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# By Dr David Muscat

Dear colleagues,

Sadly, our colleague Dr Alfred Magri Demajo has recently passed away. Please read the appreciation on page 38.

It has been an eventful year. Since September there have been several dental related events, listed on the right.

I would like to thank all the committee for their work and in particular Lino who has made a great difference with the quality of our events. All committee members give their time freely. I would also like to thank our sponsors. I invite all the dentists to please to pay their 50 euro subscriptions in January and benefit from your memberships straight away. We have given out CPE refund vouchers as prizes in our raffle at our party. We have allocated 3,000 euro towards CPE courses in 2013. Our next events will be the AGM and St Apollonia.

The DAM committee wishes you all a great Christmas and a Happy New Year.

Best regards,

# David

Dr David Muscat B.D.S. (LON) Editor, Vice President and P.R.O. D.A.M.

Advertisers are responsible for the claims they make in their ads and the opinion of the advertisers and editors of articles in the issue are not necessarily the opinion of the DAM.



Dr David Muscat presenting The Dental Probe to delegates at the FEDCAR Assembly in Paris on 30 November 2012. Dr Muscat is currently President of the Federation of Dental Competent Authorities and Regulators in Europe

#### **RECENT EVENTS**

#### **25 OCTOBER**

Maritime Museum lecture by Liam Gauci Curator 'From Slave To Captain' followed by dinner at Don Berto sponsored by Bial

#### **3 NOVEMBER**

Ellanse event Excelsior Hotel

#### **6 NOVEMBER**

'Osteonecrosis Of The Jaw' by Professor Andrew Borg at Westin with dinner sponsored by Novartis.

#### **14 NOVEMBER**

'The Socket' by Dr Mark Diacono at I Vetri with dinner sponsored by Menarini

## **21 NOVEMBER**

Smile For Health Intercontinental Hotel

#### **4 DECEMBER**

Palazzo de Piro DAM Christmas party

#### **5 DECEMBER**

Lifesaving Skills DAM course run by Drs Adam Bartolo and Dr Nicholas Dougall

#### 10 DECEMBER

Carestream seminar sponsored by Bart Enterprises

#### **16 DECEMBER**

DAM spiritual talks and Mass at Mount St Joseph

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The highlight of the Hon Dr Herbert Messina Ferrante's career occurred on Republic Day, 13 December 2012, when H.E. Dr. George Abela President of Malta (here seen sharing a joke with Herbert)awarded him the prestigious State Honour, The Medal of The National Order of Merit (M O M) for having distinguished himself in the professional field of dentistry and in humanitarian and societal pursuits. This year Herbert was also inducted into the Nobel Order of International Ambassadors (USA) and also holds this Honourable title. Our heartfelt congratulations to Herbert for being honoured with such awards





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# On failures in General Dental Practice

By Dr Antoine Camilleri

The filling that fell off, the dry socket after a simple extraction, the falling upper denture or the loose lower one, the deep restoration developing excruciating pulpitis and the fractured porcelain corner of a new anterior bridge. The list can go on, and although varied, shares a common denominator: they are all failures that dentists have to face sooner or later in daily practice.

And the irritated patient demands a solution from whom he believes is the one responsible - the dentist. We have all experienced the uncomfortable feeling of being faced with such situations. Failures can be time-consuming in terms of explanations or repeated work, and emotionally and financially draining. Failures can be bad for one's reputation, too. It is wise to try to minimize them as much as humanly possible.

Dentistry is so full of variables affecting the end result, some of which are certainly beyond the dentist's control. The heavy bruxist, the severely gagging patient, the lady with the limited mouth opening, and the patient with the dry mouth are familiar situations in which the dentist is required to perform and deliver. The patient has nowhere else to turn to, after all.

First of all, accurate and detailed patient records are essential and often prove valuable when dealing with complaints, both directly with the patient as well as from a medico-legal perspective.

Another good approach is communication before any treatment is done. The dentist tries to foresee any potential complications and notifies the patient beforehand, while letting him decide what course to

pursue. It is recommended that the dentist is not goaded by the patient into giving treatment against his/her professional judgement.

The dentist needs to understand clearly the patient's expectations. If these cannot be met, the dentist should clarify in advance. In general patients appreciate such honesty.

Dentistry isn't just a simple business transaction but a caring professional relationship. Subtle human factors are continuously contributing to this alive encounter and patients' perceptions to treatment provided can change. The psychology involved is very interesting and deserves a deep study in itself. Suffice to assert that mutual trust is the foundation of the dentist-patient relationship. Without it everything can easily crumble.

As in life, failures can be a mixed blessing in being a learning experience, an eye-opener and reveal the true nature of the dentist-dental technician and dentist-patient relationship.

It appears that the dentist always ends up as the one accountable, however certain gestures of empathy, or lack of it, from the technician, can prove to be a lesson in itself. The same holds true for the patient's behavior. Needless to say, the dentist should act considerately and fairly. This approach helps to nip unwelcome complications like legal action in the bud and reach a satisfactory solution.

On the other hand, the dentist should seek to continuously improve his/ her skills and standards. A gently self-critical eye on one's own work and clinical set-up, is healthy. Though mainly clinicians, the GDP's should strive to extract clear liquid from the dregs of the academics to enrich their

work. Evidence-based dentistry is the way to go. This could be tricky, given the plethora of research papers published, the new techniques and materials pushed by the major manufacturers, and a mixture of both.

Sometimes the expert opinion of our excellent professors and specialists can be so welcome. When sought, they always give their advice gladly and graciously.

The GDP must be aware of his/her level of skill and comfort zone, as well as the spectrum of work he/ she is legally entitled to. A good rule of thumb is: 'If in doubt, refer'. There is a dichotomy between referring and improving one's skill with a challenging case.

Of course, the more experienced one becomes, the less doubtful one gets. Ultimately the dentist is responsible for his/her actions, so one should tread carefully. On the flip side of the coin, renouncing his/her potential capability by refusing to perform certain duties in favor of referring can border on the ridiculous, as is happening in other countries.

Thankfully currently the Maltese GDP and Specialists enjoy a healthy symbiotic relationship based on respect and trust, which finally benefits our patients in terms of quality care. There should be no reason why this positive situation should change. People are getting more and more health conscious creating an ever expanding opportunity for various treatment options.

Today dentists can look forward optimistically to the future following a fulfilling vocation and continue to enhance the profession's reputation in the modern world.

# **OSTEOPOROSIS** AND JAW NECROSIS

By Professor Andrew Borg DM MD FRCP CCST (RHEUM)UK Professor of Medicine and Consultant Rheumatologist - Professor, Department of Medicine, University of Malta

## Osteoporosis is a Major Public Health Burden also in Europe

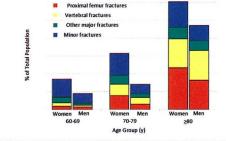
- Worldwide, an estimated 1 in 3 women and 1 in 5 men aged >50 years will have an osteoporotic fracture
- · In the EU, an osteoporotic fracture is sustained every 30
- The annual incidence of hip fracture alone in the EU is expected to increase from ~500,000 to 1,000,000 over the next 50 years
- Of the osteoporotic fractures sustained worldwide in 2000, the greatest number occurred in Europe (34.8% of the total)

### Osteoporosis:

#### The impact on morbidity and mortality

- 1 in 2 women over 50 will experience an osteoporotic fracture, as will 1 in 5 men<sup>1,2,</sup>
- A prior fracture is associated with an 86% increased risk of subsequent fracture4
- Almost a guarter of people over age 50 who suffer a hip fracture die within one year5

# Fracture incidence increases with age: 5-year fracture rates in women and men Proximal femur fractures Other major fractures Minor fractures



Adapted from Center JR, et al. Lancet 1999; 353:878-882

## Osteonecrosis of the Jaw (ONJ):

What it is -

How to Manage

## Osteonecrosis of the Jaw:

- The CHMP considered that "Osteonecrosis of the jaw related to bisphosphonates" can be defined as follows:
- "A patient may be considered to have ONJ related to bisphosphonates if all of the following 3 characteristics are
  - 1) Exposed or necrotic bone in the maxillofacial region that has persisted for more than 8 weeks
  - 2) No history of irradiation of the jaw
  - 3) Current or previous treatment with a bisphosphonate"

CHMP ASSESSMENT REPORT ON BISPHOSPHONATES AND OSTEONECROSIS OF THE JAW Procedure under Article 5(3) of Regulation (EC) No 726/2004 London, 24 September 2009 \_ FREATO-#PS-21125/2009

# Osteonecrosis of the Jaw:

- Patients receiving IV bisphosphonates for cancer indications are considered to be at the highest risk of developing ONJ (Malden et al., 2009, Silverman, 2009)
- The incidence of ONJ in patients receiving IV bisphosphonates for cancer indications is reported as ranging from 0.8% to 12 % in different studies (AAOMS position paper, 2009).
- Patients receiving oral bisphosphonates for osteoporosis or Paget's disease are considered to be at much lower risk of developing ONJ (Malden et al., 2009, Silverman, 2009).
- In the majority of published studies the incidence of ONJ in patients receiving oral bisphosphonates for osteoporosis or Paget's disease is reported to be low ranging from 0.0004% to 0.06% (AAOMS position paper, 2009).

CLIMP ASSESSMENT REPORT ON BISPHOSPHONATES AND OSTEONECROSIS OF THE JAW Procedure under Article 5(3) of Regulation (EC) No 726/2004 London, 24 September 2009, JEEA/CPAP/291125/2009

#### Osteonecrosis of the Jaw: Background

- Reports of ONJ have primarily been in patients with advanced malignancies and skeletal metastases
- · Etiology and pathogenesis are not well characterized
- > Role of bisphosphonates uncertain
- The clinical diagnosis of ONJ is usually made on the basis of visual inspection (eg, presence of exposed bone) and/or radiographic appearance<sup>1</sup>
- No uniform diagnostic criteria currently applied

### Possible Risk Factors for ONJ

- There are several theories for pathophysiology of ONJ
  - These theories have little evidence-based support
  - Probably multiple etiologies
- However, there are several suspected risk factors<sup>1-4</sup>

  - Chemotherapy including cytostatic agents and corticosteroids

  - Periodontal disease

  - Dental trauma Poor oral hygiene
  - Bacterial or fungal infection
- Alcohol or tobacco use

Orbic TI, et al. Am Dent Assoc. 2008;139:32-40. 2. Hansen T, et al. J Oral Pathol Med. 2006;35:155-10. 3. Khosla S, et al. J Bone Min Res. 2007;22:1479-1491. 4. Ruggiero S, et al. J Oncol Pract. 106;2:7-14.



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Children and adolescents below 14 years of age: not recommended. Contraindications: Active gastric or Intestinal ulcer, bleeding or perforation; known hypersensitivity to diclofenac or to any of the excipients, to aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs); Patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs; last trimester of pregnancy; severe hepatic, renal or cardiac failure. Precautions/warnings: Avold use with other systemic NSAIDs including COX-2 inhibitors. Risk of gastrointestinal (GI) bleeding, perforation or serious allergic reactions, persistent abnormal liver and renal function tests; to be discontinued if these conditions occur. Risk of allergic reactions. May mask signs and symptoms of infection. Caution recomdaily. Children and adolescents below 14 years of age: May mask signs and symptoms of infection. Caution recom-mended in patients with symptoms/history of Gl disease, asthma, seasonal allergic rhinitis, chronic pulmonary dis-eases, chronic infections of the respiratory tract, elderly or eases, chronic infections of the respiratory tract, elderly or impaired hepatic function (including porphyria), ulcerative colitis or Crohn's disease. Caution when used concomitantly with corticosteroids, anticoagulants, anti-platelets agents SSRIs. Caution while driving or using machines. Combined use with protective agents to be considered in patients with history of ulcers, elderly, and those requiring low dose aspirin. Monitoring of liver function and blood counts recommended during prolonged treatment. Monitoring of renal function recommended in patients with history of hypertenfunction recommended in patients with history of hyperten-sion, impaired cardiac or renal function, extracellular volume depletion, the elderly, patients treated with diuretics or drugs that impact renal function. Monitoring recommended in pa-tients with defects of haemostasis. As Catafast contains a source of phenylalanine, may be harmful for patients with phenylketonuria. Beware of severe fluid retention and oedema. Very rarely reported serious skin reactions, some of them fatal, including exfoliative dermatilis, Stevens-Johnson syndrome and toxic epidermal necrolysis. Discontinue at the first appearance. May be associated with a small increased risk of arterial thrombotic events. Before treatment consider carefully patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease, and before initiating longer-term treatment of patients with risk factors for cardiovascular disease. Pregnancy and lactation: Should not be used in the first and second trimester of pregnancy and by breast-feeding mothers. Not recommended to use in women attempting to conceive as it may impair female fertil-ity. Should not be administered during breast feeding in order to avoid undesirable effects in the infant. Interactions: Cauto avoid undesirable effects in the infant. Interactions: Cau-tion with concomitant use of diuretics and antihypertensives (e.g. beta blockers, ACE inhibitors), methotrexate, other NSAIDs and corticosteroids, SSRIs. Monitoring recom-mended for patients receiving anticoagulants, anti-plateiet agents as well as blood glucose level if used concomitantly with antidiabetics. Monitoring of serum lithium and digoxin levels recommended if used concomitantly. Dose of di-clofenac to be reduced in patients receiving ciclosporin. In-teractions with concomitant use of quinclones antibacterials. teractions with concomitant use of guinolones antibacterials. Adverse reactions: Common undesirable effects are: Headache, dizziness, vertigo, nausea, voniting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia, transami-nases increased, rash. Rare undesirable effects are: Hynases increased, rash. Rare undesirable effects are: Hy-persensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), somnolence, asthma (including dyspnoea), gastribitis, gastrointestinal haemor-hage, haematemesis, melaena, diamhoea haemorrhagic, gastrointestinal ulcer (with or without bleeding or perfora-tion), hepatitis, jaundice, liver disorder, urticaria, oederma. Very rare undesirable effects are: Thrombocytopenia, leu-kopenia, anaemia (including haemolytic anaemia and aplas-tic anaemia), acranulostosis; ancionautoric codema. tic anaemia, arractina (including internotytic arractina and aphasitic anaemia), agranulocytosis, angioneurotic oedema (including face oedema), disorientation, depression, insomnia, nightmare, irritability, psychotic disorder, paraesthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, taste disturbances, cerebrovascular accident, meningitis, taste disturbances, cerebrovascular accident, visual disturbance, vision blurred, diplopia, tinnitus, hearing impaired, palpitations, chest pain, cardiac failure, myocardial infarction, hypertension, vasculitis, pneumonitis, colitis (including haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, oesophageal disorder, diaphragm-like intestinal strictures, pancreatitis, fulminant hepatitis, bullous eruptions, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome toxic epidemal necrobises (fuell's syndrome). syndrome, toxic epidermal necrolysis (Lyell's syndrome), dermatitis exfoliative, loss of hair, photosensitivity reaction, purpura, allergic purpura, puritus, acute renal failure, hae-maturia, proteinuria, nephritic syndrome, interstitial nephritis, renal papillary necrosis. Marketing Authorisation number: MA 088/00303 Marketing Authorisation holder: Novartis Pharmaceuticals UK Ltd., Frimley Business Park, Frimley, Camberely, Surrey GU16 7 SR, UK. Please refer to Summary of Product Characteristics (SmPC) before prescribing. Full prescribing information is available on request from No-vartis Pharma, P.O. Box 124, Valletta, VLT 1000, Malta. Tel +356 22983217. 2009-MT-01-Catafast



# **OSTEOPOROSIS** AND JAW NECROSIS

### Continues from page 6.

## MDACC Retrospective Chart Review: Results

- 4019 patient charts were reviewed; 25 patients were excluded due to insufficient information  $% \left( 1\right) =\left( 1\right) \left( 1\right) \left($
- 3994 patients were included in final analysis: 29 cases of ONJ were identified

- Overall: - Breast cancer: 29/3994 (0.73%) 16/1338 (1.2%)

- Multiple myeloma: 13/548 (2.4%)

- Site of ONJ involvement: mandible (70% of cases) and maxilla (30% of cases)
- Of 29 ONJ cases, approximately 66% presented with exposed bone

et al. J Bone Min Res. 2008. (E-pub shead of print). DOI: 10.1359/JBMR 0802

### MDACC: Management and Outcomes

- Conservative management: antibiotics, oral rinses, good oral hygiene, and debridement of protruding bone
- None of the patients required extensive surgery or developed severe infections or cutaneous fistulas

Hoff AO, et al. J Bone Min Res. 2008. (E-pub ahead of print). DOI: 10.1359/JBMR 080205

#### MD Anderson Cancer Center Study

- In the MD Anderson study previously described
  - 0 of 271 patients being treated for osteoporosis with an IV bisphosphonate developed ONJ

Hoff AO, et al. J. Bone Min Res. 2008. (E-pub ahead of print). DOI: 10.1359/JBMR 080205

## Mail Survey: Australia and New Zealand

- In the Australian mail survey previously
  - Estimated frequency among osteoporosis patients of 0.01% to 0.04%, or 1 case per 2260 to 8470 prescriptions

MDACC: Risk Factors

- Precipitating dental events: extraction (n = 16), periodontal disease (n = 14), bone exostosis (n = 10), and trauma (dentures, implants, intubation: n = 5)
- · Compared to patients without ONJ, patients with ONJ had
  - Longer duration of disease
  - Longer duration of follow-up
  - Longer duration of IV bisphosphonate treatment
  - Higher cumulative doses of IV bisphosphonates

Hoff AO, et al. J Bone Min Res 2008 (E-pub ahead of print). DOI: 10.1359/JBMR.08020



**ONJ Frequency** in Osteoporosis Patients Treated With Bisphosphonates

# Retrospective Chart Review: German National ONJ Registry Study (2006)

- In the German National Registry study
  - 780,000 patients in Germany are prescribed bisphosphonates for osteoporosis indications
  - 1.4% (3/189) of evaluated cases of ONJ were in patients receiving a bisphosphonate for osteoporosis (oral
  - This corresponds to an estimated prevalence rate of 0.00038%, or a risk of less than 1 in 100,000 patients

## Risk: Benefit Ratio Must be Determined for Each Patient Using Bisphosphonates

- No causal relationship whatsoever has been found between development of ONJ and bisphosphonate intake in osteoporosis<sup>1</sup>
- Before deciding to treat a patient with a bisphosphonate, the risk:benefit ratio must be carefully weighed
- To put the risk into perspective, compare the risk of ONJ in osteoporosis patients taking bisphosphonates (0.0004%)  $^2$  with the risk of other diseases in non-institutionalized adults:  $^3$ 
  - Kidney disease: 1.5%
- Stroke: 2.6%
- Serious mental illness: 3.0%
- Cancer: 7.2%
- Diabetes: 10.0%
- Heart disease: 11.0% - Dental caries: 22.9%

# OSTEOPOROSIS AN

## Continues from page 9.

Prospective Adjudication of ONJ in a Randomized Controlled Trial: HORIZON-PFT

#### HORIZON-PFT: Study Design

- 3-year, randomized, double-blind, placebo-controlled, multicentre trial<sup>1</sup>
- Objective: to evaluate the effects of once-yearly zoledronic acid (ZOL) 5 mg on fracture risk in women with PMO<sup>1</sup>
- Secondary objectives included incidence of ONJ<sup>2</sup>
- Treatment<sup>1</sup>
  - Annual infusion of ZOL 5 mg or placebo
  - Calcium 1000-1500 mg/d; vitamin D 400-1200 IU/d
- Follow-up at 6, 12, 24 and 36 months1

1 Black DM, et al. N Engl J Med. 2007;356:1809–1822. 2. Grbic J, et al. J Am Dent Assoc. 2008;139-32-40.

# HORIZON-PFT Maxillofacial Events Were Adjudicated by Independent Experts

- No spontaneous ONJ cases reported
- Safety database search for possible maxillofacial AEs, using 60 MedDRA® terms
  - All hits underwent maxillofacial adjudication for ONJ (most common maxillofacial AE: sinusitis)
- Independent adjudication committee of five dental specialists, all blinded to study treatment
- Criteria consistent with ONJ
  - Exposed bone in the maxillofacial area with delayed healing for greater than 6 weeks despite appropriate diagnosis and conventional care

AE, adverse event; MedDRA $^{\oplus}$ , Medical Dictionary for Regulatory Activities Grbic J, et al. J Am Dent Assoc. 2008;139.32–40

# Adjudication Revealed One Case of ONJ in Each Treatment Group No. patients randomized No. receiving intervention No. on pleting follow-up Tho. of possible maxillofacial event rases if eatified using received for the plant re

#### Osteonecrosis of the Jaw:

Zoledronic acid 5 mg Experience in a Variety of Osteoporosis Indications

## Objectives

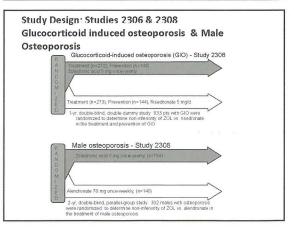
 To report the incidence of ONJ in four clinical trials of zoledronic acid

These studies include the patients who received study drug in the following studies:

- HORIZON-PFT study: study 2301 (N=7714)
- HORIZON-RFT: study 2310 (N=2111)
- Glucocorticoid-induced osteoporosis trial: study 2306 (N=833)
- Male osteoporosis trial: study 2308 (N=302)
- To address the issue of whether evaluating serum levels of  $\beta\text{-CTx}$  prior to dental surgical treatment would be useful, we determined if there is an association between low serum levels of the bone "turnover" marker,  $\beta\text{-CTx}$  and the risk of developing ONJ.
  - Serum levels of  $\beta$ -CTx (S-CTx) were analyzed in a subset of patients in the HORIZON-PFT (N=517)

Grbic J, et al. J Am Dent Assoc. 2010,141(11) 1365-1370

# Study Design: Studies 2301 & 2310 HORIZON-PFT and the HORIZON-RFT HORIZON-PFT (Study 2301) Zeleatonic ecid 5 mg once-yearly, (n=2860) Placebo once-yearly, (n=3876) 3-yr, double-blind study 7765 pts with postmenopausal observations were randomized to receive in 201 or placebo HORIZON-RFT (Study 2310) Zeleatonic ecid 5 mg once-yearly, (n=1065) Placebo once-yearly, (n=1082) Event-driven double-blind study 2127 men and women with recent low-trained for factor were randomized to receive editer once-yearly 201. 5 mg i v or placebo



# **ID JAW NECROSIS**

## Maxillofacial Events Adjudication Process for ONJ

- · An independent adjudication committee reviewed all maxillofacial adverse events possibly related to ONJ in all 4 studies
- The committee consisted of 3-5 experienced dental specialists who were all blinded to study treatment
- Safety database was searched for all possible maxillofacial adverse events using 60 predefined MedDRA\* terms
- Criteria consistent with ONJ
  - Exposed bone in the maxillofacial area with delayed healing for greater than 6 weeks despite appropriate diagnosis and conventional care

MedDRA® = Medical Dictionary for Regulatory Activities

# ONJ Frequency in Patients Treated With Bisphosphonates: Summary

- Several sources of retrospective data on ONJ incidence
  - However, retrospective analyses use pre-existing data. Prospective sources are preferable
- ONJ incidence varies widely in retrospective studies1-3
  - The frequency of ONJ is different for oncology vs osteoporosis patients<sup>4,5</sup>
- In the HORIZON trial, ONJ was examined prospectively, from the time the issue was raised in the literature
  - One case of ONJ in active treatment group, one in placebo group
  - Evidence that ONJ can develop without bisphosphonates
  - No new cases of ONJ detected in the other HORIZON trials, which enrolled >14,000 patients (glucocorticoid-induced osteoporosis, male osteoporosis, osteoporosis prevention)

## Dental Management of Patients Taking Bisphosphonates

- Recommendations from various advisory task forces:
  - Patients with concomitant risk factors should avoid invasive dental procedures if possible1,2
  - For patients requiring dental procedures, there are no data to suggest whether discontinuation of bisphosphonates reduces the risk of ONJ<sup>1,2</sup>

	Oncology patients	Osteoporosis patients Changes in dental care if bisphosphonates use < 3 years! For patients on bisphosphonates for >3 years! For patients on bisphosphonates for >3 years! Find the patients of the patients the pa	
Not recommended	Elective dentoalveolar surgery     Periapical/periodontal surgery     Dental implants		
Recommended	Nonsurgical endodontic/ periodontic therapy of symptomatic teeth only Extraction if tooth is: Very models and present acceptation in Located in negrotic base.	for >3 years:  •Perform surgery for per adoptal unsense only of reversions •He dest to one recontouring when necessary	

Novartis Europharm Ltd. Aclasta® Summary of Product Characteristics. 2. Novartis Europharm Ltd. Zometa® Summary of Product Characteristics. 3. Khoda S. et al. J Zecon Miner Res. 2007; 22:1479-1491. 4. American Association of Oral and MaxilloScala Surgeons. J Carl MaxilloSca. 2019; 2007;65:369-370.



#### ONJ:

Risks in Cancer -

Risks in Osteoporosis

## Results: Incidence of ONJ

- No spontaneous reports of ONJ were received for any of the additional studies (2310, 2306, 2308)
- After extensive review of all maxillofacial events with adjudication, the only two cases (one in the zoledronic acid treated group and one in the placebo treated group) meeting the definition of ONJ were the two cases which were previously described in the HORIZON-PFT study (2301)
- Therefore, the incidence of ONJ in patients who received zoledronic acid in these four clinical trials was less than 1 in 14,000 patient treatment-vears

# **Recommendations Concerning Patients** About to Initiate Bisphosphonate Therapy

- Treat active oral infections<sup>1</sup>
- Tooth treatment and full epithelial healing before therapy<sup>1</sup>
- Consider dental examination with appropriate preventive dentistry in patients with concomitant risk factors, e.g:2,3
  - Cancer
  - Chemotherapy
  - Corticosteroids
  - Poor oral hygiene
- Clinical judgement of treating physician should guide the patient management plan, based on individual benefit/risk assessment<sup>2,3</sup>

# Treatment Recommendations for Patients With Established Diagnosis of ONJ

Recent recommendations for oncology patients from a European group have been published, although EU-wide guidelines are lacking

	Large areas of ONJ, or non-responders to conservative treatment
nitiate 'conservative treatment' 10-15 days of antibiotic plus 1 month of chlorheoidine inses* In case of normal flora, use amodcillin or clindamydin The physician should irrigate the exposed necrotic bed with chlorheddine once every 72 hours for 1 month Re-evaluate after 1 month: I. If an improvement is codimed continue with blorheadine mass or arother month of flore-wo (patters and professional) I. If no good response, mantain conservative treatment for another roomh	Plan surgery to remove necrotic bone The magnitude of the surgery will depend on size of the ONI Consider suspension of bisphosphonate, which may be reintroduced after evaluating the risk-chenefit ratio Corticolds with

#### Clinical Evidence for Anticancer Effects of Zoledronic Acid and Clodronate in Multiple Myeloma (MM)

Aviles et al 2007 <sup>1</sup>	94	ZOL (4 mg q 28 d) Control	ZOL significantly $\uparrow$ 5-year EFS and OS rates ( $P < .01$ for both)
Berenson et al 2006 <sup>2</sup>	353	ZOL (4 mg q 3-4 wk) PAM (90 mg q 3-4 wk)	In patients with high BALP (n = 89), ZOL significantly ↓ the risk of death by 55% vs PAM (F = .04)
McCloskey et al 2001 <sup>3</sup>	619	CLO (1,600 mg/d) Placebo	CLO significantly $\uparrow$ survival in patients (n = 153) with no fractures at baseline vs placebo ( $P = .006$ )

- INIVIAI, PAIN, PAINTAINERS, 18, AVIIES A, et al. Med Oncol 2007,24(2) 227-230

  Berenson J, et al. ASH 2006. Abstract 3589.

  McCloskey EV, et al. Br J Haematol 2001,113(4):1035-1043

# **OSTEOPOROSIS** AND JAW NECROSIS

#### Continues from page 11.

## The Medical Research Council (MRC) Myeloma IX Trial in patients with newly diagnosed MM.

- · Primary endpoints

  - Overall survival (OS)
    Progression-free survival (PFS), defined as time from randomization to disease progression or death
  - Overall response rate
- Secondary endpoints
  - Skeletal-related events (SREs): Proportion of patients with an SRE Safety
- Statistical methods
  - PFS and OS were assessed by Kaplan-Meier and Cox proportional hazards models
  - Statistical significance was assigned for P < .05 with no correction for multiplicity of comparisons

### Safety Conclusions

- Overall, ZOL and CLO were generally well tolerated, and safety profiles were as expected
  - ONJ rates remained low during long-term therapy, although higher for ZOL vs CLO (3.7% vs 0.5%)
    - Incidence plateaued after 3 years of follow-up, with no evidence of cumulative in risk
  - Low incidence of acute renal failure in both groups
  - Imbalance in thromboembolic events between ZOL and CLO traced to 1 number of events associated with use of an indwelling catheter
  - No significant difference in TESAEs

ins: CLO, dodronate; ONJ, osteonecrosis of the jaw; TESAEs, treatment-emergent serious ents: ZOL. zoledronic acid

# MRC Myeloma IX (5.8 y)—ONJ Rate Plateaued After 36 Months of ZOL

Overall cumulative ONJ incidence was low at 5.8 years ZOL vs CLO: 3.7% vs 0.5%, respectively (P < .0001)

Most ONJ events occurred between 12 and 36 months



# hreviations CLO, clodronate, ON), osteoner organ GJ, et al. ASCO 2012. Abstract 8015

#### ONJ -CHMP risk communication:

- Recommended preventive dental measures before starting and during bisphosphonate therapy should be proportionate to the risk of developing ONJ. In particular dental check-ups prior to treatment in all patients for cancer indications and dental examinations only if the dental status of the patient is poor for non-cancer indications.
- The CHMP considered that the risk of ONJ is significantly greater for patients receiving iv bisphosphonates for cancer indications than in patients receiving oral bisphosphonates for osteoporosis/Paget's
- The risk of developing ONJ in association with oral bisphosphonates appears to be low. The full extent of the risk of ONJ with it bisphosphonates used in non-cancer indications is not yet known but appears to be much lower than in cancer indications.

MP ASSESSMENT REPORT ON BISPHOSPHONATES AND OSTEONECROSIS OF THE JAW ocedure under Article 5(3) of Regulation (EC) No 726/2004 don. 24 Sectember 2009 . EMEA(CHPP(2) 1125/2009

# MRC Myeloma IX (3.7 y)—Adverse Events (Safety Population)

	Arrive 4				Mr 1971 y 7375			-24	
	CVAD (n=556)		стр (	n=555)	MP (n=424) CTE		CTDa (	Da (n=427)	
	ZOL (n=278)	CLO (n=278)	ZOL (n=277)	CLO (n=278)	ZOL (n=213)	CLO (n=211)	ZOL (n=215)	CLO (n=212)	
Acute renal failure	14 (5)	17 (6)	15 (5)	16 (6)	15 (7)	13 (6)	13 (6)	14 (7)	
ONJ <sup>5</sup>	13 (5)	2 (1)5	8 (3)	0 (0) <sup>b</sup>	10 (5)	0 (O)b	4(2)	1 (<1)	
Thromboembolic	59 (21)	41 (15)	45 (16)	41 (15)	10 (5)	10 (5)	43 (20)	25(12)b	
Infection SAE	28 (10)	37 (13)	24 (9)	25 (9)	4 (2)	4(2)	12 (6)	14 (7)	
All SAEs	167 (60)	155 (56)	160 (58)	125 (45)	97 (46)	81 (38)	115 (53)	117 (55)	
TESAEs	74 (27)	69 (25)	84 (30)	72 (26)	27 (13)	18 (9)	63 (29)	67 (32)	

Abbreviations: CLO, clodronate; CTD, cyclophosphamide, thalidomide, dexamethasone; CTDa, attenuated oral CTD; CVAD, cyclophosphamide, vincristine, doxorubicin, dexamethasone; MP, melphalan, prednisolone; ONI, osteonecrosis of the jawy, SAE, serious adverse event; TSSAE, tradiment-emergent SAE; ZOL, cycledronic acid.

ONJ cases were confirmed by an independent adjudication committee.  $P \le .05$  as determined by Fisher's exact test.

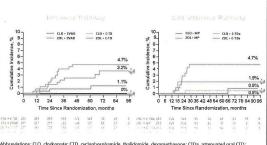
GJ, et al. *Blood*. 2012;119(23) 5374-5383

## ONJ – What is the incidence in highest risk patients?

- · Multiple Myeloma patients are highest risk when treated aggressively with a regimen known to cause ONJ (even without BPs)
  - Less than 5% even in highest risk patients
  - Plateaus to less than 3.7% after 3 years
  - All patients receiving Zoledronic acid 4mg every 4 weeks total of 52 mg per year (10 x higher that in PMO)

Morgan GJ, et al Blood. 2012,119(23) 5374-5383

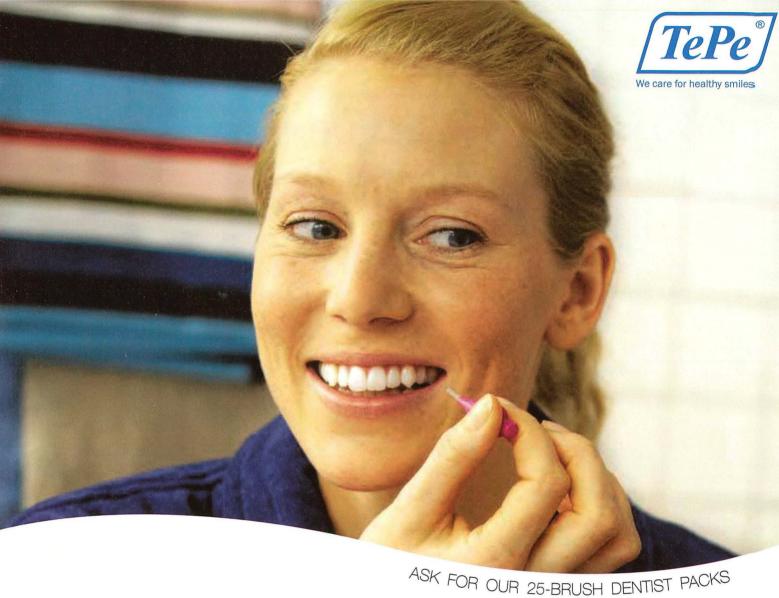
#### MRC Myeloma IX (5.8 y)—ONJ Rates less than 5% even in regimens known to increase risk.



Abbreviations: CLO, clodronate; CTD, cyclophosphamide, thalidomide, desamethasone; CTDa, attenuated or al CTD; CVAD, cyclophosphamide, vincristine, doxorubicin, dexamethasone; MP, melphalan, prednisolone; ONJ, osteonecrosis of the jaw; 201, zoledronic acid. Morgan Cal, et al. ASCO 2012. Abertact 8015

### ONJ and bisphosphonates: Summary

Osteonecrosis of the jaw (ONJ): Osteonecrosis of the jaw has been reported predominantly in patients with cancer receiving treatment regimens including bisphosphonates, including zoledronic acid. Many of these patients were also receiving chemotherapy and corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. Many had signs of local infection including osteomyelitis. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g. cancer, chemotherapy, corticosteroids, poor oral hygiene). While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop osteonecrosis of the jaw while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of osteonecrosis of the jaw. The clinical judgement of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.



# Interdental Cleaning the easy way

• Eight colour coded sizes

Plastic coated wire

User-friendly handle

 Developed in collaboration with Swedish dental professionals

 Now available with the new-generation G2 improved brush head on selected products



Improved Durability



Improved Access



Easier to Use

Made in Sweden



Now Also Available in Mixed Colour Packs

mm	0.4	0.45	0.5	0.6	0.7	0.8	1.1	1.3
ISO	0	1	2	3	4	5	6	7



Extra protection from the effects of Acid Wear



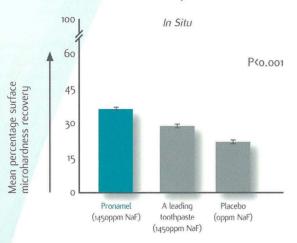
# For extra protection against acid wear...

Modern eating and drinking habits increase the exposure of tooth enamel to dietary acid that can lead to acid wear (erosive tooth wear), the biggest contributor to tooth wear.<sup>1–5</sup>

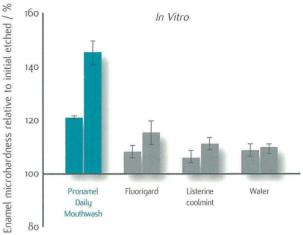
Acid wear is a widespread and growing condition, affecting both adults and children,<sup>6</sup> but in its early stages can be difficult to identify.

# ...Recommend the Pronamel combination regime

Individually **Pronamel Daily Toothpaste** and **Pronamel Daily Mouthwash** are proven to reharden acid-softened enamel compared to standard options<sup>7,8</sup>

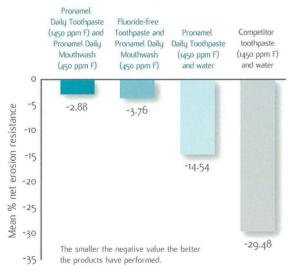


Adapted from Hara AT *et al.* Bovine enamel specimens were subjected to an erosive challenge. This was followed by fixation to palatal appliances and a 4-hour intra-oralphase in 58 human subjects.



Adapted from Young M and Willson R. 6 human enamel specimens were subjected to an erosive challenge *in vitro*. This was followed by a mean rehardening microindentation study after treatment with fluoride mouthwashes.

# But used in combination, provide **80% more protection against acid wear** than brushing with Pronamel Daily Toothpaste alone<sup>9\*</sup>



Adapted from Maggio  $\it et al. 2010.$  Original study design contained 5 test cells; the one not included here is a fluoride-free dentrifice plus water.



Extra protection against acid wear

Give your patients 80% more protection from acid erosion, compared to Pronamel Daily Toothpaste alone by recommending the Pronamel combination regime<sup>9\*</sup>



# Periodontal Regeneration Past, Present and Future

Edward Sammut BChD MSc MClinDent MFDS MRD RCSEd, Specialist in Periodontics (UK) Smile for Health Malta, 21st November 2012

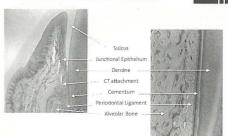
#### **OBJECTIVES**

- Describe periodontal defects and their relative potential for periodontal regeneration
- Describe periodontal wound healing and point out key differences between repair and regeneration
- Give a historical perspective on periodontal regeneration techniques
- Describe contemporary techniques for periodontal regeneration and their anticipated outcomes
- Speculate on future developments in this field

## INTRODUCTION

Periodontal problems are mainly periodontitis and recession. Both of these processes are driven by inflammation caused by plaque. In the case of recession the low-grade inflammation may be caused by chronic trauma. The key common events are loss of attachment, apical migration of the junctional epithelium and plaque contamination of the root surface.

#### Normal Periodontal Structure



TO:

#### THE GOALS OF TREATMENT

- Remove pain and sensitivity
- · Keep patient's teeth in function
- Satisfy aesthetics
  Prevent further attachment loss
  Remove cause of inflammation and
  establish conditions for it not to return
  Regenerate the lost attachment?
  Cover root surface?

A case was presented showing extreme attachment loss in an intrabony defect mesial to LR6. Patient had pulp symptoms from the tooth and extraction was considered due to the cost of RCT, perio surgery and crown being similar to a dental implant. The patient declined and simple root surface debridement was performed repeatedly. The patient demonstrated reduction in pocket depths, increase in the clinical attachment and radiographic bone fill of the defect over a two-year period.

Bone regeneration is not a new idea. In 1957: Prichard, J. published: The infrabony technique as a predictable procedure. J. Periodontology, 28: 202-216

Surgically excised all tissue in the pocket
Tin-foil placed to keep out the wound dressing
Denuded bone was allowed to granulate over – much like a socket
Predictable bone fill seen radiographically

Later on, another key paper in this field, which is special because it includes re-entry surgery:

• 1976: Rosling B, Nyman S, Lindhe J, and Jern, B: The Healing potential of the periodontal tissues following different techniques of periodontal surgery in plaque free dentitions. J Clin Periodontol 1976 3:233-250 Different surgical procedures to treat intrabony defects Re-entry surgery to confirm results Access and apically repositioned flaps showed bone fill >80%

# PERIODONTAL DEFECTS MAY BE SUPRABONY OR INTRABONY

Suprabony defects refer to horizontal bone loss with circumferential attachment loss around a tooth. It is not currently possible to consider periodontal regeneration in the suprabony situation.

Intrabony or angular defects can be classified into 1, 2 or 3 walled defects. These are graphically represented below. Periodontal regeneration can be considered in intrabony defects. There is a good supply of cells from both the PDL and the bone which can populate the defect and regenerate missing tissue.

Continues on page 25.

# **PAYMENT FORM**

Please cut out this section and send with a cheque for 50 euro payable to **Dental Association of Malta** for your 2013 DAM membership – the best 50 euro investment ever!



The Treasurer,	Dr Noel	Manche,

The Dental Association Of Malta, Federation Of Professional Associations, Sliema Road, Gzira.

NAME:			
ADDRESS:			

# Are you ready for a better way to relieve tooth sensitivity?



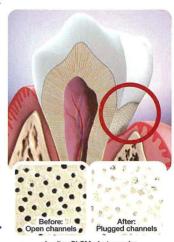
That sharp, stabbing feeling of sensitivity is something you may no longer need to endure.

Announcing the arrival of a toothpaste so revolutionary, so different, it addresses the cause of sensitivity, not just the signs.

And with direct application, it can give instant sensitivity relief.\*

New Colgate® Sensitive Pro-Relief™ is the only toothpaste to contain the advanced PRO-ARGIN™ technology. This breakthrough formula works by instantly plugging the channels leading to the tooth centre.

Brush twice a day for lasting sensitivity relief.





Sounds incredible? That's why we want you to try Colgate® Sensitive Pro-Relief™ for yourself. For details, or to learn more, log on to www.colgatesensitive.com.



Instant and Lasting Sensitivity Relief... prove it to yourself.

# THE SOCKET - RIDG

Dr Mark Diacono BDS FDS RCS RGN Specialist Oral Surgeon – Dental & Implantology Unit, St James Hospital

# EAO Consensus Meeting Denmark - 2012

Wang R & Lang N

Ridge preservation after tooth extraction
Clin. Oral Implants Res. 23(Suppl.6),2012,147-156

# Wang & Lang

- Not a literature review with inclusion / exclusion criteria
- ▶ A total of 46 reviews and research papers were presented to the 3<sup>rd</sup> Working Group of the EAO Consensus Conference in Feb. 2012.
- ➤ Wang and Lang reported conclusions of this working group in article presented at EAO Consensus Meeting, Denmark, Oct. 2012

# Remodeling

Tap et al 2012 - A systematic review of post-extractional alveolar hard and soft tissu dimensional changes in humans. Clin Oral Impl. Res. 2012;23(Suppl.5):1-21

Alveolar resorption at 6 months

Vertical 11-22%

Horizontal 29 - 63%



# Bundle Bone and Sharpey's fibres





# **Bundle Bone**

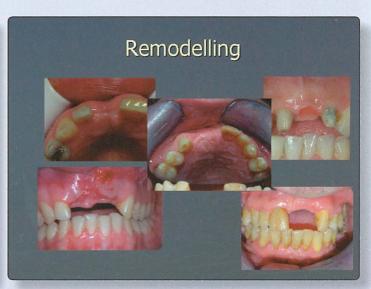
Araújo & Lindhe - Dimensional ridge alterations following tooth extraction. An experimental study in doos. 1 Clin Perin. 2005;32:212-218

- ➤ Crestal region buccal bone 100% bundle bone
- ➤ Crestal region palatal / lingual bone combination of bundle bone & lamellar bone

# Bundle Bone after extraction

- Day 1 -Bundle Bone immediately adjacent to hard tissue of socket wall investing Sharpey's fibres (PDL), Sharpey's fibres in direct contact with coagulum in socket
- Day 3 Granulation tissue replaced coagulum
- Day 7 Leukocytes and collagen fibres replace granulation tissue and PDI
- ▶ Day 14 Bundle Bone gone replaced by Woven bone
- Day 30 to 180 Woven bone resorbed and replaced slowly by Lamellar Bone

Cardinara et 4 ; — Distancia of hane tiesse formation in tooth extraction sites. An experimental study in dags, John Peril 2007:37:509-518



# Alveolar Ridge Preservation

Any procedure undertaken at the time of or following an extraction that is designed to minimize external resorption of the ridge and maximize bone formation within the socket.

Darby et al. Ridge preservation: What is it and when should it be considered. Australian Dental Journal 2008;53:11-21



# Research

- ► ANIMAL STUDIES
- ► CLINICAL TRIALS

# **IMPLANTS ALONE**

▶ Immediate implant placement with or without loading does NOT prevent bone resorption that occurs following tooth extraction

Araŭjo et al. Dimensional ridge alterations following tooth extraction. An experimental study in the dog. 1.Clin.Periodontal. 2005; 32:212-218

Blanco et al. Ridge alterations following flapless immediate placement with or without immediate loading. J.Clin Periodontol. 2011:38:762-770

Botticelli, Berglund & Lindhe. Hard tissue alterations following immediate implant placement in extraction sites, J.Clin.Periodontol. 2004;31:280-828

# THE SOCKET RIDGE PRESERVATION

Continues from page 19.

# Immediate Implants with bone grafts

- ▶ Bone graft did not stop loss of bundle bone.
- ▶ More buccal bone lost than lingual/palatal bone
- ▶ In human studies, use of Bio-Oss and membrane reduces resorption of the buccal plate by 25% in the anterior region.

en et al. A prospective clinical study of non-submerged immediate implants; Clinica outcomes and aesthetic results, Clin.Oral Imp.Res. 2007;18;552-562

# Immediate implants with membrane

- ▶ Collagen resorbable membranes can contribute to some preservation of buccal wall, the effect being less obvious towards the crest
- Better bone healing in socket void when membrane used to cover DBBM (deproteinised bovine bone mineral).

Chen et al. A prospective clinical study of non-submerged immediate implants: Clinical cutcomes and aesthetic results, Clin Oral Imp. Res. 2007;18:553-562

# Immediate Implants and GBR

- ▶ Applying Guided Bone Regeneration treatments has been shown to preserve ridge width and height.
- ▶ In some studies, there was a positive increase in bone height when using Bio-Oss. In one animal study, the gain was recorded as 3.6%

# Bone substitute

- Bio-Oss ® / Bio-oss Collagen xenograft- osteoconductive not osteoinductive (acts as a scaffold) good healing / moderate preservation of ridge width and increase in height.
- preservation of ridge within and increase in height.

  Demineralized freeze dried bone allograft (DFDBA) and mineralized freeze dried bone allograft (FDBA) give similar outcomes.

  Bone Ceramic ® (hydroxyapatite and β-tricalcium phosphate) good preservation of ridge width but poor bone quality in centre of socket higher failure of implants

  Nano-crystalline hydroxyapatite paste not effective for ridge preservation
- . Calcium sulfate hemi-hydrate reduced resorption in clinical trial
- Collagen plugs inconclusive

# **Implant Type** Tapered vs Straight walled

- ▶ The use of root formed implants aiming to close the space between the socket and implant surface does NOT preserve alveolar bone.
- ▶ Contact with the buccal wall of the socket increases resorption.

Caneva et al . Hard tissue formation adjacent to implants of various size and configuration immediately placed into extraction sockets: An experimental study in dogs. Clin.Oral Imp.Res. 2010;30:809-818

# Position of implant in socket

- Not many studies!
- Placing implant lingual and 0.8mm deep to crest lead to reduction of resorption by 80% in dogs.



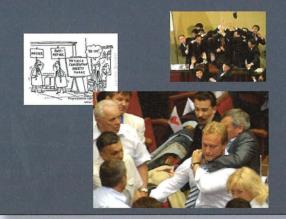
# Flap Closure

- Free gingival grafts did not definitely reduce resorption of alveolus. More studies needed.
- Primary flap closure did not reduce resorption, in fact, it lead to more post-operative discomfort and a significant crestal shift of muco-gingival line (ie less keratinised gingiva around implants).

Fickl et al. Hard tissue alterations after socket preservation: An experimental study in the beagle dogs. Clin.Oral Imp. Res. 2008;19:1111-1118.

ingler-Hamm et al Ridge preservation using a composite bone graft and a bioabsorbable membrane wit and without primary wound closure: A clinical trial. J.Clin.Perjodontol 2011;82:377-387

# Where are we now?



# Review conclusion

- ▶ No Sharpey's fibres no bundle bone
- ➤ Resorption will happen not very predictable
- ► GBR procedures will reduce bone loss depending on which material / technique used
- ▶ Primary flap closure is NOT beneficial
- ▶ Wider bone resorbs less than narrower bone

# Review conclusion

- ▶ Immediate placement of implants does NOT reduce resorption.
- ▶ Immediate placement with appropriate GBR procedure may reduce hard and soft tissue loss

This consensus review did NOT cover soft tissue type – thick or thin biotype.

# Case Study - remodeling

- > 30 yr old female
- ➤ Immediate implant 2003 — autogenous / Bio-Oss mixed bone graft. Seemed stable 2004
- Returned 2009 recession due to remodeling not infection over five years





# Case study - remodeling

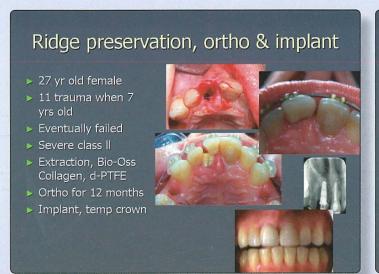
- 63 yr old lad
- Upper teeth failed due to periodontal disease
- Extracted, allow to heal for six weeks prior to implant insertion
- Autogenous bone dust into socket space
- Remodelling, not periimplantitis, resulted in exposure of implants
- Stabilised after 1 year (2001)
- No change for 12 years (2012

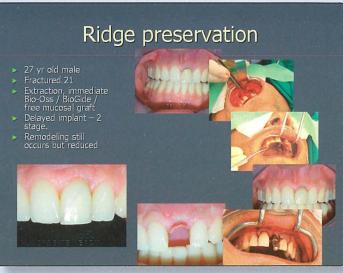


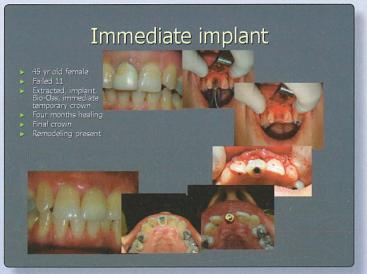


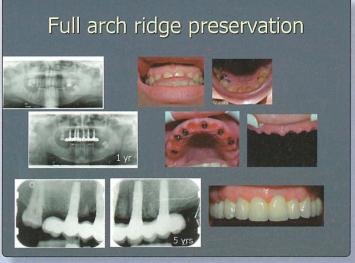
# THE SOCKET RIDGE PRESERVATION

Continues from page 21.





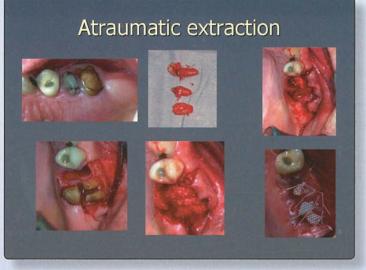


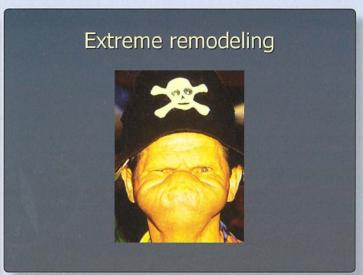




- Acid etch bridge





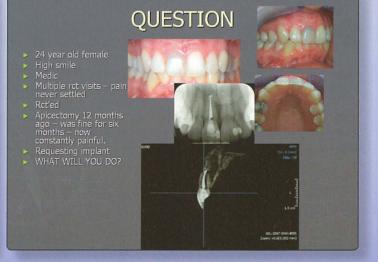


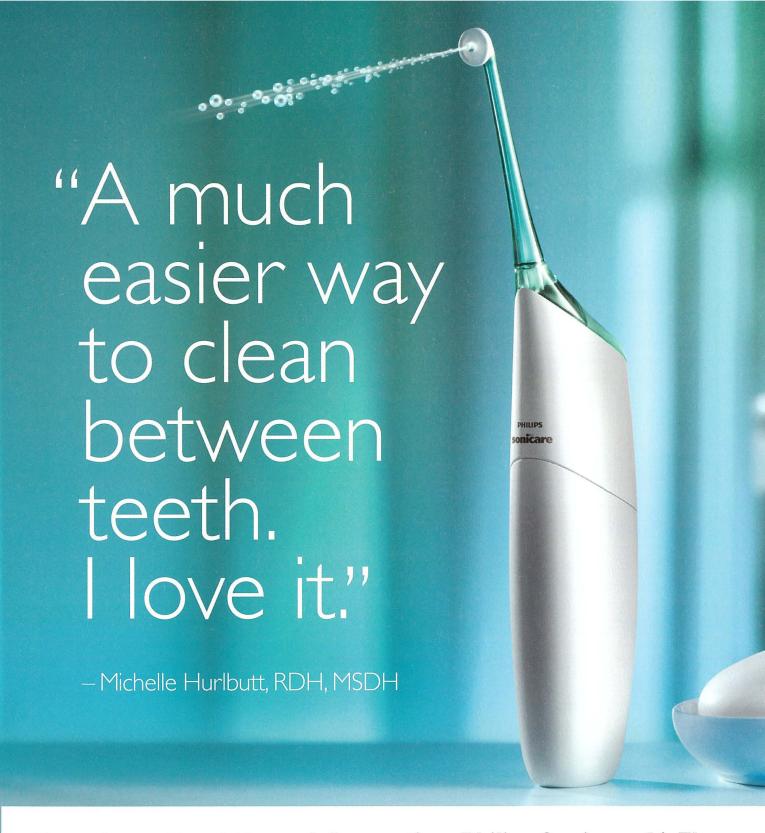
# Summary

- ▶ Bundle bone will be lost
- ▶ Atraumatic extraction
- ▶ Bio-Oss or Bio-Oss Collagen graft
- ► No primary closure use of collagen or d-PTFE membrane
- ▶ Ovoid pontic on temporary
- Final bridge or implant based restoration
- ▶ Gingival grafting if needed



# The Future - maybe Trauma Buccal bone missing Bundle bone in buccal wall gone Grafted Stable end result





# Experience Breakthrough Innovation: Philips Sonicare AirFloss

Patients who just won't floss will love the new Philips Sonicare AirFloss. Its innovative microburst technology delivers a quick burst of air and microdroplets for a gentle yet powerful clean in-between.

Effective: Sonicare AirFloss helps reduce gingivitis by up to 75% and the number of bleeding sites by up to 86% in 4 weeks'

Easy to use: Reported easier to use by 86% of patients surveyed<sup>2</sup>

**Preferred:** After 1 month, 96% of patients who flossed inconsistently used Sonicare AirFloss at least 4 times per week<sup>3</sup>

Call Bart Enterprises Ltd on 21 447340 for a trial unit so you can experience Sonicare AirFloss. sonicare.com/dp

I. de Jager M, Jain V, Schmitt P, DeLaurenti M, Jenkins W, Milleman J, et al. Clinical efficacy and safety of a novel interproximal cleaning device. J Dent Res. 2011;90(special issue A). 2. Krell S, Kaler A, Wei J. In-home use test to evaluate ease of use for Philips Sonicare AirFloss versus Reach string floss and Waterpik Ultra Water Flosser. Data on file, 2010. 3. Krell S, Kaler A, Wei J. In-home use test to assess compliance of Philips Sonicare AirFloss. Data on file, 2010.



sense and simplicity

# Periodontal Regeneration Past, Present and Future

Continues from page 16.

A true regeneration does not result only in the growth of new bone in the defect it also includes growth of new cementum on the root surface and new periodontal ligament fibres joining the root surface to the new bone. Classic animal models of healing following periodontal surgery show us that there is a very small amount of true regeneration and most healing is by repair in which a long junctional epithelium lines the root surface and separates it from the newly formed bone

The outcomes which we measure clinically - that is probing depth, clinical attachment level and radiographic bone gain may be no different in periodontal regeneration and in periodontal repair. However, regeneration is a more desirable outcome because it restores full and functional periodontal structure around a tooth.

REPAIR	REGENERATION
Bone fill	Bone fill
Root surface covered with "long" junctional epithelium	New attachment forms
No new ligament	New ligament forms
No new cementum	New cementum covers previously "diseased" root surface

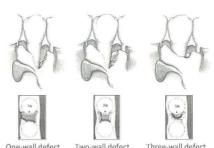
Although PDL is very rich in stem cells and PDL stem cells have the ability to form all tissues required for regeneration - this doesn't happen.

Why doesn't this happen? Epithelial down-growth along the root surface is quick Lack of adherence of PDL cells to root surface dentine

Karring, Lindhe and co-workers did a series of studies to look at healing processes between root surface, bone, ligament and gingival connective tissue.

- Part of root still covered in PDL reattached to bone or gingival tissue
- Other "denuded" part of root surface developed ankylosis and resorption where in contact with bone or gingival tissue
- PDL grew up the root in a third experiment where the root was not extracted but covered by the flap

Following these experiments, they performed a human experiment in a landmark 1982 paper: A patient who



was due to have extraction of LL2 was consented to having a GTR procedure using a Millipore membrane, and a notch was cut in the root surface to indicate the level of the attachment loss. Three months later the tooth was removed en bloc together with surrounding tissue. Histology confirmed presence of new attachment coronal to the notch on the root, demonstrating the principle of GTR.

Various membranes used over the years Non-resorbable Gore-tex Gore-tex titanium reinforced Resorbable Synthetic – eg Vicryl or Resolute Collagen - eg Bio-Gide Filler material can be used below membrane to help maintain space

Issues with the non-resorbable membranes were that they sometimes became infected and they also required a second operation to remove them. For this reason resorbable membranes became more popular.

The definitive review is: Needleman IG, Worthington HV, Giedrys-Leeper E, Tucker RJ. Guided tissue regeneration for periodontal infrabony defects. Cochrane Database Syst Rev. 2006 Apr 19;(2):CD001724.

- Large variability between studies
- Mean gain of clinical attachment (averaged out over the various studies) over OFD (open flap debridement) was 1.2mm
- Number Needed To Treat of 8 patients - before the advantage of GTR was observed.

Various bone filler materials have been used over the years

Patient's own bone (Autogenous graft)

#### Classic Animal Models



- From a cadaver (Allograft, eg Rocky Mountain)
- From an animal (Xenograft, eg Bio-oss)
- Coralline Calcium Carbonate
- Synthetic Hydroxyapatite Bioactive glass Beta-tricalcium phosphate

Clinically these results in an average reduced PPDs and improved CALs (1-2mm) over open flap debridement. They also produce nice radiographs because the materials are typically radioopaque. The problem is one cannot be sure if the image is of the radio-opaque material or any newly formed bone. Xenograft and synthetic particles tend to encapsulate in fibrous tissue - unless covered by a GTR membrane - in which case the filler is a simple space maintainer and the procedure should be viewed as a GTR procedure.

Trombelli L, Heitz-Mayfield L, Needleman I, Moles D, Scabbia A: A systematic review of graft materials and biological agents for periodontal intraosseous defects. J Clin Periodontol 2002; 29(Suppl. 3): 117-135.

A completely different approach was taken at by Swedish researchers in the late 1990s. In experiments looking at tooth development dentine on its own was insufficient stimulus for follicular cells to differentiate into cementoblasts. This challenged the understanding of the process of tooth development as it was thought that once Hertwig root sheath disintegrated the presence of the dentine stimulated follicular cells to lay down cementum. In actual fact, it was found that deposition of enamel matrix proteins onto a developing root surface is an essential step preceding formation of acellular cementum.

Continues on page 29.

# Have you taken out your **Professional Indemnity Policy?**

Over 2 years ago Mediterranean Insurance Brokers (MIB) in conjunction with the Dental Association of Malta (DAM) have put together a flexible and comprehensive Professional Indemnity policy which is exclusively available to members of DAM.

The scheme policy was recently revised, more Limits of Indemnity were included and the premium was lowered. The scheme policy offers:

- **VARIOUS AGGREGATE LIMITS** You can choose the limit that suits you best
- RETROACTIVE COVER Protection is provided

against liability for negligent acts committed before the inception date of the policy

**EUROPEAN JURISDICTION** Protects against claims made against you anywhere within the European Union

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# The #1 issue

among full and partial denture wearers?

Food trapped under their dentures.



# **NEW CLINICAL DATA**

proves zinc-free Corega® seals out up to 74% more food particles than no adhesive. 1,2

# **NEW DATA**

from 3 clinical studies among patients with well-made, well-fitting\* full and partial dentures

Zinc-free Corega® significantly improves

- Food occlusion<sup>1,2</sup>
- Comfort, confidence and satisfaction<sup>2,3</sup>

\*Determined by clinical assessment using the Kapur index.



# Periodontal Regeneration Past, Present and Future

Continues from page 25.

A thin layer of "enamel" can still be histologically seen between cementum and dentine. The formation of cementum is a critical step in the attachment of periodontal ligament and formation of alveolar bone - whether its in tooth development or in periodontal regeneration, so enamel proteins were looked at for potential to stimulate periodontal regeneration. A proof of principle study extracted animal teeth, cut cavities in the root surface, then treated the same cavities with enamel matrix proteins and re-planted the teeth. Acellular cementum formed on the root surfaces in the cavity and re-established periodontal support.

Within a short time, Enamel Matrix Derivative (EMD) was marketed as Emdogain by Biora in Sweden. EMD is purified acidic extract of proteins from pig enamel matrix:

- 90% Amelogenin protein
   hydrophobic aggregates
  - -highly conserved
- 10% mixture of other proteins

   not completely defined or
   understood but includes prolinerich non-amelogenins, tuftelin, tuft protein, serum proteins as well as ameloblastin and amelin

# EMDOGAIN WAS ACQUIRED BY STRAUMANN IN 2003.

The effects of EMD in vitro include

- Proliferation and growth of PDL fibroblasts
- Inhibition of epithelial cells
- Increase protein synthesis by PDL fibroblasts
   Formation of minoralized
- Formation of mineralized nodules in PDL fbs
- Growth of mesenchymal cells
- Release of autocrine growth factors from PDL fibroblasts
- Macrophages stimulated to produce BMPs

A case was then shown, showing successful periodontal regeneration

The Karring Story 1980-1984

- Beagle dog series of experiments
- Experimental periodontitis roots with attachment loss were cleaned, extracted and buried under flaps



in a 16 year old girl lateral incisor. The regenerated periodontal tissues were able to accept orthodontic tooth movement and space closure with almost no loss of papillary architecture.

The key reviews on EMD are

- Palmer RM, Cortellini P.
   Periodontal tissue engineering and regeneration: Consensus report of the Sixth European Workshop of Periodontology. J Clin Periodontol 2008; 35 (Suppl.8): 83 86
- Bosshardt DD. Biological mediators and periodontal regeneration: a review of enamel matrix proteins at the molecular and cellular levels. J Clin Periodontol 2008:35 (Suppl 8):87 – 105.
- Trombelli L, Farina R. Clinical outcomes with bioactive agents alone or in combination with grafting or guided tissue regeneration. J Clin Periodontol 2008;35 (Suppl 8):117 – 135.
- Cairo F, Pagliaro U, Nieri M.
   Treatment of gingival recession with coronally advanced flap procedures: a systematic review. J Clin Periodontol 2008;35 (Suppl 8):136 162.

## **FUTURE DEVELOPMENTS**

Improvement of surgical techniques – surgery is becoming more and more minimal – this progression shows us the development of flap designs over 20 years.

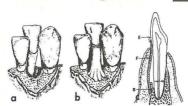
- Papilla Preservation (Takei, 1985)
- Modified/Simplified Papilla Preservation (Cortellini, 1999)
- Minimally Invasive Surgical Technique (Cortellini, 2007)
- Single Flap Approach (Trombelli, 2009)

Minimally invasive surgery has the following advantages

- Reduction in surgical trauma
- Increase of flap and wound stability
- Reduction in surgical time
- Increase in surgical accuracy
- Reduced postoperative morbidity

Interestingly if one looks at the control groups of studies looking at OFD alone

**Guided Tissue Regeneration** 



Ayman S, Lindhe J, Karring T and Rylander H. (1982) New attachment

vs OFD + EMD application shows that the results from the OFD procedure by itself are improving with time. Another improvement which was help better periodontal regeneration treatment is the 3D diagnosis and measurement of defects using CBCT imaging. This comes an increased investigation cost and a radiation dose. The images also suffer from metal-restoration artefacts. One also needs special software to carry out 3D bone defect measurements.

The future probably lies in combinations of active substances with biomaterials and cell cultures to create "Endogenous Regenerative Technology" systems.

- Active Substances
   Growth Factors
   Platelet Rich Plasma
   Enamel Matrix Derivative
- BiomaterialsScaffoldsBone Graft/FillersMembranes
- Autologous cell cultures

Systems with combinations of active substances with biomaterials are already in use. These include GEM21 – a combination of recombinant human Platelet Derived Growth Factor in a beta-TCP matrix. This product has licencing issues in the EU at the minute. Another one is OP-1 Implant which consists of 3.3mg rh-BMP-7 with 1g purified bovine Type I collagen. This product is used in spinal fusion and fracture repair and has promising lab and animal periodontal models show bone, cementum and ligament formation.

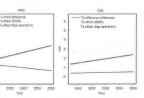
In this exciting and technological treatment, its important not to lose sight of the basics – periodontal regeneration demands patients have good control of plaque, bleeding, do not smoke and are not excessively stressed. They must also be able to cope with the follow-up regime. At the tooth level one must chose defects which are amenable to treatment, on teeth with favourable anatomy.

We are getting better at surgery



JCin Periodontol. 2008 Feb.35(2) 139-46. Epub 2007 Dec 13. Is there a tempor trend in the reported treatment efficacy of periodontal regeneration? Ametanabylis of randomized-controlled trials. Iu VK. Lignant A Gerebugh V.





# DENTISTRY AND THE

# Dentistry in the EU in 2012

- 27 member states
- 500,000,000 people
- 1,000,000 "dental workers"
- 390,000 dentists (not all active)
- Cost EUR 54,000,000,000 (in 2000)
- 63,000 dental students
- 168 dental schools



# EU Oral Health Care Workforce (2010)

- 27 member states
- 500,000,000 population
- 360,000 active dentists
- 400,000 dental nurses (Chair side Assistants)
- 150,000 dental technicians
- 30,000 dental hygienists



# Trends in Need for Care and Treatment in the EU

- Decline in Caries Prevalence in the young
- No improvement in prevalence of Oral Cancer
- Fewer people without any teeth
- Increased demand from the "heavy metal" generation
- Increased demand for "cosmetic" treatment



# How are Care and Treatment Provided in the EU?



# The Oral Health Care systems in EU countries are divided into broad categories

- Nordic system
- Bismarckian system
- Beveridgian system
- South European system
- East European
   Systems
- Mixed systems



# Nordic Model (1)

- Found in Denmark, Finland, Norway and
- Large public dental service financed by national or local taxation with free services for under 18 year-olds and some adults
- Private sector generally treats adults many of whom receive co-payment from the state



# Nordic Model (2)

- Well developed team dentistry with wide use of Dental Hygienists and Nurses (Chair-side Assistants)
- Over 90% of those under 18 years and 60% -90% of adults attend regularly for oral health care



# Bismarkian Model (1)

- Found in Austria, Belgium, France, Germany, Luxembourg and (the Netherlands)
- Based on statutory sickness insurance paid for by employers and employees
- Costs of oral healthcare totally or partially reimbursed by the insurance scheme
- Fees negotiated between insurance agencies and dental associations



# EU

# Dr Paula Vassallo - Consultant, Dental Public Health

# Bismarkian Model (2)

- Very little Government involvement
- Very small public dental service
- Apart from in Germany and the Netherlands, little use of team dentistry
- No dental hygienists in Austria, Belgium, France and Luxembourg
- Dental nurses (chair-side assistants) relatively uncommon in Belgium, France and Luxembourg (? Culture)

# Beveridgian Model (1)

- Unique to the United Kingdom
- Mixture of publicly and privately funded oral healthcare
- Publicly funded either in relatively small number of public service clinics or in private clinics where the owners contract with the
- Free of charge to all under 18 years of age and "special groups"

  \*\*Special groups | Special Groups | Spe

■ Found in Cyprus, Greece, Italy, Portugal and Spain

Southern European Model (1)

- Predominantly private provision of oral healthcare without Government involvement
- Very limited number of public clinics
- Limited number of insurance schemes



## Beveridgian Model (2)

- Widespread and increasing use of team dentistry
- Growing numbers of dental hygienists, dental therapists, dental nurses
- Also clinical dental technicians and orthodontic nurses all are registered
- Overall, 66% of population attend regularly for oral health care

# Southern European Model (2)

- Limited provision of free treatment for under 18 year olds
- Some team dentistry
- No dental hygienists in Greece
- Limited use of dental nurses in Greece
- Low rate of regular attendance for oral health care in Portugal and Spain (30-40% per year)



# Eastern European Models (1)

- Found in Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Slovenia
- Has changed from very largely public service, which was provided free of charge to a mainly private service
- Some insurance schemes are developing



# Eastern European Model (2)

- Some team dentistry
- Dental hygienists are now trained in most countries,
- Dental nurses (chair-side assistants) often not employed (? perceived cost)



### Current Situation

- Changes are being seen in all of the six patterns
- All systems are developing financial difficulties
- With the exception of Portugal and Spain where there is dynamic growth in the number of dentists the oral health workforce is expanding slowly

# DENTISTRY AND THE EU

Continues from page 31.

# Problems / Challenges we are facing

- Changing needs of patients more need for specialist care?
- · Migration of health professionals in and out of the EU
- Unequal mobility within the EU
- Patient mobility



# Problems / Challenges we are facing

- Fervent discussions about financing of health care in general
- Dental care has become politically less important
- Ageing population data on adult dental health needed
- Ageing workforce definition, retirement age, retraining, lower pensions
- Diversity of the Health workforce
- Increased costs
- Limited resources



## **EU DIRECTIVES**

- Dental Specialties
- Tooth Whitening
- Prevention of Sharps Injuries
- Medical Devices
- Dental Amalgam



Which Dental Specialties are Recognised in the European Union? (1)

- European Commission Directive (EC)
   2005/36/EC recognises only two Dental
   Specialties -Orthodontics and Oral Surgery
- In addition, Oral and Maxillofacial surgery is recognised as a Medical Specialty



Which Dental Specialties are Recognised in the European Union? (2)

- Orthodontics is recognised in 24 EU Member States (not in Austria, Luxembourg and Spain)
- Oral Surgery is recognised in 18 EU Member



# Which Dental Specialties are Recognised in the European Union?

- Periodontics is recognised in 11 EU Member States
- Paediatric Dentistry is recognised in 11 EU Member States
- Prosthodontics is recognised in 8 EU Member States
- Endodontics is recognised in 6 EU Member States



# Which Dental Specialties are Recognised in the European Union?

- Dental Public Health is recognised in 3 EU Member States (Bulgaria, Finland and the United Kingdom)
- The United Kingdom recognises 6 other dental specialties – Oral Medicine, Oral Pathology, Oral Microbiology, Oral and Maxillofacial Radiography, Special Needs and Restorative Dentistry

# Changes?

The Directive EC 2005/36/EC may be revised such that if 9 Member States (1/3) legally recognise a medical or dental specialty it will be recognised as an official specialty within the EU.

The CED is currently lobbying that this be revised to 11 (2/5) of Member states







# Feel the difference!



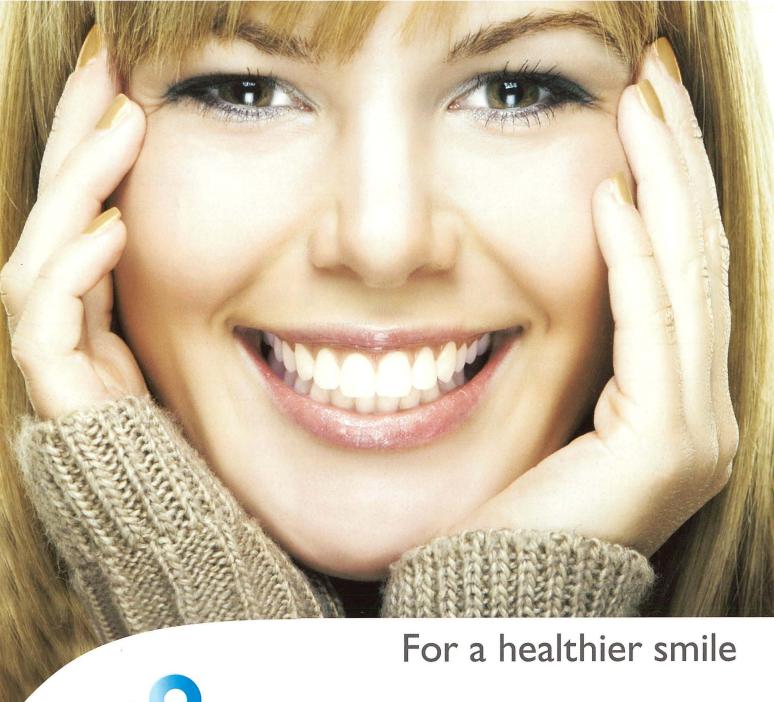
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# DENTISTRY AND THE EU

Continues from page 32.





Prevention of Sharps injuries

■ This directive was introduced in May 2010, to

introduce further protection for health care

workers exposed to the risk of sharps injuries. The directive has to be transposed into

Directive 2010/32/EU

Maltese Law by May 2013

Tooth Whitening Products-Cosmetics Directive, 76/768/EEC.



- All tooth whitening products with hydrogen peroxide levels higher than 6% are banned in the European Union.
- 6% hydrogen peroxide is equivalent to 16.62 carbamide peroxide
- Restrictions also apply to sodiu perborate and perboric acid



Prevention of Sharps injuries - Directive 2010/32/EU



 The act requires employers to provide a safe working environment in relation to sharps injuries, together with safe equipment, training, information and instructions on safe systems of work.



Prevention of Sharps injuries - Directive 2010/32/EU



mulle for Health

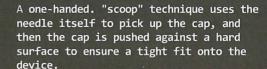
 'Where the results of a risk assessment reveal a risk of injuries with a sharp...', only then is 'recapping' banned



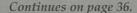
Prevention of Sharps injuries - Directive 2010/32/EU



- Resheathing is carried out only by the use of the single handed scoop technique
- Use devices which are designed to allow recapping in a safe manner eg needle blocks
- Protocols and procedures must be in place to comply with Directive







# DENTISTRY AND THE EU

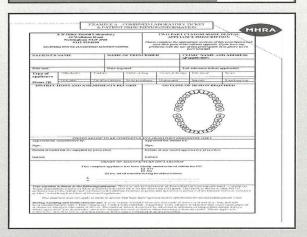
Continues from page 35.

# Medical Devices Directive - Directive 93/42/EC.

 Dental appliances, which are made for a specific patient, are 'custom-made devices' under the Medical Devices Directive 93/42/ EC. This Directive has recently been amended in March 2010



# Medical Devices Directive Directive 93/42/EC. • Following the recent changes the patient must now be advised that a statement about their laboratory work is available on request.



EX D	EXAME	LEB-PATIENT	PRESCRIPTION	& INFORMATION	
Notte	r Dental Lab Notted on Ec- tation NG9 115 9254888	ed 2008	API	ESCRIPTION AND C PLIANCE INFORMA serios regarding the fit or- twist remarks from proceeding formation.	TION
		·	PRESCRIBER	CLINIC NAME	
DATE OF APPL	EANCE:	IANUE BATE C	OF TECHNICAL	CAL LAB REFERENCE	
Product Code	Thores by also	· XX per of skyphines w	Chestoly	State State Company	
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## Dental Amalgam



- Dental amalgam is among the products that are likely to be regulated under the currently negotiated Mercury Convention (WPIEI)
- The use of mercury in dental fillings represents approx 10% of global mercury consumption
- It is one of the most difficult issues within the EU in reaching an agreed position
- Debate on potential health effects of the use of amalgam is still controversial

## Dental Amalgam



Scientific committee for Health and Environmental Risks (SCHER) and the Scientific committee for Emerging and Newly Identified Health Risks (SCENIHR) did not provide sufficient justification for amalgam restriction



# Dental Amalgam



- Bio Intelligence Service Report recommended a ban on dental amalgam
- WHO support a phase down over a long period and with agreed exemptions

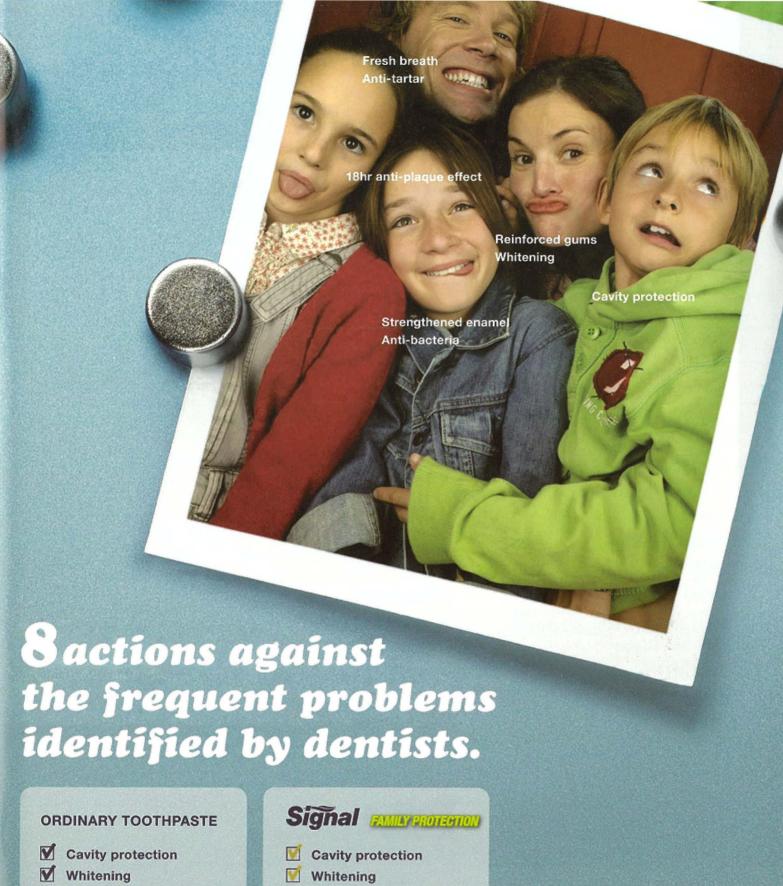


## Current Situation



- Phasing down?
- Phasing Out ?
- Restricted use?
- What exceptions would be needed if it is phased out?
- What would a reasonable timeline be?
- By end 2013 only encapsulated an be allowed (ISO 24234/TC106)





- Fresh breath
- ▼ Strenghtened enamel
- Fresh breath
- Strenghtened enamel
- Reinforced gums
- 18hr anti-plaque effect
- Anti-tartar
- Anti-bacteria











# Dr Alfred Magri Demajo

By David Muscat

Alfred clasps my hand within his. His hand is so large it envelopes mine. The skin is cold and clammy but the grip is tight, like a vice.

The nurses scurry from one patient to the next, constantly watching the monitors, and noting the blood pressure changes. They occasionally dart looks in my direction disapprovingly.....this is cardiac intensive care.....

'It was a fantastic Christmas party Dave,' whispered Alfred in a hoarse voice- 'keep it up.Filli qeghdin niedu gost u filli qieghed hawn,' he exhaled.

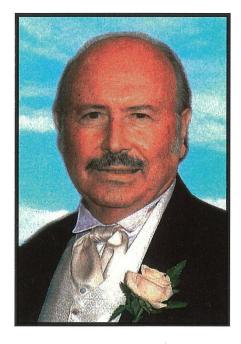
'Best let him rest,' said the male nurse in a polite but firm voice. The blood pressure was rising and the dialysis had sapped his energy.

Alfred looked me in the eye and said 'jekk ma narakx all the best'. Alfred at his worst-Alfred at his best. So stoic in the face of adversity. So proud even in his hopelessness. A keen admirer of Napoleon and his battles, Alfred was fighting his own battle now.

The winds blow mercilessly outside the hospital and the rain lashes down like the whip of a gladiator. The raindrops pelt on the windows and flow down the glass relentlessly and in the distance the sound of thunder and the flash of lightning mesmerise all who dared venture outside.

'All the best Alfred,' I said as I retreated into the corridor and looked back. Alfred closed his eyes, regaining his strength.

Once the president of The Dental Association of Malta, President of the Federation of Professional



associations and also an elected member of the Medical Council all at the same time-that was no mean feat. A man who gave his all for us in a selfless way.

Like his namesake who delivered the Magna Carta ,Alfred was a gentleman who negotiated on our behalf on many occasions and fought for our rights . I used to wonder how he and Roger Vella managed to organise so many activities for the DAM and use up so much precious time, only for me to be part of that very organisation now.

Alfred was one of the founding members of the Federation Of professional bodies and was instrumental in the setting up of the HQ of so many professions in Sliema Road Gzira-where we all converge.....a fine building we all share. Alfred the master. Alfred the grandmaster. Alfred the dentist. Alfred the Orthodontist. Alfred the farmer, the gardener, the fisherman and the friend. Alfred the great.

In the garden of the palazzo a golden eyed gecko emerges from the crisp foliage amongst the citrus trees, hoping to warm its cold blood in the midday sun. It is the end of autumn and the trees have shed their leaves. It is quiet now .Alfred had picked scores of oranges and lemons from his garden just a few days back and made up four large beautiful hampers for our Christmas raffle at the party. This is so typical of Alfred-so generous and so nice.

Alfred was a proud man –a man of presence whose deep voice would reverberate through a hall. He would sometimes appear pompous to those who maybe did not know him so well. You did not want to be around if he lost his temper, but the storm would pass after a couple of minutes with him.

Alfred would always sit in the front row at our dental association professional lectures and inevitably always asked a question. He would attend every dinner and I do not remember him ever missing our annual St Apollonia mass and lunch which he would organise with Roger.

His presence will always be with us. He will be missed by his family and his friends.

As the veil of death conceals salted tears, far from here in Birzebbugia Alfred's large solid fishing boat rocks to and fro with the Majjestral wind. The little fish nibble at the attached barnacles on its underside, and the ripples flow out towards the horizon as the sun sets on another day. The captain has gone, but he has left a sound ship behind.

# **SUNSTAR**



# Ortho



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# BECAUSE ORTHODONTIC PATIENTS DESERVE SPECIAL CARE AND ATTENTION

#### Reference

1. Klukowska M, Bader A, Erbe C, et al. Am J Orthod Dentofacial Orthop 2011; 139(5): e463-70. 2. Benson P. J Evid Based Dent Pract 2011; 11(2): 105-6. 3. Naranjo AA, Triviño ML, Jaramillo A, et al. Am J Orthod Dentofacial Orthop 2006; 130(3): 275.e17-22. 4. Shaw WC, Addy M, Griffiths S, Price C. Eur J Orthod 1984; 6(2): 137-40. 5. Tufekci E, Dixon JS, Gunsolley JC, Lindauer SJ. Angle Orthod 2011; 81: 206-10.

6. Data on file.



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