.25-100)	100 (63.33-100)	.59
Final follow-up			
SMFA dysfunction index	2.21 (0.37-6.25)	2.94 (0.74-7.35)	.17
SMFA bother index	2.08 (0-9.38)	4.17 (0-13.02)	.29
ATRS	92 (74-96)	88 (66-95.25)	.20
FAQ core score	97.75 (90.38-99)	95.50 (91.25-98.75)	.21
FAQ shoe score	100 (100-100)	100 (72.92-100)	.52

[a]ATRS, Achilles Tendon Total Rupture Score; FAQ, Foot and Ankle Questionnaire; IQR, interquartile range; SMFA, Short Musculoskeletal Function Assessment.
[b]Independent-samples Mann-Whitney *U* test. Bold indicates $P \leq .05$.

their previous jobs within 1 year of injury. Median time to initial return to work was 4 weeks (IQR, 1-12; range, 0-40) for patients treated in the boot and 2 weeks (IQR, 0-12; range, 0-26) for patients treated in cast ($P = .51$), while return to full duties at work was at a median 10 weeks in both groups (IQR, 1-16 [range, 0-52] for boot group; IQR, 0.88-14 [range, 0-30] for cast group; $P = .48$).

Clinical Measures

Calf Circumference. Calf circumference was significantly less in the injured leg than uninjured leg at all time points across both treatment groups (Table 3). The percentage deficit in calf circumference between injured and uninjured legs was greater in the cast group than the boot group at 10 weeks after injury (5.8% vs 2.8%; $P < .001$), but there was no significant difference at 6 months ($P = .82$), 1 year ($P = .68$), and final review ($P = .68$). There was no statistically significant difference in uninjured leg calf circumference between initial and final measurements in the boot ($P = .27$) or cast group ($P = .58$), while in the injured leg, there was a statistically significant difference in calf circumference in the boot group ($P = .025$) and cast group ($P < .001$); despite this, a significant deficit in circumference persisted at final follow-up in both groups.

TABLE 3
Calf Circumference for Injured and Uninjured Legs[a]

	Injured	Uninjured	Deficit, %
10 wk			
Boot	37.00 (34.63-39.88)	38.75 (36-40.50)	2.80 (0.29-5.73)
Cast	36.50 (34-38.38)	39.00 (36-41)	5.80 (4.08-8.51)
6 mo			
Boot	37.25 (35-40.38)	39.00 (36.13-41.78)	2.99 (1.33-5.02)
Cast	38.00 (36-40.50)	40.00 (37-42)	3.33 (1.23-5.76)
1 y			
Boot	37.00 (35.25-40.50)	39.19 (37-42)	2.44 (1.16-5.16)
Cast	38.00 (35.50-40)	39.00 (36-41)	2.38 (1.14-4.76)
Final follow-up			
Boot	37.00 (35-40)	38.85 (36.63-41)	2.47 (0.27-5.10)
Cast	37.75 (35.63-40)	38.75 (36.50-40.93)	2.38 (0.28-4.57)

[a]The median (IQR) calf circumference (in centimeters) was measured 11 cm below the popliteal crease. The deficit is reported as the median (IQR) percentage difference in calf circumference between injured and uninjured legs. For each difference in median circumference between injured and uninjured legs, $P < .001$ (Wilcoxon signed rank test).

TABLE 4
Ankle Range of Motion[a]

	Injured		Uninjured		Deficit[b]	
	Plantarflexion	Dorsiflexion	Plantarflexion	Dorsiflexion	Plantarflexion	Dorsiflexion
10 wk						
Boot	35 (30-40)	5.5 (5-10)	40 (40-45)	10 (10-15)	6 (0-10)	5 (0-10)
Cast	30 (20-30)	5 (0-5)	40 (35-50)	10 (10-15)	15 (10-20)	10 (5-10)
6 mo						
Boot	43 (40-45)	10 (5.50-15)	45 (40-50)	10 (10-15)	0 (0-5)	0 (0-3.75)
Cast	40 (33.75-45)	10 (5-14.25)	45 (40-50)	10 (10-15)	0 (0-5)	0 (0-5)
1 y						
Boot	40 (40-49)	10 (5.50-14.50)	45 (40-50)	10 (9-15)	0 (0-2)	0 (0-1)
Cast	40 (40-45)	10 (5-12)	41 (40-50)	10 (10-11)	0 (0-5)	0 (0-0)
Final follow-up						
Boot	40 (40-47.25)	10 (6-14.75)	45 (40-50)	10 (10-15)	0 (0-3.75)	0 (0-3)
Cast	40 (35-45)	10 (10-10.75)	41 (40-50)	10 (10-14.25)	0 (0-5)	0 (0-0)

[a]Data are presented as median degrees (interquartile range).
[b]Deficit between the injured and uninjured ankles.

Active Ankle Range of Motion. Deficits of plantarflexion and dorsiflexion (Table 4) were observed between the injured and uninjured limbs for patients in the boot and cast groups at 10 weeks, but the deficit was greater in the cast group for plantarflexion ($P < .001$) and dorsiflexion ($P = .001$).

At 6 months ($P < .001$ for both), 1 year ($P = .019$ for boot and $P = .003$ for cast), and final follow-up ($P = .004$ for boot and $P = .001$ for cast), there were persistent but clinically small deficits in plantarflexion in the boot and cast groups; however, there was no significant difference in the magnitude of this deficit between groups ($P > .38$).

At 6 months, 1 year, and final follow-up, there was no clinical difference in median range of dorsiflexion in both groups.

Single- and Double-Heel Raise. There was no significant difference in ability to undertake single- or double-heel raise at 6 months, 1 year, or final follow-up (Table 5).

Pain. Most patients reported low levels of pain. There was a small but significant difference in patient-reported pain scores between the groups at 8 weeks but not at any other time point (Table 6). At final follow-up, 17.2% (11 of 64) of the boot group and 31.6% (18 of 57) of the cast group reported experiencing any degree of pain ($P = .064$).

Complications

Reruptures. Of 125 patients whose status was known at 1 year, 16 had sustained a rerupture (12.8%) at a mean 13.99 ± 3.34 weeks after the initial injury, of which 11 of 60 (18.3%) were in a cast and 5 of 65 (7.7%) were in a boot (risk ratio, 0.885; 95% CI, 0.770-1.017; $P = .075$). All reruptures occurred within 21 weeks of the original injury. Thirteen patients were treated surgically; 2 were managed in a boot; and 1 had a concomitant deep vein

TABLE 5
Proportion of Patients Able to Complete Heel Raise

	Rehabilitation		
	Functional: Boot	Standard: Cast	*P* Value
6 mo			
Double-heel raise	52 of 52	48 of 50	.24[a]
Single-heel raise	32 of 52	35 of 50	.37[b]
1 y			
Double-heel raise	53 of 53	48 of 48	
Single-heel raise	28 of 44	30 of 42	.44[b]
Final follow-up			
Double-heel raise	64 of 64	57 of 57	
Single-heel raise	56 of 64	55 of 57	.10[a]

[a]Fisher exact test.
[b]Chi-square test.

TABLE 6
Self-reported Pain Score for Patients[a]

	Rehabilitation, Median (IQR)		
	Functional: Boot	Standard: Cast	*P* Value[b]
4 wk	0 (0-2)	1 (0-2)	.22
8 wk	0 (0-0)	1 (0-2.5)	**<.001**
10 wk	0 (0-2)	0 (0-1)	.86
6 mo	0 (0-1)	0 (0-2)	.07
1 y	0 (0-0)	0 (0-1)	.22
Final follow-up	0 (0-0)	0 (0-1)	.07

[a]IQR, interquartile range.
[b]Independent-samples Mann-Whitney *U* test. Bold indicates $P \leq .05$.

thrombosis (DVT) and therefore underwent anticoagulation and was managed nonoperatively. He went on to heal with tendon elongation and underwent delayed surgery for this.

Venous Thromboembolism. Five patients (3 treated in cast and 2 in boot; $P = .67$) developed symptomatic venous thromboembolism at a median 7.28 weeks (IQR, 1.79-11.79). Of these, 2 had an isolated DVT; 2 had a DVT and pulmonary embolism confirmed on imaging studies; and 1 had an isolated pulmonary embolism. All were managed with anticoagulation (warfarin in 3 cases and rivaroxaban in 2 cases).

Minor Skin Issues. Fifteen patients, all treated in the boot arm of the trial, developed superficial skin breakdown, maceration, or localized blistering during the course of treatment for their primary injury. Two patients were converted to cast treatment on account of this, while the remainder were treated with simple dressings. All skin lesions healed uneventfully with no long-term sequelae. No patients in the cast arm of the trial developed skin lesions ($P < .001$).

DISCUSSION

This randomized controlled trial directly compares traditional immobilizing cast management with modern functional rehabilitation and early weightbearing in a walking boot for nonoperative management of acute ATR. Improved early function was demonstrated for patients in the boot group with regard to PROMs, time to return to driving, ankle range of motion, and calf circumference. However, none of these differences persisted at 1 year or beyond. This study provides evidence that functional rehabilitation is safe, giving equivalent outcomes to traditional immobilizing management at or beyond 1 year; it also appears to give superior early outcomes, albeit with a higher incidence of transient minor skin complications.

It has been postulated that the increased use of nonoperative management may be due to good outcomes reported with functional rehabilitation,[13,22] although there is a lack of evidence to support this claim.[3,22] Similarly, a meta-analysis comparing functional and traditional treatment for ATR found that the trend toward functional management was not supported by robust evidence, despite multiple authors advocating such protocols.[22] The authors suggested that functional operative and nonoperative treatment protocols be distinguished from one another, and they highlighted the need for randomized studies that directly compare traditional and functional rehabilitation.[22] If functional rehabilitation is to become and remain the gold standard treatment for these injuries in modern practice, where nonoperative management is increasingly favored, then it must be shown to provide outcomes that are at least equal to those obtained with traditional nonoperative management.

Patient-Reported Outcomes

This study comprised a variety of PROMs, including injury-specific,[27] joint-specific,[17] and general musculoskeletal[37] PROMs, thereby giving a broad overview of patient-perceived outcome. Advocates of PROMs argue that they represent patients' subjective opinion of their outcome and that this is important, as improvement in patients' health status is the ultimate goal of most health services.[5,38] There was a statistically significant difference across the range of PROM scores used at 6-month follow-up, with better scores consistently reported by patients treated with functional rehabilitation. The minimal clinically important difference for the ATRS has not been scientifically defined, although some authors have suggested a value of 10 points,[2] while the minimum detectable change has been indicated to be 6.8 points.[8] Differences in ATRS demonstrated at 6-month follow-up comfortably exceeded these, suggesting that patients experienced a noticeable difference in Achilles tendon function after treatment with these 2 techniques. However, although statistically significant, the difference in SMFA dysfunction index was less than the previously reported minimal clinically important difference for this score.[37] Olsson et al,[30] using a very similar functional rehabilitation regimen, noted similar ATRS scores to our functionally rehabilitated

group at 6 months (median, 73 points) and 12 months (median, 90 points), as well as significant improvement in ATRS between 6 and 12 months but with a persistent deficit at final follow-up, thereby corroborating our results. However, they did not compare this regimen with traditional nonoperative treatment.

These differences did not persist at final follow-up, indicating that the benefits of accelerated functional rehabilitation are most obvious to patients earlier on in the course of their recovery but that longer-term patient-reported outcomes are similar. Both groups exhibited significant improvements between 6-month follow-up and final follow-up, but their final scores remained lower than their preinjury scores, indicating that some deficit persists after these injuries; these findings are in agreement with other studies of outcomes after ATR.[26,30]

Patient Activities

Patients treated with functional rehabilitation in a walking boot returned to driving at a median 1 week earlier than those treated in a cast. This is consistent with the shortened period of immobilization in this group, which may facilitate an earlier return to some routine activities. However, there was no significant difference in the time to return to work between the groups. A recent meta-analysis comparing functional rehabilitation with immobilization also noted no difference in time to return to work between the modalities.[22] There are no randomized controlled comparisons of return to work or driving with modern nonoperative functional rehabilitation and traditional immobilization, but 1 small study[11] did compare return to work after these, using an old bracing system for functional rehabilitation. It found no difference in time to return to work between the groups; however, the convenience of early weightbearing has also been acknowledged.[11,22]

Clinical Measures of Outcome

Calf circumference of the uninjured legs remained unchanged throughout the period of study in both groups. The deficit in injured leg calf circumference was greatest at first measurement at 10 weeks after injury for both groups and gradually diminished with the passage of time; however, at final follow-up, there was a persistent residual deficit. Other authors similarly reported that a deficit in calf circumference of the injured leg persists beyond 1 year after injury.[1,4] The observed deficit was greater in the group managed with a cast at 10 weeks, suggesting that patients who undergo functional rehabilitation and continue to weightbear throughout their course of treatment lose less muscle bulk initially than those in a nonweightbearing cast. However, there was no persistent significant difference between treatment groups at longer-term follow-up, although a deficit between injured and uninjured legs did persist in both groups. Use of the maximum calf circumference could have been a more standard measurement methodology, although fixed point measures such as those used in this study have also been described.[1] Recent studies based on modern nonoperative early weightbearing functional rehabilitation regimens[1,41] reported very similar findings to ours, with a small but persistent deficit in calf circumference noted at 1 to 2 years,[1] thereby corroborating our results.

Similarly, patients in both groups exhibited a significant deficit in plantar- and dorsiflexion range of motion as compared with the uninjured limb at 10 weeks after injury, but this deficit was greater in the cast group. With the passage of time, patients in both groups demonstrated improvements in range of motion, and there was no difference between the groups at final follow-up. A majority of patients in both groups regained a full range of dorsiflexion when compared with their uninjured limb, but there was a small persistent active plantarflexion deficit, possibly related to tendon lengthening. These findings are in keeping with previously reported outcomes after nonoperative management of ATR.[19]

Both groups noted low levels of pain after these injuries, and these findings are consistent with studies by others.[19,24] There was a statistically significant difference in median pain score between groups at 8-week follow-up in favor of the functionally rehabilitated group, although this difference was clinically small. At final follow-up, median pain scores were 0 in both groups; however, almost one-third of patients treated in a cast, as compared with almost one-fifth who underwent functional rehabilitation, complained of some degree of persisting pain. This indicates that although most patients have good PROM scores and function, a degree of persistent discomfort may persist in a notable minority of patients. The proportion of patients who cited some degree of persistent pain in the functionally rehabilitated group at final follow-up was virtually identical to that in a noncomparative study on a functional rehabilitation regimen allowing early weightbearing but not early motion, thereby supporting our results.[12]

All tested patients in both groups were able to complete a double-heel raise at final follow-up; however, around 8.3% could not complete a single-heel raise on the injured leg. There was no difference between groups. Deficits in heel-raise ability are a recognized sequela of ATR.[29]

Complications

There was a trend toward a lower risk of rerupture in the functionally rehabilitated group ($P = .075$). Rerupture rates in the cast group were more than double those in the functionally rehabilitated group, which may be a clinically important finding despite not reaching statistical significance. This may be due to the study being underpowered to detect differences in rerupture rate and is a feature of many randomized controlled trials in the field of ATR, where differences in rerupture rate are often not detected in individual studies[20,26,41] but become apparent when data are pooled into meta-analyses.[28,32] A post hoc power calculation was performed according to the rerupture rates observed between the groups, with an alpha of .05, which confirmed that the current study was underpowered (43%) to demonstrate a statistical difference in rerupture rates; this may have resulted in a type II error. It has

been postulated that functional rehabilitation may significantly reduce the rate of tendon rerupture[35]; however, this conclusion has been criticized, as it was not based on direct comparison of rerupture rates in functional and traditional rehabilitation regimens.[22] Our study facilitates direct comparison of these regimens. The rerupture rate in our functionally rehabilitated group compares favorably with other functional regimens, where rates range from 6.6% to 12%,[4,12,24,30] although it is slightly higher than those in some functional operative regimens.[4,30] All observed reruptures occurred within 21 weeks of the injury, and this finding is in keeping with reports that tendon rerupture tends to occur early on in the process of recovery.[12,33]

Minor skin issues were frequent in the group treated in a walking boot. Other authors have noted similarly high rates of minor skin issues when patients are treated in a walking boot,[24,30] while the authors of one recently published functional rehabilitation program did not report on these complications,[1] although at an oral presentation on their treatment protocol, they described a 10% incidence of skin problems in their patients.[21] It is unclear whether the skin issues are the result of treatment in a boot or early weightbearing. It appears that they occur with increased frequency in patients treated with early weightbearing functional rehabilitation regimens, and clinicians and patients should be aware of this. None of the patients who developed these complications in our study had any long-term sequelae, although in 2 cases the skin issues were significant enough to warrant conversion to cast treatment.

Limitations

This study does have limitations. Some patients did not attend their scheduled 1-year review appointments on time. However, results of those evaluated >3 months after the 1-year mark were not included in the 1-year analysis and are presented only in the final follow-up cohort, which includes results from the last review at or beyond 1 year after injury. There was no significant difference in time to final follow-up between groups, suggesting that the groups remained comparable at this time point. Lack of muscle strength assessment based on a dynamometer may also be considered a limitation. Although it was initially planned as the primary outcome measure for this study, it could not be undertaken owing to logistical constraints. This study assessed only functional rehabilitation with early weightbearing; it did not assess the effect of combining this with early range of motion exercises commencing at 4 weeks and weaning of the boot from 6 weeks, as envisaged in the original protocol for our trial. The authors of a recent meta-analysis stated that early weightbearing and early range of motion are both considered functional rehabilitation treatment, and they suggested that these be distinguished for analysis.[22] Lack of blinding of physical therapists to the treatment modality may also be considered a limitation, as it may have subconsciously altered their confidence with progressing early exercises, while inability to blind patients to their treatment method may have caused assessment bias. Additionally, lack of 2-year follow-up in the study design and a higher amount of loss to follow-up in the cast group (which may result in bias) could be considered limitations. Strengths of the study include a large and highly powered sample size and low rates of loss to follow-up at the study endpoint.

CONCLUSION

After an ATR, functional rehabilitation with early weightbearing is a safe alternative to traditional cast immobilization with prolonged periods of nonweightbearing. It is associated with improved patient-reported outcomes in the short term, but these do not persist at 1 year. It is also associated with a higher incidence of minor skin complications that had no long-term sequelae, but the rate of tendon rerupture was less than half that in the traditionally rehabilitated group. Venous thromboembolism occurred in 3 patients in the cast and 2 patients in the boot. On the basis of these results, we recommend the use of functional rehabilitation in preference to traditional cast immobilization.

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Appendix 7.2 Presentations Arising from this Thesis

June 2022 - The Epidemiology Of Achilles Tendon Re-Rupture And Associated Risk Factors. Oral presentation. 23rd EFORT (European Federation of National Associations of Orthopaedics and Traumatology) Congress, Lisbon.

June 2022 - The Epidemiology Of Achilles Tendon Rupture And The Influence Of Socioeconomic Deprivation Status. Poster presentation. 23rd EFORT (European Federation of National Associations of Orthopaedics and Traumatology) Congress, Lisbon.

- **Awarded prize – best poster presentation in scientific topic group (Foot & Ankle Trauma)**

October 2021 – Traditional Immobilising Plaster Cast Management vs Functional Walking Boot Rehabilitation for Achilles Tendon Rupture: A Randomised Controlled Trial. Oral presentation (presenting author). AOTSM Annual Scientific Meeting 2021.

June 2019 - Risk Factors For Re-Rupture After A First Time Rupture Of The Achilles Tendon. Oral presentation. 20th EFORT International Conference, Lisbon.

Appendix 7.3 EFORT Certificate: Best Poster Presentation

Certificate

EFORT - JOINT EFFORTS

Certificate of Special Mention

The European Federation of National Associations of Orthopaedics and Traumatology certifies that

Julian Maempel (United Kingdom)

contributed with the oral presentation of the poster entitled

The Epidemiology Of Achilles Tendon Rupture And The Influence Of Socioeconomic Deprivation Status

Julian Maempel , Nick Clement , Sam Mackenzie , Conor McCann , Tim White

which was selected out of its scientific topic group as the best poster presentation onsite during our 23rd EFORT Annual Congress held in Lisbon, Portugal from 22 to 24 June 2022.

Søren Overgaard
EFORT Chair Science Committee

Li Felländer-Tsai
EFORT President 2021-2022

Appendix 7.4 Transfer of MPhil Studies to PhD

L-Università ta' Malta

Doctoral School
University of Malta
Msida MSD 2080, Malta

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doctoralschool@um.edu.mt

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27 March 2020

Dr Julian Zammit Maempel
Ta' l-Andar
Triq Vincenz Galea
San Gwann SGN2927

Student Code: 345999M

Dear Dr Zammit Maempel

Transfer of Studies to Ph.D. Degree

I would like to inform you that Senate has agreed to the recommendation of the Board of the Faculty of Medicine and Surgery that you be allowed to transfer your studies to the Ph.D. degree, with effect from 1 April 2020.

A copy of the Ph.D. regulations is enclosed for your guidance. In particular your attention is being drawn to regulation 39. You are also advised to read the Principles of Procedure on the Supervision of Master's Dissertations and Doctoral Theses which may be found on the University website through the following link:
http://www.um.edu.mt/__data/assets/pdf_file/0018/104274/Procedures_for_Supervision_of_Masters_Dis.pdf

Your period of studies commenced on 1 April 2017 and, according to the regulations, you are expected to complete your studies by not later than 31 March 2023.

Yours sincerely

Colin Borg
Deputy Registrar

c.c. Dean, Faculty of Medicine and Surgery and, Principal Supervisor
Dr Nicholas David Clement, Co-Supervisor
Director of Finance
Officer i/c Faculty of Medicine and Surgery
SIMS Office

Enc.