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Swarovski Fountain, Innsbruck, Austria

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Lyttelton Manor X 03, Pretoria, 0157
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Resisting the urge to prescribe antibiotics. Antibiotic resistance and dentistry

SADJ April 2022, Vol. 77 No. 3 p119

Prof NH Wood - MDent, PhD

Global healthcare is facing increased challenges that result from antibiotic resistance. There are several factors that contribute to this global concern that range from frequent, inappropriate antibiotic prescription to incorrect self-medication and non-compliance to antibiotic scheduling by the patient. Infections in the mouth are a major public health concern, and it raises questions on how we as oral healthcare professionals approach and manage these pathologies.

Although antibiotics are revolutionary and responsible for saving countless lives, up to 50% of all antibiotic prescriptions are unwarranted.¹ Depending on the country's data, dentists issue around 10% of all antibiotic prescriptions.² According to Patrick and Kandiah³, up to two thirds of antibiotic prescriptions originating from the dental practice are not clinically indicated. This is true when looking at data for both adult and child populations. Dentists continue to prescribe antibiotics when there is no systemic involvement, and the condition can be resolved through clinical/surgical intervention. We need to exercise restraint when reaching for a prescription pad if the intention is to prescribe pro-actively, and not to deal with the cause. Even then, the correct antibiotic should be used, and not some blanket approach to buy time to treat the cause later when it is more convenient to the practitioner.

In order to mitigate the rise in antibiotic resistance and to ensure best practice is followed, some guidelines to follow will include^{4,5}:

- Diagnosing accurately
- Using narrow-spectrum antibiotics as far as possible when indicated

- Selecting the correct antibiotic for the condition
- Implementation of the correct dose and schedule, including patient compliance monitoring
- Immediate intervention in cases where such treatment will avoid any antibiotic prescription.

It is time that dentistry and its organized structures align themselves with recognized antibiotic-stewardship programs as part of an overall strategy to limit further antibiotic resistance development. Your individual effort will make a great difference in this fight.

We herewith present the April issue of the SADJ and trust that you will enjoy the content.

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Your participation into our cover pages

SADA wishes to extend its heartfelt gratitude to you for your continued contributions to the journal and to research in the oral health space. Your contributions have helped the journal to be competitive with other scientific journals globally.

In the spirit of broader inclusivity we would like to invite authors to provide us with suggestions for the cover page content of the SADJ. This should be all encompassing and not limited in appeal to a single grouping. We hope that these contributions will better our journal in line with our main objectives.

We look forward to receiving meaningful contributions from our membership, and thank you for your continued support and participation.

Warm regards,
 Prof NH Wood – Managing Editor
 Dr N Metsing – Head: Professional Development SADA

Significance of April month in Dentistry

SADJ April 2022, Vol. 77 No. 3 p120

Dr Nthabiseng Metsing, Head: Professional Development, SADA

April is oral cancer awareness and, in the USA, they also observe national facial protection month during this month as well. When it comes to identifying potential warning signs of oral cancer, dentists are often the first ones to notice any abnormalities. Screenings for oral cancers are performed during the normal dental visit, or even incidentally when patients present with other problems in the mouth. During this month we encourage dentists to be on the lookout for any suspicious lesions that may appear in the oral cavity, in order for patients to receive early intervention. While these are part of the routine visits, we use these days to amplify the messages that raise awareness because most people incorrectly regard dentists as doctors who only treat teeth.

Facial injuries due to sporting activities are a common occurrence and most of the time these are preventable by wearing proper protective gear. This month can also be used to educate athletes, parents, coaches and referees about the many ways that sport related facial injuries can be avoided (Johnsfamily dentistry, April 2018).

Oral Cancers

The risk factors for cancer are smoking or smokeless tobacco use, excessive consumption of alcohol, human papilloma virus (HPV), the use of snuff or betle nut, family history of cancer may predispose one to developing cancer as well as excessive exposure to the sun.

Diagnosing malignancies is very important in managing them and thus patients will respond positively to treatment, contrary undiagnosed malignancies can be very life threatening. Oral cancers may present on any tissues in the oral cavity, like the lips, the tongue, buccal mucosa, the tongue, hard and soft palate as well as in pharynx. As alluded before it is important to conduct further investigations or to refer the patient if you suspect a lesion may be carcinogenic. Symptoms may include lesions that do not heal, raised lesions, white or red patches on mucosa these are usually painful. Oral cancers have a slow progression rate and are mostly found in adults. More men than women get diagnosed with cancer, this may be linked to men engaging a lot of the risk factors than women. It is said that almost everyone who engages in sexual intercourse will get HPV, however a growing number of homosexual men are now presenting with oral HPV lesions. Multiple sexual partners also increase the risk of HPV.

In about 84% of people who are diagnosed early patients have a survival rate of 5 years and this number is reduced to 64% in patients who are diagnosed late in the disease progression (Poonam Sachdev,2018).

Facial injuries

Injuries to the face can have various causes which include, sporting activities, motor vehicle accidents, falls, blunt force trauma just to mention a few. These may lead to damage to your teeth, tissue or skin lacerations or even fracturing of



the bone(s) in the maxillofacial region. The treatment will be related to the type of injury sustained, which includes building up the teeth, root canal treatment, crown placement on teeth, intermaxillary fixation or even surgery to approximate the bony fragments with metal plates. Most patients respond very well to treatment however there are some patients who may require follow-up after 6 to 12 months. (Penn Medicine)

The symptoms of facial injuries include changes in sensations on the face, facial deformities or bleeding, challenges with breathing through the nose as a result of bleeding or swelling, contusion or swelling around the eye resulting in visual problems and missing teeth.

Prevention of facial injuries is related to the cause. Facial injuries caused by motor vehicle accidents may be prevented by the wearing of a seatbelt. Injuries due to sporting activities may be prevented by wearing of a face gear or a mouthguard, there are different types of face gears and mouthguards hence it is important to consult the dentist so that they advise on the best one to use based on the type of sport you engage in. Falls and blunt force trauma can happen in fights and most of the time are triggered by alcohol, so to prevent these we advise that people avoid getting into physical altercations especially when under the influence of alcohol.

Gender based violence (GBV) has been a really big topic in our country lately and research has also shown a rise in GBV cases since the advent of the COVID-19 pandemic. Although it has been revealed that some perpetrators will focus on victims' lower body, there are others who will cause facial injuries. This makes it more important in my opinion to involve law enforcement when such cases to present to your practice, this is mainly because a lot of these victims sadly end up losing their lives.

We would like encourage oral health practitioners to use the month of April to amplify the importance of being on the lookout for oral cancers and the importance of protecting your face because it is a fundamental part of the body for self-recognition.

The Induction of Bone Formation by the recombinant human transforming growth Factor- β_3 : From preclinical studies in *Papio ursinus* to translational research in *Homo sapiens*

SADJ April 2022, Vol. 77 No. 3 p121 - p134

Ugo Ripamonti¹, Jakobus Hoffman², Carlo Ferretti^{1,3}

ABSTRACT

Aim and Objectives

Skeletal bone defects of the axial or the craniomaxillofacial skeletons still present formidable challenges to skeletal reconstructionists, tissue biologists and modern medicine. In systematic research experiments in the Chacma baboon *Papio ursinus* our laboratories have shown the previously unreported osteoinductive activity of the three mammalian transforming growth factor- β (TGF- β) isoforms. This review discusses the induction of bone formation by the mammalian TGF- β s with particular reference to the substantial and rapid induction of bone by the recombinant hTGF- β_3 from the laboratory benches, to pre-clinical studies in heterotopic and orthotopic mandibular sites of *Papio ursinus* to clinical translation in human patients.

Design and Methods

A series of systematic research experiments in *Papio ursinus* using the hTGF- β_3 together with earlier experiments using the - β_1 and β_2 isoforms are reviewed and re-analyzed molecularly and morphologically to provide the basic research data for the reported clinical translation in human patients.

Results

The three mammalian hTGF- β isoforms and notably hTGF- β_3 induce rapid and substantial induction of heterotopic bone in intramuscular sites of *Papio ursinus*. Relatively low doses of hTGF- β_1 or hTGF- β_3 in binary application with hBMP-7

synergize to induce massive corticalized ossicles in the *rectus abdominis* muscle. In orthotopic mandibular sites, 125 and 250 μ g doses of hTGF- β_3 induce bone formation across large mandibular defects in *Papio ursinus* with corticalized buccal and lingual plates by day 30, with modeling and maintenance of corticalized bone by 9 to 12 months after implantation of the 250 μ g dose in 3 cm mandibular defects *Papio ursinus*.

Discussion

hTGF- β_3 significantly up-regulates *RUNX-2* and *Osteocalcin* expression on day 15 controlling the differentiation of progenitor stem cells into the osteoblastic lineage. The induction of bone by the hTGF- β_3 is *via* the bone morphogenetic proteins pathway; hTGF- β_3 controls the induction of bone by regulating the expression of *BMPs* gene and gene products *via* Noggin expression, eliciting bone induction by up-regulating exogenous *BMPs*.

Key words: Bone induction, bone morphogenetic proteins, transforming growth factors- β proteins, transforming growth factors- β_3 , redundancy, primates, human osteoinduction, inhibitors, translational clinical research

INTRODUCTION

In a previous communication to *Frontiers*¹ addressing the regenerative frontiers of craniofacial reconstruction using the mammalian transforming growth factor- β (hTGF- β) isoforms, we bluntly addressed the grand challenges still facing cranio-maxillofacial and mandibular reconstruction in human patients. We would like to copy verbatim what we have then stated; many years later the surgical perspectives of mandibular regeneration in human patients have not yet regretfully changed:

"Restoring anatomical function of complex disfiguring craniofacial defects and anomalies remains a grand unsolved challenge. Those of us who have not suffered the outrage of facial deformity visited upon patients either as developmental misfortune or as the scourge of disease or violence can only imagine the effects thereof. Loss of facial features not only denies patients the most basic human functions but also rob them of a sense of identity with all associated mental anguish".¹

The *conundrum* of regenerating large mandibular defects in clinical contexts remains a grand challenge in craniofacial tissue regeneration.² This is in spite of the surgical advances

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2. Jakobus Hoffman - Contribution 20%
3. Carlo Ferretti - Contribution 20%

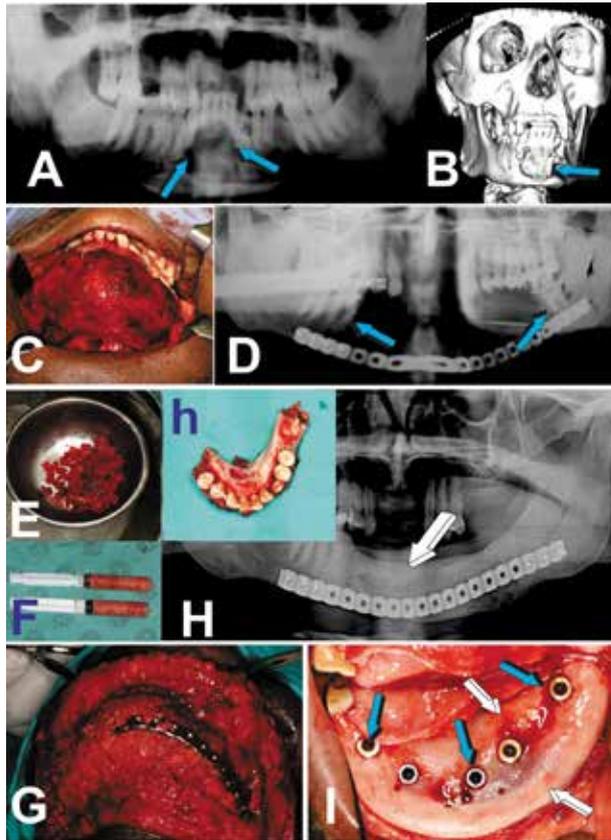


Figure 1. The overall osteogenic and osteoinductive capacity of autogenous bone grafts (ABGs) to regenerate large mandibular defects in clinical contexts. The series of digital images ending with *restitutio ad integrum* and restoration of masticatory function of the avulsed mandible illustrate the concept of "clinically significant osteoinduction".^{17,38} A,B,C. Surgical removal of a large odontogenic cyst. D, large mandibular defect E,F,G, treated with fragments of ABG harvested from the posterior iliac crest. Fragments of autogenous bone are morcellated, inserted and compacted into 20 ml syringes, ejected across the large mandibular defect stabilized by a titanium plate (blue arrows in D). H. Orthopantomograph 6 months after compacting the autogenous graft in the mandibular defect shows the quality and quantity of the regenerate bone (white arrow). The regenerated bone is adequate to be identified radiographically as regenerated normal bone with normal radiopacity and trabecular architecture.^{17,38} G. The massive mandibular defect reconstructed with morcellated compacted fragments of autogenous bone translates the "Bone induction principle"⁴⁹ by regenerating substantial bone (white arrows) for the implantation of several titanium fixtures (light blue arrows) for restoring masticatory function.

together with outstanding discoveries in molecular, cellular and tissue biology. These fundamental developmental molecular and cell biology studies have significantly increased our molecular understandings of bone formation by induction in primates. This occurred after the explosion of mechanistic molecular studies at the end of last Century. Indeed, molecular biology techniques resolved the intimate knowledge of the cell and its several interactions with the surrounding extracellular matrix (ECM),³ including the cellular/ECM communications and the interactions of the ECM with single cellular topographical microenvironments. This novel information were proposed to be used to finely tune and control the induction of postnatal tissue morphogenesis.

The molecular dissection of the extracellular matrix of bone has finally yielded the isolation of the osteogenic proteins of the transforming growth factor- β (TGF- β) supergene family.⁴ Purification to homogeneity of crude extracts of demineralized bone matrices allowed amino acid sequence

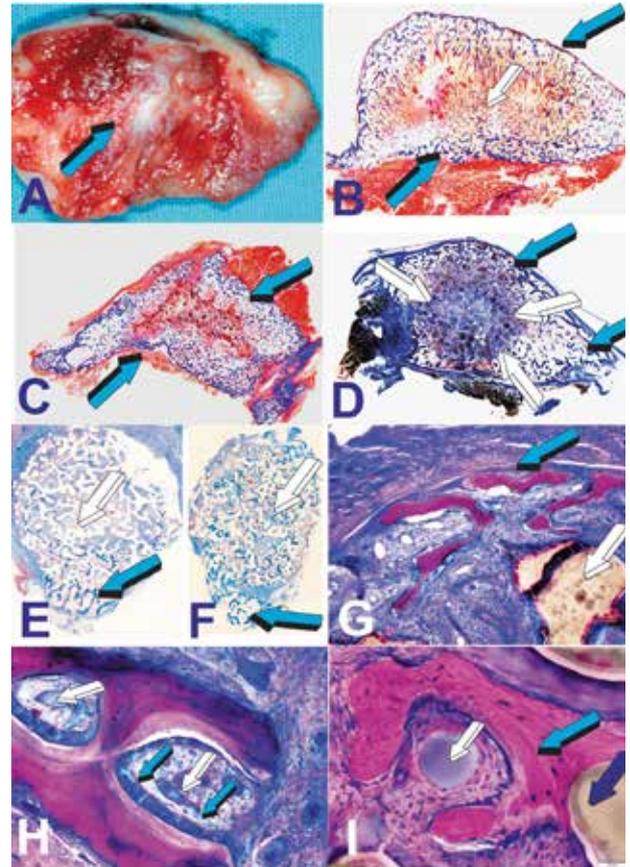


Figure 2. Redundancy of soluble osteogenic molecular signals of the transforming growth factor- β (TGF- β) supergene family⁴ initiating de novo induction of bone formation but in primates only. A. Induction of large corticalized mineralized ossicles upon implantation of 125 μ g hTGF- β_3 reconstituted with insoluble and inactive collagenous bone matrix on day 30 after heterotopic rectus abdominis implantation.

B,C. Undecalcified whole mount sections of the large mineralized ossicles showing corticalization delineating the induced mineralized bone containing scattered remnants of insoluble bone matrix and trabeculae of newly formed bone covered by osteoid seams. D. Induction of a large heterotopic ossicle upon implantation in the *rectus abdominis* muscle of a Chacma baboon *Papio ursinus* of a macroporous biphasic hydroxyapatite/ β -tricalcium phosphate super-activated by 25 μ g hTGF- β_3 and harvested on day 30.

Newly formed bone essentially initiates outside the profile of the implanted bioreactor (white arrows), expanding and corticalizing (light blue arrows) within the surrounding rectus abdominis muscle. E,F. Induction of bone at the periphery of the implanted coral-derived constructs reconstituted with 125 μ g hTGF- β_3 and harvested on day 30 (E) and 90 (F) after intramuscular heterotopic implantation.^{17,30}

D. On day 90 there is bone formation across the macroporous spaces (white arrow) not seen on day 30, with lack of bone formation within the internal and central areas of the super-activated bioreactor (white arrow). G. Substantial induction of bone formation (light blue arrow) only at the periphery of the coral-derived construct (white arrow) harvested on day 30 upon rectus abdominis implantation of 250 μ g hTGF- β_3 . Bone forms exclusively at the periphery of the calcium-phosphate based bioreactor. H. Rapid induction of bone at the periphery of a 250 μ g hTGF- β_3 super-activated bioreactor with osteoid seams populated by contiguous osteoblasts (light blue arrows) in close relationship with invading capillary (white arrows). Capillary sprouting prominently invades the macroporous space with generated newly formed bone. I. The role of the vessels in osteogenesis:⁶⁶ The central morphogenetic blood vessel (white arrow) morphogenizes the induction of bone formation (light blue arrow) in a coral-derived (dark blue arrow) macroporous space initiating the plastic morphogenesis of bone around the central blood vessel. The undecalcified Exakt section cut and polished at 27 μ m shows the plasticity of the newly formed bone with torsional forces figuratively clasping the morphogenetic vessel.

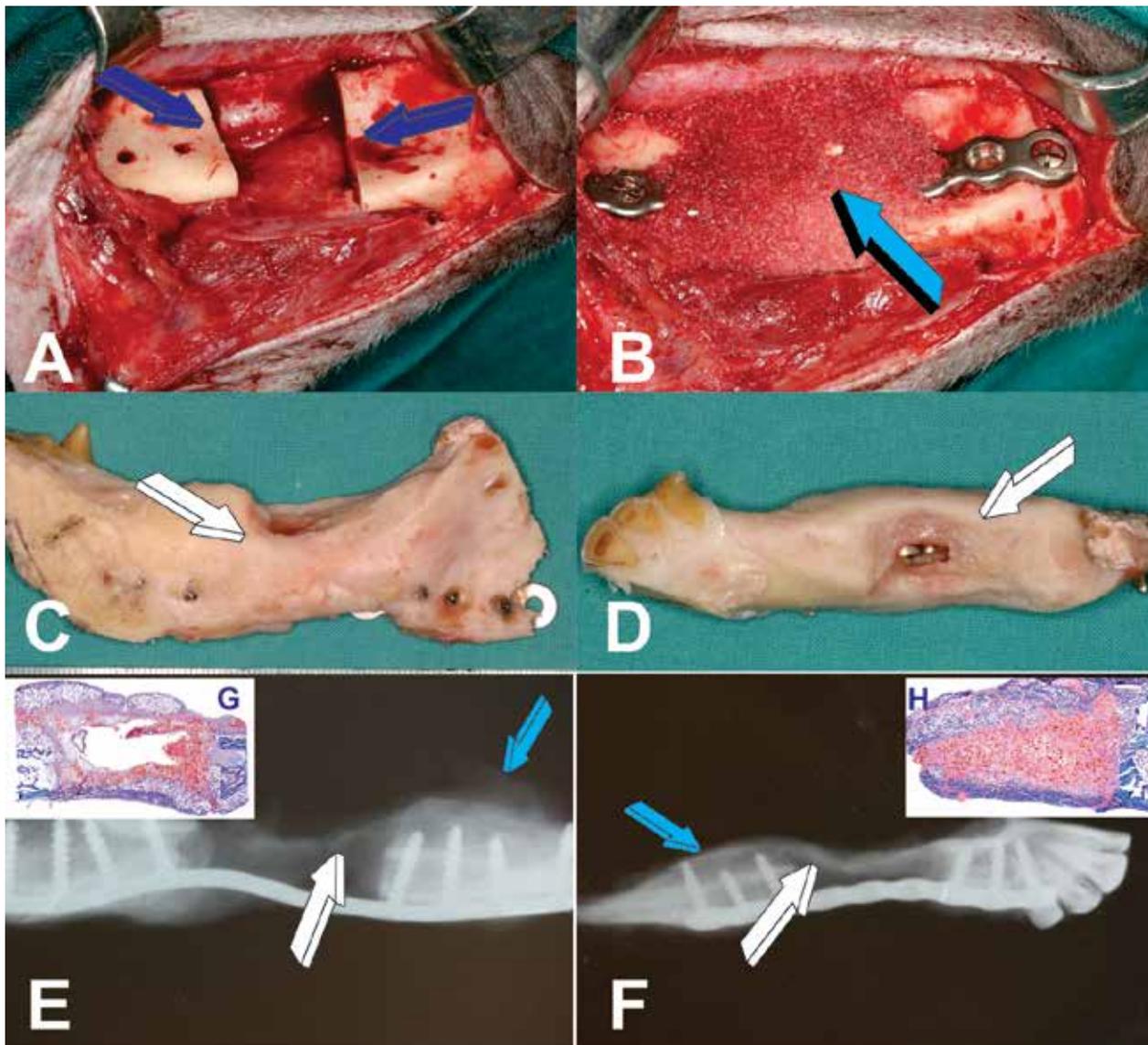


Figure 3. Regeneration of 2.5 cm full thickness defects surgically prepared in the Chacma baboon *Papio ursinus*. **A**, Defect creation (dark blue arrows), **B**, Implantation of the hTGF- β_3 osteogenic device, 125 μg hTGF- β_3 per gram of chaotropically extracted allogeneic insoluble collagenous bone matrix in the mandibular defect stabilized with a titanium plate. **C,D**, Harvested hemi-mandibles 30 days after hTGF- β_3 implantation show regeneration of the buccal and lingual plates. **E,F**, regeneration and *restitutio ad integrum* of the buccal and lingual plates as seen radiographically 30 days after implantation. Insets **G** and **H**, whole mounts undecalcified sections cut on the Reichert-Jung sledge-microtome with tungsten-carbide blades at 11 μm and stained free-floating with a modified Goldner' trichrome. Mineralized bone across the defect with corticalization of the newly formed undecalcified bone as early as day 30 in an adult non-human primate *Papio ursinus*.

information of proteins chaotropically extracted with guanidinium-HCL.^{5,6} Molecular cloning followed, reporting the human recombinant proteins belonging to an entirely new family of proteins, the bone morphogenetic proteins (BMPs), members of the TGF- β supergene family.⁷⁻¹¹

The later cloned recombinant human BMPs (hBMPs) were soon tested in a variety of animal models; these also included non-human primates' species for both appendicular and craniofacial skeletal regeneration.¹¹⁻¹⁷ Experiments in pre-clinical surgical models proposed that the newly characterized and cloned molecular signals would regenerate bone across the skeleton, including cranio-mandibulo-facial reconstructions in human patients. This review on the osteoinductive capacity of hTGF- β_3 in primates, from the Chacma baboon *Papio ursinus* to the human primate *Homo sapiens* describes with some details the biological significance of apparent redundancy of molecular signals endowed with the unique capacity to initiate bone formation in heterotopic extraskelatal sites,¹⁸

where there is no bone.^{16,17,19} All preclinical research experiments described in this manuscript have been approved by the Animal Research Ethics Committee (AREC) of the University, from the studies on the Selachian's fishes *Carcharinus obscurus* to several experiments in the Chacma baboon *Papio ursinus*. The AREC no. and title of the study under which the experiment covers the implantation of the 250 μg dose of hTGF- β_3 in large full-thickness 3 cm mandibular defects in *Papio ursinus* is under waiver 2018-11-19-0 *Translational approaches for bone constructs: their impact on facial bone reconstruction*. The study in *Papio ursinus* was partially supported by Project No. AOCMF-19-03-R of AOCMF, Switzerland. Translational clinical research in human subjects was approved by the Human Research Ethics Committee (Medical) clearance certified M170597 of the University of the Witwatersrand, Johannesburg.

Until 1993,²⁰ either naturally-extracted and purified BMPs or hBMPs were the only described signals endowed with the unique prerogative to induce bone formation

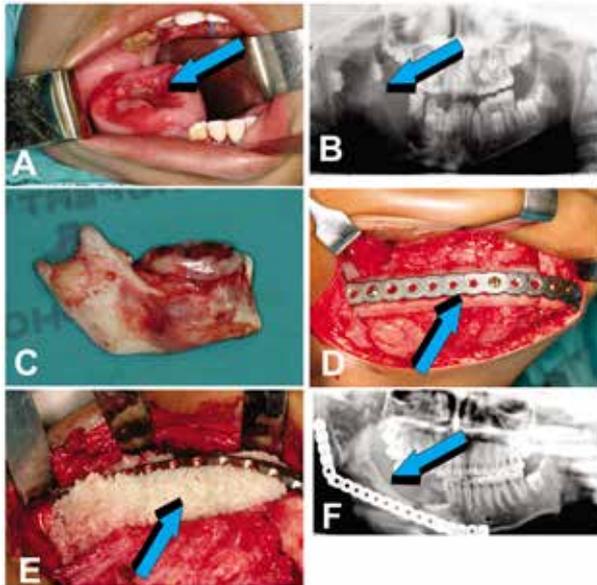


Figure 4. From the bench top to translational research in *Homo sapiens*. The significant induction of bone formation in mandibular defects of *Papio ursinus* by day 30 after hTGF- β_3 implantation stimulated our research laboratories to translate in clinical context the use of the hTGF- β_3 osteogenic device, by implanting the tested dose of 125 μ g hTGF- β_3 per gram of carrier in a large mandibular defect of a human patient (Ferretti and Ripamonti 2020). **A.** Odontogenic myxoma of the right ramus and body of the mandible of an eight-year-old male patient. **B.** Panoramic radiograph showing a multiloculated expansive lesion in the right hemi-mandible. **C.** Resected mandible after combined subperiosteal and supraperiosteal resection. **D.** Extra oral approach and insertion of a titanium plate (light blue arrow). **E.** human demineralized bone matrix (6 g of hDBM) reconstituted with 750 μ g hTGF- β_3 for the ramus and body of the resected mandible (light blue arrow). **F.** Panoramic radiograph of treated mandible 5 years after reconstruction with costo-chondral graft and hTGF- β_3 delivered by hDBM showing scattered islands of newly formed bone (light blue arrow) within the defect.

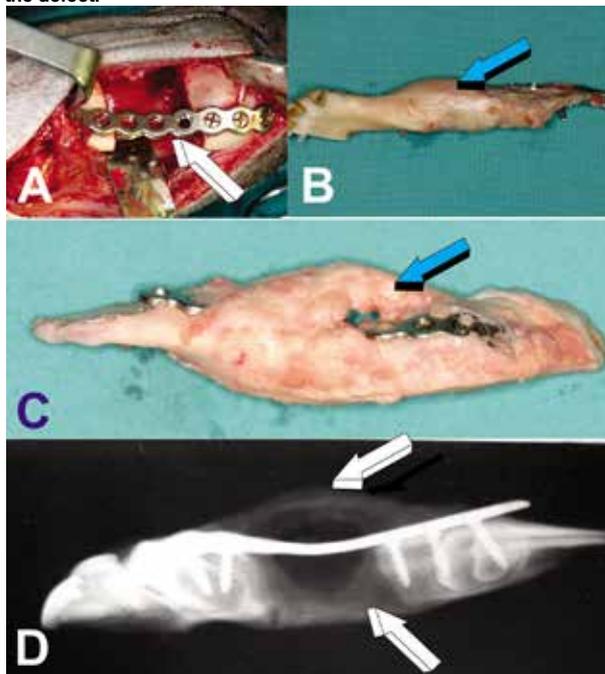


Figure 5. The synergistic induction of bone formation by binary application of 2.5 mg recombinant human osteogenic protein-1 (hOP-1), also known as hBMP-7, with 125 μ g of recombinant human transforming growth factor- β_3 (hTGF- β_3) delivered by allogeneic insoluble collagenous bone matrix and harvested on day 30 after implantation in a 2.5 cm full thickness mandibular defect in the Chacma baboon *Papio ursinus*.⁴⁴ **A.** Extra-oral approach for the creation of the defect on the exposed mandible stabilized by a titanium plate (white arrow). **B.** mandible regenerate 30 days after binary application of of 20:1 ratio by weight hOP-1: hTGF- β_3 . This ratio maximizes the synergistic induction of bone formation (light blue arrow) as previously described in heterotopic and orthotopic sites of the Chacma baboon *Papio ursinus*.^{26,37,42} Recombinant morphogens were combined with allogeneic insoluble collagenous bone matrices. **C.** Complete regeneration with expansion of the newly formed corticalized bone (light blue arrow) by day 30 after implantation of the binary application of hOP-1 with relatively low doses of the hTGF- β_3 isoform, 20:1 ratio.²⁶ **D.** Prominent induction of bone formation with induction of both mineralized lingual and buccal plates of the mandibular regenerates (white arrows).

when implanted in heterotopic extraskeletal sites, i.e. subcutaneously, intramuscularly as well as after intraparenchymatous implantation.^{11,19,21}

The work of Sampath et al.²⁰ reported a comparatively high level of homology in *decapentaplegic* (*dpp*) and 60A genes in *Drosophila melanogaster* with BMP-2, BMP-4, and BMP-5 and BMP-6, respectively. The study highlighted the critical and developmental role of BMPs' amino acid sequence motifs for the evolutionary induction of the vertebrates.^{4,20} *Drosophila* and human secreted proteins retained and thus shared common developmental roles. Indeed, gene products of the fruit fly and *Homo* have been evolutionary conserved for a billion years and as such, recombinant human DPP and 60A proteins, when reconstituted with insoluble inactive collagenous bone matrix of chaotropically extracted rat bone, initiate the induction of bone in the subcutaneous rodent bioassay.²⁰

These experiments have shown that phylogenetically ancestral signaling amino-acid motifs deployed in the fruit fly *Drosophila melanogaster* for dorso-ventral patterning are also operational to initiate the unique vertebrate trait of bone induction and development. The induction of bone crystallized the emergence of the skeleton, the vertebrate animals, the bipedal ancient hominids, the Australopithecines, speciation of *Homo habilis* and *Homo erectus* in Central and Southern Africa, soon followed by the explosion of the human clade across the planet.²²⁻²⁴

We reported that Nature has had a lesson to teach: ^{4,25,26} "Instead of evolving genes and gene products capable of initiating the induction of bone formation, Nature has rather usurped and recruited phylogenetically ancient gene products operating minor modifications in amino acid sequence motifs in the carboxy-terminal domains deployed for dorso-ventral patterning in the fruit fly to molecularly initiate the induction of bone formation, skeletogenesis, and the emergence of the vertebrates".^{21,23,24}

Pleiotropy and Redundancy

Systematic research experiments in *Papio ursinus* showed that the induction of bone formation is not restricted to naturally derived or recombinantly produced hBMPs but extend to homologous yet molecularly different members of the TGF- β family.^{4,11} The three mammalian TGF- β proteins induce substantial endochondral bone formation when implanted in intramuscular heterotopic sites of *Papio ursinus*.^{4,19,24-27}

In previous communications, we have asked the critical questions: "Which are the molecular signals that control the biological significance of apparent redundancy initiating the induction of bone formation?"^{4,11,16,17} In marked contrast to rodents, lagomorphs and canine, the three mammalian TGF- β proteins initiate the substantial and rapid induction of bone formation in non-human primates.^{4,19,26,27} The need for alternative to hBMPs to regenerate bone in man is now

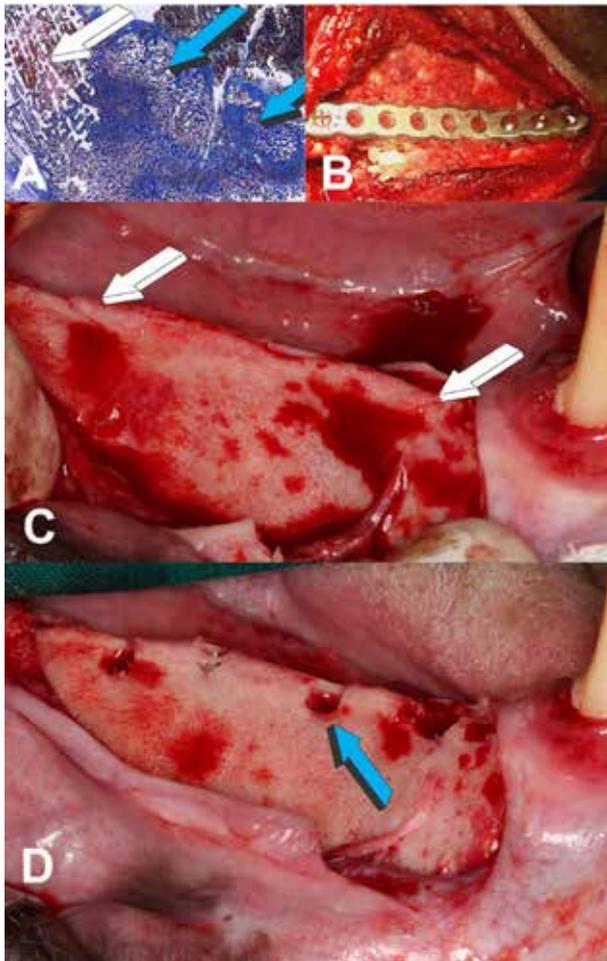


Figure 6. The substantial and rapid induction of bone formation by 250 μg of recombinant human transforming growth factor- β_3 (hTGF- β_3) pre-combined with coral-derived macroporous bioreactors proposed further studies to test the 250 μg dose in larger 3 cm full-thickness defects in *Papio ursinus* for later translation in clinical contexts. **A.** Prominent induction of bone (light blue arrows) two to three cm from the implanted coral-derived bioreactor (white arrow) super-activated by the hTGF- β_3 osteogenic device. **B.** Creation of a 3 cm full thickness defect in *Papio ursinus* inserting a titanium plate for stabilization. Doses of the recombinant morphogen were reconstituted with human demineralized bone matrix (hDBM) to enhance the non-human primate model for translation in clinical contexts. **C.** Substantial induction of bone formation with *restitutio ad integrum* of the implanted mandible one year after implantation of the hTGF- β_3 osteogenic device: complete regeneration of the defect. **D.** Exposed newly formed and mineralized bone were trephined (light blue arrow) to insert titanium dental implants with different geometric configuration. Titanium constructs were implanted at 30 and 15 days prior euthanasia and tissue harvest to provide tissue constructs at 30 and 15 days post-implantation.

critical, after the published complications and performance failures of hBMP-2 and hOP-1, the latter protein also known as BMP-7.^{17,28-30}

At long last and finally so, the biotechnology industry has acknowledged that treatments by recombinant hBMPs require supra-physiological BMP concentrations, which are “associated with potential local and systemic adverse effects”.³¹ To address the problem of high supra-physiological doses of the recombinant hBMPs to induce sub-optimal amounts of bone formation in humans, and thus to engineer and improve efficacy, a BMP/activin A chimera was constructed which showed superior activity to native BMPs at less concentrations than the currently FDA approved hBMP-2/ACS orthotopic device.³¹ It is mandatory to again quote a previous statement that “Reviews and perspectives

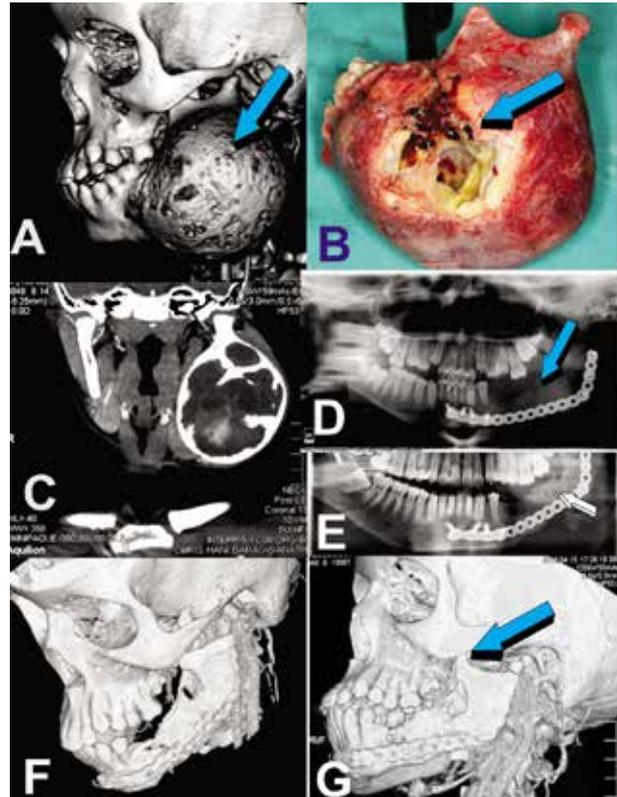


Figure 7. Clinical translation of the substantial induction of bone formation by 250 μg of recombinant human transforming growth factor- β_3 (hTGF- β_3) pre-combined with coral-derived macroporous bioreactors implanted in the *rectus abdominis* muscle of the Chacma baboon *Papio ursinus*.^{17,24} **A.** Aneurismal bone cyst shown by three- and two-dimensional CT scans (**C**). **B.** Resection resulted in 13 cm long defect of the mandible. The defect was reconstructed with a 6 cm costo-chondral graft and with 2500 μg hTGF- β_3 pre-combined with 12 g of human demineralized bone matrix (hDBM). **D.** Panoramic radiograph of the implanted hemi mandible 15 days after implantation of 12 g of hDBM reconstituted with 2500 μg hTGF- β_3 packaged within mandibular defect (light blue arrow). **E.** Panoramic radiograph 6 years after reconstruction. Regeneration of the avulsed mandible with restoration of mandibular morphology. **F.G.** 3D reformatted CT scan of the mandible 6 months post reconstruction. The granular DBM has been replaced by a cohesive bone ossicle with regeneration of a condylar and coronoid process (light blue arrow).

on bone tissue engineering for alternative to hBMPs to regenerate bone in man is now critical, after the published complications and performance failures of hBMP-2 and hOP-1, the latter protein also known as BMP-7.^{17,28-30}

As we have previously stated, “the conundrum of regenerative medicine and tissue engineering has been a newly developed research program which later morphed into the hyperbole of promised regenerative treatments based on published data in pre-clinical animal models, without any experimental evidence of translational research in clinical contexts”.¹⁷

It is mandatory to again quote a previous statement that “Reviews and perspectives on bone tissue engineering report a series of successful novel procedures in animal models with the promise that the results obtained both *in vitro* and *in vivo* will eventually result in substantial differences in acute and chronic human disorders including but not limited to, myocardial infarction following transplantation of functional contractile myoblastic cells, liver, pancreas and kidney failure following transplantation of bioactive hepatocytes, healthy grown pancreatic islets

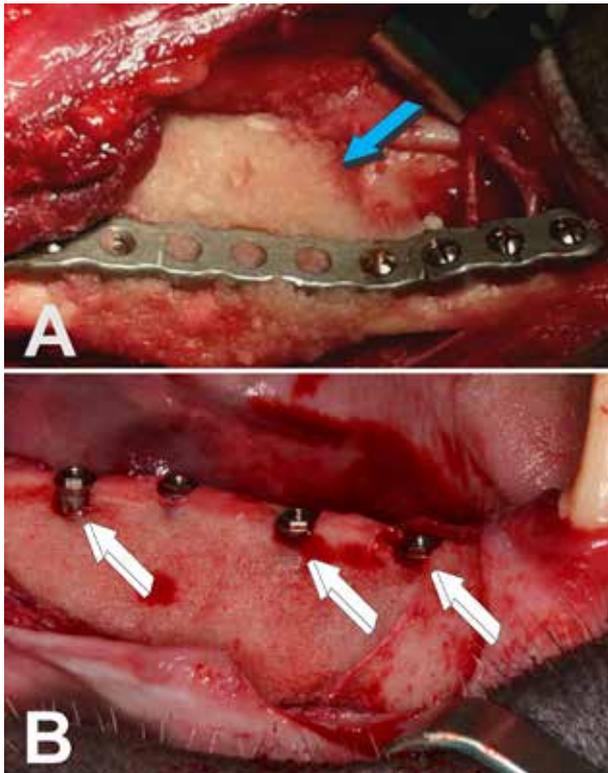


Figure 8. A. Implantation of the recombinant human transforming growth factor- β_3 (hTGF- β_3) (light blue arrow) pre-combined with human demineralized bone matrix (hDBM). Tissue healing and regeneration at 9 months and implantation of titanium constructs (white arrows) to be evaluated on day either 30 or 15 after insertion at time of euthanasia for histological processing of the mandibular regenerates.

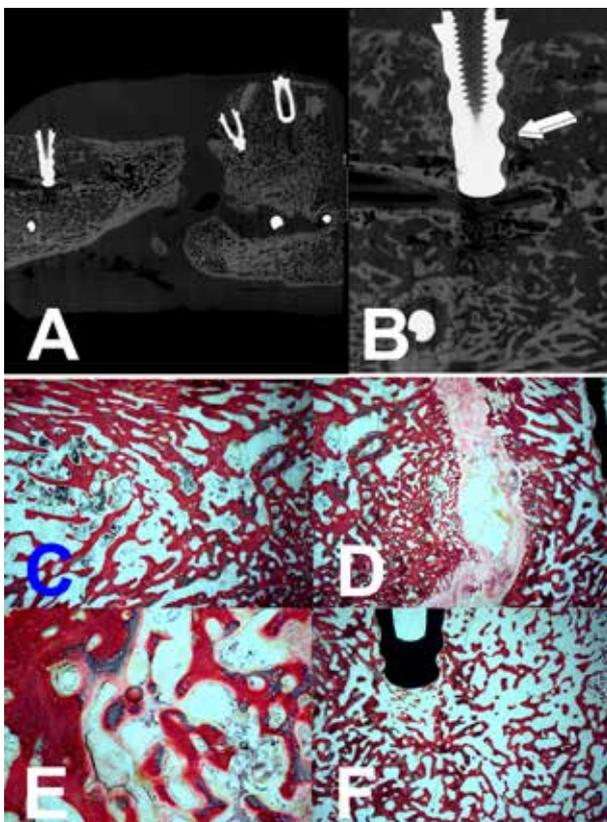


Figure 9. A. Generated μ CT scan 8 months after implantation of the hTGF- β_3 osteogenic device showing mineralization of the newly formed bone with titania constructs across the regenerated bone. B. Geometric titanium construct 30 days after insertion into the newly regenerated bone showing bone formation across the concavities (white arrow). C,D,E. Undecalcified histological sections cut on the Exakt diamond saw stained with the Movat's pentachrome stain. F. Trabeculae of newly formed bone integrating with the titanium geometric construct showing newly formed bone within the apical concavities of the substratum.

as well as supra-assembling kidney tubular structures with filtering cells".³²

Realistically however, none of the highlighted procedures above is actually routinely used in clinical contexts.³³ Furthermore, "merely hypothesized yet published advanced in tissue engineering, have been published even in the awareness that the need of such functionalities is largely not substantiated by experimental data".³⁴

The expression cloning of the BMPs, members of the transforming growth factor- β (TGF- β) supergene family^{4,7-9,11} has however failed the translational research of the "Bone induction principle"⁴⁹ in clinical contexts.¹⁷ The next three decades of therapeutic use of single recombinant hBMPs, either hBMP-27,⁸ or hOP-1⁹ showed that the translation of pre-clinical results to humans was all too unpredictable, often resulting in failure of bone regeneration.² The observed limited translation of highly encouraging pre-clinical results to human osteoinduction indicates that must exist profound molecular differences regulating the induction of bone formation between not only genera but also species, including non-human vs. human primates.^{2,11,17,21,63}

Our current studies on the initiation of bone formation by the three mammalian hTGF- β s has partly cast some insights into the induction of bone in primates vs. rodents, lagomorphs and canines. In the latter species, and for that matter in any other species but in non-human primates, and thus by extension to human primates, the three hTGF- β isoforms fail to induce bone formation in heterotopic extraskeletal sites.^{16,17,19,24} Systematic experiments in intramuscular sites of *Papio ursinus* by qRT-PCR have shown that the observed induction of bone is *via* several profiled bone morphogenetic proteins genes expressed upon the intramuscular implantation of doses of hTGF- β_3 .^{17,35,36} The downstream expression of BMPs genes may escape the antagonist activity of Noggin, whereas on the other hand, direct implantation of high doses of recombinant hBMPs (several tens of mg) activate the Noggin antagonist pathway, limiting human osteoinduction in clinical contexts.^{17,35,36} Physiological expression of BMPs genes and gene products upon implantation of the hTGF- β_3 osteogenic device escapes the antagonist activity of Noggin, ultimately regulating the bone induction cascade.^{17,25,35,36}

Experiments on day 15^{35,36} showed *RUNX-2* and *Osteocalcin* expression corresponding to the observed rapid induction of bone as seen morphologically on undecalcified histological sections. *RUNX-2* was decreased in hNoggin pre-loaded macroporous bioreactors. *RUNX-2* showed increased expression in hTGF- β_3 /pre-loaded macroporous bioreactors, once again correlating to the induction of bone formation on day 30 after heterotopic intramuscular implantation of the super-activated macroporous bioreactors.^{35,36}

The substantial induction of bone formation by hTGF- β_3 in *Papio ursinus* shows TGF- β_1 , TGF- β_3 (but not TGF- β_2), BMP-2, BMP-3, OP-1, *RUNX-2* and *Osteocalcin*

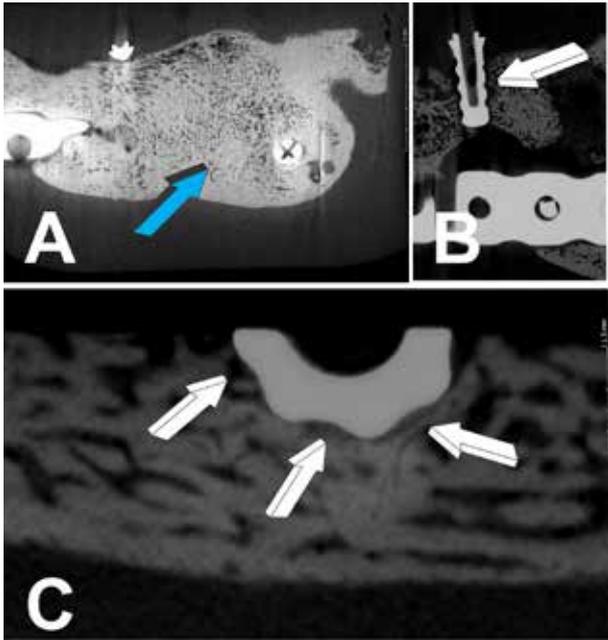


Figure 10. Series of generated μ CT scans 9 months after implantation of the 250 μ g hTGF- β_3 osteogenic device per gram of human demineralized bone matrix (hDBM) with mineralization of the construct. **A.** Regeneration of bone across the 3 cm mandibular defect (light blue arrow). **B.** μ CT scan on day 15 after implantation of the geometric titanium construct showing lack of bone induction within the concavities (white arrow) of the analysed implant. **C.** Transversal μ CT scan indicating the lack of bone formation within the concavities of the geometric implant (white arrows) 15 days after implantation into the regenerated mandibular bone.

upregulation and expression. Morphologically, the reported genes' expression above is represented by pronounced osteoblastic with osteoid deposition together with marked capillary sprouting and angiogenesis. The significant rapid initiation of bone by 250 μ g hTGF- β_3 when reconstituted with calcium phosphate-based bioreactors is the frontier for the novel molecular and morphological induction of bone formation in man.²⁴

The use of a single recombinant hBMP delivered by collagenous substrata or similar organic matrices has failed to match autogenous bone grafts in human osteoinduction.^{2,17,31,35-38} A critical reappraisal of future osteoinductive strategies in human is required.^{17,29,38} Using the autologous bone graft as a sensible biological blueprint, molecular biologist and tissue engineers alike need now to resolve the molecular insights into the multiple molecular machinery that give the capacity to regenerate bone post transplantation of autogenous bone grafts (Fig. 1), and, at the same time, to critically re-appraise human osteoinduction.

Craniofacial and mandibular regeneration in human patients using far too high doses of hBMPs has been the most severe operational and biological limitations of biotech companies' manufacturing recombinant hBMPs, i.e. hBMP-2 and hOP-1. We have also stated at few International Conferences of BMPs, that hBMPs treated human mandibular defects do not show often convincingly the induction of bone regeneration, with corticalization and remodeling of the newly formed ossicles.³⁹⁻⁴¹ Our Unit has highlighted the concept of "clinically significant osteoinduction", i.e. "the quality and quantity of regenerated bone adequate to be identified radiographically as normal bone, both in radiopacity and trabecular architecture" (Fig. 1).^{17,38}

The synergistic induction of bone formation or the induction of bone by single relatively high doses of hTGF- β_3 have shown that the recombinant morphogen induces bone following the expression of a variety of inductive morphogenetic proteins that result in the rapid induction of bone formation.^{24,37,42} Our molecular data thus show that bone induction as invoked by hTGF- β_3 recapitulates the synergistic induction of bone formation by low doses of hTGF- β_1 and hTGF- β_3 with a recombinant hBMP with a ratio by weight of 1:20.^{24,26,37}

Molecularly, the synergistic induction of bone formation by binary applications of hOP-1 with hTGF- β_1 and hTGF- β_3 , and particularly by hTGF- β_3 solo follows the up-regulation of *Osteocalcin*, *RUNX-2*, *BMP-7*, *TGF- β_1* and *hTGF- β_3* .³⁷

hTGF- β_3 generates multicellular bone organoids with the rapid induction of mineralized bone and osteoid covered by contiguous osteoblasts when implanted in heterotopic sites of the *rectus abdominis* muscle of *Papio ursinus* (Fig. 2).^{19,37,43} The morphological hallmarks of the synergistic induction of bone formation is the rapid induction of osteoid seams facing haemopoietic bone marrow that forms as early as day 15 after implantation in *rectus abdominis* sites.^{4,26,37,42}

It is noteworthy that synergistic binary applications induce the morphogenesis of rudimentary embryonic growth plates, indicating that the "memory" of developmental events in embryo is re-deployed post-natally by the application of morphogen combinations.^{4,26,37}

Importantly, our systematic studies on the hTGF- β_3 in *Papio ursinus* have shown that tissue induction and morphogenesis invoked by 250 μ g of hTGF- β_3 solo is often higher than the synergistic induction of bone formation as shown by binary application of hTGF- β_3 with recombinant hOP-1.^{4,26,27,37}

Mandibular tissue induction and regeneration by recombinant human transforming growth factor- β_3 : Short-term morphological studies using 125 μ g hTGF- β_3 solo and in synergistic binary application with hBMP-7 in the Chacma baboon *Papio ursinus*.

The substantial induction of bone formation by the hTGF- β_3 isoform singly or in binary application with a recombinant human bone morphogenetic protein (hBMP-7)^{24,26,37,42} prompted us to design experiments to test the regenerative capacity of hTGF- β_3 in full-thickness segmental defects prepared in the Chacma baboon *Papio ursinus*.⁴⁴

After extra-oral approach, the previously edentulized mandibles were exposed, and a 2.5 cm full thickness defect was prepared in each right mandible of three Chacma baboons *Papio ursinus*.⁴⁴ Defects were stabilized with a titanium plate anchored on the distal and mesial remaining mandibular bone (Fig. 3). Defects were implanted with 125 μ g hTGF- β_3 reconstituted with allogeneic insoluble collagenous bone matrix (ICBM). Animals were euthanized 30 days after mandibular implantation. Harvested tissues and prepared hemi-mandibles showed mineralization across the treated defects with regeneration of the buccal plates on day 30 with restoration of the mandibular profile (Fig. 3).⁴⁴ Histological analyses on undecalcified histological analyses (Figure 3, insets G, H) show the induction of mineralized bone within the defects (G).

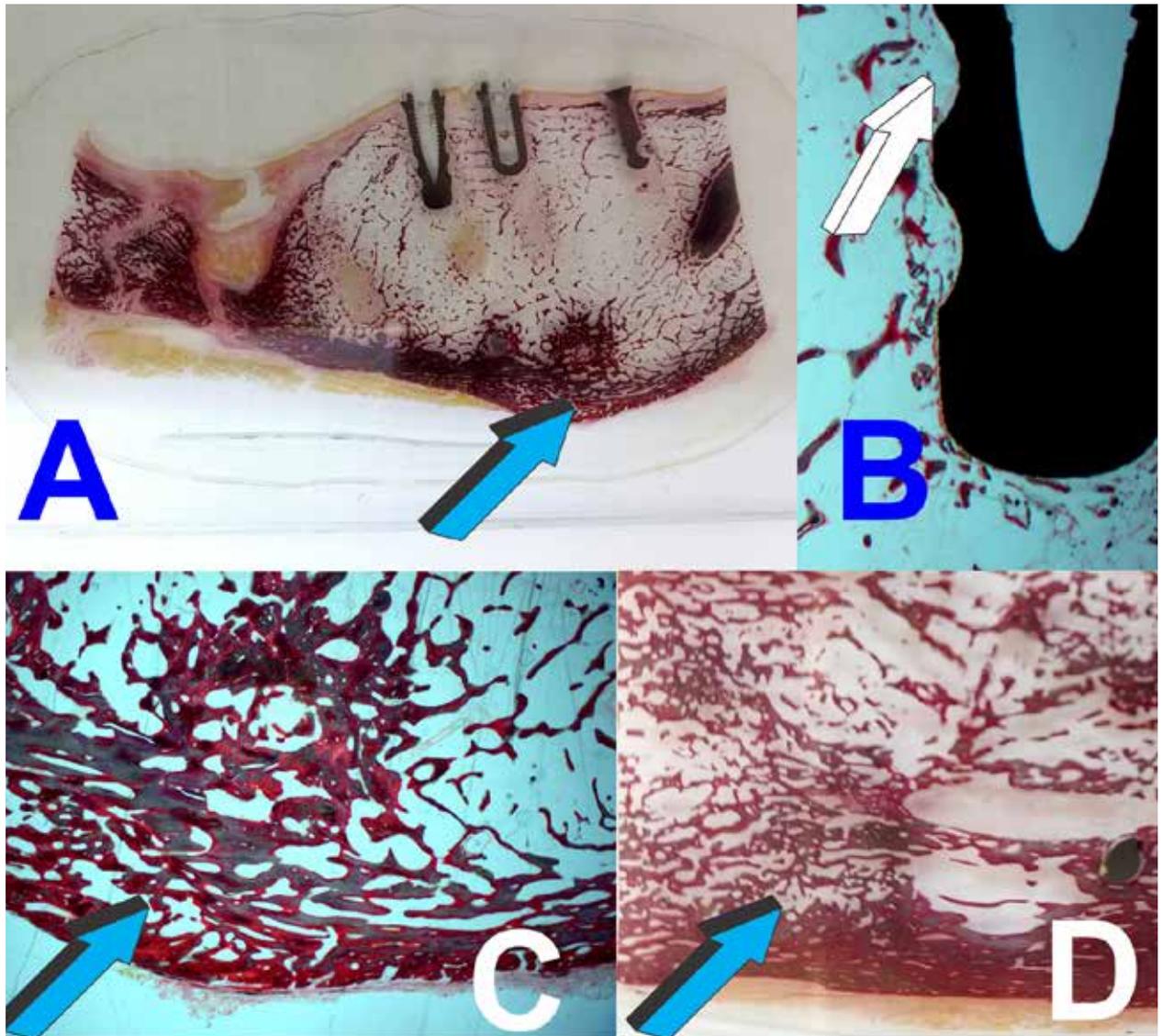


Figure 11. Whole mount undecalcified histological section cut on the Exakt diamond saw stained with the Movat's pentachrome stain. **A.** Note the regenerated bone delineating the inferior profile of the newly formed mandible (light blue arrow) 9 months after implantation of the osteogenic device. **B.** High power view of a geometric titanium construct prepared 15 days after mandibular implantation; there is minimal if any formation of bone within the concavities of the titanium' substrate (white arrows). **C.** High power view showing remodelling and maintenance of the newly generated mandibular bone 9 months after implantation of the 250 μg hTGF- β_3 osteogenic device per gram of human demineralized bone matrix (hDBM). **D.** Histological section of a mandibular regenerate 12 months after hTGF- β_3 implantation: regeneration of lamellar and trabecular bone (light blue arrow). Exakt diamond saw section stained with the Movat's pentachrome stain.

There was induction of corticalized mineralized formed bone surrounding remnants of matrix carrier 30 days post implantation (Fig. 3). The significant induction of bone on day 30 by hTGF- β_3 solo in mandibular defects of *Papio ursinus* prompted us to clinically translate the rapid induction of bone by 125 μg hTGF- β_3 (Fig. 4).⁴³⁻⁴⁶ Osteogenesis and restoration of a large mandibular defect in a human patient implanted with 125 μg hTGF- β_3 per gram pf matrix, was not comparable however to the rapid induction and mineralization of the newly formed bone as seen in our pre-clinical studies in *Papio ursinus*.⁴⁴ Healing was however uneventful, maintaining masticatory function of the treated hemi-mandible more than 5 years after implantation (Fig. 4F).^{44,45}

Because of the substantial bone forming activity by the binary application of relatively low doses of hTGF- β_1 and hTGF- β_3 with 25 μg osteogenic protein-1 (hOP-1, also known as BMP-7), additional animals were prepared with 2.5 cm full thickness mandibular defects and implanted

with 2.5 mg hOP-1 and 125 μg hTGF- β_3 at a ratio of 20:1 by weight.^{26,37,42} Morphogens, recombined with allogeneic ICBM, induced substantial osteogenesis with expansion of the newly formed and mineralized buccal plates (Fig. 5).⁴⁴

Recombinant human transforming growth factor- β_3 : Long-term morphological studies using 250 μg hTGF- β_3 in large mandibular defects of the Chacma baboon *Papio ursinus*

Concurrent studies in *Papio ursinus* to resolve the optimal dose for translation in clinical contexts, evaluated the reconstitution of 250 μg of hTGF- β_3 with coral-derived macroporous constructs. Intramuscularly implanted super-activated bioreactors were harvested on day 20 and processed for histological analyses.^{17,24} Histological analyses showed prominent and substantial bone formation outside the profile of the intramuscularly implanted super-activated bioreactors (Fig. 6A).^{17,24} The extensive induction of bone by 250 μg hTGF- β_3 albeit at the periphery of the macroporous bioreactors, proposed a novel dose for testing

hTGF- β_3 in pre-clinical and clinical studies. Concurrent to the new non-human primate study described below, the 250 μg dose of hTGF- β_3 was translated in clinical contexts by implanting the recombinant morphogen in a massive mandibular defect in a human patient (Fig. 7).^{45,46} Induction of tissue morphogenesis was seen radiographically 6 months after transplantation (Fig. 7E), with regeneration of the ramus and body of the mandible with also regeneration of the surgically ablated coronoid process (Figs. 7F,G light blue arrow).

A cohort of Chacma baboons *Papio ursinus* was selected from the Wits Research Animal Facility (WRAF) directed by a veterinarian doctor, and continuously mentored and supervised by the Animal Ethics Control Committee (AECC) of the University.

The long-term study in *Papio ursinus* evaluated bone regeneration, remodeling and maintenance of regenerated mandibular defects (Animal Ethics ref.: 2018-11-19-0, study title: Translational approaches for bone constructs: Their impact on facial bone reconstruction [Waiver approved to amend study and extension of scope of the study using samples gathered by previous experimentation to finalize cutting of undecalcified sections on the Exakt technology from mandibular blocks to be embedded in Technovit]. Remodeling and maintenance of the newly formed bone was evaluated at 12 (4 animals), 10 (two animals), 9 (two animals) and 7 (two animals) months after the hTGF- β_3 implantation in large full thickness mandibular defects, three centimeters in length, surgically prepared in the right hemi-mandibles (Figs. 6B; 8A) in 10 Chacma baboon *Papio ursinus*. Implanted hemi-mandibles were re-exposed to analyze tissue regeneration and to trephine the newly generated bone by the recombinant morphogen to insert titanium implants with planar or geometrically generated surfaces.⁴⁷ The latter prepared with a series of repetitive concavities along the titanium construct (Figs. 8B; 9B; 10B).⁴⁷ Regenerated defects showed corticalization of the newly formed bone across the 3 cm defects with regeneration of the mandibular discontinuities (Figs. 6C; 8B; 10A).

Harvested hemi-mandibles after bilateral carotid perfusion with 2 liters buffered saline and 2 liters buffered formalin were cleaned of adhesive muscular and connective tissues, processed and further fixed by immersion in 70% ethanol. Later, specimen blocks were embedded in Technovit 7200 VCL (Heraeus Kulzer GmbH, Wehrheim, Germany). Undecalcified blocks were cut longitudinally on the Exakt diamond saw cutting and polishing technology. Specimens preparation, cutting and staining was performed by Morphisto AG, Germany).

Of note, the mean weight of the Chacma baboons at surgery and implantation, before the long-term study housing and euthanasia was 20.1 kg and, at tissue harvest and euthanasia after intra-carotid perfusion by buffered saline and formalin perfusion, was 20.7 Kg.

These weight data are fundamental for our understanding of the adaptive capacity of *Papio ursinus* as well as the high standard of the WRAF of the University that provide functional non-human primate facilities and rooms with large cages highly ventilated with a positive pressure as well as diets that both maintain weight in long-term captive non-human primates' experimentation. The facilities of the University at

the Medical School Faculty of Health Sciences provide thus highly acceptable standards and conditions as shown by weight at termination higher than at the beginning of the long-term study, with optimal fur status at euthanasia more than one year after starting the study.

Mandibular blocks were analyzed by micro-focus X-ray computed tomography (μCT) scans (MIXRAD micro-focus X-ray laboratory, South African Nuclear Energy Corporation - NECSA, Pelindaba, Pretoria). An application was submitted and cleared by NECSA to scan and analyze the retrieved mandibular blocks.

All CT scans were conducted at 100kV and 100 μA for optimal contrast with a Nikon XTH225ST micro-focus X-ray machine. The samples were mounted in a polystyrene sample holder to secure the sample during the scanning procedure. One thousand separate X-ray absorption images were obtained through a full 360 degree rotation with maximum magnification to ensure a resolution of 36 micrometer. All the images were then reconstructed to a 3D virtual volume using Nikon CTPro reconstruction software. The final 3D renderings were analyzed in Volume Graphics VGStudio Max software.

μCT scans 8 months after hTGF- β_3 implantation showed tissue induction across the full thickness defect, though the section across the middle of the regenerate shows non-union, possibly reflecting the corticalization of the buccal and lingual cortices (Fig. 9A). High power view shows limited bone in contact with the concavities of the geometric titanium construct (Fig. 9B) 30 days after implantation harvested at euthanasia 8 months after hTGF- β_3 implantation. Histological analyses on undecalcified sections show bone formation across the surgically created full-thickness defects. There was the induction of corticalization of the newly formed mandibular ossicles (Figs. 9C,D). Remodeling and corticalization of the newly formed bone were evident on both 8 and 9 months after implantation (Figs. 9, 10), together with mineralized bone covered by osteoid seams as seen in 8 months specimens (Fig. 9E).

Inserted hydroxyapatite-coated implants (Figs. 9A,B) represent images 30 days after implantation in the newly regenerated mandibular construct. Inspection of the geometric profile of the titanium implants with concavities shows by day 30 still limited induction of bone within the profiled concavities (white arrow Fig. 9B).

μCT scans 9 months after implantation of 250 μg doses of hTGF- β_3 showed substantial reconstruction of the large full-thickness mandibular defect surgically prepared in *Papio ursinus* (Fig. 10A). Of interest, the profile of the titanium implants harvested on day 15 from the 9 months mandibular regenerate show limited if any bone contact with the geometric configuration of the harvested implant (Fig. 10B). Lack of integration is also shown in a transversal μCT scan across a titanium construct that show limited bone formation against the concavities of the substratum (Fig. 10C white arrows).

Histological analyses on undecalcified Exakt polished and grounded sections showed remodeling and the induction of corticalization of the mandibular plate newly formed after implantation of the 250 μg doses of hTGF- β_3 (Fig. 11A). Histological detail of the titanium inserted in the 9 months mandibular regenerate and harvested on day 15 at euthanasia

shows lack of bone formation into the concavities of the geometric construct (Fig. 11B white arrow). Limited bone deposition is thus shown in a corresponding histological section that correlate with the μ CT scan on day 15, reporting minimal if any bone differentiation within the concavities of the geometric constructs (Fig. 11B, undecalcified Exakt section; μ CT scans Fig. 10B). There is remodeling and corticalization of the newly formed mineralized bone at 9 months after implantation of the hTGF- β_3 osteogenic device. Remodeling and maintenance of the newly formed bone is maintained up to 12 months after implantation of the recombinant morphogen, keeping the corticalized profile of the newly formed hemi-mandible (Fig. 11D).

DISCUSSION

Restoring normal function and appearance of complex disfiguring craniofacial defects and/or anomalies in human patients still remains a grand unsolved challenge. Systematic studies in the *rectus abdominis* muscle, the calvarium and the mandible, respectively, showed that the cellular and molecular machineries of non-human primate tissues are differently activated when compared to rodents, lagomorphs and canine tissues when challenged with the soluble osteogenic molecular signals of the TGF- β superfamily.^{4,11,17,19,24,36}

The molecular machinery of primate tissues and cells is endowed with transmembrane receptor' ligands that phosphorylate and respond to the three mammalian TGF- β proteins. In the non-human primate *Papio ursinus*, the three mammalian proteins, and prominently the TGF- β_3 morphogen, induce the substantial formation of endochondral bone. Research so far has shown that the TGF- β proteins initiate endochondral bone formation in primates only.^{17,21,24} Results obtained in full thickness mandibular defects of *Papio ursinus* have shown the remarkable inductive capacity of hTGF- β_3 in craniofacial defects of non-human primate species with regeneration as early as 30 days post implantation, and with corticalization of the outer cortices.^{43,44}

The substantial bone initiated in both heterotopic intramuscular and mandibular orthotopic sites prepared in *Papio ursinus*^{17,19,24,36} proposed the clinical translation of the newly developed hTGF- β_3 osteogenic device in a human patient affected by a large mandibular odontogenic myxoma. The multiloculated expanding lesion in the right ramus and body of mandible was ablated *via* combined subperiosteal and supperiosteal resections. Panoramic radiograph 5 years post-reconstruction with costo-chondral graft and 125 μ g hTGF- β_3 per gram of hDBM shows the induction of bone within the defect.

Though healing was uneventful, later pre-clinical studies showed the substantial induction of bone by 250 μ g hTGF- β_3 when implanted intramuscularly in *Papio ursinus* pre-combined with coral-derived macroporous bioreactors.^{17,24,30} The 250 μ g hTGF- β_3 dose was then implanted in larger 3 cm full thickness mandibular defects in *Papio ursinus*, and the reported study in this communication was partially supported by Project No. AOCMF-19-03-R of AOCMF, Switzerland. The pre-clinical study showed mandibular regeneration by the selected dose of the recombinant morphogen when recombined with human demineralized bone matrix (hDBM). The use of hDBM in *Papio ursinus*

further translated the clinical potential of the pre-clinical study in *Papio ursinus*.

μ CT scans and histological analyses showed regeneration across the mandibular defects with maintenance and remodeling of the newly formed and mineralized bone up to 9 and 12 months after implantation of the recombinant morphogen. Of interest, osteoid seams were seen over newly formed mineralized bone up to 9 months after healing, highlighting the substantial osteogenic capacity of the hTGF- β_3 soluble molecular signal.

μ CT scans showed the induction of mineralized newly formed bone filling the treated defects. Undecalcified histological sections prepared by the Exakt diamond saw technology confirmed mineralization and corticalization of newly induced bone across the defects. Long-term studies in non-human primates are critical to study remodeling and maintenance of the newly formed bone. The presented undecalcified sections show maintenance and continuous remodeling of the newly induced bone with regions of osteoid synthesis up to 9 and 12 months after implantation of the hTGF- β_3 osteogenic device.

In his Editorial Comment "*The reality of a Nebulous Enigmatic Myth*" 48 Marshall Urist stated that research on the bone induction principle "*are bound to dispel the myth and appreciate the reality of bone induction for the benefit of patients with crippling diseases of the bone and joints*". More than fifty years later, the Bone Research Laboratory not in Los Angeles but in Johannesburg still strongly perceives "*The reality of a Nebulous Enigmatic Myth*" when reading that a disproportionate number of milligrams of now available hBMPs are needed to induce limited bone volumes in human patients.

The promise of therapeutic osteoinduction has been recognized during last Century research, and pre-clinical studies including non-human primate experimentation have suggested a primary role for hBMPs in human osteoinduction. Tissue and molecular biologists together with skeletal reconstructionists alike have learned that human osteoinduction is a totally different biological topic when compared to results obtained in pre-clinical animal models. It is also possible that preclinical animal studies may or may not adequately translate and reproduce morphogen-related therapeutic responses in clinical contexts.⁶³

The study reported here evaluates the 250 μ g dose of hTGF- β_3 to test in non-human primates a possibly more incisive formation of bone not only in *Papio ursinus* but in human patients too. The latter showed viable regenerates after mandibular reconstruction with 250 μ g hTGF- β_3 several years after human implantation.⁴⁵

The paradigm of bone tissue engineering is epitomized by the remarkable work of AH Reddi and his School at the National Institutes of Health (NIH), Bone Cell Biology Section, where it was found that molecular combinations of soluble and insoluble signals or substrata initiate the bone induction cascade.¹⁰ As Reddi reported in a classic title by now: "*Morphogenesis and tissue engineering of bone and cartilage: inductive signals, stem cells, and biomimetic biomaterials*"¹⁰, the reconstitution of a soluble morphogenetic signals with an insoluble signal or substratum triggers the induction of bone morphogenesis, even if the signals are

implanted in heterotopic sites of animal models, where there is no bone.

Of note, our laboratories have reported a modified paradigm in which the insoluble signal or substratum initiates resorption via a downstream of molecular and cellular cascades sculpting resorption pits and lacunae in the shape of concavities within the implanted bioceramic bioreactor.⁵¹ Lacunae, pits and concavities are the biological *continuum* of the induction of bone formation.⁵⁰⁻⁵⁵ This has resulted in the substantial induction of bone formation in biomimetic bioreactors almost completely resorbed and replaced by bone 365 days after calvarial implantation in *Papio ursinus*.⁵⁰

To further study the role of the concavity initiating the induction of bone formation, the reported long-term study of the 250 µg hTGF-β₃ also compared different geometric configurations of titanium implants, i.e. planar surface implants vs. modified surfaces with a series of concavities along the titanium surfaces.⁴⁷ The presented images showed lack of bone formation within concavities on day 15 with some bone forming in the concavities by day 30.

In previous studies,⁴⁷ we have reported as a first that titanium implants with geometric configurations in the form of repetitive concavities along the titanium coated by highly crystalline hydroxyapatite were shown to be intrinsically osteoinductive.

In our studies, we have asked the critical question: can bone spontaneously initiate by uncoated titanium substrata with or without geometric configurations, that is, a series of repetitive concavities along the planar surfaces? Our previous experimentation in *Papio ursinus* showed that titanium concavities coated by crystalline hydroxyapatites *per se* initiate the induction of bone formation even when implanted in heterotopic intramuscular sites, where there is no bone.^{47,52,54,55}

A review of the literature shows that the only available experiments reporting the intrinsic osteoinductivity by titanium' substrata is a study where titania' constructs were implanted heterotopically in the dorsal musculature of canines.⁵⁶ The reported data have highlighted that the implanted titania were macroporous titanium constructs with a superior *in vitro* and *in vivo* apatite forming capacity, bonding directly to living bone *in vivo*.⁵⁶ This *in vivo* apatite-forming could have possibly initiated the formation of bone as reported by Fujibayashi et al.⁵⁶ Of note, macroporous constructs were also chemically and thermally treated, including alkali and heat treatment with sodium removal.⁵⁷

Though the presented titania' bioreactors short implantation study does not cast as yet any mechanistic insights into the allegedly proposed spontaneous inductivity by titanium substrata, the limited bone formation against the bioreactors implanted into newly formed bone further indicate that titanium metal is not osteoinductive *per se*, and that the reported *in vivo* osteoinductivity^{56,57} is due to its *in vivo* apatite-forming ability after chemical and thermal treatments. Indeed macroporous blocks were acid- and heat-treated to form apatite layers on the titanium surfaces.⁵⁸⁻⁶² The most convincing results that pure titanium is not intrinsically osteoinductive is that titanium' bioreactors without alkali and heat treatments lack osteoinductive capacity when heterotopically implanted in identical canines models.^{56,61,62}

The hTGF-β₃ reported in our studies in non-human and human primates has shown once again that the translation of the "bone induction principle"⁴⁹ is still a difficult if not an impossible target when compared to the results obtained in non-human primate species that showed substantial bone formation by the newly developed hTGF-β₃/based osteogenic device.

The cellular and molecular basis responsible for the reported substantial differences in regenerative patterns amongst mammals and particular in non-human vs. human primates need now to be evaluated, and basic research should be devoted to analyse genetically the mammalian wound healing traits controlling tissue induction and morphogenesis beyond morphogens and stem cells.

Animal experimentation and the use of different animal models are also critical challenges for translational research in human patients. As Brubaker and Lauffenburger state, "Direct translation of observations in rodents or nonhuman primates to humans frequently disappoints, for reasons including discrepancies in complexity and regulation between species".⁶³ Mechanistically, the molecular machinery of rodents vs. non-human and human primates is fundamentally different, at least when responding to the osteogenic proteins of the TGF-β supergene family.⁴

In his contribution to the physiological functions of TGF-β, Sporn and colleagues describe that TGF-β induces the rapid induction of fibrosis and angiogenesis *in vivo*, together with stimulation of collagen formation *in vitro*.⁶⁴ In marked contrast, the three mammalian TGF-β isoforms, and notably the hTGF-β₃ protein are inducers of substantial and prominent induction of bone formation in heterotopic extraskelatal sites, where there is no bone, thus showing a molecularly significant response to selected proteins and ligands at the receptor levels, with phosphorylation and induction of bone via the Smad' related pathway.

To end, research into translational regenerative induction of bone formation will require further studies particularly highlighting the reasons and why the three mammalian TGF-β isoforms induce bone in primates but not in mice, rodents, lagomorphs and canines and how to boost the substantial induction of bone formation in heterotopic sites vs. orthotopic mandibular sites. Blueprints for translational regenerative medicine are offering pathways that may help to better define regenerative molecules and morphogens.⁶⁵

ACKNOWLEDGMENTS

The experiments describe above report research data spanning decades of research experimentation at the Bone Research Laboratory (BRL) since its inception in 1994 at the Medical School of the University. The merging of the BRL with the School of Clinical Medicine enhanced strategic research collaboration with the Laboratories of Molecular and Cellular Biology of Internal Medicine headed by Raquel Duarte PhD. The molecular and morphological *connubium* jointly resolved the molecular insights into the induction of bone formation by the recombinant human transforming growth factor-β₃ and the spontaneous and/or intrinsic induction of bone formation by calcium phosphate-based macroporous bioreactors in non-human primates. The incisive molecular insights of Raquel Duarte and of her team are greatly acknowledged. The described studies were continuously supported by the University of the Witwatersrand, Johannesburg, the South

African National Research Foundation and by ad hoc grants to the BRL. We thank the University for the continuous privilege of using non-human primates in experimentation. Novartis AG, Zurich, Switzerland, is greatly acknowledged for the gift of the recombinant hTGF- β_3 . We would like to thank Southern Implants of Graham Blackbeard for the kind gift of the titania' constructs.

The described studies using the 250 μg hTGF- β_3 dose implanted in larger three cm full thickness mandibular defects in *Papio ursinus* were partially supported by Project No. AOCMF-19-03-R of AOCMF, Switzerland. The presented work would not have been possible without the continuous expertise of Barbara van den Heever and Ruqayya Parak, who brought undecalcified bone histology to a superior art. Ruqayya added her unique expertise of processing undecalcified sections cut on the Exakt diamond saw donated to the BRL by a Wellcome Trust grant in 1997/98. To her, special recognition is offered. The senior author gratefully thanks Angela De Gouveia for providing continuous IT connection outside her M&B shop at Broederstroom that provided capacity at any day and time to write, revise and continuously polishing the manuscript. A final thank to the Chacma baboon *Papio ursinus* for continuously providing optimal microenvironments for the induction of bone formation. To the senior author, the pleiotropic multi-faceted niches of the induction of bone formation by the osteogenic soluble molecular signals in *Papio ursinus* still provide an exhilarating ride across tissue induction, morphogenesis, differentiation and de-differentiation, stemness, from chondrogenesis in the shark *Carcharinus obscurus* to osteogenesis in non-human and human primates.

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Prevalence of Sharps Injuries at a Tertiary Teaching Oral Health Centre, Gauteng, South Africa

SADJ April 2022, Vol. 77 No. 3 p135 - p141

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ABSTRACT

Introduction

Needle-stick and sharps injuries are an occupational hazard in dental training institutions. The study aimed to quantify and describe the nature of Needle-stick and sharp injuries (NSI) at a Tertiary Teaching Oral Health Centre (TTOHC) in South Africa.

METHODS

An analytic, cross-sectional study was conducted among students engaged in clinical service and oral health staff supervising them at the Oral Health Centre, Gauteng, South Africa. An adapted 18-item self-administered questionnaire was provided to all students and staff. Standard ethical guidelines were followed according to institutional ethics committee approval (M171131).

RESULTS

A response rate of 88% (n=73) was obtained from students, with the majority of participants being female (67%), dentistry students (88%), aged between 18-25 years, in their fourth

year of study (45%) while only 3.7% were final year oral hygiene students. The staff participants were dentists (80.6%) while most staff participants (88.3%) were employed for 3 years or less. The NSI prevalence at the TTOHC was 41.3% (n=45). The number of staff reporting the injury for both staff and students was recorded to be 80% (n = 36 of 45 injuries), with 77.3% of injured individuals receiving post-exposure prophylaxis (PEP) against possible HIV-infection, however, more than a third (39%) reported not to have completed the PEP. The department in which the most NSIs occurred was Maxillofacial and Oral Surgery. Sharp injuries were mostly due to needle sticks. Most NSIs occurred among senior students with more clinical experiences and particularly during the early and late periods in a year.

CONCLUSION

The prevalence of needle and sharp injuries was high and of concern. The sharps injury reporting rate was good, however, less than half of injured individuals completed the PEP treatment. The findings highlighted which students were most at risk to encounter NSI, including the period during their training when it was most likely to occur, thus enabling directed re-emphasis and training in Infection Control and Prevention.

KEY WORDS

Needle-stick, sharps injuries, dentistry, training institution

INTRODUCTION

Needle-stick and sharps injuries (NSI) are described as "puncture wounds, cuts, or scratches inflicted by medical instruments that may be contaminated with a patient's blood or other body fluids"¹. NSI are a major occupational hazard in the oral healthcare professions, especially in the busy academic tertiary institutions, due to the high workload and inexperience among students².

Globally the pattern of NSI is experienced differently in various health facilities. Lee *et al.*, reported 40.87% NSI prevalence amongst clinicians (dentists and students) at a Taiwan University while (Lee *et al*, 2012) Leggart (2009) revealed a higher prevalence of 72% among United States of America (USA) dental students³. A relatively low prevalence 23% of NSIs was reported at a College of Dentistry in the United Arab Emirates (UAE)⁴. In developing countries, a Kenyan University reported 29% prevalence among dental students, slightly higher than the UAE prevalence⁵. In South Africa, however, Siddiqi *et al* reported a very high prevalence among undergraduate students (62.1%), followed by postgraduate students (17; 14.7%) in a Dental Teaching University in Cape Town⁶.

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The risk of NSI are particularly concerning in dentistry due to the use of a wide variety of sharp instruments². Routine medical and dental sharp apparatus such as needles, scalpels, burs, scalers, probes, and forceps contribute to most of the injuries⁷. NSI carry the risk of infection by saliva and blood-borne infections organisms, particularly in the oral cavity where a multitude of organisms exist. Infection resulting from blood borne pathogens include, but is not limited to Hepatitis B and C virus and HIV⁸. The risk of HIV infection from occupational NSI range from 0.03% to 0.3%, which increases with the depth of injuries, volume of inoculated blood and hollow needle injuries whereas the risk for hepatitis B infection following exposure from a HBsAg-positive patient is between 6 - 30%. Hepatitis C virus (HCV), with an infection rate of 10%, hepatitis is of greater concern than HIV-infection in the event of NSI⁹. Apart from the physical effects and infection risk of NSIs, it was found that mental health consequences may be experienced subsequent to the injuries¹⁰.

The Tertiary Training Oral Health Centre (TTOHC) enforces a compulsory Hepatitis B virus (HBV) vaccination for all clinical workers and students to minimise post exposure risks. Non-compliance with vaccination or failure to acquire regular booster doses and decreased antibody titres can result in infection, especially with highly infectious strain⁹. Choi and co-workers suggest that the lack of reporting of injuries constitute noncompliance with institutional guidelines¹¹.

Various factors, such as inexperience during early clinical years, senior students who become complacent, the time of year (July-September), the day of the week (Wednesdays and Fridays), different dentistry disciplines (Restorative Dentistry and Maxillofacial Dept.) have been reported to influence the prevalence rate and increased likelihood of injuries^{2,4}.

The NSI injuries are a particular public health concern, especially among oral health care professionals due to the high frequency of occurrence and because it is preventable. Because of significant differences on the prevalence of needle-stick and sharps injuries reported among dental teaching institutions, it is important that each institution determines what their prevalence is¹², hence the aim of the current study was to not only quantify but also describe the nature of NSI at a TTOHC in Johannesburg, South Africa.

METHODS

An analytic, cross-sectional study was carried out to investigate the prevalence, the outcome of NSIs and the factors associated with the injuries. Qualified dentists, dental therapists and oral hygienists who supervised students, as well as all oral hygiene and dentistry students engaged in clinical service were invited to participate in the study at the Oral Health Centre, which is a tertiary teaching hospital in Gauteng, South Africa. Excluded from the study were departmental and unit heads and laboratory staff members as they do not routinely handle contaminated sharp instruments used in patient's mouths.

Data collection

A self-administered questionnaire was made available to staff and students during March 2018. During March 2018, when the survey was conducted, there was a total of 83

students involved in clinical service and 55 staff members who supervised them. The questionnaire was modified and adapted from a percutaneous exposure incidents tool by Siddiqi and co-workers⁶. The questionnaire was piloted for feasibility, clarity and the time required to complete it. The 18-item questionnaire sought information on student and staff demographics, occurrence of needle-stick and sharps injury, mode of injury, when and where the injury occurred, action taken after the injury.

Approval to carry out the study was obtained from the relevant authorities and the Human Ethics Research Committee (M171131).

Data Analysis

Data from the questionnaires was captured, verified and cleaned using Microsoft Excel 2010. The data was then exported to Stata version 14.1 (StataCorp, USA) and analysed. Descriptive statistics was done. Group differences were assessed by using the Pearson Chi-squared test and the Fischer exact test for cells less than 5. Bivariate analysis was conducted for factors most likely to influence the needle stick injury outcomes.

RESULTS

A response rate of 88%; (n=73) was recorded for students and 65% (n=36)-for staff. Completing the questionnaire took approximately 15 minutes.

Table 1 reveals the majority of the all participants to be female (67%) and aged between 18-25 years (56%). Among student participants, dentistry students in their 4th year of study constituted the majority (30.3%), followed by students in their 5th year of study (14.7%). Oral hygiene students in their final year (3rd) represented 3.7% of the student participants. Among staff members, the majority were dentists/specialists at 80.6% while the majority of staff members (88.3%) had been employed for 3 years or less.

The total NSI prevalence at the TTOHC was 41.3% (n=45) with the split of 27.5% (n=30) among students and 13.8% (n=15) staff members. The reporting status refers to the number of staff reporting the injury. The sharps injuries reported following an injury by both staff and

Figure 1: Prevalence of Sharp Injuries versus the Reporting Status.

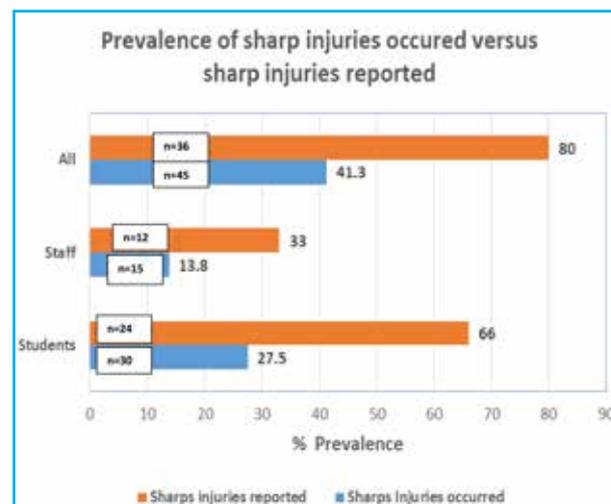


Table 1: Demographic characteristics of participants.(n=108)

Variable	All n (%)	Students n (%)	Staff n (%)
Sex			
Female	73 (67.0)	50(68.5)	23(65.7)
Male	35(32.1)	23 (31.5)	12(34.3)
Total*	108	73 (67.6)	35* (32.4)
Age Category			
18-25	61(56.0)	59(81.9)	2 (5.6)
26-30	13(11.9)	10(13.9)	3(8.3)
31-35	11(10.1)	2(2.8)	9(25.0)
36-40	6(5.5)	1(1.4)	5(13.9)
41-45	8(7.3)	-	8(22.2)
46-50	4(3.7)	-	4(11.1)
>51	5(4.6)	-	5(13.9)
Total*	108	72* (66.7)	36* (33.3)
Students/Staff			
Dentistry 3rd year	15 (13.8)	15 (13.8)	-
Dentistry 4th year	33(30.3)	33(30.3)	-
Dentistry 5th year	16(14.7)	16(14.7)	-
Oral Hygiene 2nd year	5 (4.6)	5 (4.6)	-
Oral Hygiene 3rd year	4(3.7)	4(3.7)	-
Dentists/specialist	29(26.6)	-	29(80.6)
Oral Hygienists	7 (6.4)	-	7(19.4)
Total	109	73 (66.9)	36*(33.1)
Staff Years Employed			
1	19(55.9)	-	19(55.9)
2	4(11.8)	-	4(11.8)
3	7(20.6)	-	7(20.6)
4	3(8.9)	-	3(8.9)
5	1 (2.9)	-	1 (2.9)
Total	34*	-	34*

*Totals ≠ 100 or different due to missing values;

students was recorded to be 80% (n= 36 of 45 injuries) (Fig 1). Most of the NSI sustained by students occurred in the Maxillofacial and Oral Surgery department, followed by Oral Rehabilitation. The fourth year dental students sustained the most injuries. The lowest percentage of injuries occurred in the Paediatric Dentistry Department and at Community Outreach sites (Fig 2). Among staff members, Maxillofacial and Oral Surgery site resulted in the highest frequency of injuries.

Table 2 illustrates the differences between students and staff members regarding the number of times of experiencing NSI, with a significant majority only experiencing one incident. One participant reported incurring more than five injuries within 12 months. The needle stick was the most common injury, with a statistically significant higher prevalence among students than staff members. Students sustained more injuries during the 1st Term (Jan-Mar), followed by 2nd Term (Apr-Jun) and 4th Term (Oct-Nov). From Table 3 it is evident that of those reporting a sharps injury, 77.3% were prescribed PEP against possible HIV-infection, however, 38.5% did not complete the course. Similarly, about 22.7% of those injured did not take PEP at all. Among participants who reported a NSI injury, students were more likely to perceive the PEP to be inadequate (70.4%) as compared to staff members (6.7%) ($p < 0.001$).

The qualitative analysis of the responses to open ended question on the sharp injuries protocol prescribed by the training centre, the common themes were “i) difficulty with obtaining the protocol; ii) long queues to access the post-exposure prophylaxis; iii) difficulty to acquire the full course of medication on site at the dental hospital.”

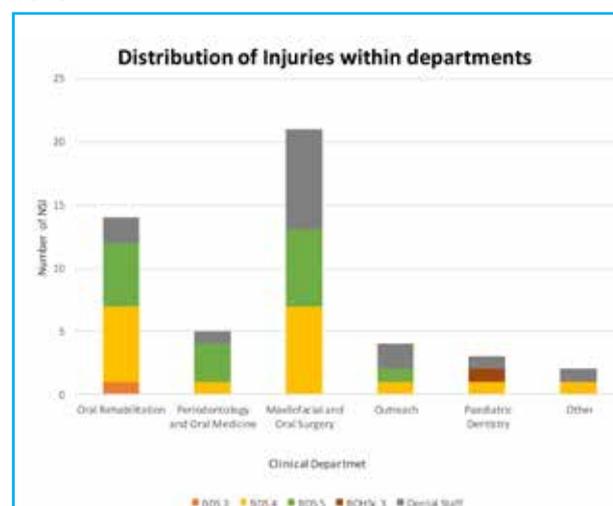
Figure 2 : Frequency and distribution of injuries within departments

Table 2: Sharp injuries prevalence and contributing factors

Variable	All		Students		Staff		P-value
	N	%	N	%	N	%	N
Number of injuries							
1	29		23	79.3	6	40.0	0.02*
2-3	12		6	20.7	6	40.0	
4-5	1		-	-	1	6.7	
>5	1		-	-	1	6.7	
Total			29	100.	14		
Latest injury occurrence							
Within 6 Months	12	27.3	10	34.5	2	13.3	0.09
>6 But <1 Year	10	22.7	8	27.6	2	13.3	
> 1 Year	21	47.7	11	37.9	10	66.7	
Do not Remember	1	2.3			1	6.7	
Total	44		29	100.0	15		
Period of Injury							
Jan-Mar	7	15.9	6	20.7	1	6.7	0.00***
Apr-Jun	11	25.0	11	37.9	0	0	
Jul-Sep	7	15.9	5	17.2	2	13.3	
Oct-Nov	8	18.2	7	24.1	1	6.7	
Total	33		29	100.0	4		
Mode of injuries							
Needle	20	47.6	12	44.4	8	53.3	0.4
Scaler Tip	6	14.3	5	18.5	1	6.7	
Bur	4	9.5	4	14.8	0	0	
Forceps	2	4.8	1	3.7	1	6.7	
Scissors	1	2.4	0	0	1	6.7	
Other	2	4.8	1	3.7	1	6.7	
Two modes	4	9.5	3	11.1	1	6.7	
Three modes	3	7.1	1	3.7	2	13.3	
Total	42		27		15		

p<0.001***; p<0.01**; p<0.05*, using Chi-squared and Fischer Exact tests for cell <5

DISCUSSION

This study aimed at determining the prevalence and nature of needle and sharps injuries (NSI) at the Tertiary Training Oral Health Centre in Johannesburg. It does not merely cover the prevalence of NSI but also adds valuable information in terms of the sites where injuries occurred, period of injury and compliance with infection control and prevention measures. The prevalence of the NSIs was high, with 45 injuries reported among the 109 participants. Not surprisingly, the highest contributors to injuries were students as they were still in training and almost one third of students sustained at least one injury (27%). Of the 45 participants that have NSI, 16 participants had more than 1 injury per individual. Considering that there were staff members and students who did not participate in this study, the prevalence may be even higher than that reported.

The overall NSI prevalence at this TTOHC was similar to a Taiwanese study at a teaching dental school where they reported 41%², but in contrast, lower than a study in the United States of American (USA) where it was much higher at 72%³. The student NSI burden in the current study (28%) was similar to that reported at a Kenyan University at 29%⁵. Conversely, another dental

school in South Africa in Cape Town recorded a higher prevalence of 62% among dental undergraduates⁶. From the available literature, the lowest prevalence of NSI were reported in the United Arab Emirates⁴.

It is important that the findings are taken into cognisance considering the consequences of NSI. With the burden of blood borne disease in South Africa, all efforts should be made to provide training in the prevention of NSI, to support the students and staff subsequent to injuries in order to minimise the negative psychological impact related to the injuries¹⁰. While NSI increases the risk of exposure to blood-borne infections such as Hep B and C, it is heartening that 95% of participants are vaccinated against Hepatitis B virus, however, they still remain at risk of Hepatitis C and HIV infections.

It was not surprising that students contributed most to the prevalence of needle-stick and sharps injuries. In this study, students had sustained more injuries than academic staff, which resulted in a student to staff ratio of 2.14:1. The high prevalence of needle-stick and sharps injuries (n=15; 13%) among the academic staff members could be attributed to a variety of factors which may be unique to staff members at the TTOHC. These include being a full-time educator which entails a particularly high workload of clinical supervision in

Table 3: Infection prevention protocol followed in terms of NSI among students and staff

Variable	All		Students		Staff		P-value
	N	%	N	%	N	%	N
Hepatitis B Vaccination							
Yes	105	96.3	71	98.6	34	94.4	0.1
No	2	1.8	-		2	5.6	
Do not Remember	1	.9	1	1.4	0	0	
Total	108	99.1	72	100.0	36	100	
Reported Sharps							
	N	%	N	%	N	%	N
Injury							
Yes	36	81.8	24	66%	2	13.3	0.09
	12	22.7	8	27.6	2	13.3	
	33%	<0.05	11	37.9	10	66.7	
No	8	18.2	5	17.2	3	20	
Total	44	100	29	100.	15	100	
Post-Exposure Prophylaxis Taken							
Yes	34	77.3	23	79.3	11	73.3	0.7
No	10	22.7	6	20.7	4	26.7	
Total	44	100	29	100.0	15	100	
Completed Exposure Prophylaxis							
Yes	23	58.9	15	53.6	8	72.7	<0.05
No	15	38.5	12	42.9	3	27.3	
Do not Remember	1	0.03	1	3.6	0	0	
Total	39	100	28	100.0	11	100	
Perception of treatment Adequacy							
Yes	17	40.5	7	25.9	10	66.7	
No	20	47.6	19	70.4	1	6.7	
Do not Remember	5	11.9	1	3.7	4	26.7	
Total	42	100	27	100.0	15	100	
Using Chi-squared and Fischer Exact tests for cell <5; p<0.001***; p<0.01**; p<0.05*, # n not 45 due to missing value							

addition to teaching and research responsibilities, including being personally involved in post-graduate studies. The majority of staff members reported to have been in employment for three years or less, indicating inexperience and possible uncertainty regarding their work environment. This was a factor that Lee *et al* (2014) strongly associated to increased fatigue resulting in a higher incidence of needle-stick and sharps injuries². The higher NSIs among staff members confirms that dentistry as a profession has a particularly high risk of needle-stick and sharps injuries.² It is anticipated that with increased clinical experience less needle-stick and sharps injuries would occur, as found by Lee *et al*, in which the annual incidence of NSI per person-year were 21.28% for interns, 7.50% for residents, 6.77% for nursing staff, 3.33% for clerks, and 0.85% for attending doctors².

In this study the highest rate of needle-stick injuries were experienced among the dentistry students, followed by oral hygiene students, which in all likelihood can be because dental students perform more invasive procedures as compared to oral hygiene staff and students. Our findings are consistent with the Taiwanese study in which the prevalence of NSI among dentists and students was 40.9% at the National Taiwan University Hospital².

Year of study and degree of study

The trend of needle-stick and sharps injury events among students also deviated from what was expected, as the students with more clinical experiences (Dentistry 4th year

and Dentistry 5th year as well as Oral Hygiene 3rd year) sustained more injuries than the new clinical students. This could be attributed to increased level of pressure on more senior students, who have a significantly higher academic and clinical load, including increased assessment pressure. Dental students and qualified dentists and dental specialists had a higher prevalence of needle-stick and sharps injuries when compared to oral hygiene students and academic staff. It is possible that the results may be skewed by the higher number of dental staff and students, compared to oral hygiene staff and students (4.14:1). Dentists and dental students perform more invasive and surgical procedures and routinely have to use a dental syringe, which was the most common device causing NSI in this study and other studies^{2,6}.

Time of the year

What is evident from our study is that NSI occurred most frequently during the first 3 months of the academic year and students sustained less injuries as the year progressed². Dentistry students in their 3rd Year of study only sustained injuries in the January-March period when they first entered the clinics. Students in their 4th year of study had the most injuries 33.3% (N=5) in the October-November period when the anxiety of the final examinations and quota demands could have played a role. This may lead to working while fatigued or rushed due to mentioned constraints. The Dentistry 5th year class, however, had more injuries in the April-June period. The findings are comparable to the findings of Lee *et al* where

most injuries took place between July to September and mid-week from Wednesday to Fridays. July to September was their period where new dental trainees begin their clinical practice². Among the 2nd and 3rd year oral hygiene students, only one person experienced a needle-stick injury but did not remember which time of year. Among dental staff, 50% were injured in the July-September 3-month period during which staff members are usually still marking and moderating assessments.

Dental disciplines and Departments contributing to NSIs

At the TTOHC, there are eight departments namely Prosthodontics, Rehabilitation, Periodontics and Oral Medicine, Oral Pathology, General Dental Practice, Orthodontics, Community Dentistry/Outreach and Maxillofacial and Oral Surgery. The Department of Maxillofacial and Oral Surgery was the site of most of the NSI compared to the other departments. A total of 61.9% (N=13) of these injuries were sustained by the Dentistry 4th year and Dentistry 5th year students. This observation followed the trend seen in a study by Cleveland *et al.* who found that more than one-third of percutaneous injuries are reported by the Oral Surgery unit¹³. The increased number of NSI in this department could be due to the high volume of patients seen during clinical sessions than other departments, as well as the use of a number of invasive instruments for the procedures performed. The Department of Oral Rehabilitation had the second highest occurrence of NSI reported at 38,6% (N=17). This could be attributed to the duration the procedures in this department require, for example, an endodontic procedure could last an entire two-hour session. A total of 11.4% (N=5) of the injuries were sustained in the Department of Periodontics and Oral Medicine. In the latter department there are numerous sharp instruments used in periodontal procedures. Additionally, patients in the periodontal department mostly present with inflamed gingivae leading to increased bleeding and reduced vision of the work field. The Department of Orthodontics had no needle-stick injuries reported and this is clearly attributed to the lack of sharp instruments involved during orthodontic procedures. Community outreach sites also pose a risk of injury to the students. Depending on the site where services are provided, the students may be expected to work in confined spaces which might lead to mistakes and injuries. Clinical practice in mobile dental truck has been reported to be challenging due to limited space and might lead to cross-infection.¹⁴

Instruments involved in NSI

The majority of the sustained injuries (47.6% (n=20) were caused by the needle of the dental syringe. The report is consistent with the findings of Lee *et al.* and may be credited to the dental syringe being used most frequently during the administration of local anaesthesia across many departments². Scaler tips were recorded as the instrument responsible for 14.3% (n=6), which is the second most common injury. Extensive scaling procedures are usually carried out to remove staining and calculus deposits to perform a comprehensive diagnosis of tooth structures before further treatment can be administered. Fine scaling is required as part of the treatment of gingival and periodontal diseases. Injury sustained from scaler tips may occur as a result of incorrect finger rest and support during the procedure, scratching oneself against the tip when it is mounted on the controls station or during disassembly of the scalers following completion of procedures. The number of injuries caused by burs/drill bits were found to be

9.5% (N=4) which might also be sustained during mounting on similar powered hand pieces. Other reported injuries included forceps, eye splashes and from the Nabers probe and suturing needle.

Behaviour and protocol after sharps injury

The response pertaining to the PEP protocol against HIV-infection at the time of the study is of concern. In the current study, the responses to the question about PEP varied from no knowledge of what the protocol entails and where to find it, long queues when reporting the incident and obtaining the full course of antiretroviral medication on site, to the availability of nursing staff to assist in the matter.

Of the 45 NSI reports in the survey, 36 subjects reported their injuries, with only 34 commencing PEP treatment and only 23 completing the treatment. Students found the guidelines of what to do after injury and the implementation of these guideline to be inadequate, while most staff members were content that the treatment and execution of the NSI protocol was adequate. The reasons for this could be diverse, varying from inexperience with previous NSI (for many this would be the first exposure), lack of understanding of the NSI protocol amongst students, lack of authoritative privilege as compared to staff or relative inflexibility of schedules as per reports of not receiving adequate time to follow the procedure due to the students workload. The concern is that these difficulties may contribute to further underreporting, in fact, Choi *et al* also found in their study that the lack of reporting injuries was common due to the time it consumed to comply with the protocol¹¹. Our findings show that 18.8% (N=8) did not report their injuries, choosing to either receive treatment privately, or not to receive treatment at all. Siddiqi *et al* in 2017 described the benefits of documenting needle-stick and sharps injuries⁶. The benefits include the effective implementation of educational programs, ensuring proper treatment post-exposure as well as assisting with the development of adequate NSI protocol.

While the PEP treatment may be adequate, a challenge with adherence was evident from responses because 39% did not complete the course. Non-compliance with HIV PEP has been attributed to the side effects associate with the afore mentioned drugs, which include diarrhoea, nausea and vomiting. Failure to complete the recommended 28 day course of ARVs reduces the efficacy of PEP treatment and increases the risk of acquiring HIV infection¹⁵. Counselling and follow-up of injured staff and students is important in order to improve compliance.

CONCLUSION AND RECOMMENDATIONS

The hazard of NSI was found to be high at this TTOHC at 41%. It is not surprising that most injuries were among students. but what was surprising was that the more senior dental students sustained more injuries. The majority of injuries occurred in busy departments such as Maxillofacial and Restorative departments. Dental needles were reported to be the common cause of sharp injuries and most occurred around April-June as well as October-November period. The reporting rate was good however, it is concerning that less than half injured completed the PEP treatment. It is therefore necessary that counselling is conducted among the injured individuals to improve the compliance and the completion

rate of PEP. Greater awareness and education are recommended at students' clinical orientation platforms and new staff clinician orientation sessions. In addition, students should be orientated with the protocol for PEP. It is also recommended that the guidelines and protocols to be followed subsequent to injuries should be made clear and posted where clearly visible. as they found it inadequate as opposed to staff. Lastly, the availability of PEP for the full 30 days should be available in-house within the TTOHC to encourage a speedy acquisition process.

ACKNOWLEDGEMENT

The authors would like to thank, V Yengopal, M Molete, M Thekiso, T Ralephenya for inputs during protocol writing. In addition, the authors would like to thank all the participants and the School Of Oral Health Sciences for providing support and an environment to conduct research.

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Factors Enabling and Constraining CPD compliance amongst South African Dental Technicians practising in KwaZulu-Natal, South Africa.

SADJ April 2022, Vol. 77 No. 3 p142 - p146

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ABSTRACT

INTRODUCTION

Health professions' regulatory bodies are experiencing numerous challenges with compliance to Continuing Professional Development (CPD) requirements. The South African Dental Technicians Council (SADTC) stipulates that dental technicians be CPD compliant and accrue an annual minimum of 30 Continuing Educational Units (CEUs). The SADTC acknowledged that there is a lack of compliance with CPD by dental technicians.

AIM

The study aimed to elicit dental technicians' opinions on, and experiences of, continuing professional development.

DESIGN

The study utilized a descriptive cross-sectional research design within a quantitative framework. A purposeful sampling technique was used to select and invite registered dental technicians ($n=103$) from KwaZulu-Natal (KZN).

METHODS

Dental technicians ($n = 103$) in KZN were invited to participate in the study by completing an online questionnaire, which elicited their experiences with regards to meeting their CPD requirements.

RESULTS

Dental technicians preferred formal, employer-funded CPD activities that are conducted during working hours as compared

to online CPD activities. Dental technicians acknowledged that mandatory CPD is a costly requirement. They further recognised that they were unaware of non-attendance based CPD activities as methods of accruing CEUs.

CONCLUSION

The study revealed that dental technicians in KZN experience challenges in being CPD compliant.

KEY WORDS:

Continuing Professional Development; dental technicians; Compliance

INTRODUCTION

Digital technology is rapidly transforming the practises of various healthcare professions, particularly dental technicians who are required to attend virtual CPD activities to accrue their annual CEU's. Consequently, Continuing Professional Development (CPD) is high on the South African Dental Technicians Councils (SADTC) agenda.¹ Notably, CPD enables health care professionals to improve and enhance their knowledge, skills, ethical and professional behaviour throughout their working lives.²⁻⁵ In contrast to the mandate of most professional bodies such as the Health Professional Council of South Africa (HPCSA), who for the longest time required their members to be CPD compliant, the SADTC only mandated CPD in 2014. Dental technicians are therefore required to obtain a minimum of 30 Continuing Educational Units (CEUs) to maintain and renew their annual registration with the council.

The reported benefits of CPD compliance is it ensures that practitioners continually improve their skills, competency and also acquire new skills to improve the quality of patient care.^{4, 6-8} The indirect benefits of CPD are personal and professional development and acquiring higher levels of personal job satisfaction.⁹ Contrary to the above benefits, the reported challenges associated with being CPD compliant are a general lack of awareness of the CPD requirements and activities, insufficient CPD activities being offered by CPD providers, geographic remoteness of CPD activities offered, and insufficient support from employers to enable employees to attend CPD activities.¹⁰⁻¹² Time constraints, insufficient funds, and an overall malaise by health care professionals towards compliance with CPD requirements further exacerbate this lack of compliance. In the absence of any known studies on CPD compliance amongst dental technicians, it is unclear why dental technicians are not accruing the required number of CEUs annually. This reinforces the SADTCs¹³ claim that there are high levels of CPD non-compliance amongst their members.

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2. Anisa Vahed: Conception and design, data analysis and interpretation, drafting and revising of paper. - 30%
3. Tufayl Muslim: Data analysis and interpretation, drafting and revising of paper 25%

The study aimed to elicit dental technicians' opinions on, and experiences regarding continuing professional development. It is anticipated that the results of this study could guide stakeholders in the provision and management of CPD, and inform CPD policy formation and reform initiatives.

OBJECTIVES OF THE STUDY

- To determine the factors enabling CPD compliance among dental technicians using an online questionnaire.
- To determine the factors constraining CPD compliance among dental technicians using an online questionnaire.

METHODOLOGY

Study design and sampling

A descriptive cross-sectional research design within a quantitative framework was used. The study followed a positivist paradigm, which assumes that reality exists 'out there' and that it is observable, stable and measurable.¹⁴ A purposeful sampling technique was used to select and invite registered dental technicians ($n=103$) from KwaZulu-Natal (KZN) to complete an online questionnaire, which elicited their experiences on CPD. A noteworthy point is that in the pilot testing of the questionnaire, 10% of the study population ($n=114$) was randomly selected ($n=11$) from a list of dental technicians obtained from the SADTC.

Ethical Considerations

Ethical clearance and permission to conduct the study was obtained from the Durban University of Technology (DUT) Institutional Research Ethics Committee (IREC 011/19). Informed consent was sought from the participants.

Dental technicians completed the online questionnaire via a link. There were five sections and a total of 26 survey questions, some of which were 5-point Likert scale questions. Six open-ended questions allowing for free responses about CPD participation and suggestions for accruing CEUs were also included in the questionnaire. Data was collected from the 9-30 November 2019. Descriptive statistics (univariate and bivariate analysis) and inferential statistics (Mann Whitney test and Chi Square Test) were used to analyse the data, with $p < 0.05$ set a significantly different (SPSS - Version 25[®]). Data from the open-ended questions were thematically analysed by capturing the common phrases from the responses, which were subsequently grouped into sub- and main themes. Content validity and Cronbach's Alpha were used to maintain the validity and reliability of the study.

RESULTS

There was an 81% response rate to the questionnaire. The reliability scores for the Likert scale questions exceeded

the recommended Cronbach's alpha value of $\alpha = 0.70$, indicating consistency of scoring. The Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO > 0.50) and the Bartlett's Test of Sphericity ($p < 0.05$) test results indicated that the data was factor analysable (Table 1).

The majority of dental technicians who responded to the questionnaire were male (57.8%) and the minimum and maximum age of the dental technicians who participated in this study were 26 and 66, respectively. Dental technicians between the ages of 30-39 preferred engaging in online CPD activities such as questionnaires. Dental technicians older than 40 years, by contrast, preferred formal face-to-face CPD interaction. The accounts from the open-ended questions corroborate this:

"I prefer face to face interaction. Online is good but to learn at my age is difficult, face to face is a better learning tool".

"CPD should be hands-on and face to face. When I studied, everything was thought directly and dental technology is a hands-on profession not online".

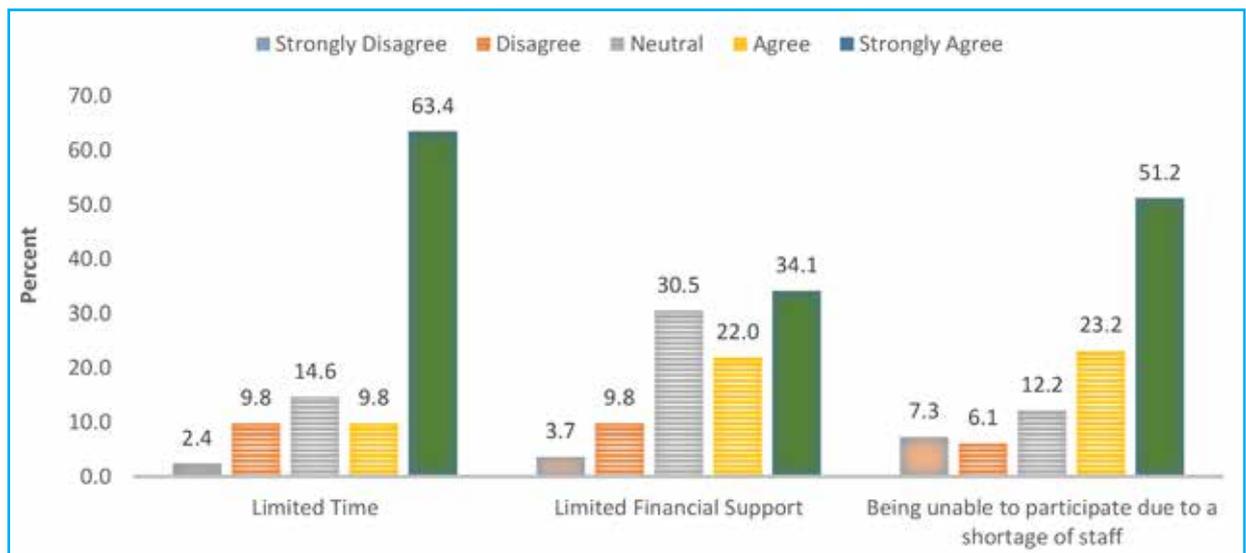
Close to 39.8% of the dental technicians practised in multidiscipline areas of specialisation namely, fixed (crowns and bridges) and removable (complete or partial dentures) prosthodontics, orthodontics and cobalt chrome. Moreover, 75% of the dental technicians had a higher qualification in addition to their Diploma in Dental Technology.

From the rotated varimax Factor Analysis, and with the exception of Question 10, the average loading of items per theme was above the acceptable Eigen values (> 1.0). Notably, factor analysis is used to describe variability among observed, correlated variables in terms of a potentially smaller number of unobserved variables called factors. The variables that constituted Question 10 loaded along two components (sub-themes), which suggests that respondents identified different trends in terms of their perceptions of CPD. Generally, dental technicians agreed ($p < 0.05$) that CPD improves professional competency (61%), knowledge (69.5%), practical skills (54.9%), and professional standards while supporting learning for advancements in technology (67%). Although there was a low level of agreement (43.9%) with regards to CPD being an investment for the employer, it was still higher than the levels of disagreement (32.9%). Dental technicians strongly disagreed that CPD is cost effective (76.9%). Although dental technicians confirmed that they visit the SADTC website (60%) and are aware of CPD being mandatory (70%), 43.9% of them were unaware of the penalties for CPD non-compliance, and of the opportunities (34.1%) and guidelines (41.4%) for accruing CEUs. Regardless of this, dental technicians confirmed that attending or presenting at conferences and seminars ($n=59$); responding to a CPD

Table 1: Factor Analysis Results

Question	Kaiser-Meyer-Olkin	Bartlett's Test of Sphericity		
	Measure of Sampling Adequacy	Approx. Chi-Square	df	Sig
Q9	0.891	576.502	21	0.000
Q10	0.707	142.071	6	0.000
Q13	0.879	587.476	28	0.000
Q17	0.683	130.788	6	0.000
Q18	0.661	51.408	3	0.000

Figure 1. Factors hindering CPD participation



approved questionnaire ($n=56$); and attending an annual general meeting (AGM) of an accredited professional association ($n=40$) are the most common methods of accruing CEUs. Article publications and attending Dental Technology curriculum meetings were atypical methods of accruing CEUs.

Workshops and conference attendance were the popular forms of CPD participation. A fair percentage of dental technicians also agreed that they access online journals (90.4%); have opportunities to undertake CPD (66.3%); have transport (71.1%) and funds (60.2%) to attend CPD workshops/seminars. They revealed, however, that having limited time (63.4%) and staff shortages (51.2%) largely hindered their participation in CPD activities (Figure 1).

Five prominent themes emerged from the open-ended questions of which one was an enabling factor, namely personal commitment of being CPD compliant (84%) and being CPD compliant as per the SADTCs requirements (68%). In particular, 36% of dental technicians indicated that the SADTC audit processes were efficient and 65% kept evidence of their CPD attendance. From the 38% of dental technicians in KZN who were audited by the SADTC, only 18% were CPD compliant. A noteworthy point, however, is that dental technicians who were non-compliant did declare that the SADTC had granted them a grace period to become compliant. The other themes, which aligned to factors constraining CPD compliance, included improving CPD processes (78%), CPD administration (88%), and audit process (74%).

DISCUSSION

Generally, dental technicians maintained that even though "CPD is definitely an investment as employers and workers benefit from CPD opportunities", laboratory owners provide very little support to attend CPD activities. Some dental technicians were of the opinion that employees "cannot expect employers to pay for everything" because when "they leave work, they take their knowledge with them." Consistent with the findings of Gawugah, Javda-Patel and Jackson¹⁵; Mathers, Mitchell and Hunn¹⁶; and Naidoo¹⁷, dental technicians who complete CPD training during working hours do not necessarily participate in CPD

activities after working hours or over weekends, and *vice versa*. Qualitative feedback from the open-ended questions supports this, as dental technicians conveyed that "when they do CPD, working time is the best" and "if they do it during working time, they do not do any CPD during weekends".

Analogous to Moonasar's¹⁸ study, a lack of guidelines and opportunities to accrue CPD points was the predominant reason cited by dental technicians for not being CPD compliant. They claimed that "they do not get to know anything from the council", especially on "how to achieve their CPD goal for the year." Dental Technicians therefore recommended that the "guidelines and ways to get their CPD needs to better defined". Given that 70% of dental technicians confirmed that they are aware of CPD being mandatory and monitored by the SADTC, it can be argued that dental technicians' unawareness of the CPD guidelines could be the result of them not regularly accessing the SADTC website to remain informed. The 60% of dental technicians who confirmed that they frequently access the SADTC website further support this. Concurring with Sholer et al⁵, the non-participation in CPD activities adversely influences the upskilling of professionals, which is critically needed to provide credible oral healthcare service to patients.

In addition, dental technicians declared that dental laboratory owners should "assist with payment to attend CPD" as this "builds bonds between staff and boss." This supports Austin⁹ and Ikenwilo and Skatun's¹⁹ advice that employers are to adopt a 'pro-CPD culture' to motivate employees to learn new techniques and skills. Other reasons constraining dental technicians from engaging in mandatory CPD activities range from the CPD "course is not near and we have to travel out of town", to employers not allowing "us to attend during working hours without cutting our pay". Essentially, "time, staff and money are the three most important" aspects affecting dental technicians from participating in CPD related activities and task. Corroborating the findings of Mathers, Mitchell and Hunn¹⁶, time constraints and high workloads affect CPD participation, which often results in professionals working after hours. Inevitably, attending CPD activities during and outside of normal working days results in dental technicians

incurring a loss in their income. A virtual CPD system however, could “reduce travelling costs” and can enable dental technicians to learn in the comfort of their own personalised space. Some dental technicians, however, maintained that while “online is good”, “face-to-face is a better learning tool”. Hence, they suggested that “CPD should be hands-on, as dental technology is a hands-on profession”.

From an operations perspective, an online automated CPD system could effectively lessen the administrative burden of a cumbersome manual process by streamlining the CPD operational processes and to effectively monitor and track CEUs. This could potentially reduce the high stress levels associated with the conduct of random audits. Such a system could also facilitate corrective action for non-compliant members. Notwithstanding the above, and even though 36% of dental technicians indicated that the audit processes were efficient, 38% of them were of the opinion that it was “biased and unhelpful” and that the SADTC behaved “as a policeman” when “they have not given them the tools to be compliant”. Others conveyed that “the audit process was poorly executed by SADTC” as it was done to check “if we had our points” and “not if we gained any skill or knowledge”. This suggests that the criteria governing the accrual of CPD points need to be revised to include a more thorough assessment of the relevant laboratory-based practice skills and knowledge acquired by dental technicians. There also appears to be negligible adherence to the underpinning audit principles of SANS 19011 (ISO 19011), which is an audit standard document. In general, the SANS 19011 document guides the auditing management system by detailing the principles of auditing, management of an audit programme and conducting management system audits.

LIMITATIONS AND RECOMMENDATIONS

Although this is the first known study on CPD compliance amongst South African dental technicians, the results of this study cannot be generalised as the knowledge and perception of dental technicians was limited to those residing in KZN. Further research is required to analyse the results obtained nationally, together with interviewing relevant stakeholders such as the SADTC and DENTASA.

Dental laboratory owners are encouraged to develop internal company policies to assist staff in attending CPD activities and provide more in-house and work-based CPD activities. They could apply for CEUs to be awarded to their employees’ post in-house training and to the employer as a CPD service provider. This will reduce the high costs associated with CPD participation, and for staff spending time away from work.

The SADTC needs to revise the current CPD document to align with the profession, which is constantly evolving. Attending a seminar or conference has very little to do with improving practical skills, even though points may be accrued. Interactive learning through the combination of skills and knowledge workshops needs to be promoted, along with study groups, virtual breakfast meetings, and journal clubs. Furthermore, engaging with the Health

and Welfare Sector Education and Training Authority (HWSETA) and the skills levy fund to source funding for CPD activities for dental technicians is recommended.

CONCLUSION

The prominent features of this study revealed that the high costs associated with CPD training, relief of time from employers to attend CPD workshops, and understanding the various methods of accruing CEUs were the predominant factors constraining dental technicians from being CPD compliant. While employer support for CPD engagement is critical, it is ultimately the dental technician’s responsibility to accrue their annual CEUs, which is a requirement to being compliant. Dental technicians may need to engage with CPD virtually and adjust to the ‘new normal’ of accruing CEUs during this sustained disruptive period of the coronavirus disease (COVID-19) pandemic. Ultimately, this requires them to be more accountable for their own development. Aligning with the SADTC, the training and education of dental technicians at the various South African Universities of Technology need to ensure that knowledge of CPD is scaffolded throughout the undergraduate curriculum to enable student dental technicians to understand the significance and various methods of becoming CPD compliant.

ACKNOWLEDGEMENTS

The authors extend their gratitude to Mr. Deepak Singh (DUT) for his expert statistical guidance, and Dr Gillian Cruickshank (Queen’s University Belfast) for expertly proof reading the article.

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Exploring the feasibility of a framework to align a competency framework in a dental curriculum: a Delphi study

SADJ April 2022, Vol. 77 No. 3 p147 - p154

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ABSTRACT

Aim

The aim of this study was to test the feasibility of an implementation framework for an undergraduate competency framework by means of a Delphi study.

Methods

A modified Delphi research design consisting of two rounds was conducted and aimed to seek consensus defined as agreement of 70% or more from a group of experts. Twenty-two (22) dental experts were purposefully selected from the four dental schools in South Africa. An online survey consisting mainly of closed-ended questions was used and analysed quantitatively. In addition, the second part of each question included a comment section to allow participants to elaborate on their answer. Comments were considered as adapted statements for the second round of the Delphi.

Results

Thirteen (13) participants completed the first round, and 10 participants completed the second round of the Delphi study. Following the first round of the Delphi, consensus (70%) was reached for five of the seven statements. These statements focus on the impact of internal and external stakeholders on the dental schools, leadership support for faculty development, teaching and learning changes, and curriculum mapping. Statements that needed further consideration in round 1 included impact of institutional framework and diversity of academics. Consensus was reached for both the diversity of academics statements in round 2.

Conclusion

The results suggest that the proposed framework to align and implement the AfriMEDS core competency framework was feasible. However, from the comments of the dental

experts there seems to be no common understanding of implementation and alignment of the institutional frameworks and the AfriMEDS core competency framework.

Keywords

Competency framework, Delphi study, dental curriculum, competencies

INTRODUCTION

Competency frameworks are documents produced by regulating and accrediting bodies to create a shared model of performance standards of particular milestones along the professional career continuum.¹ The African Medical Education Directions for Specialists (AfriMEDS) core competency framework was adapted from the Canadian Medical Educational Directives for Specialists (CanMEDS) by the Health Professions Council of South Africa (HPCSA) to inform undergraduate medical and dental curricula in South Africa.² Evidence of the incorporation and alignment of the core competencies in the undergraduate dental curricula outlined in AfriMEDS is required during the HPCSA accreditation processes. No explicit guidelines for the implementation of AfriMEDS were prescribed, allowing dental schools' autonomy to incorporate and implement this core competency framework. Competency-based education (CBE) provides a framework for developing educational programmes, but it is with implementation that various challenges emerge.³

Differences of CBE from the more traditional approaches are: (i) a focus on outcomes, (ii) an emphasis on abilities, (iii) a reduced emphasis on time-based training, and (iv) the promotion of learner-centredness. These differences cause challenges and implications for designing and implementing CBE.³ Essential key differences between CBE and traditional educational frameworks lie in the structure and process of education. Traditional education tends to focus on what and how learners are taught and less on whether or not they can use their learning to solve problems, perform procedures, communicate effectively, or make good clinical decisions.³ The focus is more teacher-centred with attention mostly on the content or curriculum. Contrarily, CBE places the curriculum as an end-product of a needs assessment rather than as the structure that constrains educational objectives and assessments.³

Considering the differences between the traditional model of education and CBE, a shift from a teacher-centred to a learner-centred approach that focusses on addressing the health needs of the society is required to transform traditional curriculum to CBE. Implementing the CanMEDS competency framework requires a systematic multifaceted approach that includes: standards for curriculum,

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teaching and assessment, faculty development, research and development, and outreach.⁴ This multifaceted implementation approach aligns with the CBE model (Figure 1) that involves competency outcomes, curriculum, and assessment. Factors that foster the implementation of a competency-based curriculum include accrediting bodies' support of this change; support and buy-in from stakeholders, i.e., institutional leaders; available resources; and effective change management.⁵

Another facet for the implementation is the involvement of a diversity of stakeholders, both within and outside academia, and a careful 'orchestration' of the change process.⁶ A combination of strong external pressure, internal dissatisfaction with the existing educational quality (often latent among teachers, students, and alumni), and courage of the institutional leadership to make a fundamental change, will make transformation from a 'traditional' curriculum to a competency-based curriculum possible.⁶ The alignment to face accrediting and certifying bodies in support of the competencies and outcomes assessment provided a major implementation of curriculum reform or changes thrust.⁷ As a consequence of the HPCSA's adoption of the AfriMEDS core competency framework, it provided external pressure for transformation to a CBE model for all undergraduate dental curricula in South Africa. When both accreditors and certifiers require evidence of competency attainment, residency programmes will be doubly motivated to increase their emphasis on these areas.⁷

Concerns have identified challenges in the implementation of competency-based medical education (CBME), and consequently have advised caution. Addressing the challenges in the implementation of CBME requires consideration of the implications for the complex systems

in which our education programmes exist.⁸ This study is the final phase of a larger study of the first author that aimed to develop a framework to implement the AfriMEDS core competency framework (Figure 1). The aim of this study was to test the feasibility of this implementation framework by means of a Delphi study.

METHODS

Research Design

A Delphi approach works best with higher-level concepts as opposed to an in-depth exploration of the topic.⁹ In addition, this technique is a creative and efficient method of facilitating health sciences education research.¹⁰ The technique brings advantages of clarity, privacy, voice, and collegiality. In doing so it engages the issues of anonymity and disclosure of relevant information whilst protecting participants' rights to privacy.¹¹ Therefore, the Delphi research design was considered appropriate to test the feasibility of the proposed implementation framework for the AfriMEDS core competency framework. The Delphi study was used to assess the feasibility and seek consensus from a group of experts to validate the designed intervention.¹² A modified version of the traditional Delphi was used as depicted in Figure 2. In the first round, the designed implementation framework was presented to the panel of experts to elicit consensus compared to the traditional first round that includes questions or expert opinions in order to gain insight into a specific issue.

Participants are usually required to rate their level of agreement with each statement using a Likert scale. Offering a finite number of ranking options is a way of encouraging the panel to commit to a particular item.¹⁰ In this study, experts were asked to respond to a 4-point Likert

Figure 1: Core competency implementation framework

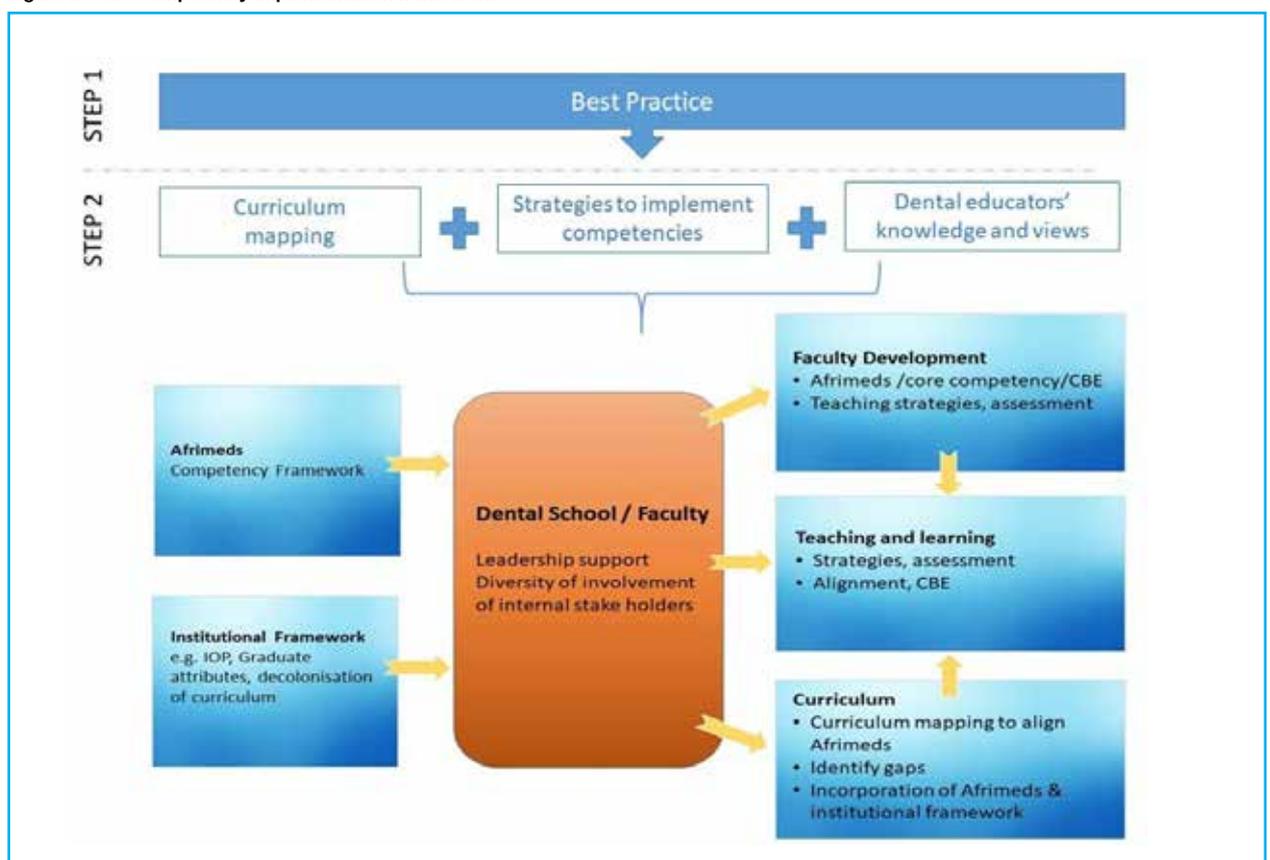
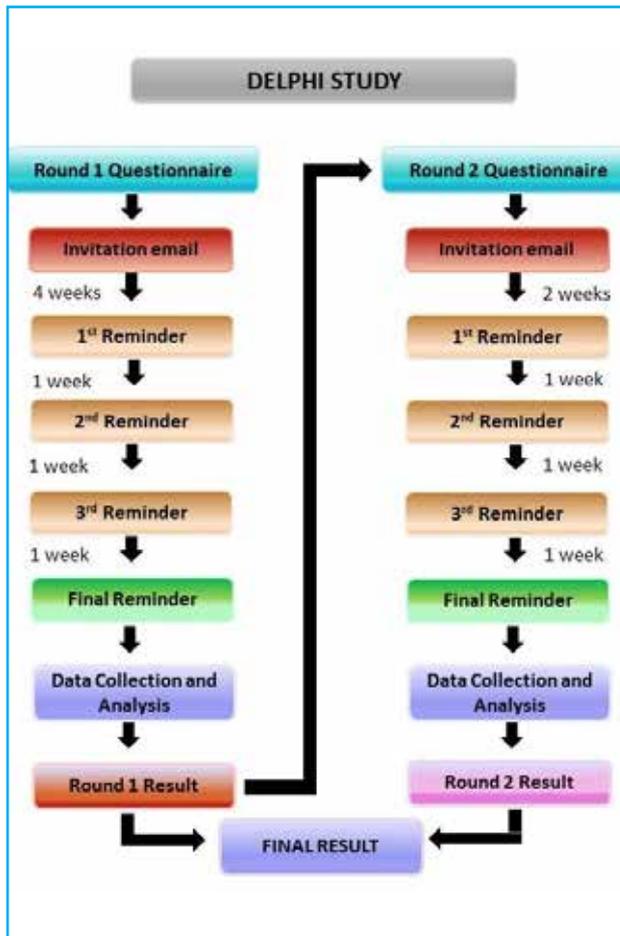


Figure II: Study flow



scale offering the options: “strongly disagree”, “disagree”, “agree”, and “strongly agree”. A neutral middle point was excluded to compel respondents to choose a particular option. This strategy assisted in making clear calculations on agreement and disagreement.^{13,14} It is critical that the researcher carefully determines what particular definition of ‘consensus’ is to be used in his/her study in advance. The first and second round of consensus was defined as when 70% or more of the respondents agreed with a statement.

Panel of experts

There are no criteria upon which to determine the nature of the “expert”, the optimal panel size, or even selection criteria of the panellists in a Delphi study.¹² For this study, the experts – dental academics with experience in curriculum development, design, or as programme accreditors – were purposefully selected. These experts were invited from all four dental schools in South Africa. Invitations to participate in this online Delphi study were emailed to a total of 22 dental experts from the dental schools/faculties. Information sheets explaining the purpose of this study and the relevant information regarding the study were included in the invitations.

Survey

The Google Forms platform was used to send a Google survey link to all participants via their email. Regular emails (4 in total) with reminders to complete the online survey were sent to all the participants. The consent form was included in the first part of the online survey. The surveys consisted mainly of closed-ended statements that were analysed quantitatively. In addition, the second part of each question included a comment section to allow participants

to elaborate on their answer in the first part of the statement. Comments were adapted to statements for the second round of the Delphi.

Ethics

Ethics clearance was obtained from the University of the Western Cape’s Biomedical Research Ethics Committee (BM 19/1/23). True anonymity is ensured when no one (including the researcher) can link a response to a participant. Because of the iterative process inherent in the Delphi technique, true anonymity cannot be guaranteed as the individual panel member’s responses are unknown to the other participants but known to the researcher.¹⁵ At all phases of the study an information sheet was provided with enough detail to clarify the purpose of the project and what it entails. All of the participants signed a consent form and had the right to withdraw from the study at any stage without repercussions. The information gathered was kept anonymous by assigning numbers to the dental experts instead of using their names.

RESULTS

Round 1 of the Delphi study

Thirteen (13) participants (59%) completed the first round of the Delphi study. The socio-demographic information collected included age, gender, and number of years as an academic, years of experience in curriculum design, and HPCSA accreditation (Table I). Of the participants, six (6) were male and seven (7) were female. The average age was 51 years, and the average number of years as an academic was 19. In addition, as a collective, the years of experience in curriculum design ranged from 3 to 30 years, with an average of 13 years. The participants also had 10 years of experience with HPCSA accreditation processes.

Results of round 1 of the Delphi study

The first round of the Delphi aimed to reach consensus on seven statements (Table II), which was defined as being achieved when 70% or more of the dental experts agreed with each of the statements of the questionnaire. From the results, the dental experts reached consensus for five of the statements (numbers 1, 3, 5, 6 and 7) in the questionnaire. Verbatim quotes are provided below to offer some understanding of the dental experts’ opinions. No consensus was reached for statements 2 and 4, and comments relating to these statements were analysed to inform the second round of the Delphi study.

Statement 1: AfriMEDS core competency framework informs or impacts dental schools/faculties.

The excerpts below capture some of the comments of the dental experts that disagreed with this statement:

“My experience with accreditation is that very few dental academics either know of these or can translate them into meaningful attributes for their students”. DE 1

“At the moment very, few people understand it – it’s a lot of hype and talk, but not many wet nosed clinicians or junior academics have any idea about its actual contents and impact”. DE 5

“Each dental school has autonomy and tends to follow university framework. [The] AfriMEDS framework is only relevant as [a] paper pushing exercise when accreditation is on the horizon”. DE 6

Dental experts	Age	Gender	Years as Academic	Experience in Curriculum Design (years)	HPCSA accreditation (internal)	HPCSA accreditation (external)
1	42	Female	10	3	2	0
2	73	Male	35	25	25	25
3	55	Female	30	20	15	0
4	41	Male	13	10	1	0
5	38	Female	9	4	4	0
6	59	Female	36	20	17	14
7	52	Male	15	10	5	1
8	67	Male	35	30	25	20
9	42	Female	9	3	6	3
10	48	Female	10	4	5	2
11	60	Male	16	16	3	3
12	50	Female	25	22	21	11
13	37	Male	6	4	2	1

No	Statements	Strongly agree (n)	Agree (n)	Disagree (n)	Strongly Disagree (n)	Consensus (set at 70%)
1	AfriMEDS core competency framework informs or impacts dental schools/faculties.	23.1% (3)	53.8% (7)	23.1% (3)	-	76.9%
2	The specific institutional/university framework informs or impacts dental schools/faculties. An example is the institutional operation plan (IOP) of University of Western Cape, that provides the overarching goals for the University with regards to teaching and learning, research, people management, etc.	-	69% (9)	23% (3)	7.7% (1)	69%
3	Implementation of AfriMEDS requires dental schools/faculty leadership support.	61.5% (8)	38.5% (8)	-	-	100%
4	Implementation of AfriMEDS requires dental schools/faculty leadership support.	61.5% (8)	38.5% (8)	-	-	100%
5	Implementation of AfriMEDS requires the inclusion of diversity of internal stakeholders. For example, the inclusion of junior, senior academics, diversity of disciplines.	30.5% (4)	30.5% (4)	-	38.5% (5)	61%
6	Dental school/faculty leadership need to support faculty development by identifying and facilitating training/ upskilling required in a competency-based education, e.g., interactive teaching strategies.	53.8% (7)	38.5% (5)	-	7.7% (1)	92.3%
7	Curriculum mapping provides a complete picture of the dental undergraduate curriculum.	38.5% (5)	61.5% (8)	-	-	100%

Statement 3: Implementation of AfriMEDS requires dental schools/faculty leadership support.

All of the dental experts agreed with this statement, as noted in the following excerpts:

"Any change needs strong leadership". DE 1

"Without buy-in from the key decision-makers, such drastic approach changes will usually not succeed". DE 3

Statement 5: Dental school/faculty leadership needs to support faculty development by identifying and facilitating training/upskilling required in a competency-based education, e.g., interactive teaching strategies.

Most of the dental experts supported this statement, as reflected in the following excerpts:

"Most dental educators have no formal T&L [teaching & learning] training, and are merely just clinicians with experience in treating patients and some minor understanding of education strategies". DE 10

"Faculty development can help in furthering scholarship, collaboration, leadership, and professionalism, which are central in AfriMEDS". DE 3

"Of course, leadership must support development. What is more important, is how they identify the needs, and what criteria will they use". DE 1

Statement 6: Changes in teaching and learning needs to be encouraged to promote a competency driven framework.

The comments of dental experts that supported this statement are captured below:

Statement 7: Curriculum mapping provides a complete picture of the dental undergraduate curriculum.

All of the dental experts agreed with this statement. Some of their comments are included below:

"Any map or picture is useful to illustrate a complex arrangement in a nutshell". DE 7

Table III: Results of Delphi round 2

No	Statements	Strongly agree (n)	Agree (n)	Disagree (n)	Strongly Disagree (n)	Consensus (set at 70%)
1	For a specific institutional framework to impact or inform dental schools/ curriculum, it requires the alignment with the dental curriculum	20% (2)	50% (5)	23.1% (3)	-	76.9%
2	All levels of academics that includes junior and senior staff from all disciplines are required to ensure successful implementation of the AfriMEDS competency framework in dental schools/faculty.	30% (3)	40% (4)	-	30% (3)	70%

"Curriculum mapping will allow us to view operational curriculum and actually see if it speaks to the competencies needed for the modern South African dentist". DE 12

Comments about the AfriMEDS core competency framework highlighted the lack of knowledge and level of importance given to this framework at the dental schools. Dental experts agreed that this framework impacted and informed the dental schools. However, it is suggested that the superficial manner that dental academics engage with AfriMEDS contributes to their level of understanding. Accreditation of dental schools is undertaken every four years, and if AfriMEDS is only engaged with superficially as part of the accreditation process, it limits the level of understanding and impact on the dental curriculum. The practice of most of the dental schools is that the accreditation process is managed and conducted by senior academics. Therefore, the more junior dental academics have limited exposure, which contributes to their lack of understanding and knowledge of AfriMEDS. Similarly, the impact of the institutional framework and how it translates to the dental curriculum is influenced by the lack of knowledge and understanding by all levels of staff, particularly junior dental academics. The dental experts agreed that the implementation of the AfriMEDS core competency framework requires support from the leadership, referred to as 'buy-in'. Absence of the latter could underpin the lack of understanding and knowledge of dental academics regarding the AfriMEDS core competency framework. The dental experts underscored the importance of informing all levels of dental academics that changes in teaching and learning practices are required for the successful implementation of a competency framework. The latter's perceived resistance to changes could possibly be attributed to their lack of consultation or involvement in curriculum related matters.

Comments of dental experts related to the survey statements

Statement 2: The specific institutional/university framework informs or impacts dental schools/faculties. An example is the institutional operation plan (IOP) of one university in South Africa that provides the overarching goals for the university with regards to teaching and learning, research, people management, etc.

From the results, nine (9) (69%) of the dental experts agreed that the specific institutional framework impacts or informs dental schools/faculties. As the consensus was defined at 70%, this statement was reframed and included in the second round of the Delphi.

Some comments related to this statement in the first round of the Delphi are indicated below:

"Though the curricula responds to professional accreditation requirements in principle, local institutional plans are central too". DE 3

"Sometimes the use of such models are merely lip service to impress accreditors. Models are often not fully implemented or understood". DE 5

"A school/faculty is part of a university and as such its framework contributes and informs the university framework and therefore should be aligned". DE 6

"The IOP is a generic framework which does not adequately address all the competencies required to be taught/transferred to the oral health professional". DE 8

"I became aware that in general academic lecturers are not familiar with the contents of the IOP. Lecturers' involvement and contributions to the IOP are limited. Although there is an effort from lecturers to align their learning outcomes with the UWC graduate attributes, the enactment in teaching, learning and assessment is limited". DE 9

"Faculty plans need to be aligned with [the] institutional plan so that the system functions in alignment and not out of sync with each other. Staff need to understand how they fit into the whole institutional plan as a department, as well as a faculty/school". DE 10

It appears that the dental experts agreed that the institutional framework impacts the dental schools/faculties. Concerns were raised about the alignment of the dental specific competencies guided by the HPCSA and the institutional frameworks. Similar to the AfriMEDS core competency framework, it was suggested that the understanding and knowledge of the institutional plans were superficial and there was limited engagement related to accreditation processes. Another concern is that lecturers in the dental schools were not familiar with the institutional framework and its translation to their teaching and learning practices. Therefore, this statement was restructured in round two of this Delphi study to include the dental experts' views.

Statement 4: Implementation of AfriMEDS requires the inclusion of diversity of internal stakeholders. For example the inclusion of junior, senior academics, diversity of disciplines.

From the results, the dental experts agreed that implementation of AfriMEDS requires the inclusion of a diversity of internal stakeholders: four (4) dental experts (30.5%) "strongly agreed", four (4) (30.5%) "agreed", and five (5) (38.5) "strongly disagreed" with statement 4. As the consensus was determined at 70%, this statement was reframed and included in round 2 of this Delphi study.

The following extracts reflect some of the dental experts responses to this statement:

"All role players and stakeholders that are involved in teaching and training should be part of the process". DE 1

"There needs to be a lot more information provided to all staff and not just at the higher levels". DE 3

"It seems the lower-level staff never get all the info[rmation] and don't have much [of a] voice. Once a decision is made, they are told to comply without understanding the full implications or how to adapt". DE 3

"Including diverse stakeholders will ensure that [the] framework is understood by all, but also helps the development of competencies through multidisciplinary and interdisciplinary collaboration". DE 3

"Dentistry is multifaceted in its clinical structure and disciplines; the expertise and experience of senior academics will be enhanced with innovation on a technology level from junior academics. Ensuring the team is diversified from a clinical discipline perspective is important to ensure a student that qualifies with competencies in all fields of dentistry". DE 8

"Equal opportunities – all staff are expected to understand and enact the faculty's commitment to ensuring equality and diversity in all activities". DE 10

"All stakeholders play a role in owning and crafting a sound academic programme/curricula". DE 12

"Young academics see the industry very differently and should be key drivers in shaping it for the future". DE 12

From the above comments, it appears that dental experts agree that the inclusion of diverse stakeholders is important to ensure the successful implementation of the AfriMEDS competency framework in dental schools/faculties. It is suggested that the exclusion of all levels of academics (particularly junior) in curriculum changes and accreditation processes contributes to the overall lack of knowledge and understanding of the implementation of AfriMEDS. The views of junior academics appear to be ignored and devalued. However, no consensus was reached, and no suggestions or alternative statements were offered. Statement 2 was rephrased for better clarity and included in the second round of the Delphi study.

Delphi round 2

Round 2 of the Delphi survey was sent to the selected dental experts that responded in the first round. Consent was completed again, and the same demographic information was included. Following the results of round 1, only two statements were included in this round of the Delphi study, as illustrated in Table III.

Round 2 of the Delphi study

In this round, four sets of invitations were mailed to the dental experts. Ten (10) participants responded and participated in the second round of the Delphi study. Consensus of 70% (Table III) was reached for both statements included in round 2.

Comments from the dental experts who agreed with statement 1 are included below:

"For consistency, faculty plans must be in place". DE 2

"Institutional documents set the context for faculty curricula". DE 4

"Most are still run in the way they always have but with a lot more paperwork and red tape to make them look different". DE 5

A dental expert who disagreed with statement 1 mentioned the following:

"In line with the above research, to answer the question why institutional documents does not impact faculty curricula, faculty curricula supported by research validated by rigour may be perceived as less relevant and is often not implemented or sustained widely, because it does not fit nuanced, real-world context[s] such as the university and classrooms; and (i) evidence-based practices that are perceived [as] relevant, but less rigorous are liable to promote ineffective practices". DE 3

Comments from the dental experts who agreed with statement 2 are indicated below:

"Generic competencies like that are taught by everybody". DE 2

"Need buy-in from everyone". DE 5

"For a plan to work, every person must buy in". DE 6

The dental experts who disagreed with statement 2 stated that:

"We have not implemented this curriculum at our faculty, it has not informed our teaching & learning practise". DE 1

"But only if all levels understand the desired outcomes". DE 3

DISCUSSION

Consensus was reached regarding the statement that the AfriMEDS core competency framework informs or impacts dental schools or faculties. Of those who disagreed, dental experts expressed their concern about dental academics, especially junior academics' knowledge of AfriMEDS and how this translates to meaningful attributes for their students. In addition, some dental experts commented that this framework had no significant impact on dental schools. Dental experts expressed concern that dental academics are only trained in the dentistry discipline and not as teachers. The recent shift in pedagogic focus towards a more student-centred education impacts the educator.¹⁶ Similarly, the shift to CBE in South Africa impacts the dental educator. The suggested exclusion of all levels of academics in curriculum related matters and the accreditation process contributes to the lack of understanding and knowledge of AfriMEDS.

Furthermore, the dental experts in this study supported faculty development, specifically in teaching and learning

that would benefit the transition of CBE and alignment of the AfriMEDS core competency framework with the undergraduate dental curricula. The areas of competence identified for dental educators include educational theories, principles and methods, assessment and feedback, curriculum and evaluation, management, healthcare system, and professionalism.¹⁶ Teachers also need pedagogic education to be able to implement changes, therefore dental schools should organise a variety of ongoing training activities for teachers.¹⁷ Individual educators may not need to be competent in every area but should be competent in areas relating to their specific roles.¹⁶

From the comments, it was suggested that the AfriMEDS competency framework was not completely understood and integrated in the dental curriculum and was only a superficial exercise related to the HPCSA accreditation process.

Interestingly, there were comments to more than one statement that related to dental academics. Inclusion and training of all dental academics in curriculum matters, AfriMEDS, faculty development, and other educational faculty development was suggested. Experiences or views of some dental experts were that only selected dental academics were involved in curriculum changes and accreditation. However, previous research has focused on educational change processes, rather than preparing educators to support changes.¹⁶ Inclusion and faculty development relating to curriculum changes and accreditation would result in improved understanding and cooperation of dental academics. It is important for educators to understand curriculum evaluation, which is required for curriculum development and implementation. However, leadership and teamwork are needed to manage change, solve institutional problems, and secure the future profession.¹⁶ In this study, dental experts reached consensus that implementation of AfriMEDS requires dental schools/faculty leadership support. Similarly, the transition towards CBME requires a strong leadership for change.¹⁸

Most (69%) of the dental experts agreed that the specific institutional framework impacts or informs dental schools/faculties. Although consensus was not reached on this point, there were no disagreements; therefore, this statement was reframed and included in the second round of this Delphi study. Results from the second round showed that the dental experts reached consensus (70%) that the institutional framework impacts or informs the dental schools. Following the rephrase of the second statement in round 2, the dental experts reached consensus (70%) relating to all levels of academics, which includes that junior and senior staff from all disciplines are required to ensure successful implementation of the AfriMEDS competency framework in dental schools/faculties.

The transition towards a competency framework must be supported by a systematic approach of curriculum mapping, which will provide the transparency necessary for students, teachers, and the medical school to know what is taught and/or should be learned by when.¹⁸ Complete consensus (100%) was reached that curriculum mapping provided a comprehensive picture of the dental undergraduate curriculum. Coordinated use of a common framework to evaluate the implementation within different

medical schools, combined with the curriculum mapping process, would be an excellent basis to learn from each other and to be able to compare the different curricula.¹⁸

The role and impact of institutional frameworks on the four dental schools varied. This is understandable as the focus and background of the four institutions differed. For example, the university rankings, graduate offerings, and demographics of staff and students impact the underpinning of the institutional framework. From the responses of the experts, it was suggested that the institutional framework did not align or impact on the dental schools' curriculum. Van Melle et al.,⁹ suggest that educational innovations such as CBME are often complex, and highly sensitive to context, thus aligning with the varied impact of the institutional framework on dental schools in this study. From the comments from the dental experts, the AfriMEDS competency framework and CBE have not been implemented in their dental schools. In a study by Sohrmann et al.,¹⁸ which introduced a new competency framework into undergraduate medical curricula, the importance of developing a shared understanding of the concepts underlying CBME and their implications for teaching and learning were highlighted.

Similarly, in this study another dental expert suggested that consideration of the AfriMEDS competency framework is a "paper exercise" related to HPCSA accreditation visits. The varied comments regarding the AfriMEDS core competency framework amongst dental experts from all four schools suggest that there is no common understanding relating to this.

CONCLUSION

The results suggest that the proposed framework to align and implement the AfriMEDS core competency framework in an undergraduate dental curriculum was feasible. However, from the comments of the dental experts, there seems to be no common understanding, implementation, and alignment of institutional frameworks with the AfriMEDS core competency framework. In addition, to address the overall lack of understanding and knowledge of AfriMEDS, leadership of dental schools in South Africa need buy-in and support for a specific faculty development workshop. These faculty development workshops should explore how the AfriMEDS core competency framework translates and aligns to the undergraduate dental curriculum in order to establish a common understanding and buy-in from all dental academics. In doing so, the inclusion of all dental academics in these workshops have the potential to facilitate the success of the implementation of the AfriMEDS core competency framework across all four dental schools in South Africa. In turn, it would allow a more meaningful engagement of all dental academics with the AfriMEDS core competency framework and its alignment to the dental curriculum as part of the accreditation processes. Since institutional frameworks and the contexts of dental schools vary, this needs to be considered and included in the HPCSA accreditation process.

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Evolution of Sialendoscopy in clinical practice: Survey of attending practitioners

SADJ April 2022, Vol. 77 No. 3 p155 - p160

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ABSTRACT

Introduction

Sialendoscopy is a relatively new technique that is safe, minimally invasive and effective as a diagnostic as well as a therapeutic tool for the management of deep seated, proximal, salivary ductal obstruction. However, more than 20 years since its inception it is still not in mainstream use worldwide.

Objectives

Our aim of this study was to ascertain the awareness of sialendoscopy amongst the medical fraternity in South Africa. More specifically, to determine whether it was frequently used amongst practitioners and the type of cases managed using sialendoscopy.

Methods

An exploratory survey design involving 100 practitioners was used to collect data, using an online survey involving 10 closed-ended multiple choice questions.

Results

The results of the study revealed that while practitioners saw patients who could benefit from sialendoscopy, most practitioners did not feel comfortable performing the procedure independently, and as such, most patients were referred on to other professionals for management.

Conclusion

The majority of attending practitioners believed that they

would benefit from further practical and theoretical training in the field of sialendoscopy, illustrating the need for continued professional development in this area.

Key words

Sialendoscopy; sialolithiasis; salivary glands; gland-preserving treatment

INTRODUCTION

Sialendoscopy is a relatively new technique, first described by Katz *et al.* in 1991.¹ Before the advent of sialendoscopy, distal salivary gland obstructions were removed via intraoral excision. However, proximal obstructions were impossible to reach, and as such, treatment methods ranged from the use of antibiotics and anti-inflammatories to the use of sialadenectomy.²

The technique of sialendoscopy has evolved over the years and is now used across the world.² The technique entails using semi-rigid endoscopes to cannulate and view the interior of the salivary ducts. These endoscopes can be used as both diagnostic and interventional tools due to the presence of a hollow working channel that allows the passage of wire baskets, drills and fibre-optic lasers to fragment and remove calculi.³

Salivary duct obstruction is, however, not confined to the presence of salivary calculi alone. Salivary ducts can also be obstructed by polyps, mucous plugs and strictures.^{4,5}

The role of adenectomy in the treatment algorithm for salivary gland ductal obstruction may have become significantly smaller since the advent of sialendoscopy, however, it still has a place.

The management of these patients differs across the clinical units and there is still no consensus as to what factors are used by attending clinicians to determine which patients qualify for gland preservation therapy.

Capaccio *et al.*, state that although available clinical evidence supports minimally invasive gland preservation because it significantly reduces the use of invasive sialadenectomy⁶, there is a lack of consensus within the literature regarding sialendoscopy practice and patient parameters such as age, gender and antibiotic treatment.

AIM OF THE STUDY

The aim of this study was to ascertain the current clinical practices amongst attending medical practitioners with respect to sialendoscopy. This was done by means of a structured closed-ended survey conducted amongst practitioners managing these patients. Data on the

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clinical practice of sialendoscopy and the management of sialolithiasis is important to inform evidence based practice both locally and internationally; and can be used to implement a specific sialendoscopy protocol which can be disseminated widely.

METHODS

The study utilized an exploratory survey design with the use of a purposive convenience sampling approach to select participants for this study. A purposive sampling method allows for participants to be chosen based on set criteria stipulated by the research topic. As such, the sample size included 100 treating clinicians which included medical trainees, otorhinolaryngologists, maxillofacial surgeons, general surgeons, dentists and general practitioners.

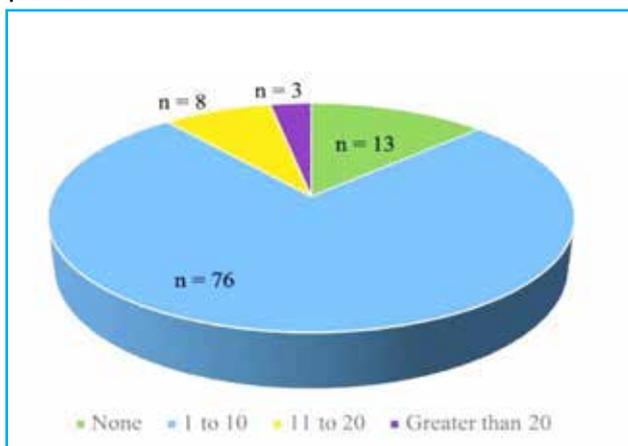
Data collection was conducted using an online survey via Survey Monkey, which included 10 closed-ended multiple choice questions, as displayed in Figure 1. The online link to the survey was distributed digitally to individuals who met the inclusion criteria for the study, to the discretion of the researchers. Data was analysed using descriptive statistics, whereby, the answers from the respondents were coded and classified according to the percentage of their occurrence.

As part of the research conducted by the researchers for the study entitled "The evolution of sialendoscopy in clinical practice", ethics clearance was received from the relevant university human research ethics committee and clearance was granted unconditionally. This clearance certificate was extended by the Ethics Committee for the current study. All information was kept confidential and anonymous and was coded by the researchers. In the current study there was a threat to validity based on there being a risk of bias, between the survey result and population value. This is as there was a sampling bias and a small sample size, which meant that the results obtained may not have been representative of the wider population of practitioners, and as such, the results of this study cannot necessarily be generalized to a wider population.

RESULTS

A total of 100 practitioners partook in the study, with 89 people completing the full survey by answering all 10 questions posed. Table 1 describes the level of experience of practitioners who completed the survey. Figure 2 displays

Figure 1: Number of patients with Sialoliths seen per year by attending practitioners



Sialendoscopy	Survey (n = 100)
Experience	Prevalence (%)
Dentist	34
General Practitioner	27
Specialist ENT	24
Trainee	7
General Surgeon	5
Maxillofacial Surgeon	3

Presence of Sialoliths	Disease	Non-Disease	Total
Positive	3	97	100
Negative	2	98	100

the number of patients per year, seen with salivary stones by clinicians in the study. The majority of practitioners (46%; N = 100) reported that in their experience, salivary stones was most prominent amongst young adults between the ages of 16 and 40, followed closely by middle aged people between the ages of 40 and 60, which was noted by 42% (N = 100) of practitioners. Practitioners noted that salivary stones were not common amongst elderly patients greater than 60 years of age and in children under the age of 16.

Most practitioners prescribed Penicillin to treat salivary stones (69%; N = 100) while 17% (N = 100) of practitioners prescribed other antibiotics aside from Penicillin, Macrolides or Quinolones. Most respondents (23%; N = 100) reported using a Sialogram to investigate patients with suspected salivary stones, followed closely by CT scans (16%; N = 100) and ultrasound of the salivary glands (15%; N = 100). Nineteen percent of practitioners used more than one method to investigate the salivary glands, and no practitioners reported using MRI scans.

The majority of practitioners (82%; n = 99) reported that they did not have access to sialendoscopy within their clinical settings. As per Figure 3, the majority of practitioners reported that they were unable to perform sialendoscopy and very few practitioners (10%; N = 100) felt confident performing sialendoscopy independently, with 76% (N = 100) of people preferring to refer these cases to fellow colleagues. If assisted by another surgeon, 14% (N = 100) of practitioners noted that they would be able to perform the procedure.

Figure 2. Number of Patients with sialoliths seen per year and the practitioners' level of confidence in performing sialendoscopy (n = 100).

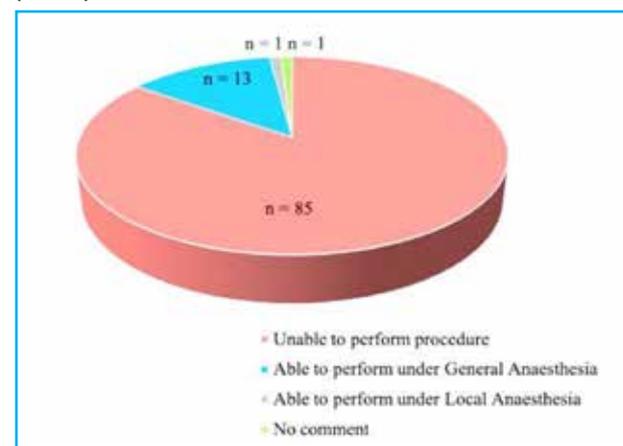
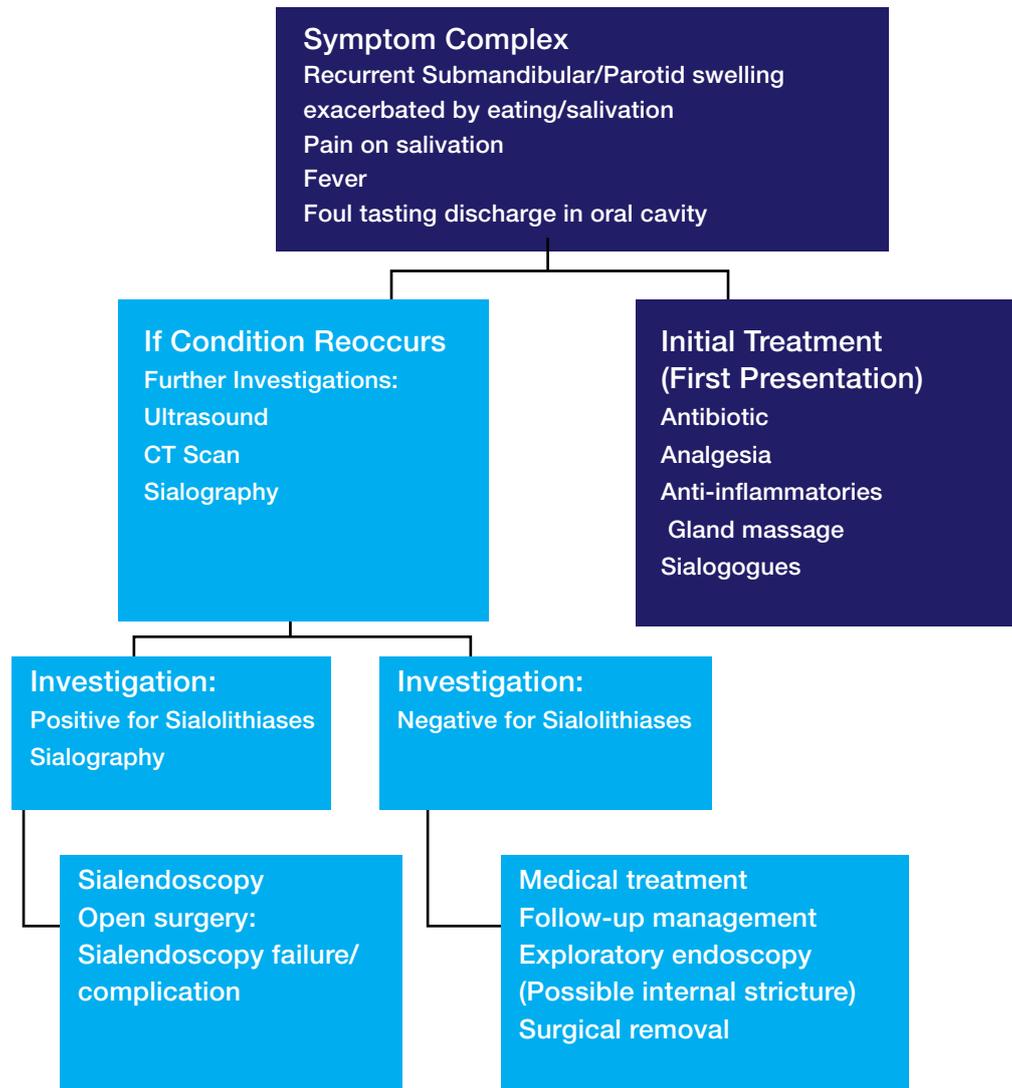


Figure 2. Number of Patients with sialoliths seen per year and the practitioners' level of confidence in performing sialendoscopy (n = 100).



Almost all practitioners felt that they would benefit from training workshops in sialendoscopy (89%; $N = 100$), with 68% ($N = 100$) noting that both theoretical and practical training would be useful. Eleven percent ($N = 100$) of practitioners did not feel that they would benefit from training. While most practitioners (68%; $n = 97$) were not sure if sialendoscopy changed the number of patients with salivary stones treated with open surgery, 21% ($n = 97$) believed that it decreased the number of open surgeries and 9% ($n = 97$) did not think that it made a difference.

DISCUSSION

Sialendoscopy is a relatively new and an increasingly used modality in the management of obstructive diseases of the major salivary glands. Based on international studies salivary glands removed for sialolithiasis have normal glandular architecture, therefore organ preservation should be the goal, thus reducing the morbidity of the open surgery.

It is noted that 73% of practitioners included in the survey were less to not experienced colleagues (general surgeons, dentists, general practitioners, medical trainees)

in the management of sialolithiasis. These are colleagues who are mainly referring, and may not be treating those patients. Most may not be familiar with salivary gland diseases and this was evident concerning tumors, but even more for inflammatory or obstructive diseases. This is also underscored by the low number of salivary stones seen by majority of the participants in this study (76%; $N = 100$) saw between 1 and 10 cases per year. Not surprising that for instance a general practitioner has no access to sialendoscopy as this is a rare diagnosis in their practice and/or the equipment is very specific. Therefore, general practitioners may not have been an appropriate group to participate in this study and evaluate this.

Sialendoscopy is a specific procedure mostly managed by ENT specialists, or Maxillofacial surgeons, however it is noted that only 27% of these practitioners took part in this study. This may indicate that this study seems not to be representative to judge if this technique is used adequately or not and/or should be implemented more intensely.

Training workshops may be beneficial for practitioners not familiar with salivary gland diseases to better understand

the indications of sialendoscopy and to refer these patients to more experienced units/colleagues.

It was noted in the results that 68% of participants were not sure if sialendoscopy changed the number of patients with salivary stones treated with open surgery. This seems to correspond with the 73% of practitioners who supposedly are not experienced with obstructive salivary diseases. These and all other data should be discussed within the discussion part (see below).

Demographics

The incidence of sialolithiasis has according to our knowledge not been described in the South African setting. The vast majority of respondents' saw between 1 to 10 patients a year that presented with salivary stones and most of these patients were young adults. This illustrates that practitioners are exposed to the kind of patient load that would benefit from sialendoscopy.

Ideally sialendoscopy should be performed by experienced units. Diagnostic sialendoscopy may be performed by less experienced colleagues. Interventional sialendoscopy, if successfully performed, needs much more practical experience and should be performed at least not in low volume units (1-10 patients/year). Prerequisites of performing sialendoscopy are firstly sufficient and appropriate equipment and secondly experienced personnel (including experienced assistant personal). Otherwise the results will be not sufficient for the patient, in particular in the long-term course.

Based on the cohort from our study, the prevalence of salivary stones was estimated to be 2.5%. This is comparable to international studies that reported the prevalence to be between 1% and 3% of the population.⁸ Based on the current body of knowledge, there is a peak incidence between the third and fifth decade. As many as 4% of cases occur in individuals younger than 20 years of age.⁸ These trends were noted in our study as well.

A study by Gallo *et al.* (2016), in which 1152 sialendoscopies were performed, showed a male to female preponderance of 52% vs 48%. Sialoliths made up 53.1% of the pathology in this cohort. Stenotic ducts made up 9.4% of the study population. Idiopathic recurrent sialadenitis cases were 27.2% of the total number of cases. Autoimmune cases were 3.4%, while radioiodine exposed cases were 1.6% of cases and 0.5% of cases were post radiotherapy.⁹ The total Juvenile Recurrent Parotitis cases came to 4.1%.¹⁰ The overall success rate was 97.5%. The majority of cases were of the submandibular glands at 55.4% and parotid gland cases accounted for 44.6% of cases.

Deenadayal *et al.*, found in their study of 133 cases that obstruction occurred bilaterally in 26 cases, while 10 cases were normal, and in a total of 149 glands, pathology was found. 78 patients were male and 55 patients were female and 16 were paediatric cases. The age range of the study population was from age 3 to age 76.¹¹

Investigations

Traditionally, the established gold standard in diagnosing salivary duct obstruction was the sialogram. It has since been superseded by ultrasound, CT (computerized tomography) scan and MRI (magnetic resonance imaging) scanning.

In our study the investigation of choice was the sialogram. The advantage of sialography is that it can show the salivary ductal system beyond a calculus, however there is radiation exposure to the patient along with the possibility of perforating the duct or pushing a calculus more proximally into the gland. Although this is not regular sequelae, it may render sialendoscopy thereafter, more difficult. Ultrasound is non-invasive, widely available, cost effective. It represents a first line diagnostic technique. The quality of the results is dependent on the experience of user/operator. It is better for the one performing the sialendoscopy to be the one who performed the initial ultrasound. CT scan of the region is significantly more expensive and as such, no practitioner in the current study reported utilizing it.

Conservative treatment

Therapeutic strategy depends on the size and location of the calculi. Conservative treatment, rather than surgical removal, is accepted as the first choice in managing small calculi located in the distal section of the duct, expecting their spontaneous expulsion. Hydration should be administered to patients with infrared heating and massage of the gland. Natural sialogogues such as a slice of lemon or medications such as pilocarpine are beneficial as they stimulate the production of saliva and subsequent flushing of calculi. Antibiotics should be initiated whenever infection is suspected to be combined.¹² Administration of penicillinase-resistant and staphylococcal agents for 7-10 days, is generally accepted. However, many cases fail to respond to such a regimen. The success rate of spontaneous passage of stones with conservative management for a period of 3 months is only 10%.

Surgical treatment

Sialendoscopy is a relatively new procedure for the diagnosis and treatment of salivary duct diseases. As with any new procedure it seems that there is a definite learning curve involved in achieving success with sialendoscopy.

According to Steck *et al.* (2016), a study was conducted to evaluate learning progression of a single surgeon with the aim to estimate how many procedures were necessary to achieve better results and for the surgeon to perform a safe sialendoscopy and to establish if complication rates were higher in the beginning of the learning. In this study most of the endoscopies (85%) were performed under general anaesthesia however the procedure can be performed under local anaesthesia. In the initial cases performed by the surgeon using the same equipment and after initial hands on training, two of the most common problems encountered included the failure to cannulate ducts and the failure to remove stones. Operative times was slightly higher in the first 50 cases (56 minutes) compared to the subsequent 63 cases (41 minutes). The complication rates were higher in the first 50 cases as opposed to subsequent cases where better outcomes were evident and complications low.¹³

Luers *et al.* (2010) concluded that the performance of sialendoscopy improves with time and experience. The study highlighted that in order to improve skills to an adequate level to achieve satisfactory operation times and performance ratings, it required a number of 30 cases, however, true proficiency occurred after the first 50 cases. Within this study, the average operative times were 39 minutes and there was a significant improvement in the

average operative time and performance rating after the first 10 cases performed and a further improvement was noted then again after 30 cases.¹⁴

The above studies are indicative that the performance of sialendoscopies improves with time and amount of experience and demonstrates the remarkable learning curve of surgeons. Koch *et al.*, in their study published in 2012, found that gland-preserving treatment was possible in 96.8% of the patients in their study, with 92.2% of the patients reporting no relevant symptoms postoperatively.¹⁵

Long term results of sialendoscopy are to be judged on its ability to avoid gland resection with its concomitant complications, whether its results are long lasting and whether it has fewer and less severe complications than sialadenectomy.¹⁶

CONCLUSION

Analysis of our data shows that most of the respondents were aware of the procedure, and were exposed to the type of patient load who required sialendoscopy. However, the majority of practitioners were not able to perform the procedure independently, and reported that they preferred to refer patients requiring the procedure on to other colleagues as they may be less to not experienced in management of salivary duct diseases. While a portion of practitioners were unsure of its effects, many indicated that sialendoscopy had led to a decrease in the need for open surgery.

Despite the majority of practitioners not having access to sialendoscopy equipment, if practitioners were better equipped to perform the procedure, they were most likely to use it in their clinical settings, based on the number of patients requiring it and the positive views towards the procedure. Diagnostic sialendoscopy may be performed by less experienced colleagues. Interventional sialendoscopy, if successfully performed, needs much more practical experience. In fact, most practitioners felt that they would benefit from further theoretical and practical training. Training workshops may be beneficial for practitioners not familiar with salivary gland diseases to better understand the indications of sialendoscopy and be able to make more informed referrals to experienced units and practitioners.

The results of the study reveal that there is a need for further training in sialendoscopy in the South African setting and that this would enhance clinical practice to the benefit of the South African public.

Compliance With Ethical Standards

i) Research Funding

No research grant was utilized for the study conducted.

ii) Conflict of Interest

The authors hereby declare that they have no conflict of interest.

iii) Ethical Approval

All procedures performed in this study involving human

participants were conducted in accordance with the ethical standards of the University of the Witwatersrand Human Research Ethics Committee (Protocol Number M111130) and permission was taken from the committee prior to conducting the research study.

iv) Informed consent

Informed consent was obtained from the individual participants who were included in the study and participants were assured that anonymity would be maintained as no identifying information would be disclosed within the article or to others outside of the researchers who were conducting the study.

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CPD questionnaire on page 176



The Continuous Professional Development (CPD) section provides for twenty general questions and five ethics questions. The section provides members with a valuable source of CPD points whilst also achieving the objective of CPD, to assure continuing education. The importance of continuing professional development should not be underestimated, it is a career-long obligation for practicing professionals.

An evidence-based guide to occlusion and articulation. *Part 3: A guide to functional occlusion: teeth vs joint*

SADJ April 2022, Vol. 77 No. 3 p161 - p166

CP Owen¹

SUMMARY AND PREAMBLE TO THE SERIES

Although this is essentially a review, it has not been written in the passive, third-person style normally associated with scientific writing, as it is intended to be thought-provoking and, hopefully, educational. It has therefore been written in more of a conversational style, and is aimed at students, dentists and dental technicians who are receptive to a slightly different view of occlusion and articulation, based on evidence.

Occlusion is a topic that has become a kind of archaic minefield of conflicting ideas, propositions, and above all, solutions, most of which are based on a complete lack of understanding of the evolution and development of teeth, and by extension, of clinically objective evidence.

That in itself is a statement of conflict (and perhaps even heretical), but it is by way of warning that this guide is not going to be much like anything you will find in standard text-books of dentistry or dental technology. It is, rather, an attempt to help you navigate through what you will read elsewhere, in the hope that eventually you will find an understanding that you can live with. It will appear as a sequential series in 7 Parts.

A guide to functional occlusion: teeth vs joint

Thousands and thousands of words have been written on the form of the teeth and their arches, and here we are in the 21st century of the present era, and still we use terminology from the pioneers of the early 20th century! This is a problem, because it gives rise to a purely mechanistic approach, especially when replacing all the teeth with complete dentures. Yes, the teeth are not upright when viewed from the front (coronal) nor are they in a straight line when viewed from the side (sagittal). But why? If you understand that, hopefully after reading this, you will not refer to 'curves of Wilson, Monson, Spee' but to curves that compensate for the arcs of movements of the mandible: just coronal and sagittal compensating curves.

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To work out how it all happens, we have to go back to how our teeth functioned whilst they were wearing down under natural conditions of eating unrefined, coarse and abrasive food. We first started with cusps, which helped guide the teeth to contact the opposing arch, because of two forces: a continuous eruption force, and a mesial vector of force which directs the eruptive force forwards. Both the eruptive force and alveolar bone growth continue throughout life, which may explain why our faces get longer if we don't wear our teeth down.¹ Natural (pre-refined foods) dentitions, such as in Fig. 1, show occlusal wear, but also, because of the mesial force vector, interproximal wear.



Fig. 1. The posterior teeth from a mandible of a young man who lived about 10,000 years ago.

Note how flat the interproximal surfaces between the teeth are. All this was pointed out in 1954 already, when it was calculated that this wear is the equivalent of the mesio-distal width of a first molar;² hence there is always room for the third molar. How many people do you know who have not had to have their third molars extracted because there was no room for them?

So as the dentition wore down under the effects of chewing, so then did the chewing gradually take place more evenly, and the forces became distributed throughout the arch. This applied to all teeth, including the incisors, so that the concept of an "intercuspal position" became pretty meaningless. Interestingly, the inclination of teeth helped this. To those of you who have been taught mechanistically, this may not make sense as it seems the wrong way round. The teeth are inclined not only because of the forces of eruption but also because this will create the best and most efficient pattern of wear, given the varied movements of the mandible, which are never in a straight line, but

in a pattern under the control of the central pattern generator in the brainstem.

These patterns have been shown graphically by tracing either a point of light attached to the lower incisors, or electronically by tracing a magnet attached there.³ And they confirm that, the omnivores that we are, our mandibles have vertical and horizontal phases, closing mostly on one side, and then opening by moving to the other side. Fig. 2 shows tracings of jaw movements made by the same subject from three separate occasions in a frontal plane while chewing on the right side.



Fig. 2. Tracings of jaw movements in a frontal plane (from Wilding and Lewin³)

These movements, and the wear of the teeth, are also reflected in the adaptability of the joint itself, and in particular in the condyle of the mandible, which is capable of remodelling throughout life, as a necessary response to the changes occurring in the dentition: the faceting of the condyle has been correlated to the wear of the teeth in naturally worn dentitions.⁴ This can also apply, though to a lesser extent, to the fossa,⁵ and the articular eminence can show a flattening with tooth wear.⁶

Understanding cusp angles and joint angles

It is somewhat ironic that, with our unworn dentitions, to understand how they end up with a pattern of tooth wear that provides contacts on both sides of the arch, which they do, and which the mechanistically oriented would be horrified to see (more of that later), dentists and dental technicians first learn how to construct complete dentures.

It is generally agreed that an even distribution of forces around the arch would assist in the stability of the dentures, especially mucosa-borne dentures, which exist by 'floating' on a layer of saliva over a surface of varying degrees of softness and sponginess. The challenge is to set the artificial teeth, whether with cusps or not, such that they will contact as much as possible at any reasonable position of the mandible, by compensating for the curving movements of the mandible. So I will try to explain this by means of a series of diagrams, which are re-drawn and based on a long-ago text book first published in 1976.⁷ We simplify the mandibular movements into a forward protrusive movement, and a lateral one.

Protrusive movements

There are two determinants of mandibular movement in any forward direction, the incisal guidance angle and the sagittal condylar guidance angle. The incisal

guidance angle (IGA) is formed by the vertical overlap (overbite) between the teeth (Fig. 3). It is only dependent on the amount of horizontal overlap (overjet) to the extent that there is no guidance until the teeth actually contact. In natural teeth, these dimensions of overbite and overjet are determined by the positions of the teeth; in complete dentures, they are determined by other factors, mainly aesthetics, phonetics, and function. This means they can be controlled by the dental technician and the dentist, within the limitations of the other factors that determine overall tooth position (mainly the need to achieve stability).

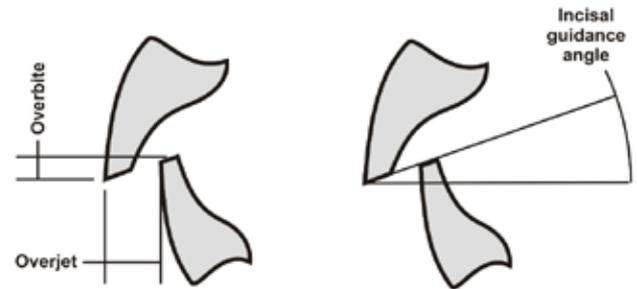


Fig. 3. The incisal guidance angle is formed by the amount of vertical overlap or overbite between the teeth, when viewed in the sagittal plane.

The sagittal condylar guidance angle (SCGA) (Fig. 4) is not under the control of the dentist at all, and is determined purely by the biomechanics of the joint itself. This is the net result of the condyle-disc assembly passing forwards and downwards, under the influence of the anterior slope of the glenoid fossa. As we have already discussed, the condyles do not traverse along a straight-line path as in the diagrams given here, but take a very shaky zig-zagging pathway, the net result of which can be represented by a somewhat artificial straight line as the difference between the starting and end points of the movement.

The form of the condyle and fossa means that any forward movement of the mandible is also a downward movement: if record blocks are placed midway between

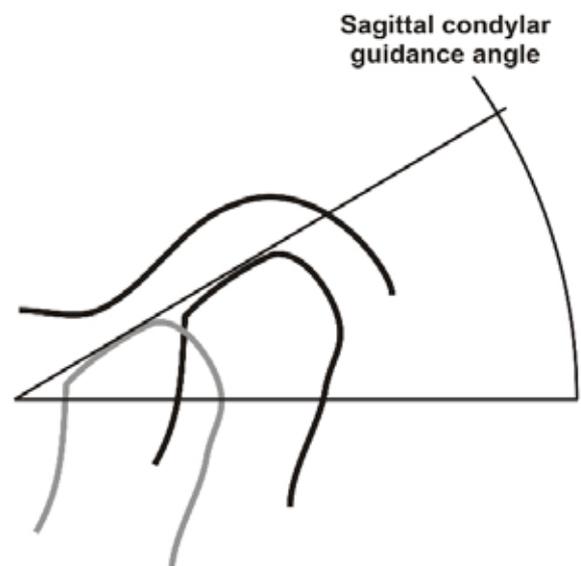


Fig. 4. The sagittal condylar guidance angle is the average path taken by the condyle during a forward movement, when viewed in the sagittal plane.

the incisors and condyles on a flat plane, they will separate if the mandible moves forwards. This is the so-called "Christensen phenomenon" (Fig. 5).

Now, if teeth are placed in place of flat record blocks, again on a flat plane, they will also separate, unless they can have inclines that may fit in with the geometry of the path of movement of the mandible. Fig. 5 is, though, misleading in that it shows a straight mandibular path, and we know it is not. It is also misleading in that it shows the same path for both incisors and condyles, and in reality these paths are not the same. The incisal guidance angle is less than the condylar guidance angle, so the average movement of the mandible under the influence of both of these will be a curve, that is

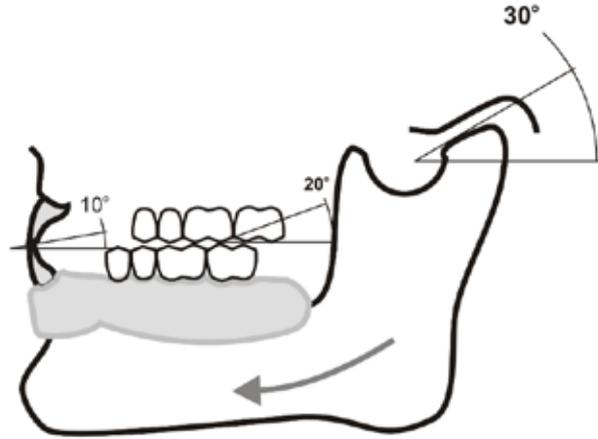


Fig. 6. The mandible's path is an arc which is steeper posteriorly than anteriorly. The only teeth that will remain in contact are those mid-way between the 30° movement posteriorly and the 10° movement anteriorly, i.e. whose cusp angles are 20° at the mid-point of the arc (30+10=40; half of 40=20). Note that the inclines that need to contact are the distal inclines of the maxillary teeth and mesial inclines of the mandibular teeth

steeper posteriorly than anteriorly. So if we are to set teeth, and they are to maintain contact in protrusion, they must be set in such a way that the inclines of their cusps will also vary and be shallower anteriorly and steeper posteriorly. But artificial teeth all have the same inclines or cusp angles (usually 20° or 33°). So if we set the teeth on the flat record block, the geometry of the situation means that most of the teeth will no longer contact. This is shown in Fig. 6 where the sagittal condylar guidance angle is 30° and the incisal guidance angle is 10° so only the teeth with cusp inclines of 20° half way between them would remain in contact.

Now if you want all the teeth to contact, then those nearer to the condyle would need steeper inclines, and a tooth nearer the incisors would need shallower inclines. To change those angles, you would have to grind the teeth, but in such a way that they will be in harmony with the curve of movement of the mandible. Clearly this makes no sense, but interestingly, this is what happens in the natural dentition: as the teeth wear, they all contact in all movements. But back to the denture teeth: rather than grinding everything, you can change the angles of the cusp inclines if you change the inclination of the whole tooth, as shown in Fig. 7.

Back to the geometry: if steeper inclines are needed nearer the condyle, and shallower ones nearer the incisors, then the teeth nearer the condyle must be tilted to create that, and the teeth nearer the incisors need to be

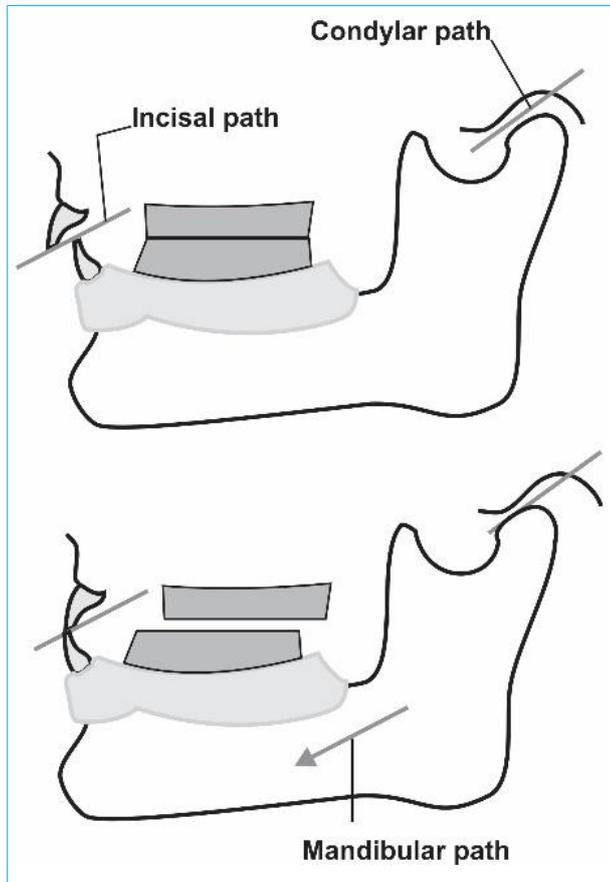


Fig. 5. The so-called "Christensen phenomenon", in which the mandibular path in a forwards direction produces a downward displacement of the mandible. This means that record blocks, for instance, set on a flat plane will separate when the mandible moves forwards, assuming a straight-line movement if the incisal and condylar paths are the same.



Fig. 7. The tooth on the left, upright on a flat plane, as a cusp angle of 20°. On the right, it has been tilted 5° and so the distal incline has now become 25°.

tilted in a different direction. If you do this, and join up the cusp tips, you will have created a curve that will allow the teeth to remain in contact, and therefore compensate for the curvature of the mandible as it moves forwards. This is shown very diagrammatically in Fig. 8.

You can call this compensating curve the “curve of Spee” if you want: the teeth are in positions that, if they are to remain in contact, must compensate for the curving movement of the mandible as it moves downwards and forwards. There are biomechanical advantages to this too, in terms of the efficiency with which occlusal forces are applied⁸ and it is logical, given now our (your, I hope) understanding of natural teeth and tooth wear. It is entirely not logical to ascribe any other purpose to this curve as you may if you still think mechanistically, and as has been done even comparatively recently.⁹

Lateral movements

These are a little more complicated, again because of the way the mandible moves sideways which, as you may have gathered by now, is also never a pure sideways movement in function, but includes forward and back movements during chewing. However, to understand how cusps must work if the teeth are to remain in contact, it is useful again to look at the edentulous situation and the need to have as many of the teeth contacting as possible.

As I am sure you know, when the mandible moves sideways, the side to which it moves is called the working

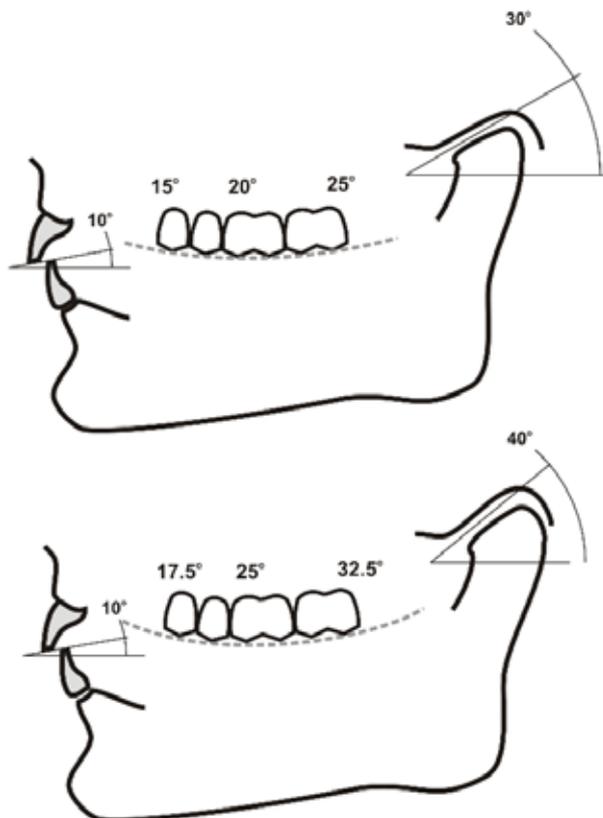


Fig. 8. The steepness of the curve created by the teeth will vary according to the condylar guidance angle if the incisal guidance angle remains the same. So with a 30° condylar guidance angle, the curve is shallower (upper diagram) than that required for a 40° condylar guidance angle (lower diagram).

side, and the opposite side of the arch, moving now towards the mid-line is the nonworking, or balancing side. The term “non-working” is also a misnomer and also steepened in the mechanistic theories that said that teeth should only contact on one side when the mandible moves sideways. This has been shown to be not the case, and is certainly not the case in natural, worn, dentitions, in which there are multiple contacts on both sides – which is what we need in complete dentures. It would be far better to refer to chewing and non-chewing sides which emphasises the function, as it appears that even in unworn dentitions (our ‘modern’ ones) there are contacts during chewing on both sides.¹⁰ This has been known, but largely ignored, for a long time.

But for now, I will try to use all the terms to make sure we are quite sure which side we are referring to. Consider a movement of the mandible to the left. As in protrusion, this movement is also not a flat one, but is under the influence of posterior and anterior determinants. The anterior determinant in this case will be any vertical overlap at the corners of the arch, i.e. at the canines. As with the incisal guidance angle, this canine guidance angle is under the influence of the operator but subject to the similar constraints of aesthetics, arch form, etc. The posterior determinant is, again, dependent on the anatomy of the joint, as the condyle-disc assembly now comes under the influence of the angulation of the medial wall of the glenoid fossa.

So, as it moves to the left, the left (working, chewing side) condyle hardly moves at all, and mostly seems to rotate. This makes the arc of movement of this side of the mandible shallow, influenced by the lateral wall of the left fossa (Fig. 9).

However, on the other side, the right (non-working, non-chewing, balancing) side, the condyle has to move more downwards as well as sideways and is now under the

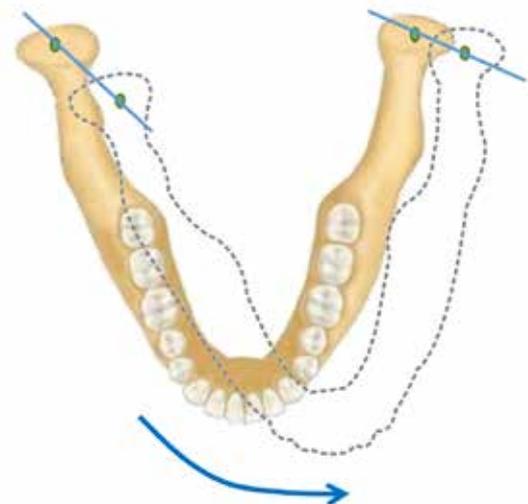


Fig. 9. The movement is exaggerated, to show the differences between the left and right sides when the mandible moves to the (patient's) left. The lines join the centres (green dots) of the condyles. The mandible moves on a curved arc, as indicated by the arrow, steeper on the patient's right than on the left.

influence of the medial wall of the fossa and the movement is therefore quite steep, or at least steeper than the other side. The average path taken is the medial condylar guidance angle, when viewed coronally, which is also referred to as the Bennett angle (after Norman Bennett who first described it in 1908 ¹¹). Fig. 10 shows this and the sagittal condylar guidance angle three-dimensionally.

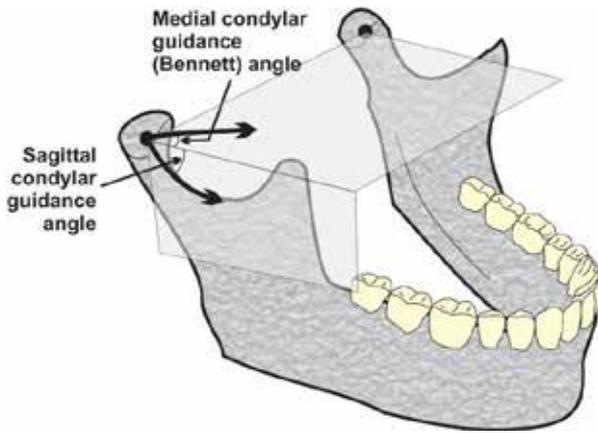


Fig. 10. A three dimensional representation of the sagittal and medial condylar guidance angles.

Precisely the same geometric principles as followed for protrusive movements can be used to explain the necessary changes in tooth morphology required to ensure tooth contact during these lateral mandibular movements. But first we must be sure we are referring to the correct inclines of the cusps, just as in protrusive we found that it was the distal inclines of the maxillary teeth and the mesial inclines of the mandibular teeth that needed to remain in contact. In lateral movements it gets a bit more complicated. Fig. 11 shows which inclines of which cusps must remain in contact.

Using the geometry as before, because of the curved arc of movement, it means that the working (chewing) side inclines must be shallow, and the non-working (balancing, non-chewing) inclines must be steeper. So we have the same problem with denture teeth, in that all the inclines are the same. Is the solution the same? Yes, but only to a certain extent. Fig. 12 shows (again, very diagrammatically) a medial condylar guidance angle of 40°, lateral condylar guidance of 10° and a canine guidance angle of 10°. So half way, as we did with protrusion, we

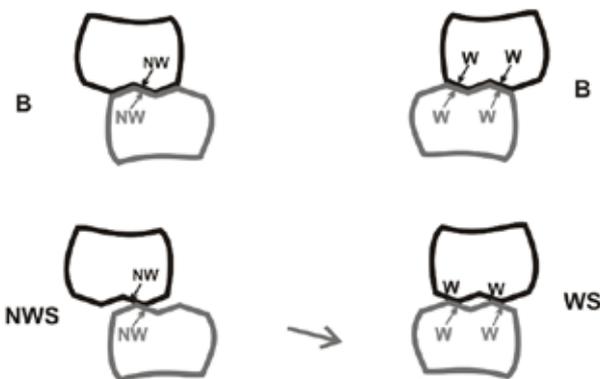


Fig. 11. When the mandible moves to the left, the inclines marked W must remain in contact on the working side (WS) and the inclines marked NW must remain in contact on the nonworking side (NWS), for them to remain in contact.

need to increase the angle of the non-working cusp inclines, and decrease the angle of the working cusp inclines and we do that by tilting the teeth relative to a horizontal plane to make the non-working inclines steeper and the working side inclines shallower.

And lo and behold, we have another curve! The tilt of the teeth are again compensating for the curvature of the arc of movement of the mandible. You can call this the curve of Wilson or Monson if you like.

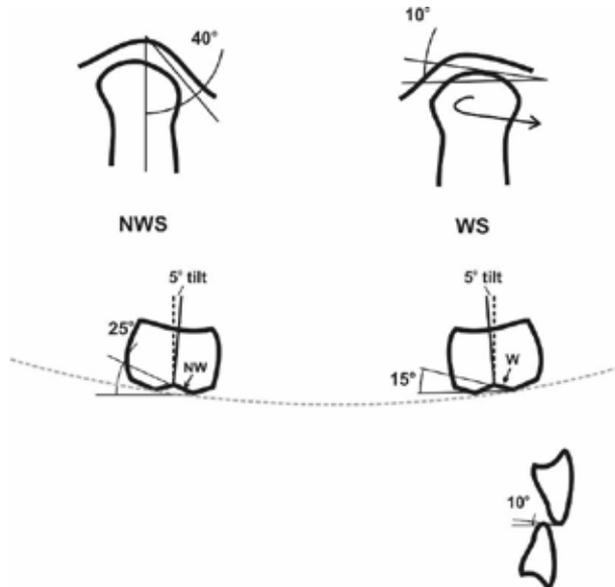


Fig. 12. The nonworking inclines (NW) have been effectively increased to 25° by tilting the teeth, and the working inclines have been reduced to 15° thus generating a curve when viewed in the frontal plane.

There's only one problem though, when it comes to complete dentures and that is that the tilt that provides steeper non-working (balancing, non-chewing) inclines doesn't really make the working side inclines shallow enough, as any dental student and dental technologist will tell you as they find it impossible to produce full balance without having to grind those working side inclines. It might be easier to understand if we look again at the animal kingdom, and those chewers par excellence, the herbivores. Fig. 13 is the maxillary dentition of a Springbok (the antelope which has become the symbol

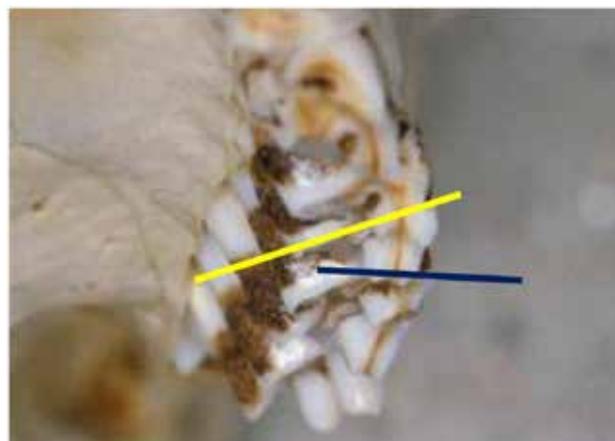


Fig. 13. The natural wear of the Springbok's teeth showing the steeper inclines (yellow) of the palatal, non-working side cusps, and the shallow inclines (blue) of the buccal, working-side cusps.

of South African Rugby). The yellow line is against the inclines of the palatal cusps, which are the non-working cusps, and the blue line is against the incline of the buccal, working-side cusp.

This difficulty is the reason that alternative methods have emerged to provide a balanced articulation in complete dentures, although the evidence for the absolute need for this has been challenged by some short-term studies with few patients in which lateral contacts were provided only on the canines.¹² The patients adapted, but in doing so experienced much more ulceration and worse maxillary denture retention than with the occlusally balanced dentures, which a moment's thought would show to be logical, because the dentures would be moving around considerably. Not necessarily when chewing, but certainly if the patient has any parafunctional habits like clenching and grinding.

So there have emerged other schemes, and my preference is that of lingualised occlusion for complete dentures, as there is now evidence that patients may prefer this over other schemes,¹³⁻¹⁵ and it is in fact much easier to set up and adjust for both the dental technician and the dental clinician. A full explanation is available at www.appropriatech.com.¹⁶

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What's new for the clinician– summaries of recently published papers

SADJ April 2022, Vol. 77 No.3 p167 - p171

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1. Is there a clinical association between Periodontitis and COVID-19?

Whilst the COVID-19 pandemic continues throughout the world, dental professionals have been focusing on the oral signs and symptoms associated with the infection. Published studies have shown that almost 4 in 10 COVID patients experience impaired taste or total loss of taste, and an even greater proportion report having a dry mouth. Other oral manifestations include ulcer, erosion, bulla, vesicle, pustule, fissured or depapillated tongue, macule, papule, plaque, pigmentation, halitosis, whitish areas, haemorrhagic crust, necrosis, petechiae, swelling, erythema, and spontaneous bleeding.¹

Periodontal disease is considered a pandemic in its own right, with the reported case load far exceeding that of COVID-19. There are several hypotheses that have pointed towards the possibility of a link between periodontal disease and COVID-19.¹ Detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in the gingival crevicular fluid (GCF) further gives credence to this theory and introduces the possibility of another point of entry.

SARS-CoV has been known to cause alterations in lung tissue due to numerous pathways, of which one involves mediation via matrix metalloproteinases (MMPs). These MMPs have been implicated in facilitating early virus entry into cells.¹ MMPs are derived from polymorphonuclear leukocytes (PMNs) found in the diseased periodontium and an MMP-8 point-of-care (aMMP-8 POC) test has been developed for use in both adolescent and adult populations as a means to define active and inactive sites of periodontal disease, assess prognosis and evaluate patients in the treatment and maintenance phases. ¹This particular point-of-care testing methodology possesses a sensitivity of 76–83% and specificity of 96% with results being returned within 5–7 minutes. ¹

A number of hypothetical models have been put forth to assess the possibility of a link between oral hygiene and/or periodontal disease and the COVID-19 disease process.¹ Gupta and colleagues from India (2022)¹ reported on a study that sought to assess the association of periodontal health

on the complications of COVID-19. These researchers performed real-time clinical assessments of patients suffering from COVID-19 along with utilising a validated aMMP-8 point-of-care bedside diagnostic test kit in order to evaluate the presence of active periodontal disease among COVID-19 infected patients.

MATERIALS AND METHODS

The cross-sectional analytical study involving 82 patients with COVID-19 infection confirmed by nasopharyngeal swab (NPS) testing. A patient information sheet was given to all the patients, and written informed consent was obtained from all the subjects. Pregnant ladies, patients less than 18 years old and those unwilling or not in a position to give written informed consent were excluded from the study. Demographic data was recorded, and chairside tests run for evaluating the expression of aMMP-8 at the site with maximum periodontal breakdown as well as via a mouthrinse-based kit for general disease activity. Covariates like age, sex, smoking habits and other COVID-19-related comorbidities/risk factors such as diabetes, hypertension, pulmonary disease, chronic kidney disease, cancer, coronary artery disease, obesity and any other comorbidities were recorded. Blood parameters relevant to the disease progression such as C-reactive protein (CRP), D-dimer, platelet count, ferritin, glycosylated haemoglobin (HbA1c), haemoglobin (Hb), vitamin D3, neutrophil/lymphocyte ratio (N/L), troponin, procalcitonin and N-terminal-pro-brain natriuretic peptide (NT-proBNP) were recorded. These parameters were noted from the patients' records, if available. Hence, the number of samples varied in each parameter.

Periodontal clinical examination was conducted by a single calibrated examiner using a 10-mm round-tip manual Williams's periodontal probe. All permanent teeth, excluding the third molars, were examined at six sites per tooth (disto-buccal, mid-buccal, mesio-buccal, disto-palatal, mid-palatal, mesio-palatal). Gingival recession (GR), gingival marginal level (GML), periodontal probing depth (PPD), bleeding on probing (BOP) and number of teeth present/missing/carious were recorded. Clinical attachment loss (CAL) was calculated. Patients were categorised into periodontally healthy, gingivitis and stage I–IV periodontitis, as per the new classification of periodontitis. No intra-oral radiographs were taken as this was not feasible.

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Samples were collected using aMMP-8 PoC mouthrinse- and site-specific kits. These tests were conducted by a periodontist who was unaware of the clinical examination results. aMMP-8 chairside lateral flow mouthrinse immunoassay test (PerioSafe) and aMMP-8 chairside lateral flow site-specific immunoassay test (ImplantSafe) were done on patients. The colour changes due to immunoreactions were read after exactly 5 min. In both cases, a single blue line indicated aMMP-8 levels less than 20 ng/ml (negative; no risk), whereas two blue lines were representative of aMMP-8 levels more than 20 ng/ml (positive; increased risk), indicating active periodontal disease.

COVID-19-related complications such as presence of COVID-19 pneumonia, death due to COVID-19, type of hospital admission and need of assisted ventilation were also assessed. Patients requiring oxygen via high-flow nasal cannula (HFNC), non-invasive ventilation (NIV) or through intubation and ventilator were categorised as patients requiring assisted ventilation, whereas those able to maintain their status quo on room air were categorised as patients not requiring assisted ventilation. Admissions were categorised into those isolated at home and those admitted in the hospital either in the wards or in the ICU as per their disease severity and treatment requirements. An attempt was made to evaluate the presence of active periodontal disease using a validated aMMP-8 point-of-care bedside diagnostic test kit.

RESULTS

Forty-eight male patients and thirty-four female patients were enrolled in the study. There was an overall increase in age distribution with increasing stages of periodontitis in COVID-19 patients. Fifty-one patients had typical symptoms of COVID-19, whereas thirty-one were asymptomatic on presentation. Presence or severity of periodontal diseases was not found to be associated with gender or presence/absence of COVID-19 symptoms. Of the patients, 52.43% presented with one or more comorbidities. A statistically significant association was observed for diabetes mellitus, cardiovascular diseases and cancer. Predictors of COVID-19-related outcomes such as hospital admission, requirement of assisted ventilation, COVID-19 pneumonia and eventual survival were observed to increase with a concomitant rise in the stage of periodontitis. Particularly, patients with a higher stage of periodontitis underwent ICU admission as opposed to those with a healthy periodontium or gingival disease who were found to be under home isolation or ward admission.

The need for assisted ventilation was more prevalent among patients with stage III and IV periodontitis. Twenty-two patients presented with COVID-19 pneumonia and fourteen had ground-glass opacities on CT chest. Majority of the patients survived and 9.7% (n = 8) of the patients succumbed. These patients had a greater severity of periodontitis. One of the eight deceased patients had diabetes along with hypertension. Five of the deceased had other comorbidities like hypertension, CKD, history of CAD and acute necrotising pancreatitis. Bleeding on probing was commensurate with the stage of periodontal disease.

Bleeding on probing was not associated with any recorded blood parameter. Gingival recession and number of teeth missing due to periodontal reasons were associated with D-dimer and troponin values. Probing depth was significantly associated with HbA1c, CRP, D-dimer and ferritin levels. Higher CAL was associated with elevated levels of CRP, D-dimer, pro-BNP, troponin and procalcitonin. Subjects with more severe forms of periodontitis had higher levels of D-dimer, pro-BNP and troponin.

Patients with bleeding on probing had 4.14 odds of requiring assisted ventilation, 3.18 odds for hospital admission and 3.63 odds of suffering from COVID-19 pneumonia. Probing depth, gingival recession and CAL were significantly associated with all the included complications of COVID-19. Increasing probing depth, CAL and presence of gingival recession in these patients put them at increased odds for these complications. Patients with gingival recession required assisted ventilation (OR = 8.22), had less chances of survival (OR = 14.07), and 6.50 odds of COVID-19 pneumonia. However, missing teeth was only associated with increased odds of hospital admission (OR = 12.52). Also, it was found that deceased patients had significantly higher mean probing depth, gingival recession and CAL compared to the survivors. Periodontal status was associated with all the included complications of COVID-19 in the present study. Higher severity of periodontitis led to 7.45 odds of requiring assisted ventilation, 36.52 odds of hospital admission, 14.58 odds of death and 4.42 odds of COVID-19 pneumonia.

Subjects requiring admission in hospital had significantly elevated levels of HbA1c, CRP, D-dimer, ferritin, N/L ratio, haemoglobin, pro-BNP, troponin and procalcitonin. Survival was found to be associated with elevated N/L ratio and platelet count, whereas subjects with higher levels of HbA1c, CRP, D-dimer, ferritin and procalcitonin required assisted ventilation.

CONCLUSION

The researchers found that there was a direct association between periodontal disease and COVID-19-related outcomes. They further added that since periodontal disease was both reflective and deterministic of systemic health, it might also play an indirect role in worsening the status of comorbidities more directly associated with a poorer prognosis of COVID-19-related adverse outcomes.

Implications for practice

This study provided further evidence of the link between oral health and general health status- poor oral health indicators and markers are correlated by poor general health indicators and markers. Readers must be cautioned that a causal relationship in this paper cannot be established due to the cross-sectional design of the study.

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2. Motivational interviewing for caries prevention in adolescents: a randomized controlled trial

Dental caries continues to be a major public health problem globally with a huge unmet treatment burden in children and adults especially in developing countries. Providing dental care is expensive and most countries do not have the resources to manage the huge burden of unmet treatment needs. Hence, the focus, over the last few years, has been on providing health education and promotion interventions to prevent or reduce the initial caries burden. The prevention and control of dental caries rests primarily upon both upper-streaming approaches addressing social determinants and the adoption of healthy behaviours by individuals.¹ Early adolescence is a life stage in which many health behaviours are perpetuated and health interventions during early adolescence are likely to produce a long-term impact on one's health outcomes.¹

Although adolescence is recognized as a critical period for health promotion, health intervention during adolescence is challenging as adolescents are often resistant to overt persuasion or direct advice provided by others.¹ Instead, they are more likely to accept particular values and goals that are central to their own identity, because personal identity establishment is one of the milestones of their growth and development.¹ Furthermore, since pursuits of personal autonomy gradually emerge, adolescents often have a strong desire to make their own decisions and regulate their own behaviours without undue controls from adults.¹

Given its autonomy-granting and evocation-focused nature, motivational interviewing (MI) may play a unique role when working with adolescents.¹ As a collaborative conversational style, MI explores one's own good reasons for change and activates his/her own motivation, commitments, and resources for change.¹ Originally developed for treating substance abuse, MI has been introduced to change other health-related behaviours and conditions, with promising.¹

To facilitate dental MI, an interactive patient communication tool, Cariogram, could be incorporated into different stages of the counselling process. It graphically illustrates one's overall risk for dental caries along with a risk breakdown associated with various behaviours, such as cariogenic diet and poor oral hygiene.¹ Instead of prescribing a list of do's and don'ts, it demonstrates the possible health gains (risk reductions) through different behavioural changes and offers alternative solutions. It assists client's systematic reflection of his/her status quo and facilitates informed decision-making and goal setting.¹

Wu and colleagues (2022)¹ reported on a randomized controlled trial (RCT) that sought to evaluate the effectiveness of three intervention schemes (prevailing health education, MI, and MI aided by Cariogram) in enhancing adolescents' oral health self-efficacy, changing their oral health behaviours (snacking and toothbrushing),

and preventing dental caries. The null hypothesis was: There is no difference in changes of adolescents' oral health self-efficacy and behaviours and in caries increment among three intervention groups.

MATERIAL AND METHODS

Allowing for a 25% lost-to-follow-up rate, 147 subjects were needed for each group. Adolescents from 15 participating secondary schools in Hong Kong were recruited under the following inclusion criteria: (i) full-time students; (ii) 12 or 13 years old; and (iii) having unfavourable oral health behaviour, defined as "toothbrushing less often than twice a day" and/or "snacking three times or more a day." The exclusion criteria were (i) having any major systemic disease or (ii) unable to communicate in local languages. A screening questionnaire was used to identify eligible participants. Adolescents' assent and parental written consent were obtained.

Cluster randomization was applied and schools in each district were randomly assigned by drawing lots to three intervention groups (I) prevailing health education; (II) MI; and (III) MI aided by patient communication tool. The allocation ratio was 1:1:1. Allocation concealment was ensured by using sealed and opaque envelopes.

The intervention for the control group was delivered through an oral health talk and pamphlets. The oral health talk was delivered to all participants of each school in group I. The talk lasted for about 30 min, including a 10-min session for raising questions. Each participant received an education package, comprising of three pamphlets titled "Cleaning teeth properly—you can do it," "How to use dental floss," and "Healthy diet, healthy teeth"

Each participant in group II joined a one-on-one face-to-face MI session, which lasted 15–30 min. The MI sessions followed a standardised approach that included four spirits (evocation, compassion, acceptance, and collaboration), four processes (engaging, focusing, eliciting, and planning), and four core skills (open questions, affirmation, reflection, and summary).

In group III, the patient communication tool, Cariogram, was used at appropriate stages of the one-on-one face-to-face MI session, depending on the participant's response, to stimulate his/her own thinking and help him/her to identify the discrepancy between the status quo and personal goals, to explore possible behavioural changes and their respective health gains (reduction in caries risk), to make informed decisions and set his/her own goal and agenda (what to change and to what extent).

For both group II and group III, the sessions were audio-recorded. To assist the start of behavioural change, maintain the change, and avoid relapse, each participant in groups II and III received five telephone calls at 2

weeks, 1 month, 2 months, 4 months, and 6 months after the initial counselling.

All interventions were delivered by two oral hygienists who were trained by an expert panel composed of a clinical psychologist and a behavioural scientist experienced in health promotion and MI in healthcare settings. The training sessions included lectures (3 h), group discussions (2 h), video analysis (2 h), demonstrations (1 h), role plays and real plays (4 h), and continuous feedback. All interventions were periodically reviewed to ensure they were delivered consistently. A total of 51 (15%) audio records were randomly selected and the fidelity of MI intervention was scored by using the Motivational Interviewing Treatment Integrity (MITI) Coding Manual 4.1. MITI generates global scores and behaviour counts. For global scores, a "relational" score measures "partnership" and "empathy," whereas a "technical" score measures "cultivating change talk" and "softening sustain talk." Both global scores range from 1 to 5; a higher score indicates a higher MI adherence. The behaviour counts can be converted into % CR (proportion of complex reflection) and R:Q (reflection question ratio). A % CR of 50% or above and an R:Q of 2 or above are considered as "good." A % CR of 40% or above and an R:Q of 1 or above are considered as "fair."

The effectiveness of the interventions was evaluated and compared using psychological outcomes (self-efficacy in controlling snacking and toothbrushing), behavioural outcomes (snacking and toothbrushing frequency), and clinical outcomes (plaque score and caries increment). Data were collected at baseline and 6, 12, and 24 months post-intervention. This paper reported the 24-month findings of the trial.

A self-administered questionnaire was completed to collect information on participants' demographic and socioeconomic background, oral health self-efficacy, and oral health self-care behaviours. To evaluate self-efficacy in controlling snacking and toothbrushing, participants were asked to what extent they agreed with the following statements: "I have the ability to control frequent sugar snacks between meals on all occasions" and "I can do a good job brushing my teeth thoroughly twice a day even when I am very busy." Response was solicited by using a five-point Likert scale and was converted to "positive self-efficacy" ("strongly agree" or "agree") and "negative self-efficacy" ("neutral," "disagree," or "strongly disagree"). Two questions were asked on their toothbrushing frequency and snacking frequency. "Snacking three times or more a day" and "toothbrushing less often than twice a day" were defined as unfavourable oral health behaviour. Participants were also asked to provide information on any dental visit and the treatments received at each follow-up time point (6, 12, and 24 months post-intervention).

Clinical examination was performed by an examiner, who was blinded to the participants' group allocation. The oral hygiene status was evaluated using Silness-Löe Plaque Index. Four surfaces (distal, buccal, mesial, and lingual) of 6 index teeth (16, 12, 24, 36, 32, and 44) were examined. The cleanliness of each surface was rated from score 0 to 3. No plaque disclosing agents were applied. Dental caries was recorded by visual and tactile inspection using illuminated mouth mirror and CPI probe. The International

Caries Detection and Assessment System (ICDAS) was followed. Excluding wisdom teeth, 28 teeth were assessed for each participant. As required for the ICDAS assessment, supervised toothbrushing was conducted before the caries examination.

RESULTS

A total of 512 participants were recruited (161, 163, and 188 in groups I to III, respectively). Among them, 460 (89.8%) were followed up 24 months post-intervention. The reasons for drop out were "withdrawn from the school" (n=24), "withdrawn from the study" (n=10), and "absent from school" (n=18). There was no significant difference in sociodemographic and behavioural variables, oral hygiene, and caries status between drop-outs and those who remained in the trial ($p>0.05$).

All participants in group I attended the oral health talk and received the oral health pamphlets. All participants in group II and group III joined the MI session; most of them (91.4% in group II and 85.6% in group III) received all five phone calls after the session, with all receiving at least one phone call. The fidelity of MI intervention was rated as reasonably high. The mean (SD) global rating scores were 4.16 (0.60) and 3.80 (0.66) for "relational" and "technical" aspects, respectively, out of a highest possible score of 5. The mean % for CR (complex reflection) was 43.4%, whereas the mean R:Q (reflection question ratio) was 1.90. The percentages of MI sessions that were coded as "good" or "fair" for the "relational aspect," "technical aspect," "% CR," and "R:Q" were 94.1%, 92.2%, 70.6%, and 94.1%, respectively.

Among the 512 participants, 262 (51.2%) were boys and 250 (48.8%) were girls. The percentages of males were 34.2%, 50.3%, and 66.5% in group I to group III, respectively. Secondary school was the highest education level for 66.8% of parents; 70.8%, 65.0%, and 64.9% in groups I-III, respectively. Less than half (45.3%) of the participants snacked three times or more daily and around two-thirds (65.4%) performed toothbrushing once a day or less. The mean (SD) numbers of cavitated carious teeth (DICDAS II 3-6MFT) were 0.60 (1.20) for the whole sample; 0.61 (1.11), 0.74 (1.39), and 0.55 (1.07) in groups I-III, respectively.

There was no significant between-group difference in sociodemographic variables, oral health self-efficacy and behaviours, oral hygiene status, and tooth status ($p>0.05$), except for gender. No significant difference was found among schools in parental socioeconomic status and children's caries status at baseline ($p>0.05$). Compared with group I, (i) positive self-efficacy in controlling snacking and toothbrushing was more common in group II and group III ($p<0.001$); (ii) significantly higher proportion of participants restricted frequent snacking and brushed their teeth twice a day in group II and group III ($p<0.001$); (iii) mean plaque score was significantly lower in group II and group III ($p<0.001$); and (iv) no significant difference was found in caries status of the three intervention groups 24 months post-intervention.

As compared with group I, (i) the improvement in self-efficacy in controlling snacking was more likely in group II

[OR (95% CI): 3.63 (1.02–12.94)]; (ii) positive behavioural change in snacking was more likely in both group II and group III, with ORs (95% CIs) of 3.91 (1.48–10.33) and 6.33 (2.46–16.27), respectively; (iii) group II and group III were more likely to change their negative self-efficacy in toothbrushing, with ORs (95% CIs) of 4.65 (1.86–11.63) and 4.30 (1.74–10.64), respectively; and (iv) participants in group III had a higher likelihood to start performing adequate toothbrushing [OR (95% CI): 4.80 (1.79–12.85)]. The greatest plaque score reduction was achieved in group III, followed by group II and then group I ($p < 0.001$); (ii) increment of cavitated lesions (Δ DICDAS II 3-6MFT) was lower in groups II and III than in group I (0.34, 0.12, and 0.11 for groups I to III; $p = 0.006$); and (iii) group III had lower total caries increment (Δ DICDAS II 1-6MFT) than group I (0.71 vs. 1.49; $p = 0.004$).

CONCLUSION

The researchers reported that MI outperformed prevailing health education in improving oral health behaviours and preventing dental caries among adolescents

Implications for practice: MI has been found to be a useful tool to incorporate in health promotion intervention targeted at adolescents.

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Special-IST versus Special inter-IST

SADJ April 2022, Vol. 77 No. 3 p172 - p173

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ABSTRACT

Dentists who wish to specialize in a specific discipline have to undergo and complete a rigorous, structured and extensive postgraduate academic and practical training programme, and pass all the requisite exams. Only then can they be registered with a regulating professional body and be recognized as such in that field. Thereafter their scope of practice becomes limited to that specialty alone. This differs from general dentists, who are not restricted in their scope of practice, but may have limitations to the extent of their capabilities. They may choose to upskill themselves through attendance at short courses, hands-on training workshops, informal study groups, dental company workshops or even YouTube videos. Unlike the trainee in a formal institution, this is unstructured and outcomes are unspecified, yet some of these practitioners then market themselves as specialists in these fields. While the Health Professions Council of South Africa (HPCSA) has set out a list of core ethical values and standards for good practice, there are no regulations enforcing the need for these practitioners to undergo and pass HPCSA recognized examinations to assess their capabilities, knowledge and skill in these modalities. This opens the profession up to risks of practitioners contravening a number of core values and standards expected of trusted professionals and can mislead and put the general public at risk. This paper aims to explore if regulation of this type of practice is required, who should be allowed to offer additional training to dentists, and who should be regulating the trainers.

INTRODUCTION

Having successfully completed one's studies, graduated, and being registered as a healthcare professional confers on a practitioner the right and privilege to practice their profession¹. However, with this right, comes a number of legal and ethical obligations and duties. In reality, it is impossible to create a definitive set of prescriptions to follow that will encompass all clinical situations, and the onus often remains on the clinicians to decide for themselves which actions or treatment decisions could be defended if challenged. This will require them to engage in a process of reasoning and rationalisation, based on their training and expertise; and grounded in core moral values and standards

of good practice. Their final decision should always be in the best interest of their patients and society, bearing in mind that it may also impact on their reputation.¹ In order to help practitioners with this process, the Health Professions Council of South Africa (HPCSA) has set out a list of core ethical values and standards for good practice.¹

Core ethical values and standards

There are eleven basic core ethical values, however not all may apply to each individual case scenario. Furthermore, there may be times when adherence to some standards may clash, making it all the more crucial for the practitioner to apply ethical reasoning in coming to a final decision. These values are listed below as several of them will be used to discuss the main theme of this paper, which revolves around practitioners' skills, expertise, and training, and how they present themselves to the public in this regard:

1. **Respect for persons**, and acknowledgement of their worth, dignity and sense of value.
2. **Best interest** or well being (**non-maleficence**) wherein the practitioner should not harm or act against the patient's best interest even if this is in conflict with their own interests
3. **Best interest** or well being (**beneficence**) wherein the practitioner should act in the patient's best interest.
4. **Human rights** of all should be recognised.
5. **Autonomy**, which gives each patient the right to self-determination and to make their own, informed decisions based on their own beliefs, values, and preferences.
6. **Integrity** of the practitioner as evidenced by them being responsible and adhering to the core values.
7. **Truthfulness**, which forms the basis of the trust between the practitioner and their patients.
8. **Confidentiality** and treating of all personal or private patient information as confidential unless there are overwhelming moral or legal reasons for disclosure.
9. **Compassion**, sensitivity and empathy with individuals as well as societal needs and the striving to provide comfort and support where ever appropriate or possible.
10. **Tolerance** of patient's different ethical beliefs and desires.
11. **Justice** and treatment of all individuals and groups in an impartial, fair and just manner.¹

Specialist, special interest and expertise

A specialist is a practitioner who has completed an extensive period of postgraduate academic and practical training with specialization in a specific and limited area of dentistry; and should have passed all the requisite examination processes needed to be recognised and registered in that field. Thereafter they will restrict their scope of practice to that area alone, and no longer carry out general dentistry.² This differs vastly from general dentists, who are not restricted by their scope of practice, and can undertake work in

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1. LM Sykes: 70%
2. TI Mmutlana: 30%

any aspect of dentistry they choose. They may have a keen interest in a certain field, and develop their skills and expertise in that area. They may undertake various short training courses offered by recognised teaching institutions, informal study groups, dental companies or even YouTube videos.³ They do not necessarily complete any structured training programmes nor do they have to undergo and pass HPCSA recognised examinations, to validly assess how capable they are of carrying out these specialised procedures. They are then free to continue practicing routine dentistry, or to devote a major portion, or all of their time to this single domain.⁴ Some even advertise themselves using terms such as “dentist with special interest in...”, “expert in...”, “cosmetologist”, “authority in..”, “trained..” etc. While not illegal, such testimonials can be misleading to the general public who interpret these titles as an indication of specialised training. Some even charge substantially higher fees for this service. They may argue that they are even more specialised than the specialists and as such feel legitimately and ethically entitled to their designation and remuneration. After all they are fulfilling the main aim of treatment, which is “the management and care of a patient by provision of therapy focused on combating a disease or disorder, or with interventions aimed at improving health”.⁵ The question is how and/or should this practice be regulated?

Issues to consider

There is no doubt that there are general dental practitioners who have spent time, effort and expenses upskilling their knowledge and technical skills in certain specific areas of dentistry. Some may have even limited their practices to this field and earned themselves a trustworthy reputation within the dental community. While they remain general practitioners, they seldom carry out the various other treatment modalities within the scope of general dentistry. Technically, they are not specialists and so cannot “legally” advertise themselves as such or charge specialist fees. However, they certainly do carry out specialist type and quality of work. Why then can they not present themselves as experts and charge accordingly? Clearly if one considers this in terms of the core ethical values and standards, they could fully justify their actions.

The concern is more with dentists who have completed short training courses, attended basic workshops or online programmes, or worse, been taught about products and techniques by company representatives. They then promote themselves on public platforms and social media as specialists. They may even augment their “adverts” with questionable testimonials, show “before and after” patient photographs, or in extreme cases, offer limited deals and discounts. Those in the know may realise the illegitimacy of this, and thus twist the terminology used to describe themselves as mentioned above in order to avoid litigation. To the unsuspecting public, specialist and expert sound the same and they accept the authenticity of the clinician who labels themselves as such. These same dentists may continue doing both general and the more complex work, yet charge substantially higher fees for the latter even at specialist rates or higher. From an ethical perspective this runs the risk of contravening a number of core values and standards expected of trusted professionals. There is clearly no respect for persons, as it may not be in their best interest or well-being, and can potentially lead to more harm than good (maleficence). Untruthful self-promotion shows no respect for human rights or compassion for unsuspecting

patients. In addition, autonomy will be compromised in that clinicians have not been truthful about their expertise and limitations when offering these modalities to their patients. Their actions cannot be justified and undermine their own integrity as well as that of the entire profession.

CONCLUSION

In conclusion, one final point of consideration with regard to clinicians performing specialised dentistry is the question of who trained them? Can a professional be taught by a company representative or manufacturer? Are short courses and internet videos able to impart practical skills? Who assesses the quality or monitors accreditation of privately arranged education courses? How much participation and training in a field is needed to justify charging higher fees? Can a clinician be trained by someone who has a lesser degree than their own? Can general dentists teach specialists? These questions remain in most part unanswered and unmonitored, and perhaps need to be taken up with controlling bodies.

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SADJ April 2022, Vol. 77 No.3, p174 - p175

C Smit¹, L Robinson²

CASES

Two paediatric male patients presented with painless bilateral facial swellings (Figures 1 and 2A&B). What are the pertinent radiological findings and your diagnostic hypothesis?



Figure 1: Panoramic radiograph of patient 1

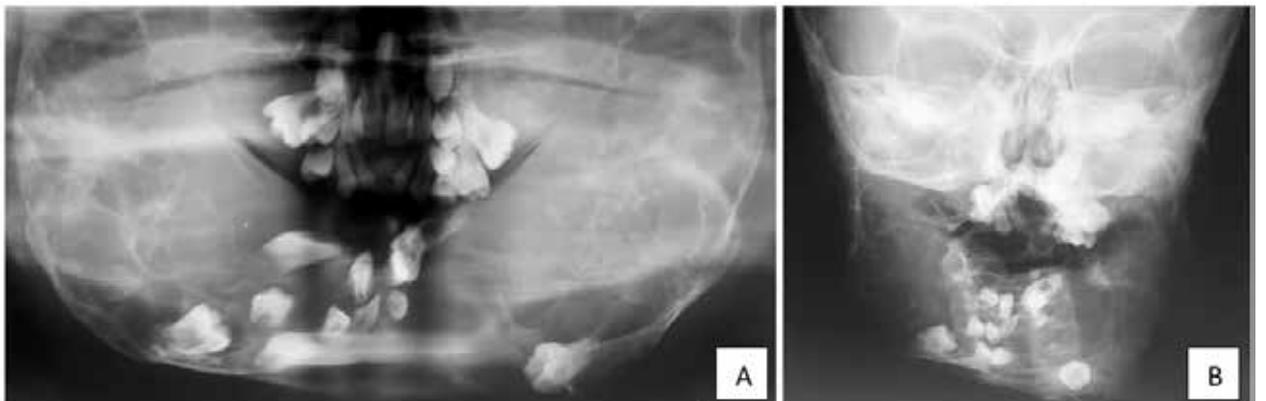


Figure 2: Panoramic radiograph (A) and Posterior anterior skull radiograph (B) of patient 2

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Authors contribution:

Liam Robinson: 50%
Chané Smit: 50%

INTERPRETATION

Both patients presented with bilateral multilocular radiolucent lesions that were highly expansile with varying degrees of tooth displacement, including multiple impactions. In case 1 the lesions were limited to the mandible, whereas case 2 presented with extensive involvement of both jawbones.

Cherubism is a rare bone disorder that may be inherited in an autosomal dominant pattern (68% of cases) with varying penetrance, or in rarer instances may occur sporadically. The aetiopathogenesis involves a mutation of the SH3 domain-binding protein 2 (*SH3BP2*) resulting in extensive giant cell lesions replacing bone.¹ *SH3BP2*-

dependant signal transduction seems to be involved in the regulation of osteoclastic and osteoblastic activities.² Clinically, patients present with symmetrical expansion of the jaws that characteristically undergo regression after puberty. Maxillary involvement may lead to displacement of the orbital floor giving an 'eyes turned to heaven' or 'plumped-cheek angel' appearance. Cherubism shows a slight male predominance, presenting at a mean age of 6 years. Radiologically, cherubism presents with highly characteristic features of bilateral well-defined multilocular radiolucent lesions with significant bony expansion. Tooth displacement (95%), tooth agenesis (62%), root resorption (40%) and cortical destruction (35%) are also commonly seen.¹ The second and third molars are frequently absent, as noted in case 2.² This could be explained by the correlation between the timing of development of cherubism and the associated missing molars. Others speculate that this presentation may be related to the pathogenesis, as a genetically determined alteration of tooth germ development.² Unilateral cases have been reported, however strict clinicopathological workup is required to rule out other differential diagnoses. Due to spontaneous regression after growth, longitudinal observation is the suggested management modality. Numerous drugs including bisphosphonates, calcitonin,

interferon, and imatinib, amongst others, have been used with varied outcomes. Currently, due to limited studies on these therapeutic approaches, conclusions on their effectiveness cannot be drawn. Surgical intervention is only indicated in the presence of functional or aesthetic impairments, as some cases treated via surgical intervention resulted in rapid regrowth.¹

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CPD questionnaire

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GENERAL

An evidence-based guide to occlusion and articulation. Part 3: A guide to functional occlusion: teeth vs joint

- Select the CORRECT option. Pre-Industrial Revolution teeth usually showed
 - Little wear except with age
 - Only occlusal wear
 - Some interproximal wear
 - Occlusal and interproximal wear
- Which of the following options is CORRECT. Teeth are inclined to both the vertical and horizontal
 - To improve aesthetics
 - As a result of eruptive force vectors
 - To maintain cusps and prevent wear
 - All of the above
- Choose the CORRECT answer. In complete dentures, teeth are set such that when viewed in the sagittal perspective, they are on an antero-posterior curve
 - Because they must conform to the curve of Spee
 - For aesthetics
 - To create anterior guidance
 - To maintain contact during protrusive movements
- Select the CORRECT answer. In complete dentures, to create a balanced occlusion, amongst other things
 - Make the working cusp inclines shallower than the non-working side inclines
 - Make the balancing side cusp inclines shallower than the working cusps
 - Always grind the non-working side cusps
 - None of the above

Prevalence of Sharps Injuries at a Tertiary Teaching Oral Health Centre, Gauteng, South Africa

- Select the CORRECT percentage. How many subjects who reported sharps injuries went on post exposure prophylactic treatment and completed it
 - 31%
 - 21%
 - 10%
 - 14%
- Choose the CORRECT answer. In which oral health centre department did the most injuries suffered by students occur?
 - Maxillofacial and Oral Surgery
 - Oral rehabilitation
 - Periodontics
 - Oral medicine
- Which one of the following options is CORRECT. What was the most common mode of sharps injury amongst all participants?
 - Forceps
 - Burs
 - Scaler tips
 - Needles
- Choose the INCORRECT answer. The population for the study included:
 - Dental students in their clinical years (BDS 3, 4 and 5)
 - All oral hygiene students (BOHSc 1, 2, 3)
 - Laboratory staff
 - Academic staff members, who provided clinical services at WOHC

Exploring the feasibility of a framework to align a competency framework in a dental curriculum: a Delphi study

- Choose the CORRECT statement. For the first round of the Delphi, consensus of the dental experts was defined as being reached:
 - when 100% or more of the dental experts agreed with each of the statements of the questionnaire.
 - when 80% or more of the dental experts agreed with each of the statements of the questionnaire.
 - when 70% or more of the dental experts agreed with each of the statements of the questionnaire.
 - when 60% or more of the dental experts agreed with each of the statements of the questionnaire.
- Which of the following options is CORRECT. The areas of competence identified for dental educators include:
 - educational theories, principles and methods
 - assessment and feedback
 - curriculum and evaluation, management,
 - all of the above
- Choose the CORRECT answer. Inclusion and training of all dental academics in the following was suggested:
 - clinical expertise
 - research
 - educational faculty development
 - communication
- Which of the following options is CORRECT. The proposed framework to align and implement the AfriMEDS core competency framework in an undergraduate dental curriculum was:
 - not feasible
 - feasible
 - impossible
 - considered

Evolution of Sialendoscopy in clinical practice: Survey of attending practitioners

13. What is level of experience is needed to treat sialadenitis:
- Trainee
 - Specialist ENT
 - Maxillofacial Surgeon
 - Registrar
 - General Practitioner
14. Approximately how many patients are seen in a year with salivary stones by a general practitioner?
- 0
 - 1-10
 - 11-20
 - Greater than 20
15. What is the predominant age group of the patients seen?
- Children < 16 years of age
 - Young adults 16- 40
 - Middle age 40-60
 - Elderly > 60
 - Other
16. What antibiotic group is best prescribed as first line treatment for these patients?
- Penicillin
 - Macrolides
 - Quinolones
 - Cephalosporins

Evidence-based Dentistry: What's new for the clinician

17. The study design used in the Gupta et al study was
- Case -control
 - Cross-sectional
 - Longitudinal
 - Randomized controlled
18. The only type of study design that can infer causality is
- Case-control study
 - Cross-sectional study
 - Longitudinal study
 - Randomized controlled trial

Radiology Corner – Cherubism

19. In most cases cherubism is inherited via which of the following patterns:
- Autosomal dominant
 - Autosomal recessive
 - X-linked dominant
 - X-linked recessive
 - Mitochondrial
20. Cherubism presents radiologically as:
- Unilocular radiolucency
 - Unilateral, multilocular radiolucency
 - Bilateral, multilocular radiolucencies
 - Ill-defined moth-eaten radiolucency
 - Mixed radiolucent-radiopaque lesion

Ethics: Special-IST versus Special inter-IST

21. Which of the following answers is CORRECT. Patient confidentiality can be breached if:
- A spouse requests for information on their partner
 - A medical aid company ask for patient information
 - The dentist wishes to discuss the case with a colleague
 - The dentist feels they have a moral obligation to reveal information
 - Both b) and c) are correct
22. Select the CORRECT answer. Dentists who have specialized in a specific discipline:
- Can only call themselves specialists if registered with a regulating body in that specialty
 - Have to limit themselves to that field if registered as a specialist
 - Can still do general dental work as long as they charge GP fees for those procedures
 - All of the above are correct
 - Only a) and b) above are correct
23. Which of the following statements is most CORRECT. There are eleven basic core ethical values.
- Not all are applicable to dentistry and these others may be ignored
 - Not all are applicable to all cases but should still be considered
 - Some may clash with each other, in which case both can be ignored
 - Some may clash with legal obligations, in which the law can be disregarded
 - Most are not relevant to modern day practice and need not be considered
24. Which of the following options are CORRECT. Autonomy can be overlooked when:
- The patient's decision goes against the dentist's advice and preferences
 - The patient's beliefs differ from those of the dentist
 - The patient's choice would lead to them being exposed to harm
 - The patient's would not be able to understand the dentist's suggestions
 - Both a) and b) apply
25. Select the CORRECT option. Clinicians who consider themselves experts may:
- Advertise themselves as specialists if they have had enough training
 - Charge specialist fees if the patients can afford to pay
 - Limit their practices to that area or skill and charge higher fees but not at specialist rate
 - Advertise their services using real-life patient testimonials
 - Both b) and c) are applicable

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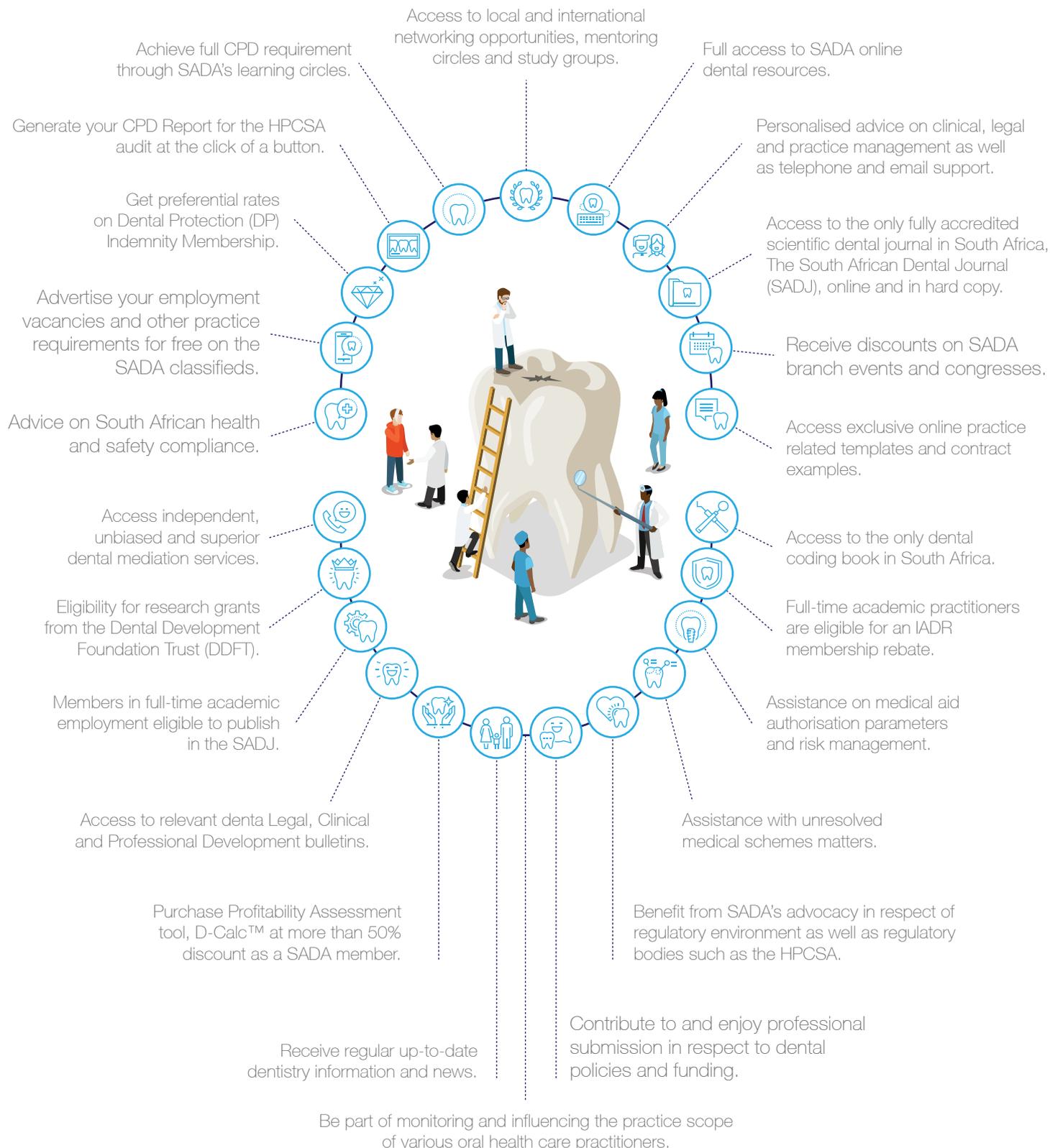
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