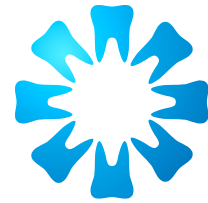


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THE SOUTH AFRICAN  
DENTAL ASSOCIATION

*Pierre Fauchard*  
*The father of modern Dentistry*



**Pierre Fauchard (1678 - 1761):**

The man credited to be the "father of modern Dentistry". Pierre Fauchard was a dentist of unsurpassed skill and knowledge. He used the title "Chirurgien Dentiste" (surgical dentist), developed several instruments, often based on jewellery, watchmaking and even barbers' tools ...indeed he designed a first dental drill... powered manually using catgut wrapped around a cylinder. Apart from the technological advances Dr Fauchard introduced, he also had considerable influence on the ethics of the profession and on clinical etiquette. He pursued a philosophy of endeavouring to save teeth rather than simply extracting the offending item. He also suggested the dentist should stand behind the nervous patient! Implacable foe of charlatans, he denounced medical malpractice. Today a bust of the famous dentist stands in the grounds of the chateau Grandmesnil, at Bur sur Yvette to the south of Paris.



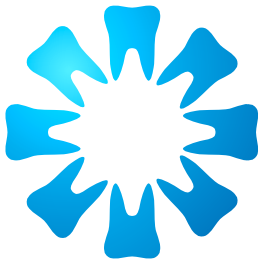
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## Our Front Cover for this Issue...

The theme for the Front Cover of the South African Dental Journal this year provides for some historical figures, some characters illuminating dental history and some important achievements in South African Dental history. A fitting start will be made on the February issue with the man credited to be "The father of modern Dentistry". Read more on page 3.

**Pierre Fauchard:**

The man credited to be the "father of modern Dentistry", Pierre Fauchard was a dentist of unsurpassed skill and knowledge. He used the title "Chirurgien Dentiste" (surgical dentist), developed several instruments, often based on jewellery, watchmaking and even barbers' tools ...indeed he designed a first dental drill... powered manually using catgut wrapped around a cylinder.

Apart from the technological advances Dr Fauchard introduced, he also had considerable influence on the ethics of the profession and on clinical etiquette. He pursued a philosophy of endeavouring to save teeth rather than simply extracting the offending item. He also suggested the dentist should stand behind the nervous patient! Implacable foe of charlatans, he denounced medical malpractice. Today a bust of the famous dentist stands in the grounds of the chateau Grandmesnil, at Bur sur Yvette to the south of Paris.

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# Pierre Fauchard

## the father of modern Dentistry (1678 - 1761)

Pierre Fauchard (1678 -1761) started his working life at the age of 15 as a cadet in the French Navy. There he was greatly influenced by a Navy Surgeon, Alexander Potelert, who lit the interest in the healing arts which was to direct the career of the young Pierre. Pursuing that commitment, Fauchard left the navy after three years at sea, during which time he had observed many oral diseases, especially scurvy, amongst his colleagues.

Pierre simply began working as a dentist.. there were no formal training courses and no formal regulatory bodies at that time. At the University of Angers, he undertook revolutionary medical and dental work and pioneered the sciences of Oral and Maxillo-facial surgery. He used the title "Chirurgien Dentiste" (surgical dentist), developed several instruments, often based on jewellery, watchmaking and even barbers' tools. He pursued a philosophy of endeavouring to save teeth rather than simply extracting the offending item.

Uncharacteristically for the time, Fauchard was eager to share his knowledge, skills and techniques and between 1716 and 1718, he spent much time travelling, studying and teaching. Pierre settled in Paris in 1718 ...a city which saw him refine his techniques, extend his acumen... and commence work towards his seminal contribution to dental literature. There were then scant books on Dentistry and Pierre decided to produce an encyclopaedic volume on oral surgery.

Considerable devotion to that endeavour included many interviews with colleagues and he drew heavily on personal diaries he had kept over the years. By the time "Le Chirurgien Dentiste" was finally published in 1728 it was in two volumes carrying together 783 pages. A German translation was ready in 1733, a revised and enlarged edition in French appeared in 1746 ...the English version was eventually competed in 1946... two hundred years later!

The book introduced many new and innovative concepts ...indeed he designed a first dental drill... powered manually using catgut wrapped around a cylinder.



Page 203 and 204 of *Le Chirurgien Dentiste* by Dr Pierre Fauchard.



Fauchard identified sugar as a major hazard to dental health ...and disproved the German theory of a "tooth worm". Intriguingly he recommended braces to correct poorly positioned teeth and suggested amalgams for tooth restorations. No less intriguing is his recommendation for a daily gargle with urine!

The practice of the Surgeon Dentist in Paris was highly successful for Pierre Fauchard was a dentist of unsurpassed skill and knowledge. He attracted the rich and the famous! Quite apart from the technological advances Dr Fauchard introduced, he also had considerable influence on the ethics of the profession and on clinical etiquette. He suggested the dentist should stand behind the nervous patient! Implacable foe of charlatans, he denounced medical malpractice.

Dr Fauchard married Elisabeth Chemin in 1729 and five years later the couple purchased a small chateau ...Grandmesnil, at Bur sur Yvette to the south of Paris.

Today a bust of the famous dentist stands in the grounds of the chateau. Pierre passed away in 1761 and was buried in Paris.



Indubitably the "father of modern Dentistry".

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# Editor's notes

SADJ February 2020, Vol. 75 No. 1 p4

NH Wood



Welcome to the first issue of the South African Dental Journal (SADJ) for 2020. This year holds much promise and potential, and I take great pleasure in wishing you a prosperous year ahead.

Our social media platforms and news feeds have been heavily loaded with the constant reports on the outbreak of yet another respiratory viral infection, in this case the “novel” coronavirus, temporarily named 2019-nCoV.

We have previously faced two betacoronavirus outbreaks in the forms of SARS-CoV and MERS-CoV, both of which cause respiratory illness and may be fatal. However, the spread of the airborne 2019-nCoV is extremely rapid with number higher than the total reported SARS cases of the 2002/2003 outbreak in which 774 people from 17 countries lost their lives.

Initial reports of the 2019-nCoV infection describe the clinical and epidemiologic aspects of this viral infection.<sup>1-3</sup> The World Health Organization (WHO) has estimated the global risk to be “high”, but at the time of writing these notes still advised against any travel restrictions being implemented by authorities.

The 13<sup>th</sup> situation report issued by the WHO showed 14 557 confirmed cases globally (305 deaths). Notably 168 of these are from 23 countries outside of China. Although the spread of the virus is rapid, accurate reporting has been hamstrung by many false reports and claims, and paradoxically, also by an information overload dubbed an “infodemic” by the WHO.<sup>4,5</sup>

The potential impact this infection may have on us in South Africa is uncertain, and the sequelae for the vulnerable, immunocompromised or otherwise medically compromised is not yet clear due to the lack of data, but speculation leads to a more negative outlook.



However, the South African Department of Health has published a statement reassuring citizens that health-care facilities and staff are prepared and ready to deal with any case of 2019-nCoV to enter our borders.<sup>6</sup>

For your information and in order to keep up to date, we recommend that reliable sources be used for gathering information such as the WHO<sup>4,5</sup> and the Centres for Disease Control (CDC)<sup>7</sup> pages. This will also assist to curb the spread of misinformation.

Basic infection control procedures and avoidance of close contact with individuals suffering from any acute respiratory illness form the foundation of the WHO recommendations.

I would like to thank the leadership of the South African Dental Association for the opportunity to be a part of the SADJ team. We remain committed and are excited about the year ahead. I must also thank Professor Bill Evans, my predecessor, for his energetic efforts and hard work as the Managing Editor of the SADJ. His academic integrity, breadth and depth of knowledge, and his work ethic are exemplary, and set the bar high, where it should be. His masterful wordsmithing continues to be a source of inspiration.

Thank you for joining us as our readers. As we consider the possibilities this year holds, I look forward to engaging you as our contributors.

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# Managing mental health wellness

SADJ February 2020, Vol. 75 No. 1 p5

PD Moipolai



The beginning of a new decade is on us and we need to take lessons from the previous decade if we are to move the profession forward. One of the key issues from the recent decade that was forefront in the health-care profession and in society at large is mental health wellness. Locally, we have not been excluded from the ravages of this phenomenon, with the untimely passing of the then dean of UCT's Faculty of Health Sciences – the world renowned Prof Bongani Mayosi, may his soul rest in peace.

It is well established that dentistry is a stressful profession,<sup>1</sup> including the demanding route to attaining that professional qualification.<sup>2</sup> It has been reported that dentists experience more stressful conditions than all other professionals.<sup>3</sup> The stress is attributable to a variety of factors including the nature of the profession, the working conditions in the dental surgery<sup>4</sup> and the academic requirements of dental school programmes.<sup>5</sup> Some of the factors identified as major stressors, contributing nearly 50% of the stress, include the fragility of the patient-dentist relationship, patient scheduling, time spent for treatment provision, HR issues, financial obligations, technical problems and job satisfaction.<sup>6</sup> The stressors faced by health professionals may not only affect their own mental and physical health, but may adversely affect the quality of care provided to patients. The dramatic changes (technologically and regulatory) which are taking place in the profession, and at a phenomenal pace, make it important that we recognise the impact on the mental wellbeing of ourselves and our colleagues. It is indeed difficult being a dentist or dental student!

With the changing local healthcare regulatory landscape, it may not be remiss to postulate that this potentially may have adverse effects on the professionals and the quality of service provided. The national public service is already under immense pressures to provide quality oral healthcare, in the face of considerable limitations and challenges in the provision of basic preventive and restorative oral healthcare. The critical question to ask at this juncture, is how is the envisioned NHI going to address the current deficiencies that are burdening the profession - without adding to an already stressful environment? The uncertainty amongst oral health practitioners around the implementation of the NHI regarding its impact on the provision of oral health, cannot be underestimated as a potential major stressor.

SADA has been working very hard on these matters. The Association organised a profession-wide NHI Task

Team that included all associations in the oral health space. The resulting document adopted by all was sent to the Department of Health as well as the War Room on NHI chaired by Dr Olive Shisana. The Association has provided input on the NHI green paper and the Bill. We have also identified able members of the profession whom have been nominated to sit on various committees of the NHI. SADA remains closely involved and is giving input to the relevant bodies as they work on the implementation of the NHI.

Added to this scenario are the reported challenges that plague the HPCSA, resulting in President Ramaphosa having had to order a probe into the Council by the State's Special Investigation Unit. This turn of events can also not be seen as providing any sense of comfort to the profession! The level of confidence in which the Statutory Body is held by its membership is at an all-time low. Without an alternative to the HPCSA to protect the profession, members are left in a vulnerable state with respect to being supported in the provision of their respective services.

The above picture speaks to a chronic systemic problem which fundamentally impacts not only on individual professionals, but also on the working environment. Many of the interventions advocated previously to assist healthcare professionals have targeted individuals, rather than the system. Organisational or structural change is needed to improve working conditions and environments to effect more long-lasting positive outcomes.

As a profession, it is incumbent on all of us to raise awareness of the effects of mental health for the survival of our profession and to ensure that our members are supported in preventing and managing the ill effects of this condition.

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Pusetso D Moipolai: President, SADA

# Appointment of Managing Editor - Prof Neil H Wood takes office in January 2020

Prof Neil Wood qualified as a dentist from the University of Pretoria and later specialized in Oral Medicine and Periodontics at the University of Limpopo, Medunsa Campus. He further developed his clinical and academic experience at the latter University before being appointed as Associate Professor and Head of Clinical Unit at the University of the Witwatersrand, Johannesburg.

He has then served as consultant specialist in two specialist Oral Medicine and Periodontology departments and has supervised a number of post-graduate students to completion. Currently Neil holds the position of Full Professor and Head of Clinical Unit at Sefako Makgatho Health Sciences University (SMU), where he is also the Acting Head of Department.

In addition to research activities, he is involved in undergraduate teaching and training, and in specialized service delivery in the fields of Oral Medicine and Periodontics. He also has extensive experience with Post-Graduate accreditation with the HPCSA.

Prof Wood has participated in the publishing of numerous national and international peer-reviewed papers as co-author and author, and has a special interest in Human papillomavirus, the topic of his PhD work.

He is a Past-President of the South African Society for Periodontology, Implantology and Oral Medicine (SASPPIO), has served on a number of organizations such as the International Association for Dental Research, the Ethics Institute of South Africa, and the International Academy of Oral Oncology.



Additionally, Neil Wood has been on editorial boards of some peer-reviewed dental journals and has held office as a sub-editor of the South African Dental Journal.

Professor Wood has not taken his appointment as Managing Editor lightly, for he has carefully considered possible innovations and improvements and indeed has some exciting and far-reaching concepts for the Journal, starting with a workshop for new and current referees, and also introducing an electronic tracking system for papers. The Association is most happy to welcome Neil to the post and wishes him a highly successful tenure of office.

# In memoriam - Dr Ingrid Masello Ntombenhle Mokhine



On the 30<sup>th</sup> December 2019, the South African dental fraternity woke up to the news of the passing of our colleague and friend, Dr Ingrid Mokhine.

Dr Mokhine obtained her BChD degree at the University of the Western Cape in 2004. She joined the School of Oral Health Sciences at the University of the Witwatersrand in 2009 and worked predominantly in the Department of Paediatric and Restorative Dentistry. She then went on to obtain her MScDent degree in 2015.

Dr Mokhine had a keen passion for the treatment of special needs children and aspired towards making paediatric dentistry a speciality in South Africa. She will be missed by all that had the pleasure of knowing her.



# Self-reported oral hygiene practices and oral health status among dental professionals

SADJ February 2020, Vol. 75 No. 1 p7 - p13

SR Habib<sup>1</sup>, AK Alotaibi<sup>2</sup>, MA Alabdulkader<sup>3</sup>, SM Alanazi<sup>4</sup>, MS Ahmedani<sup>5</sup>

## ABSTRACT

### Aims and objectives

The aim of this study was to evaluate the oral hygiene practices and oral status of dental professionals working in Riyadh, KSA.

### Methods

Questionnaires were distributed to a conveniently selected sample of 400 dental professionals. The questionnaire included the demographics, oral-hygiene practices, past-dental history, self-reported current-dental status, dental appointments, self-reported family-dental condition, self-grading of oral-health and possible reasons for negligence in oral health.

### Results

The response rate was 68.8%. Significant differences between male and female participants were observed regarding the reported frequencies of brushing ( $p=.001$ ) and the history of dental visits ( $p=.013$ ).

Differences between the responses to the social habits on the consumption of coffee, tea, soft drinks, cigarettes and water pipe were insignificant. Generally, the participant's experiences with dental treatment was excel-

lent to very good. Avoiding dental visits due to a fear of cross infection was very high (Likert scale=3.47 out of 4) among participants.

### Conclusions

Participating dental professionals, oral hygiene practices and oral health status were satisfactory. Gender-based differences were found with females expressing more care regarding their oral health. Gingival bleeding/gingivitis and bruxism were prevalent among the male and female participants respectively. Poor oral hygiene was the primary cause for the damaged dentition. Fear of cross infection from the dental treatment prevented the participants for seeking dental treatment.

### Keywords

Oral health attitude; Oral health behavior; Oral Hygiene Practices; Dental Professionals; Oral hygiene.

## INTRODUCTION

Oral health is an integral part of an individual's general health. Disease-free oral cavities and healthy tooth-supporting tissues are essential for optimum oral functionality. Interplay of various factors affect the socio-economic status, education and availability of health care facilities which are significant factors that greatly influence oral health.<sup>1</sup>

Dental caries, gingival inflammation and eventual tooth loss requiring artificial tooth replacement are deleterious consequences of oral hygiene neglect. The majority of people believe that loss is inevitable, which eventually needs replacement; also contributing towards the negligence of maintaining good oral hygiene.

Neglect in oral hygiene massively affects the quality of life and expectancy.<sup>2</sup> Oral diseases as a result of poor oral hygiene may lead to the manifestation of various systemic diseases. Various studies have investigated the relation of oral cavity and its microbiology to several other organ systems. This reflects how important it is to maintain good oral hygiene.<sup>3</sup>

Education plays a major role in guiding people regarding their oral hygiene. Individuals at higher education levels show more responsibility towards eating habits and performing necessary oral hygiene routines.<sup>4</sup> They are more aware of the consequences and problems caused by neglect in oral hygiene.

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1. **Syed R Habib:** Study Design, over all supervision, interpretation of data, write up and final review - 35%
2. **Asim K Alotaibi:** Data collection, write up, review and submission - 20%
3. **Malek A Alabdulkader:** Data collection, data entry - 15%
4. **Samer M Alanazi:** Data collection, data entry - 15%
5. **Muhammad S Ahmedani:** Statistical analysis, interpretation of data and results - 15%

Dental health education can help improve individual, group and community well-being. Education tends to shape behavioural patterns which begin with change in attitude and transformation in conduct.<sup>5,6</sup> Health care sector needs to invest more towards increasing awareness and helping educate individuals about oral hygiene measures.<sup>7</sup> Oral hygiene education should be promoted alongside medical health since both are intertwined.<sup>8</sup>

General awareness for maintaining oral health is either acquired through dental check-ups and appointments. The majority of people don't routinely visit dentists unless one experiences dental pain. Visiting dentists is considered unnecessary and may be because people are unaware of the consequences of neglecting their oral health. Prevention is better than cure but only few out of thousands believe so.<sup>9,10</sup>

Dental professionals are extensively trained regarding the importance and maintenance of good oral hygiene. They are well aware of the consequences oral health disease due to compromises in oral hygiene measures and they can effectively deliver these guidelines to patients over time.<sup>11</sup> Dental professionals become oral health providers who need to address key oral health issues in their communities. Dental professionals are aware of oral hygiene habits and their practices reflect their dedication towards health care.

In order to be able to deliver great care and perform dental health duties for preventing and treating oral diseases, they should also be monitoring their own oral hygiene levels. They should have an increased responsibility to maintain oral hygiene measures themselves and advise patients accordingly.<sup>12</sup> A dentist is required to advise on and to address oral hygiene measures, but it is important for them to realize how important it is to evaluate their personal dental hygiene status on a regular basis.

The reason why dental professionals should strictly observe and adopt optimal oral hygiene practices is that emphasis on the oral health during clinical procedures are part of the integral routine of their work.<sup>13</sup> When they set good standards of oral health care for themselves oral healthcare practitioners would in all probability deliver optimum care to their patients. Moreover, oral health professionals are also responsible for imparting dental education to their students and respective institutes. They are mentors of dental students which are the future of the oral health sector. Any negligence in their conduct not only affects students but also the patients.<sup>12,14</sup>

Some studies concluded the lack of adequate dental health practises amongst the dental professionals exist despite having adequate knowledge and awareness about it. Personal behaviour is a reflection of the individual's beliefs, experiences and teachings. Various studies have investigated the correlation between the attitudes of dental health care providers and improvement of their patient dental care.<sup>15,16,17</sup> The aim of this cross sectional research study was to assess the oral hygiene practices and the self-reported dental status among the dental professionals in Riyadh, KSA.

## MATERIALS AND METHODS

### Ethical approval

The cross sectional research design was used. The study was approved by the ethical committee of the College of Dentistry Research Centre, King Saud University, Riyadh (CDRC # IR 0226). The study was carried out between April 2017 and April 2018.

### Data collection

The required information was collected through a self-administered questionnaire. Some questions of the questionnaire were adopted from previous studies<sup>1,11,12</sup> and modified to suit the requirements of the present study.

The questionnaires along with a cover letter and consent form stating the instructions, rationale and purpose of the survey were distributed by hand to a conveniently selected sample of 400 male and female dental professionals studying and working in various private and governmental clinics and dental schools within Riyadh, Saudi Arabia.

This method was adopted for convenience and to avoid the poor response rate by online distribution. The participants who were willing to participate in the study filled in the consent form and the questionnaire by hand and returned it immediately. There was no time limit for completion of the questionnaire. 275 participants completed the questionnaire with a response rate of 68.75%.

### Questionnaire details

In addition to the demographic details the participants responded to questions related to their oral hygiene practices, past dental history, current dental status, dental appointments and dental condition of their families.

The questionnaire comprised of 25 questions and the participants were requested to select one answer and fill the numbers where required. In addition, they also graded their oral health condition on a 5 point Likert scale as: Excellent; Very good; Good; Fair and Poor.

The last question of the questionnaire was to get information about possible reason/reasons for negligence in oral health care of the participants, which comprised of 10 subsections.

The answers were based on Likert Scale as score of: 0 = Strongly disagree; 1 = disagree; 2 = Undecided; 3 = Agree and 4 = Strongly Agree. The mean score of each question was calculated out of 4.0 with higher the number, indicating more negligence for that particular reason.

### Statistical analysis

The data was analysed using IBM SPSS (Version 21) software. Descriptive statistics and Chi-square tests were used for statistical analysis of the responses considering a P-value of <0.05 as the cut-off level.

## RESULTS

The response rate was 68.75%. Most respondents (81.8%) were males and (18.2%) were females. According to the distribution by groups: 27 (9.8%) were Dental Specialists; 57 (20.7%) were General Dentists; 164 (59.63%) were Dental Students; 20 (7.3%) were Dental Assistants and 7 (2.5%) were Dental hygienists (Table 1).

**Table 1.** Distribution of the study participants by groups and gender.

Groups	Males		Females		Total		
	N	%	N	%	N	%	
Dental Specialist	25	11.1	2	4	27	9.8	
General Dentist	49	21.8	8	16	57	20.7	
Dental Students	1st Year	31	13.8	10	20	14.9	
	2nd Year	23	10.2	5	10	28	10.2
Dental Students	3rd Year	29	12.9	4	8	33	12
	4th Year	25	11.1	5	10	30	10.9
	5th Year	30	13.3	2	4	32	11.6
Dental Assistants	10	4.4	10	20	20	7.3	
Dental Hygienists	3	1.3	4	8	7	2.5	
<b>Total</b>	<b>225</b>	<b>100</b>	<b>50</b>	<b>100</b>	<b>275</b>	<b>100</b>	

The questions used for assessment of the participants' self-reported oral hygiene practices and dental history are presented in Table 2. A significant difference between the responses of the male and female participants was observed for the questions related to the frequency of brushing ( $p=.001$ ) and the history of dental visits ( $p=.013$ ).

The frequency of tooth brushing as well as the time taken for brushing was more for the female participants compared to the males. History of the dental visits and past dental history were not significantly different between male and female participants.

The number and gender-wise percentage of participants' past dental complaints and social habits are presented in Table 3. Comparison using Chi-Square test only showed significant differences between males and females for extractions due to orthodontic treatment.

Differences between the responses related to coffee, tea, soft drink, cigarettes and water pipe (hookah) consumption or use were also insignificant.

The responses of the participants self-reported causes for their damaged dentition are presented in the Table 4. The majority of the participants (64% males and 68% females) agreed on poor oral hygiene to be the cause for their damaged dentition.

The percentage of bruxism causing damage to the dentition was higher in females (24%) than in males (10.7%). Generally, the participants' overall experience with their dental treatment was very good to excellent.

Interestingly the percentage of participants with bad previous experiences of the dental treatment and dental anxiety was also very high (Figure 2). For the oral health of their family members, the participants reported a high percentage of fair oral health (49) (Figure 1).

The mean scores of the possible reasons for negligence in oral health by the participants are presented in Figure 2. The maximum score of 3.5 out of 4 was to avoid cross infection. This reveals that the dental professionals themselves are not confident about the cross infection control measures. The majority of the participants also believed that dental treatment is not very critical.

## DISCUSSION

This study provides information about the oral hygiene practices and the oral health status of a group of dental professionals based on the information collected via a custom-designed self-administered questionnaire. The response rate of the questionnaire (55%) was found to be satisfactory.

Although some studies<sup>1,12-17</sup> have been carried out about the oral hygiene practices and the oral health status of health care professionals, similar studies among the dental professionals are scarce in Saudi Arabia.

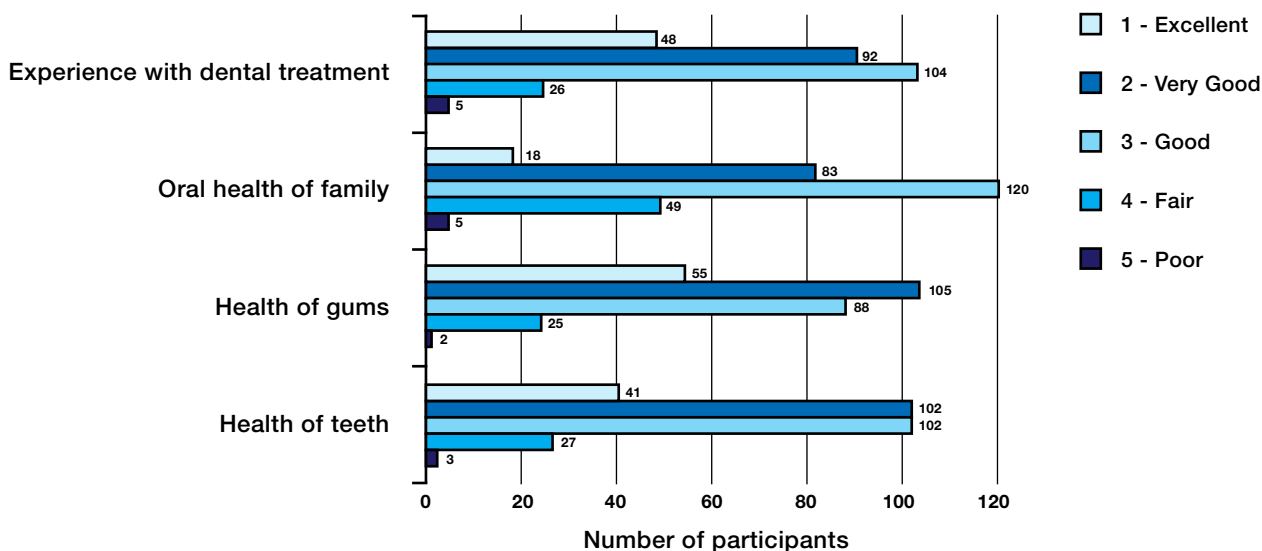


Figure 1. Participants self-grading oral health.

**Table 2.** Bivariate analysis of self-reported oral hygiene practices and dental history of the participants.

Practice	Males		Females		Whole participants		Chi-square p-value	
	N	%	N	%	N	%		
Frequency of brushing teeth	Rarely or never	11	4.9	0	0	11	4	.001
	Once a day	95	42.2	9	18	104	37.8	
	Twice a day	93	41.3	28	56	121	44	
	More than twice	26	11.6	13	26	39	14.2	
Time for brushing	< 1 minute	33	14.7	5	10	38	13.8	.846
	1-2 minutes	112	49.8	26	52	138	50	
	2-3 minutes	57	25.3	13	26	70	25.5	
	> 3 minutes	23	10.2	6	12	29	10.5	
Use of dental aids	Electric toothbrush	31	13.8	11	22	42	15.3	.072
	Toothpick	40	17.8	3	6	43	15.6	
	Mouth wash	80	35.6	26	52	106	38.5	
	Floss	152	67.6	43	86	195	70.9	
	Tongue cleaner	23	10.2	14	28	37	13.5	
	Miswak	37	16.4	5	10	42	15.3	
History of dental visit	Never	40	17.8	3	6	43	15.6	.013
	Occasionally	67	29.8	11	22	78	28.4	
	Emergencies only	50	22.2	8	16	58	21.1	
	Every 6 months	35	15.5	17	34	52	18.9	
	Once a year	32	14.2	11	22	43	15.6	
History of last dental visit	Check up	66	29.3	17	34	83	30.2	.339
	Tooth ache	62	27.6	11	22	73	26.5	
	Bleeding gums	13	5.8	3	6	16	5.8	
	Halitosis	5	2.2	1	2	6	2.2	
	Sensitivity	12	5.3	5	10	17	6.2	
	Mobility	1	.4	2	4	3	1.1	
	Orthodontics	37	16.4	7	14	44	16	
	Scaling/ Cleaning	29	12.9	4	8	33	12	

**Table 3.** Bivariate analysis of self-reported past dental complaints and social habits of the participants.

Practice	Males		Females		Whole participants		Chi-square p-value	
	N	%	N	%	N	%		
Past Dental Complaints	Swelling / infection	29	10.5	22	9.8	7	14	.258
	Halitosis	44	16	39	17	5	10	
	Toothache	139	50.5	111	49.30	28	56	
	Bleeding gums	81	29.50	68	30.20	13	26	
	Gingivitis/periodontitis	110	40	96	42.70	14	28.70	
	Extraction due to peri-	27	9.80	22	9.80	5	10	
	Cariou teeth	241	87.6	197	87.6	44	88	
	Extraction due to caries	58	21.10	48	21.3	10	20	
	Extraction for orthodon-	55	20	38	16.90	17	34	
Smoking /Drinking Habits	Coffee	206	74.9	171	76	35	70	.186
	Tea	182	66.2	149	66.2	33	66	
	Soft Drinks	94	34.2	82	36.4	12	24	
	Cigarettes	60	21.8	58	25.8	2	4	
	Hookah/ Water pipe	45	16.4	42	18.7	3	6	

**Table 4.** Bivariate analysis of self-reported past dental complaints and social habits of the participants.

Self-perceived cause for damaged dentition	Males		Females		Whole participants		Chi-square p-value
	N	%	N	%	N	%	
Poor oral hygiene	144	64	34	68	178	64.7	.359
Smoking	38	16.9	9	18	47	17.1	.496
Carbonated drinks	56	24.9	12	24	68	24.7	.527
Burxism/Clenching	24	10.7	14	28	38	13.8	.003
Congenital	24	10.7	13	26	37	13.5	.006
Incompetent Dentist	29	12.9	6	12	35	12.7	.540

Some limitations were that respondents may not have been 100 percent truthful with their answers due to differences in understanding and interpretation of some questions and they may have been casual while completing the questionnaire as it was lengthy.

Another drawback of this present study was the lack of correlation of self-reported oral health with clinical or laboratory based evaluation. The authors were aware of limitations but still considered the method useful due to its practicability and speedy results. However, the interpretation of the results must be done with caution keeping in view the limitations mentioned above.

The evaluation of the results showed that there were differences in the oral hygiene practices, oral health status and oral health behaviour, between the male and female participants. However, the self-reported oral hygiene habits were excellent among the study participants, with most of the population reporting brushing twice daily. This was however anticipated as the subject population comprised of dental professionals.

Effective tooth brushing and flossing can significantly reduce oral malodour<sup>18,19</sup> and the usage of dental aids such as the electric tooth brush, mouth wash, floss and a tongue cleaner were higher among females when compared to males. This could imply a more conscious attitude among females than among males and was evident from the results as the regular six monthly dental visit was two-fold higher among females (34%) as compared to males (15.5%).

In general, females engage in better oral hygiene behaviour measures, and studies have reported that females possess a greater interest in personal oral health than males.<sup>20</sup> Studies conducted in Lebanon, Thailand, and Malaysia, have also found that female university students have better habits in term of tooth brushing than male students.<sup>21</sup> However, in this study, no significant differences were noted among male and female students.

The results of this study showed the prevalence of dental caries among the male and female participants was the same. However, the percentage of males having gingival bleeding and gingivitis/periodontitis was higher in comparison to females. This finding could be related to the frequency of brushing, which was low among the males as compared to females; or related to the social habits such as smoking of cigarettes and water pipe (hookah) use.

Smoking has many confirmed adverse associations reported in a large quantity of literature ranging from negative impacts in gingival and oral health, to malignancies.<sup>22-25</sup> The percentage of the male smokers (25.8%) was three to four folds higher compared to the females (4%) in this study.

Bivariate analysis of the self-perceived causes for damaged dentition of the participants showed no significant differences between the males and females, except for bruxism/clenching and congenital anomalies. The prevalence of bruxism is found to occur predominantly among females.<sup>26</sup> This is also evident from the results of the study as the percentage of female participants having bruxism was three times higher than the male participants.

Generally, the majority of the participants reported to have had excellent and very good experiences with the dental treatment, oral health of the family and their own gum/teeth health for their self-evaluation of the oral health. This finding is line with the results reported by Al-Wahadni et al.<sup>12</sup>, in which the dental students were found to have more positive dental attitudes and behaviour, such as worrying more about visiting the dentist, having less gum bleeding when brushing their dentition. This might be explained by the fact that dental students receive more professional education in oral hygiene maintenance as compared to the general population and that the dentistry students are introduced to dental clinics very early and intensely during their dental education.

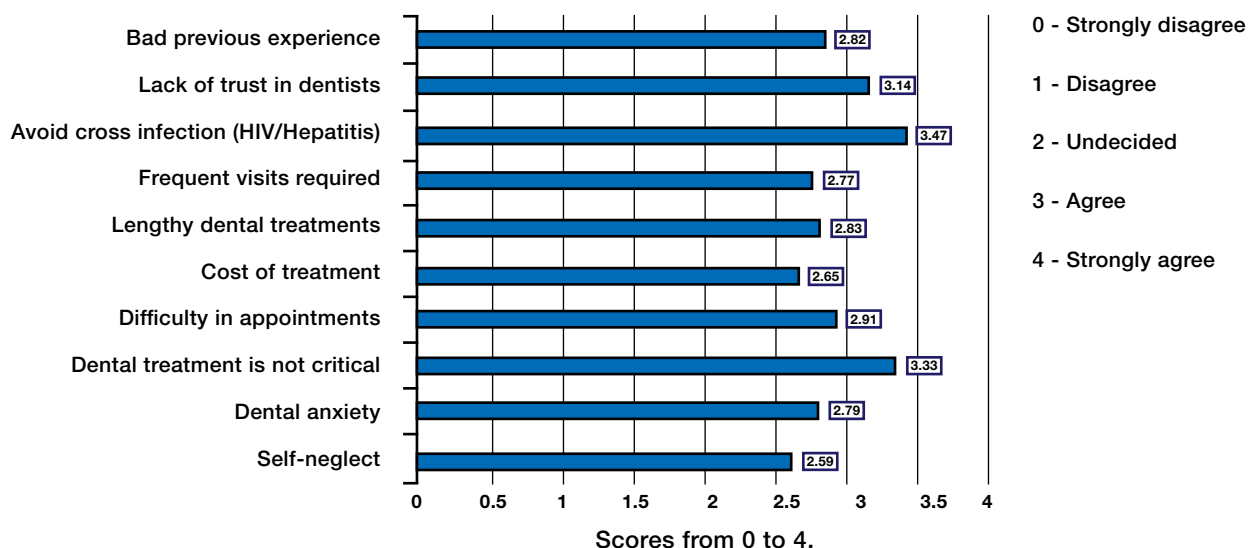


Figure 2. Possible reasons for negligence in oral health by the participants.

There are many reasons for possible negligence in oral health care that directly or indirectly affects the overall oral health status of the individuals.<sup>27</sup> This study identified many reasons for negligence by the participants. Despite being involved in the cross infection control themselves the majority of the dental professionals were reluctant to seek dental treatment because of cross infection fear (Figure 2, Table 4).

Dental treatment which is not urgent, and a lack of trust in fellow dentists were also among the highlighted reasons for negligence in oral health by the participating dentists. Self-neglect was considered the least important reason for personal oral health negligence. These findings are similar to the previous studies conducted by Al Kawas et al.<sup>28</sup>, Al-Hussaini et al.<sup>29</sup> and Halboub ES et al.<sup>30</sup>

Although the current study provides some information on the oral health behaviour among the dental professionals in this group, there is a need for further detailed studies among dental professionals to address this important subject. The factors affecting the oral health care such as fear of cross infection and the awareness of oral health care need to be evaluated and addressed further.

The authors believe that emphasis on dental health care should be developed and maintained during early education and training in order to improve the dental health behaviour of oral healthcare professionals later on. This is a key factor in developing their dental health attitudes and behaviours in order to allow them to have a positive impact on the dental health attitudes and behaviours of their patients.

## CONCLUSION

The results show satisfactory oral hygiene practices and oral health status the participating dental professionals. Gender-based differences among the participants with regards to oral health attitude and behaviour revealed that females were more careful about their oral health. Gingival bleeding/gingivitis and bruxism were prevalent among the male and female participants respectively.

The majority of the participants' poor oral hygiene was the cause for their damaged dentition. Fear of cross infection from the dental treatment, dental treatment that was not critical, and a lack of trust in fellow dentists were the common reasons for negligence of oral health care among the participants.

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# Dental biomaterials: challenges in the translation from lab to patient

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E Patel<sup>1</sup>, YE Choonara<sup>2</sup>, V Pillay<sup>3</sup>

## ABSTRACT

Biomaterials are essential components of modern medicine. Dental biomaterials include any material or device used within the oral cavity for the diagnosis and treatment of oral conditions, diseases, and disorders.

Whilst the literature remains abuzz with innovative and diverse technologies, an apparent disconnect is evident in the follow-through, affecting the impact on current clinical treatment regimens.

This review will explore the product development process from concept to clinical application, in conjunction with the commercial aspects that affect clinical translation.

Though serving the purpose of a roadmap for novice inventors, the primary intention of the paper is to focus on some of the challenges cited in the literature and to highlight factors that delay or, in due course, actually prevent clinical translation of even the grandest inventions.

Clinicians should also be alert to the complexities affecting the arrival in their surgeries of new products and technologies. The ultimate aim is to assist in the decision-making of researchers when they may be initiating novel advances in oral-related therapies, by ensuring they are cognisant of past errors and limitations, whilst at the same time recognizing present hurdles.

## Keywords

Biomaterials, challenges, clinical translation, dental biomaterial challenges, biomaterial commercial challenges.

## ACRONYMS AND FORMULAE

<b>CaP:</b>	Calcium Phosphate, Ca <sub>3</sub> PO <sub>4</sub>
<b>PPA:</b>	Provisional Patent Application
<b>RPA:</b>	Regular Patent Application
<b>USPTO:</b>	US Patents and Trademarks Office

## INTRODUCTION

Biomaterials have become essential components in modern medicine. Advancements in medical technology have led to an updated definition, which, according to the journal *Biomaterials* (Elsevier), may be quoted as: "any substance that is engineered to take a form, which either alone or as part of a complex system, interacts with components of living tissue to direct the course of any therapeutic or diagnostic procedure".

In general, biomaterials are categorized as being either bioinert, bioactive or biodegradable. Bioinert materials do not interact with the tissue/environment in which they are placed e.g. bone screws and plates. In contrast, bioactive materials directly interact with their surrounding environment. Such interactions include those in which the material binds chemically to hard or soft tissue, those which induce the release of a biological substance, or those improving the healing ability of a tissue, etc. The objective of a biodegradable material is to offer distinct advantages for a limited time period. A typical example would be suture materials that degrade at a rate similar to tissue regeneration.<sup>1,2</sup>

There are five major classes of biomaterials; namely: polymers, metals, bioceramics, natural materials, and composites.<sup>3</sup>

## Polymers

Polymers represent the largest class of biomaterials. They may be harvested from natural resources (such as plant and animal materials) or synthesized in a laboratory. Examples of polymers derived from plant material include cellulose and sodium alginate, whereas polymers derived from animals include collagen, hyaluronic acid and heparin. Synthetic polymers are produced by the co-polymerization of conventional monomers. Due to the nature of their synthesis, they can be manipulated to suit almost any environment.

These materials can be biocompatible, hydrophobic or hydrophilic, biodegradable or non-resorbable, and so forth. Their versatility allows for structural changes to occur upon introduction to a biological environment, which is why they are a favoured component of

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3. **Viness Pillay:** Third author - 15%

controlled drug release systems. Examples of synthetic polymers include polyamides, poly (D,L-lactide-co-glycolide) and polyethylene.<sup>4</sup>

### Metals

Metallic biomaterials have been used in medical treatment for over a century. Whilst Lane in 1895 reported the use of metallic plates for fixation of bone fractures, there is archaeological evidence of gold being used in dentistry as early as 1600 BC in Egypt.<sup>5,6</sup> Examples of metal biomaterials include stainless steel, titanium, aluminium and cobalt-chromium (Co-Cr).

The use of these materials has gained much popularity in the fields of Orthopaedics and Dentistry. Biomedical applications in these fields include dental implants, dental prosthetics (denture, crown and bridgework), hard tissue replacements (artificial joints) as well as cardiac implants (artificial vascular stents).

Whilst the metals remain bioinert in most cases, surface modifications (for example, those in dental implants) allow for interaction with the biological system making them bioactive.<sup>7,8</sup>

### Bioceramics

Bioceramics refers to the use of specifically designed ceramics for the reconstruction and repair of damaged or diseased areas of the body. They may be bioinert (e.g. aluminium and zirconia), biodegradable (e.g. tricalcium phosphate) or bioactive (e.g. hydroxyapatite and bioactive glass). Bioceramics are employed in Dentistry for periodontal treatment, endodontic treatment, and maxillofacial reconstruction. Their use in orthopaedics includes, but is not limited to, the treatment/replacement of hips, knees, tendons and ligaments.<sup>9,10</sup>

### Natural materials

Natural biomaterials are further classified as: protein-based (collagen, gelatin), polysaccharide-based (cellulose, chitosan) and tissue-derived (decellularized heart valves, blood vessels) materials. They offer distinct advantages over the synthetic materials, including biocompatibility, biodegradability and remodelling.

In addition, they offer prospects of functioning at a molecular level, as opposed to the macroscopic level. However, due to their complex structure, more intricate strategies are often required for their manipulation to achieve the desired function.<sup>11,12</sup>

### Composites

Composites refer to biomaterials that contain two or more constituent materials or distinct phases. They are either synthetic (such as dental composite filling materials) or natural (such as bone). They may also be either particulate or fibrous, or both, in nature.

Similar to polymers, a major advantage of composites is the ability to manipulate the manufacturing process to yield the desired material properties. These materials can be employed in both hard and soft tissue applications including: dental restorations, bone fracture repair, joint replacement, wound dressings, implants and grafts.<sup>4,8</sup>

### The product development process

The development of a novel biomaterial requires several steps prior to its use in clinical treatment.

Figure 1 outlines a generic timeline from conceptualization to application in patient treatment.

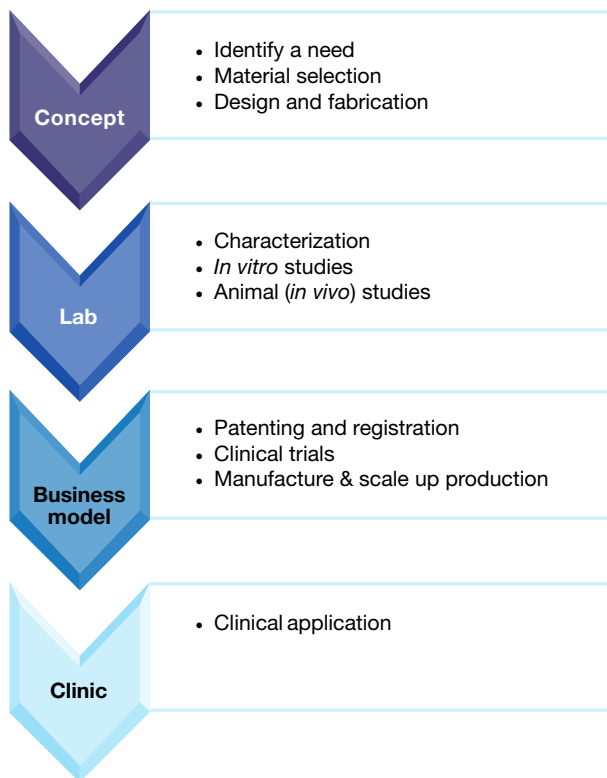


Figure 1. Schematic representation of the translation process of the pre-final version of SA POQL tool.

### Concept

#### a. Identifying a need

The conceptualization of a novel biomaterial is the foundation of the development journey. To identify a need within a specific treatment modality, or to recognize a gap within the current literature, the researcher/scientist requires a certain level of expertise in the chosen field of study.

The creativity and open mindedness of the researcher at this initial phase is conceivably the greatest limiting factor. Great inventions are reliant on the ideas and ambitions of workers in the field, who identify and explore new areas to improve and augment current medical strategies. An additional factor that hinders the beginning of the journey is the perceived disconnect between clinician and scientist.

Often we find that the clinician is in fact the scientist and it is in those cases that many great ideas are conceptualized. Whilst scientists possess the knowledge of materials and their capabilities, it is the clinicians who will recognize shortcomings within their respective fields. Collaborations are thus important to yield discussions that will cultivate innovative strategies for improved and enhanced patient care.

## b. Material Selection

The dynamic environment of the oral cavity requires a concerted effort from oral biologists in the unveiling of its intricate mechanisms. Biomedical engineers attempt to replicate these processes using biomaterials.

Clinicians then assist in the translation of these materials to patient treatment.<sup>13</sup> In the hope to hasten clinical application, scientists often choose to use for their novel inventions constituents which had been previously approved by regulators.

There are stringent criteria governing the selection of constituents which may be incorporated in dental biomaterials. These criteria stem from the expectations of functions in a complex environment. Materials exposed to the oral cavity are constantly bathed by saliva and its components including enzymes (salivary amylase) and immunoglobulins (IgA). Sporadic thermal changes may also occur during mastication when ingested food and liquids come into contact with these materials.

Periodontal materials are bathed by crevicular fluid and possibly constituents of the inflammatory process (should the tissue be injured by disease or otherwise). Whilst materials used in endodontic treatment are protected from the effects of the oral cavity at large, they function in an anaerobic environment with little or no fluid.

This affects biodegradable materials which usually require a catalyst to drive their degradation. An additional subset of dental biomaterials includes those used within bone such as dental implants. These materials are subject to innate and humoral immune responses and often come in close contact with adjacent blood vessels.

Nanotechnology is one of the cornerstone achievements of dental biomaterials. Dental nanomaterials offer several functions including: antimicrobial activity, mechanical reinforcement, aesthetics and therapeutic effects.<sup>14,15</sup> Nanoparticles such as silver, zinc oxide and titanium dioxide are utilized in endodontic, restorative and implant treatments for their antibacterial properties.

Other nanoparticles such as gold have been used as radiosensitizers, photothermal agents and drug delivery carriers. Apprehension around these materials usually stems from technical challenges (related to agglomeration that hinders expected properties) and a failure to fully understand their possible toxicity *in vivo*.

An important example of a dental nanomaterial is calcium phosphate,  $\text{Ca}_3\text{PO}_4$  (CaP). CaP is often utilized for dental applications due to its biocompatibility, bioactivity and composition which is comparable to mineralized tissue (bone and teeth). A major component of natural mineralized tissue is carbonate apatite which is a form of CaP.<sup>16</sup>

Whilst CaP's are osteoconductive, they lack the ability to induce bone *de novo*. Thus, periodontal and maxillofacial applications for these materials require the addition of bioactive proteins, growth factors and osteogenic drugs to enable inductive properties.<sup>17</sup>

The particle size of the CaP's must also be accounted for. Particles exceeding 200 nm in size may lead to excessive entry of calcium ions in to cells endangering homeostasis. The challenge to maintain these CaP nanoparticle sizes occurs following drug incorporation where maintenance of the size within range is difficult.<sup>17</sup> As previously described, polymers represent the largest class of biomaterials and have been employed in several materials. Natural polymers such as chitosan, hyaluronic acid, alginate, fibrin and collagen etc. are derived from natural sources. A major advantage of this subgroup is their biocompatibility and biological activity which is often manipulated in tissue engineering for cell adhesion and growth.<sup>18</sup>

The shortcomings of natural materials relate to their low mechanical strength which makes them difficult to engineer, and restricts processing and manufacturing capabilities. In addition, batch variability and the risk of pathogen transmission negatively impact decisions to use this polymer subgroup.<sup>13</sup>

Synthetic polymers have overshadowed the natural materials due to their apparent advantages including well-defined chemistry and formulations, ease of processing, tunable degradation kinetics and function-specific manipulation.<sup>19</sup> Then again, the synthetic variants are not inherently biocompatible and often provoke unsolicited inflammatory responses.

The magnitude of this inflammatory response is often driven by the heterogeneity, surface topography, and physical and chemical properties of the material.<sup>1</sup> Efforts to overcome this challenge are usually linked to the attachment of biomolecules to reduce the cytotoxicity of the material.<sup>20</sup> One such example is the addition of sodium phosphorylated chitosan to reduce the cytotoxicity of zinc oxide nanoparticles.

An additional group of polymers that have gained popularity, with a greater intensity observed in associated research, are "smart" or "intelligent" polymers. Smart polymers offer trigger-related drug delivery and are sensitive to changes in temperature, light, pH, magnetic field and ionic strength.<sup>21-23</sup> Smart polymers that have a low critical solution temperature are valuable drug delivery agents for fever and/or local infections and are therefore employed as thermo-sensitive biomaterials.

A prior challenge for thermo-sensitive polymers was to create a biodegradable material that functioned (with a release of the drug) at just above normal body temperatures.

This requirement was supposedly solved, with excellent prospects for thermo-sensitive polymers.<sup>24</sup> However, the intra-oral applications for these materials may still be limited in areas of poor thermal control (e.g. the dental root canal space).

Similarly, light-activated smart polymers require the patient to maintain the device in a dark environment to prevent premature drug release. This phenomenon has been termed "dark toxicity" and is an additional concern for light activated smart polymers.<sup>25</sup>

## Design and fabrication

Once the appropriate materials have been chosen for incorporation into a novel biomaterial or drug delivery device, the scientist must then decide on a suitable design and method of fabrication. Whilst the particular methods of synthesis may be generic for most materials, the clinical requirements often guide deviations from the norm. Moghanjoughi et al. listed some of the disadvantages of controlled drug delivery systems that hinder clinical translation.<sup>23</sup>

Amongst the factors were possible dose dumping, cytotoxicity, delayed onset of action, increased risk of hepatic first-pass metabolism, high manufacturing costs, and surgical procedures which may be required for insertion or removal of the device/material. To counter these factors, the design and fabrication process often requires remodelling to yield the desired clinical results. However, manufacturing costs may then increase, placing further strain on the possibility of clinical translation.

Fabrication methods are based on the functions for which the material is intended. Examples of oral drug delivery devices include: tablets, sprays, mouthwashes, gels, patches, pastes and wafers/films. These formulations are dependent on trans-mucosal delivery of the active constituent and must offer practicality, adequate drug release, and most importantly, patient acceptability. Drug release is directly dependent on the ability to penetrate the oral mucosa's epithelium, whilst factors that deter patients from accepting a new drug include disturbances to eating, taste and speech.<sup>26</sup> More recent technologies to aid trans-mucosal delivery include permeability enhancers, absorption enhancers, enzyme inhibitors, drug delivery vectors (liposomes & polymericosomes) and muco-adhesives.

Muco-adhesive drug delivery systems present an additional domain in fabrication methods. Within the confines of the oral cavity, these systems include: mucosal patches, films, gels and ointments. These systems boast many advantages over their systemic counterparts including; prolonged adhesion that enhances absorption (further amplified by the blood circulation of the region), a faster onset of action, increased drug bioavailability due to no first-pass metabolism, decreased drug degradation in the acidic GIT environments and improved patient compliance.<sup>26,27</sup> However, they are not exempt from the complexities of the oral environment. Differences in the degree of keratinization and epithelial thicknesses across the varying mucosal surfaces lead to diverse permeabilities which in turn affect drug absorption rates and bioavailability.

The buccal mucosa is considerably less permeable than the sublingual mucosa, which decreases absorption and bioavailability. On the other hand, the sublingual mucosa is uneven, mobile and constantly washed by saliva making it an unsuitable area for muco-adhesion.<sup>28</sup> A compromise is thus made with current systems that utilize the buccal mucosa. Novel inventions must account for these shortcomings if they are to improve current therapeutic standards.

Fabrication methods incorporating surface modifications of biomaterials to improve properties such as biointegration have gained momentum. Padovani et al. described the possible difficulties experienced whilst optimizing the concentration of nanoparticles at the implant surface.<sup>15</sup> They inferred that an overactive rate of drug of nanoparticle/drug release could produce toxicity that would result in necrosis of healthy cells.

Furthermore, León & Jansen described the non-uniform deposition of CaP coatings on bone screws when techniques such as sputter deposition, pulsed laser deposition and ion beam deposition were used.<sup>29</sup> A recent method, biofabrication, attempts to incorporate cells into biomaterial constructs that enhance cellular attachment, migration and growth.

Biofabrication may also serve as a method for controlled drug delivery and release. However, at present, there is no engineered substitute generated by such biofabrication techniques that can be scaled up for clinical use.<sup>30</sup>

Larry Hench, the father of modern bioactive glass and ceramics, admitted that whilst dozens of ceramic compositions are tested *in vitro*, few ever achieve clinical application.<sup>31</sup> He further explained that the clinical success of these materials requires the simultaneous achievement of similar mechanical behaviour between the material and tissue, coupled with a stable interface at the connective tissue juncture. In addition, the complications of these materials were linked to their failure to maintain strength and stability during the material degradation-tissue replacement phase of healing.<sup>31-33</sup>

Requiring the resorption rate of the material to match the repair rate of the biological tissue, while ensuring that the material consists only of metabolically acceptable elements, has imposed considerable limitations on the composition, design and fabrication of these bioactive materials.<sup>31-33</sup>

Electrospinning is a technique used to synthesize continuous nanofibers from various polymers such as polycaprolactone (PCL), polyethylene oxide (PEO) and poly-L-lactic acid (PLLA). Electrospun nanofibers have been explored for use in endodontic disinfection, tooth regeneration, caries prevention, mucosal and wound repair, implant modification and tissue guided regeneration.<sup>34-36</sup> Several limitations with electrospinning as a technique have been reported in the literature, as well as with their resultant fibres.

Electrospinning requires the use of solvents and cross linking agents for which *in vivo* biocompatibility may not be well established.<sup>37</sup> Degradable synthetic polymers yield acidic by-products (during degradation) that cause inflammation in the region of their implantation.<sup>38</sup> In addition, electrospun materials are mechanically weaker than their cast membrane counterparts and do not provide an ideal structure for dental regeneration applications requiring cellular infiltration. This is attributed to the technique yielding random unwoven mats and pore sizes, as well as not being able to fabricate micron size fibres.<sup>39,40</sup>

Furthermore the production efficiency of these fibres is quite low, complicating scale up production and clinical translation.<sup>36</sup> However, the plausible advantages of electrospun scaffolds for dental therapies warrant further investment and research.

Multiple fabrication methods and technologies have been described over the years. More recent advances include additive manufacturing techniques which incorporate selective laser sintering, robocasting, stereolithography, fused deposition modelling and three dimensional (3D) printing.<sup>41</sup> The motivation to employ such technology in Dentistry is driven by the opportunity for patient-personalized models.

At present, 3D metallic and ceramic constructs have been explored for implants, crowns and bridges using biocompatible polymers. Biological constructs including DNA plasmids, peptides, proteins and polysaccharides have also been described for use in tissue engineering therapies such as periodontal regeneration.<sup>42,43</sup>

Dental laboratories, on the other hand, have employed 3D printing for dental wax ups, orthodontic patterns, crown and bridge moulds, prosthodontic casts, etc.<sup>44</sup> Whilst the indications for 3D printing are promising, the current laser- and inkjet-associated bioprinting techniques offer low output, with print speeds around 5kHz, limiting manufacture to small scale.<sup>45</sup>

Furthermore, biological scaffolds are plagued by challenges facing the degradation kinetics and by the by-products of materials, due to the mass transport limitations that occur in thicker scaffolds.<sup>43</sup> Thus, prior to encouraging the use of a 3D printed construct in clinical practice, factors such as: material costs, production volume and speed, energy costs, long-term construct performance, etc., must be evaluated and compared with traditional fabrication methods.<sup>46</sup>

## Laboratory studies

### a. Characterization and *in vitro* studies

*In vitro* studies involve testing of a novel material following successful fabrication and characterization. *In vitro* cytotoxicity tests are an essential component of biocompatibility screening, with several tests being used to ascertain the effects of a material on cell membrane integrity, cell growth and enzyme activity, or genetic expression.<sup>47</sup>

Examples of *in vitro* studies found in the dental implant literature include cell adhesion assays, cell proliferation assays and cell differentiation assays.<sup>48</sup> Epithelial and fibroblast cell lineages are often chosen for biocompatibility evaluation, as ultimately these are the cells in contact with a majority of dental materials.<sup>49</sup> Of special note here is that the cell phenotypes used in culture must match those found *in vivo*.

These cultured cells must be monitored not only for cell death, but for changes in their cell cycles, differentiation, and molecular biology. These are of utmost importance to account for cellular modifications that may occur following exposure to a material or device.<sup>50</sup>

Anselmo & Mitragotri reported that whilst a plethora of preclinical studies described cellular interactions related to the introduction of inorganic nanoparticles, experimental conditions could not be normalized, leading to questionable and inconclusive claims.<sup>50</sup> Thus, the results of biocompatibility studies must be viewed prudently especially for studies that do not acceptably simulate the oral tissue and oral environment.

Novel biomaterials require methodologies for investigating the reaction between the material and living tissues. There is no one-size-fits-all in this regard. Dental materials must account for the interactions with the tissues they encounter, which are specific to the function of the material. These include enamel, dentine, bone, periodontal ligament, and the varying oral mucosal tissues (depending on the site of action).

Materials utilized within tooth structure must be characterized according to their effects on the enamel and dentine. Those meant to bond with dentine often undergo testing for surface mechanical properties.

One such example is the modulus of elasticity which may be measured by nano-indentation tests or, by more conventional, three-points bending tests. Whilst nano-indentation boasts superior precision by quantifying changes in the submicron surface depth, it is unable to measure overall change in the dentine as a whole and is acutely affected by dentine surface roughness (which may be altered during specimen preparation).<sup>52</sup>

In order to establish an accurate biological profile for a particular material, a combination of qualitative and quantitative tests should be employed. This is necessary as, if used alone, tests may contradict one another, yielding completely different conclusions. An example of this requisite can be found in the studies by Camp et al.,<sup>53</sup> Tawil et al.,<sup>54</sup> and Torabinejad and Abu-Tahun.<sup>55</sup>

Camp compared the cell attachment properties of Mineral Trioxide Aggregate by using quantitative attachment tests with fluorescent dye.<sup>53</sup> The same test, when later compared with *in vivo* histological examinations, yielded the controversial findings reported in the studies by Tawil<sup>54</sup> and Torabinejad.<sup>55</sup>

Ding and Ma emphasized the inefficiencies with *in vitro* and *in vivo* studies in tumour research.<sup>56</sup> They explained that the several barriers to tumour drug delivery require an in-depth understanding of the molecular mechanisms of translocations in varying pH environments. It is not possible to reproduce these environments without that knowledge in place. Gjorevski et al. highlighted the importance of reproducing the mechanical environment in devices functioning within the extracellular matrix and its components.<sup>57</sup>

The authors acknowledged that these environments are often difficult to establish and control in culture, in spite of recent advances in synthetic analogs and stem cell research. Hence, in the absence of this knowledge, results from *in vitro* studies must be interpreted with caution.

Hench expressed concern that many materials are introduced to the clinic without lifetime prediction tests.<sup>31</sup> He reinforced the need for standardized test methods to determine the lifetime performance of materials (specifically bioceramics) under realistic physiological stresses, including grain-boundary attack and slow crack growth.<sup>31,33</sup>

Chai et al. in their review of CaP-driven osteogenesis, highlighted the difficulties of translating intricate *in vivo* osteogenic environments to *in vitro* systems.<sup>58</sup> The authors cautioned against the reliability of predictions and the correlation of *in vitro* results to what may actually occur *in vivo*.

Their argument was based on key issues relating to the selection of cell types and culture conditions for specific CaP-based materials. Moreover, blood vessel infiltration and body fluid composition and dynamics pose technical challenges to translation from *in vitro*.

Ultimately, the aim of *in vitro* studies should be to develop human cell-based tests that are predictable, cost-effective and appropriately reliable. This will decrease the dependence of using *in vivo* animal tests to establish product safety, which in itself poses many ethical and economic concerns.

#### a. *In vivo* studies

*In vivo* studies require the selection of an appropriate animal model. The selected model should mimic human physiology as closely as possible so that appropriate conclusions can be drawn. In addition, a full description of the animal model design and evaluation (including microbiology, radiopathology and histopathology) should be available in order that the efficacy and feasibility of the material/device be established relative to current therapeutics.<sup>59</sup>

Animal ethics clearance must be obtained from the appropriate Animal Ethics Committee/s prior to initiating any animal study. Researchers may select an appropriate animal model for tests, but it is not always possible to gain approval based on the specific ethical guidelines of the relevant country. This may hinder the selection of the best suited model which at times may lead to questionable correlations and assumptions, which in turn will affect and delay approval for clinical trials.

Examples of animal models identified in the literature include monkeys, beagle dogs, pigs, rats and sheep.<sup>60</sup> Furthermore, promising studies in mice and rats must also be translated to higher animals such as pigs, dogs and sheep to confirm the translational potential of prior results.<sup>13</sup> Pigs, in particular, share higher sequence homology with *Homo sapiens* making them a superior choice for animal study (as opposed to mice and rats).<sup>61</sup>

An additional challenge to *in vivo* studies is the requirement to reliably and reproducibly induce the same condition/s for which the experimental material/device will be indicated. An example of this necessity was explained by Jackson et al., whereby osteoradionecrosis was reliably reproduced in the mandibles of athymic rats, whilst minimizing any sources of error and variation.<sup>62</sup>

Rosa et al. demonstrated the successful regeneration of pulpal tissue when transplanting human roots in the subcutaneous tissue of mice.<sup>63</sup> However, the authors recognized the inability of this model to completely simulate clinical conditions such as the presence of stem cells in the apical papilla. Furthermore, Guilak et al. observed that a majority of the current *in vivo* models simulate only normal tissue.<sup>64</sup> Advanced disease and degenerative processes lead to major compositional and/or structural changes, which then require complex simulation models *in vivo*.<sup>64</sup> Failure to achieve such environments accounts for the poor correlation of such studies to human disease.

The oral cavity poses a greater challenge to biomaterials than most other aspects of the human body. *In vivo* elucidation of the effects of mucosal contact, pH and the buffering capacity of saliva are required to negate any possible toxicity of the materials in this environment.<sup>15</sup> In addition, materials exposed to the oral cavity are at risk of pellicle formation on their bare surfaces. Whilst there are advantages to pellicle formation, minimal colonization with pathogenic bacteria is always desired.

Pellicle formation interferes with the physicochemical surface properties of a material, and may act as a hindrance to materials possessing functions of ion and/or drug release. Furthermore, bacterial invasion may lead to infection and suboptimal tissue integration decreasing the lifespan of the device.<sup>65</sup> Hence, low-energy surfaces are desirable to reduce these phenomena.<sup>66</sup>

Biomaterials intended for long term survival (such as dental restorations) face the challenge of water uptake, hydrolytic degradation and hygrothermal degradation.<sup>67-69</sup> These phenomena lead to surface softening, exposing susceptible bonds which then become targets for oral enzymes, thus promoting further destruction of the material.<sup>70</sup> Whilst water-repellant monomers have been explored, they are unsuitable due to their extensive curing time.<sup>71</sup> Studies have proposed an antibacterial-laden monomer on the surface of oral biomaterials with the aim of preventing these challenges. However, to date, no such commercial product exists, possibly due to the augmented water uptake effect that may occur.<sup>72</sup>

*In vivo* studies are crucial to ascertain the effects of proposed biomaterials in a well simulated tissue environment. Researchers must strive to select and develop clinically appropriate animal models that will generate predictive data that closely correlates to human disease, which in turn will streamline the process to clinical trials.

#### Business model

Biomaterials have been an area of great research activity with numerous novel ideas and inventions being developed in the past decades. Yet, the number of products reaching clinical therapeutics is limited.

Whilst researchers, scientists and inventors are able rapidly to develop prototypes in their laboratories, they may at times lack the business acumen to ensure the progression of their inventions. There are several as-

pects of the business model, each with its own hurdles, which must be fulfilled prior to clinical entry. For the purposes of this review, we have categorized them as patenting, registration, clinical trials, manufacture and scale up production. An additional factor to consider in the business model is cost. Cost will not be featured separately but will be discussed alongside every other facet of the model.

#### a. Patenting and registration

Novel inventions must be patented to protect the intellectual property of the inventors. Intellectual property refers to the any idea born of the intellectual creative efforts of an individual or team. It can be owned, licensed or transferred.

Forms of ownership include copyright, trademarks, utility patents, design patents, plant patents and trade secrets. This ownership is fundamental to ensuring the development and growth of a specified field, as well as granting companies expanded business and financial opportunities.<sup>73</sup>

Pressman provides useful definitions in his book “Patent It Yourself”, to familiarize one’s self with patents.<sup>74</sup> An **invention** is “any new article, machine, composition, or process or new use developed by a human”. A **patent application** is “a set of papers that describe an invention and that are suitable for filing in a patent office in order to apply for (or in the case of a Provisional Patent application, establish a date to apply for) a patent on the invention”. Furthermore, a **patent** is defined as “a grant from a government that confers upon an inventor the right to exclude others from making, using, selling, importing, or offering an invention for sale for a fixed period of time”.<sup>74</sup>

The regulations and laws around patenting of an invention must be well understood by the research team to ensure successful patents. Firstly, the inventor must ensure that the invention satisfies the “novelty” and “unobviousness” requirement of the Patent and Trademark Office (PTO) examiner. Second, the inventor must cognisant of the “First-to-File” law which came in to effect in March 2013.

Under the provisions of this law, should two inventors submit an application for the same patentable invention, the patent will be awarded to the person who files first, irrespective of who initially conceived and tested the invention. Exceptions are only entertained in cases where one inventor can prove the unlawful acquisition of the invention by the other inventor. Third, and of great importance, is timing. Researchers must register a patent application to secure their intellectual property prior to any research publications.

This refers not only to journal publications, but any form of conference or congress proceedings, meetings, etc. Once the invention is made public, it loses novel status and the patenting process is placed in jeopardy.

The only country that grants a one-year grace period for the submission of a patent application following public disclosure, is the United States of America.

An additional factor the inventor must be mindful of is that the registration of a patent is region and/or country specific, with no mutually agreed standardised guidelines. Some countries, like South Africa, allow for non-examinable patents whereas others, such as the US Patents and Trademarks Office (USPTO) and European Patents Office (EPO), examine patents prior to granting them. The disadvantage of a non-examined patent is that errors and over-extended claims may go undetected.

Patents that have unjustifiably broad claims also hinder future research and development in the field. Some inventions may not even meet patentable criteria (‘sub-patentable inventions’).<sup>75</sup> The research team must identify all of the countries in which they wish to register their patent and apply as required. The researcher may then pursue publication once the patent application has been successfully filed.

There are two types of patent applications: a Provisional Patent Application (PPA) and a Regular Patent Application (RPA). The benefit of a PPA is that it grants an earlier filing date prior to building and testing an invention and does not count toward the 20 year patent term. However, no amendments or additions may be made to the PPA once filed and the earlier filing date is only valid if the description of the invention is legally sufficient.

The inventors must bear in mind that PPA’s are not examined, have no legal grounds other than the filing date, and require the RPA be filed within one year following the initial PPA.<sup>74</sup> Figure 2 outlines the process for obtaining a utility patent as described by the USPTO on their official website.<sup>76</sup>

Recent partnerships between academic laboratories and pharmaceutical companies have augmented fundamental drug delivery research, patenting and registration and the resultant translation to improved clinical therapeutics.

Once a prototype is patented and, and preclinical studies confirm its function and value, inventors will look to the US Food and Drug Administration (FDA) for regulatory approval. The FDA poses an enormous barrier to the clinical translation of new materials and devices.

The FDA’s Office of Medical Products and Tobacco houses three centres of regulation; namely: the Centre for Drug Evaluation and Research (CDER), the Centre for Biologic Evaluation and Research (CBER), and the Centre for Devices and Radiological Health (CDRH). New materials must pass through clinical trials, which often extend over a 6-12 year testing and review period, involving thousands of patients with resultant costs escalating to the hundreds of millions of dollars.

Start-up companies, funded by venture capitalists, are at their highest risk during this process. The risk of inventions failing to gain FDA approval, coupled with poor initial sales (failing to overcome production costs) are often factors cited for the shutting down of small companies. One such example is the company Organogenesis (Canton, MA) who launched Apligraf Ò skin equivalent.



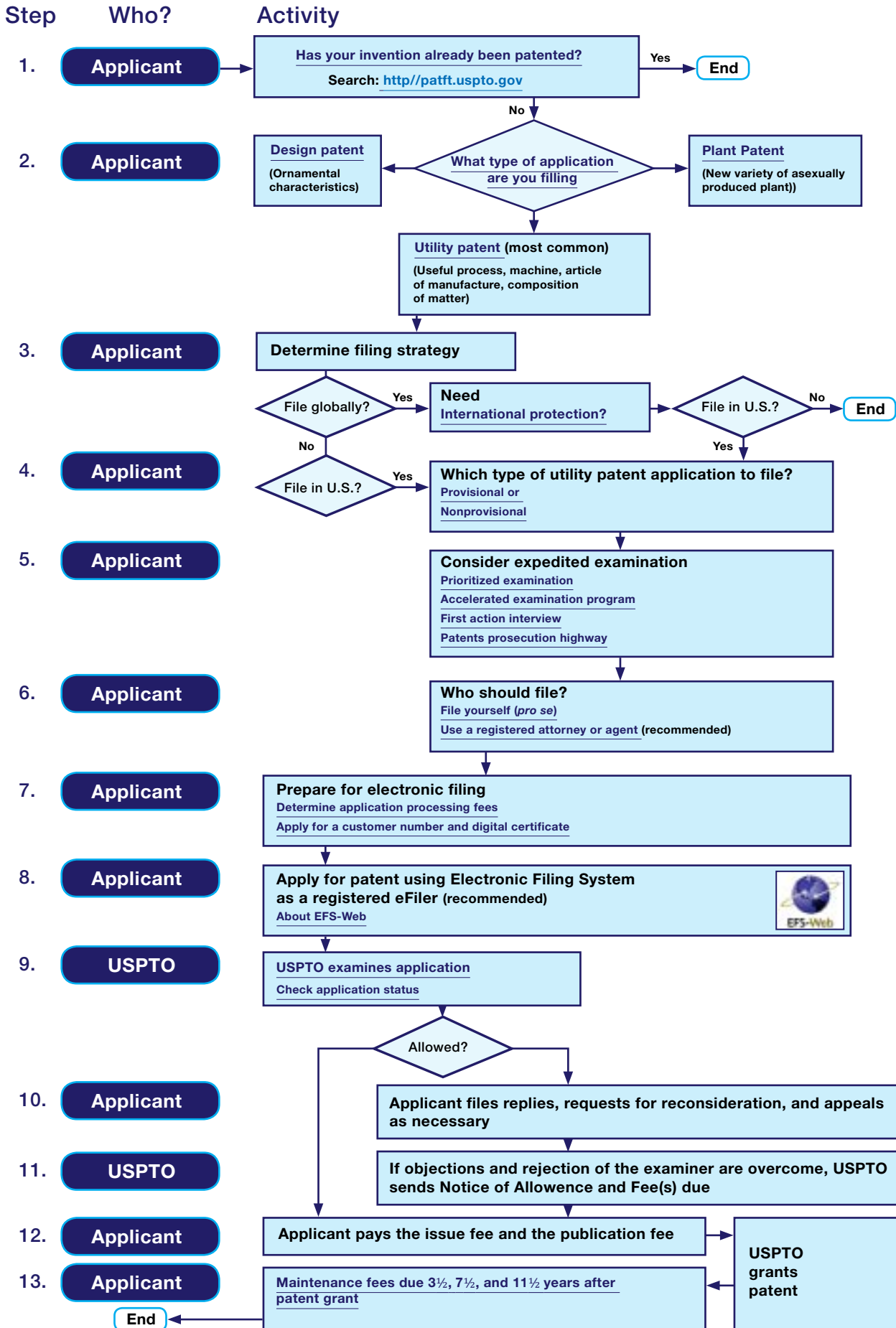


Figure 2. Process for Obtaining a Utility Patent (Reproduced from the USPTO, 2015).

Whilst the product gained regulatory approval, market sales failed to achieve profits leading to the company filing for bankruptcy in 2001.<sup>77</sup> Lysaght et al. further described 18 other companies that either filed for bankruptcy or simply closed their doors following devastating results from their clinical trials, combined with irredeemable financial losses.<sup>77</sup> Hence, both new and existing companies must take into account that the uptake of their product in the market will be gradual. Whilst high profits may be attained, but in all likelihood that will be over a period of several years.

### b. Clinical trials

Following successful *in vitro* and *in vivo* tests that establish manufacturing standardization, efficacy and safety of an invention, ethical clearance is acquired for human clinical trials. The main objective of clinical trials is to confirm the safety and efficacy of the invention in humans. These are then followed by an application for regulatory approval of commercial sales of the invention which is submitted to the appropriate regulatory authority, for example, the FDA.

Anselmo and Mitragotri aligned the success of clinical translation of an invention to it being safe, performing its desired function, offering convenient administration and easy fabrication.<sup>51</sup> Whilst numerous inventions are explored at laboratory level, few develop to clinical products.

The failure to obtain regulatory approval for clinical trials may be attributed to limited *in vitro* and *in vivo* data, and perhaps short-sightedness on the part of inventors in not completely understanding the biological mechanisms of the regions in which the invention will be applicable.<sup>78</sup> A restriction of clinical trials is that study samples are limited to tissue biopsies, swabs or fluid aspirates. Animal (*in vivo*) studies, on the other hand, allow for endpoint microbiological and histological examinations of the tissue, enabling more rigorous analysis.<sup>59</sup>

Regulatory approval requires a satisfactory set of pre-clinical data backed up by equivalent *in vivo* (animal) data. A large quantity of animal data may at times be required, which escalates costs. In addition, the clinical trial in itself poses a severe cost factor which is difficult to predict. One such prediction required for approval is survivability, which for inventions such as implants, must be established for 3-5 years.<sup>33</sup>

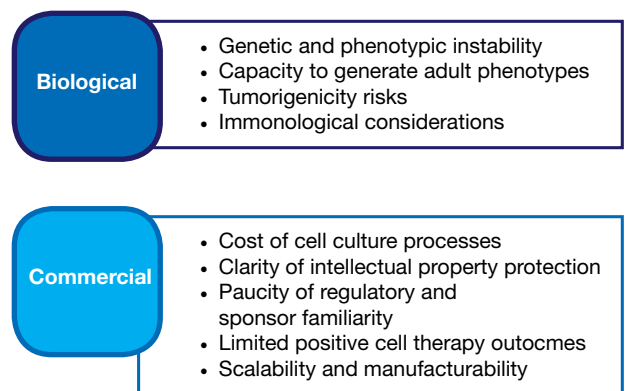
French et al. explored the use of human pluripotent stem cells to address unmet clinical needs.<sup>79</sup> They identified two companies, Geron Corporation (Menlo Park, California) and Advance Cell Technology Inc. (Santa Monica, California), who were the first to evaluate the safety of embryonic stem cells in clinical (patient) trials.

Whilst not all of these trials ran until completion, the exercise proved educational for the researchers and for the regulatory authority. The authors noted several regulatory challenges to the clinical translation of stem cells (depicted in *Figure 3*) and concluded that uncontrolled irreproducibility and variability were the key factors hindering clinical therapeutics.

### c. Manufacture and scale up production

Reaching this stage of the business model sheds first light on clinical entry. No doubt, the monetary investment of the invention has surpassed millions at this stage and it is in the interest of the investors to push forward. At this juncture, the calculation of potential cost/profit and risk/reward ratios are not yet possible and the decision to proceed is based on the confidence of all those concerned.

Furthermore, the company launching the products needs to survive through to the realisation of profit. The phase from breaking even to realizing acceptable profit margins must be accelerated and is frequently a challenge for smaller businesses. However, money aside, the manufacture and scale up process comes with its own challenges.



**Figure 3.** Regulatory challenges to successful clinical translation of stem cells (adapted from French et al., 2015)

Laboratory synthesized inventions face severe engineering challenges in their scale up to safe, reproducible, clinically effective, and economically stable designs.<sup>80</sup>

The sale volumes of inventions are dependent on the cost of production and the resultant price to consumer. These prices must be within an acceptable range to ensure buy-in from the market and consequent patient benefit. Furthermore, inventions that require additional procedures (such as surgery) may initially be frowned upon unless the market demand is high and the invention is replacing alternatives that are more expensive.<sup>81</sup>

A plethora of inventions are usually synthesized within laboratories, by researchers and scientists who themselves drive the processes. These manual methods of fabrication make scaling up difficult. One such example is cell-based therapies that rely on manual seeding and culturing of scaffolds, which is inefficient, time-consuming and operator dependent.<sup>82</sup>

An opportunity presents here for synergistic collaboration between large companies and scientists to remodel and automate fabrication methods that ensure successful scale up. This requires the development of reproducible and consistent techniques that will optimise manufacturing processes, and enable an increase in production volumes whilst reducing costs.

Schiller et al. (2015) described a novel focused ultrasound technique to manufacture nanoparticles which could possibly serve as a tool to enhance clinical translation of such particles.<sup>83</sup> Additive Manufacturing (AM), also known as rapid prototyping, is another example of a developed technique that guarantees standardisation of the manufacturing process, and allows for the fabrication of materials that meet stringent performance criteria for clinical use, whilst offering the flexibility to scale up fabrication.<sup>30</sup>

Ramshaw et al. stressed that straightforward purification processes are required to display the scalability of products, whilst Langer and Peppas also highlighted the issue of immunogenicity and purification (of contaminants) during large scale production.<sup>84,85</sup> Strategies for the preservation, packaging and distribution of the invention must also be developed at this stage due to their financial impact on the final product.<sup>64,81</sup> Luong et al. demonstrated dry storage strategies for bioactive hydrogels that yielded adequate shelf life, when appropriate stabilization was employed.<sup>86</sup> It is worthwhile considering and improving these factors prior to the application for clinical trials. Clinical trials pose a major financial burden on the company, and further escalate the price of the emerging product.

The constituent materials of an invention may also affect the manufacturing process. A reproducible invention requires consistent properties of the constituent materials. Unfortunately, due to the differing production processes between the various suppliers, companies may be left with no choice but to select a sole supplier. This introduces an additional risk factor to the manufacturing process, in that suppliers may raise material costs, or unexpectedly close down.<sup>51</sup> While a brief explanation of natural and synthetic polymers has already been given, it is necessary at this point to discuss some of the reservations around the use of natural materials.

The natural variability of animal tissue preparations has led to concerns regarding their purity, predictability of performance, and the possibility that disease transmission that may occur.<sup>84</sup> In addition, though having been proven to be safe and effective, some natural materials (such as bovine collagen) have indeed induced adverse immune reactions in a small percentage of patients.<sup>87</sup> These shortfalls have been countered by more recent advances in genetic recombinant technology which offers scientific superiority in designing biologically complex structures.

Other advantages include standardized product quality and ease of isolation and purification with no risk of cross infection. However, the initial setback of this technology is that a thorough knowledge of the genetic sequence is required before it can be employed.<sup>88</sup> Furthermore, commercial scale production of recombinant technology is more difficult to achieve and requires evaluation of the manufacturing and economical processes.<sup>81</sup> A good example to demonstrate the importance of these mechanisms is the product Nutropin®, a recombinant growth hormone for paediatric application.

The product acquired FDA approval in 1999 and was marketed by Genentech. However, Nutropin® was discontinued in 2004 for reasons associated with its high costs and protracted manufacturing process, two weeks being required to synthesise each batch.<sup>89</sup>

### Clinical application

Accomplishing clinical entry is a great achievement for any material or device. No doubt, by this time, millions have been invested in the product and the investors will be anxious about the market response. However, the success of previously introduced novel products may offer some solace. One such example is Abraxane®, for which the company reported a 52 percent year-on-year increase with a value of \$649 million.<sup>90</sup>

One of the final challenges to clinical entry is to gain buy-in from the end users. Clinicians are often resistant to change and will be unlikely to try a new product in the absence of quality assurance. This poses a challenge to companies introducing novel inventions in that the data displayed by the company is often seen as biased, with clinicians looking to other sources for confirmation of the proposed claims for the inventions. Studies in which a conflict of interest exists are commonly distrusted as the authors are supposedly seen as biased toward the product. One approach of the dental companies has been to approach university faculty staff to assess the claims of an invention. This has led to independent research that either confirms or refutes the claims of the product and which seeks to confirm reproducible results whilst satisfying the required clinical criteria. Padovani et al. suggested that for dental restorative materials, the important factors for consideration must be the results from long-term studies, post-operative sensitivity, retention of prosthodontic restorations and marginal sealing ability.<sup>15</sup> Thus, further clinical studies are always recommended to augment understanding of the mechanism of action of each material within the dynamic oral cavity.

Additional factors to consider are cost and product comparison. Novel products must outperform their existing counterparts, at a competitive cost not considerably greater, if they are to be accepted by clinicians. Companies often approach leading clinicians in a field to test their inventions (free of charge).

Should the chosen clinicians provide positive feedback, they are invited to become the face of the new product to drive acceptability and incorporation of the novel material or device in to clinical treatment modalities.

### CONCLUSION

In 1987, Williams defined a biomaterial as a nonviable material used in a medical device, intended to interact with biological systems.<sup>91</sup> Material science has come a long way since then and newer definitions are being offered with every passing year to account for novel advances in clinical medicine.

A substantial part of the literature still reports five fundamental classes of biomaterials, namely: natural materials, polymers, metals, bioceramics and composites. However, the boundaries of these individual classes have blurred with combinant technology that draws on the strength of differing materials to yield innovations of superior character.

A deep understanding of the product development process is mandatory when conceptualizing novel ideas. It is imperative that the end-goal of clinical translation be borne in the minds of researchers when they contemplate the materials, designs and fabrication methods for novel inventions. A thorough understanding of the biological complexities found in both physiological and pathological environments enable the design of appropriately suited dental biomaterials. The limitations of manual production methods should also be recognized, with an emphasis placed on automated manufacturing processes to assist product scale up. Utilizing approved constituent materials in conjunction with standardized fabrication methods are examples of strategies which are effective in accelerating the development process.

The commercial viability of products must be gauged at the point of invention to protect intellectual property, following approval by regulatory authorities. In addition, a substantial monetary investment is required for the successful translation of novel products. This burden remains a major hurdle for start-up companies, who cannot always absorb the delay in market response.

Whilst several obstacles to successful clinical translation have been highlighted in this review, none are beyond resolution. Collaborations must be encouraged between clinicians and scientists that may yield discussions which will cultivate innovative strategies for improved and enhanced patient care. Biomaterial science is a crucial element in the advance of all clinical disciplines.

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## Do the CPD questionnaire on page 53

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.

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- 4 Select the questionnaire that you wish to complete.
- 5 Enter your multiple choice answers. Please note that you have two attempts to obtain at least 70%.
- 6 View and print your CPD certificate.

# Cross-cultural adaptation of the Paediatric Oral Health-Related Quality of Life (POQL) tool in South Africa - a pilot project

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Y Malele Kolisa<sup>1</sup>, PJ van Wyk<sup>2</sup>

## ABSTRACT

### Aims and objectives

To translate and adapt a paediatric oral health-related quality of life (POQL) questionnaire into the South African languages of Sepedi, IsiZulu and Afrikaans.

### Methods

The POQL-version: Parent-Report-on-child was translated twice into local languages. Translated-versions were revised and back translated into English by the different language-experts. A pre-final draft South African-version of POQL was tested on parents at the Pretoria Oral & Dental Hospital (n=94). Impact-scores were calculated, chi-squared and t-tests were used to determine construct validity. Principal component analysis was used to determine structural validity.

### Results

Responses were recorded in a 5-Likert-type scaling but could not be replicated in the manner of the original-tool. Seventy percent of responding parents were female and 53% were employed with significant differences between male (62%) and female (38%), ( $p < 0.05$ ). The male-parents were significantly older (40-yrs. vs. 35-yrs.;  $p < 0.05$ ).

Most (61%) children had consulted the hospital for 'non-emergency' care. Internal consistency in the pre-final version was good with a Cronbach  $\alpha$ -score of 0.91. Component analysis of the pre-final SA-tool, produced multiple different dimensions when compared with the 4-dimensions of the original tool in the American setting.

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2. Phillipus J van Wyk: Secondary author - 40%

## ACRONYMS

OHRQoL: Oral Health-Related Quality of Life  
POQL: Paediatric Oral Health-Related Quality of Life

## Conclusions

The piloted pre-final SA version displayed good internal consistency yet had weaknesses with content, structural and construct validity.

## Keywords

Dental health, children oral health, oral health-related quality of life, socio-dental indicators.

## INTRODUCTION

The importance of assessing oral health-related quality of life (OHRQoL) has been widely recognised in Medicine,<sup>1</sup> because the subjective patient-based quality of life measures give more insight into the effect of disease on communities. Oral health has physical, economic, social and psychological consequences for society.<sup>2</sup> The latest national children oral health survey in South Africa (SA) revealed a high caries prevalence in four, six and 12 year-olds and up to 55.1% of the caries remains untreated.<sup>3</sup> Such high prevalence of disease may add to social problems and it is thus essential that socio-dental indicators are incorporated into health surveys in South Africa.

Developing children's OHRQoL is important as children are a major focus of dental public health. Measuring children's OHRQoL allows for an evaluation of their oral health status and of treatment efficiency.<sup>4</sup> There are several validated OHRQoL tools specifically developed for children including the Paediatric oral-health-related quality of life (POQL).<sup>5</sup>

Pilot studies are often useful and are recommended to address several important aspects of research including preliminary instrument development.<sup>6</sup> Conducting a pilot study does not promise success in the main study, but it does increase the chances as it forecasts what might/might not happen.<sup>7</sup>

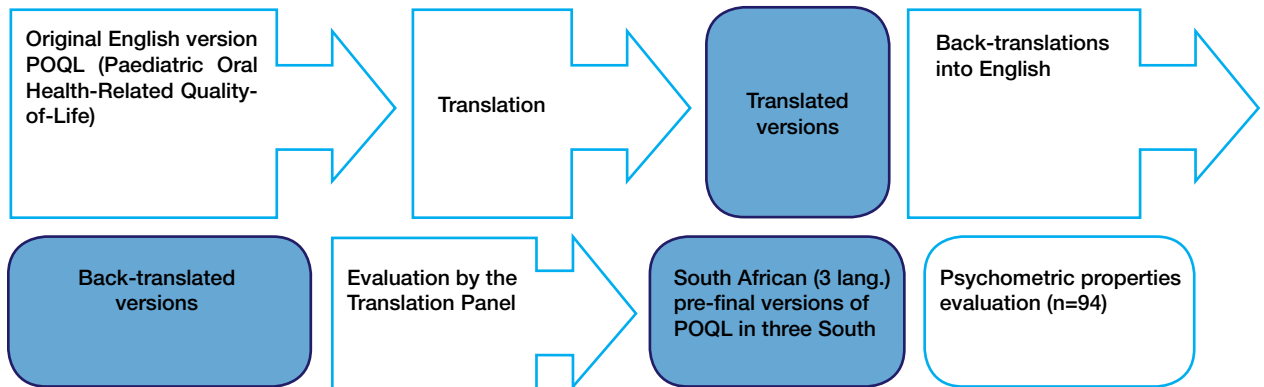
The online database search on the PubMed revealed that most of the validated tools specific to children's OHRQoL and dentistry were developed in English,<sup>5,8</sup>

and have been translated into the Portuguese<sup>9</sup>, Spanish<sup>10</sup>, Kiswahili-Tanzania<sup>11</sup>, Dutch<sup>12</sup>, Thai<sup>13</sup> and Chinese<sup>14</sup> languages. The current unavailability of children's OHRQoL tools in South African languages implies that the majority of the population would have to be excluded in any survey, resulting in systematic bias<sup>15</sup> necessitating either development of such tools or a translation with possible adaptation of the tools.

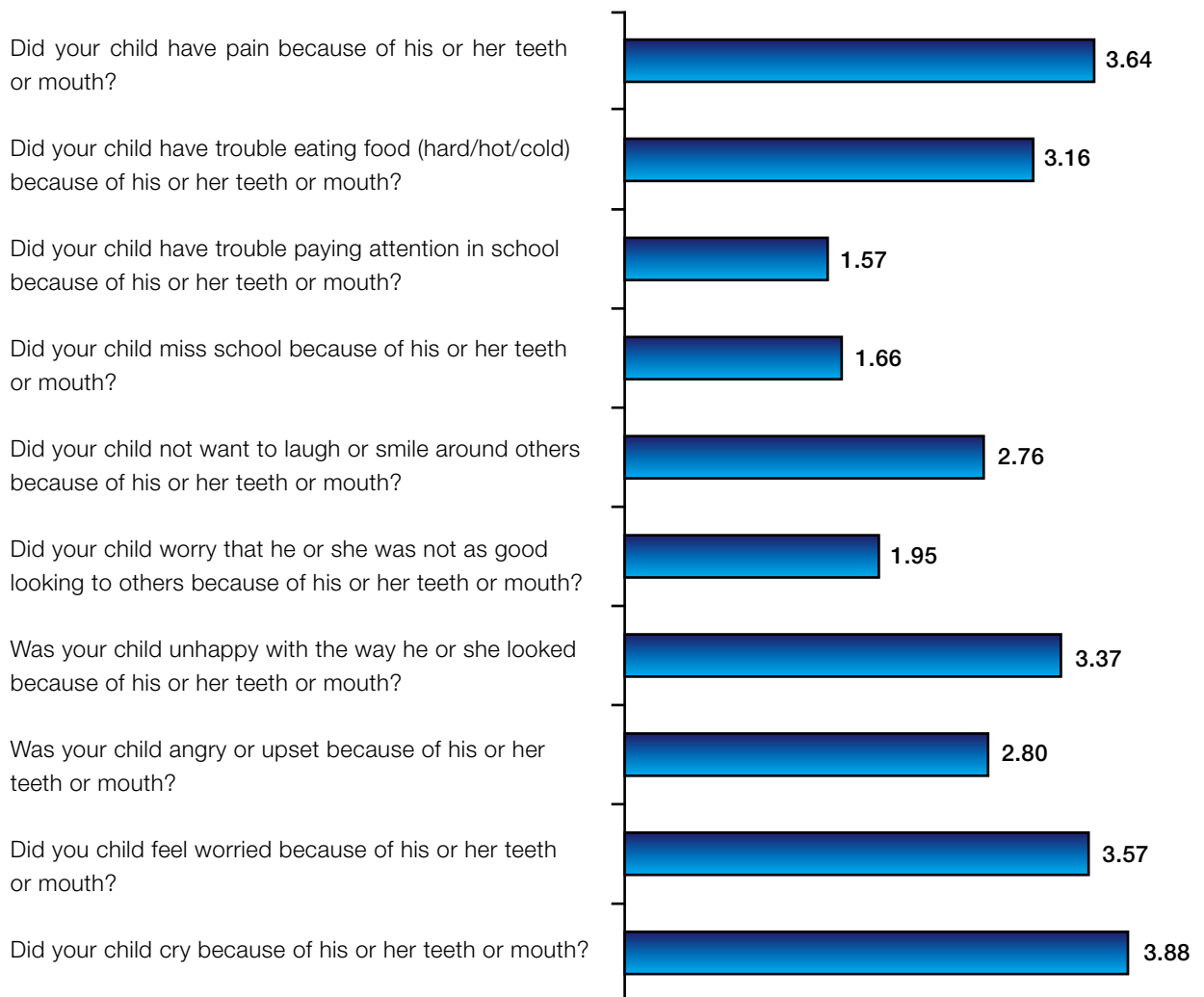
Cross-cultural adaptation is imperative when a tool is to be applied in a different culture, language and country,<sup>15</sup>

but must result in a product which maintains relevance between source and target. Therefore, the guidelines of cross-cultural adaptation prescribe that further tests should be conducted on the psychometric properties of the adapted questionnaire after translation.

The aim of the present pilot study was to translate and culturally adapt a paediatric oral health-related quality of life (POQL) measure for those South Africans who speak the Sepedi, IsiZulu and Afrikaans languages.



**Figure 1.** Schematic representation of the translation process of the pre-final version of SA POQL tool.



**Figure 2.** Impact scores for 10-item questionnaire for all languages.



## METHODS

In preparation for a broader regional study, this pilot study was undertaken to ascertain the suitability of the pre-final version instrument for this population.

### The qualitative process

#### Description of Pediatric oral health-related quality of life (POQL)

POQL is a measurement tool developed with an explicit emphasis on the experiences and views of children and parents from low-income or minority populations.<sup>5</sup>

The premise behind the conceptualization of the tool is that economic and cultural differences in oral health attitudes and beliefs are important enough to warrant a specific measure of OHRQoL applicable especially to the low-income or minority population where rates of disease are usually the highest.<sup>5</sup>

The POQL consists of two versions: Parent Report on Child version (PCR) which includes a Parent Self-Report and has 10 items, and the Child Self Report (CSR8-14 years) with 10 items.<sup>5</sup> The latter has four dimensions, namely: - Physical Functioning, Role Functioning, Social Functioning and Emotional functioning. The response choices on "How often did the event happen?" were described by a four dimensional Likert-scale: *all of the time, some of the time, once in a while and did not happen*.

The question "How bothered were you by the event?" was also asked for the same item, with five Likert-scale responses: *very bothered, somewhat bothered, bothered a little bit, never bothered and did not happen*.

The PCR and CSR versions of the POQL were found to show a strong sensitivity to change<sup>16</sup> and deemed valid and reliable for use in preschool, school-age and preteen children. Appropriate translation of the tool into other languages is the important recommended next step in testing the POQL.

#### Adaptation and translation of POQL

The two POQL versions (Parent Report on Child including Parent Self-Report and Child Self-Report) were each translated twice into the Sepedi, IsiZulu and Afrikaans languages.

Translation was performed for Afrikaans and IsiZulu by experts in the Department of Languages in the University of Pretoria and for the Sepedi questionnaire by the Department of African languages, University of South Africa.

The documents were then revised and back-translated into English by different language experts in the same departments. A committee of experts, comprised of dentists and dental specialists within the School of Dentistry who could read and write the language, together with the language experts in the previously stated departments, formed a Translation Panel to review the back-translation (Figure 1).

Two versions of the POQL in each of the three languages were obtained and were severally unified per language, leading to the pre-final versions of South African POQL documents. These translated questionnaires were tested by three groups of the parents of paediatric patients, each group speaking one of the three languages. Focus group discussions were held when they visited the Pretoria Oral and Dental Hospital.

In addition, individual interviews were conducted to solicit feedback on how well the oral health issues, initially included in the English versions, were understood by the different populations. The participants were asked to express opinions on how easy it would be for the general population speaking the specific language to understand, and feel at ease, with the translations used in the questionnaire.

During these interviews, comments on the wording, contextual meanings and format were also achieved. The resulting version of the instrument was evaluated in terms of presentation and content validity by a panel comprised of the same experts who had participated in the initial phase.

## ANALYSIS

### Psychometric evaluation

The three pre-final versions were subjected to psychometric property evaluation of the questionnaire items. The item scores were calculated by multiplying the 'how often' response (0-3) by the 'how bothered' response (0-4) to give the 'Impact score' with the possible range being from 0 to 12. Higher scores indicated poorer OHRQoL.

The questionnaires also sought responses on self-rated oral health (poor to excellent), the oral condition of the child and socio-demographic data such as age and employment status of the parent. Descriptive and factor analyses were done using SPSS version 20.

Chi square and t-tests were used to calculate the difference between variables. Construct validity was evaluated based on comparison of the total scores among groups according to categories of oral conditions (non-emergency & emergency) and one way ANOVA was used to determine the differences in the impact scores between groups.

Scale scores for the four dimensions of the POQL were created by calculating the mean scores for the questionnaire items. Categorical principal component analysis was used to determine the structural validity by identifying whether the translated tool would have dimensions the same as those originally found in the English questionnaire.

Cronbach's Alpha( $\alpha$ ) was used as a measurement of internal consistency in the responses. The measure assesses whether the set of items share enough variation to support the notion that they measure the same general construct, and produce comparable scores.<sup>26</sup> Indices of reliability are often used in the early stages of developing a multiple-item measurement, to ensure

the degree of homogeneity and to determine if all the items measure a common concept. Items are added, removed, and modified, according to whether the indices of reliability improve.

The  $\alpha$ -scores of 0.7, 0.8 and 0.9 means the reliability is acceptable, good and excellent, respectively. Very high reliabilities (0.95 or higher) are not necessarily desirable, as this indicates that the items may be entirely redundant.<sup>17</sup>

## RESULTS

### Qualitative phase

Responses were recorded in a 5-Likert-type scaling in the original English questionnaire but could not readily be transferred to the translated SA languages tool.

There were discrepancies with the local vernacular with regards to ordering of the responses from 'bothered a little bit' to 'somewhat bothered'.

These two seemed to mean the same in the local dialect. However, with regards scaling, direct translation was not critical as the aim was to write the response

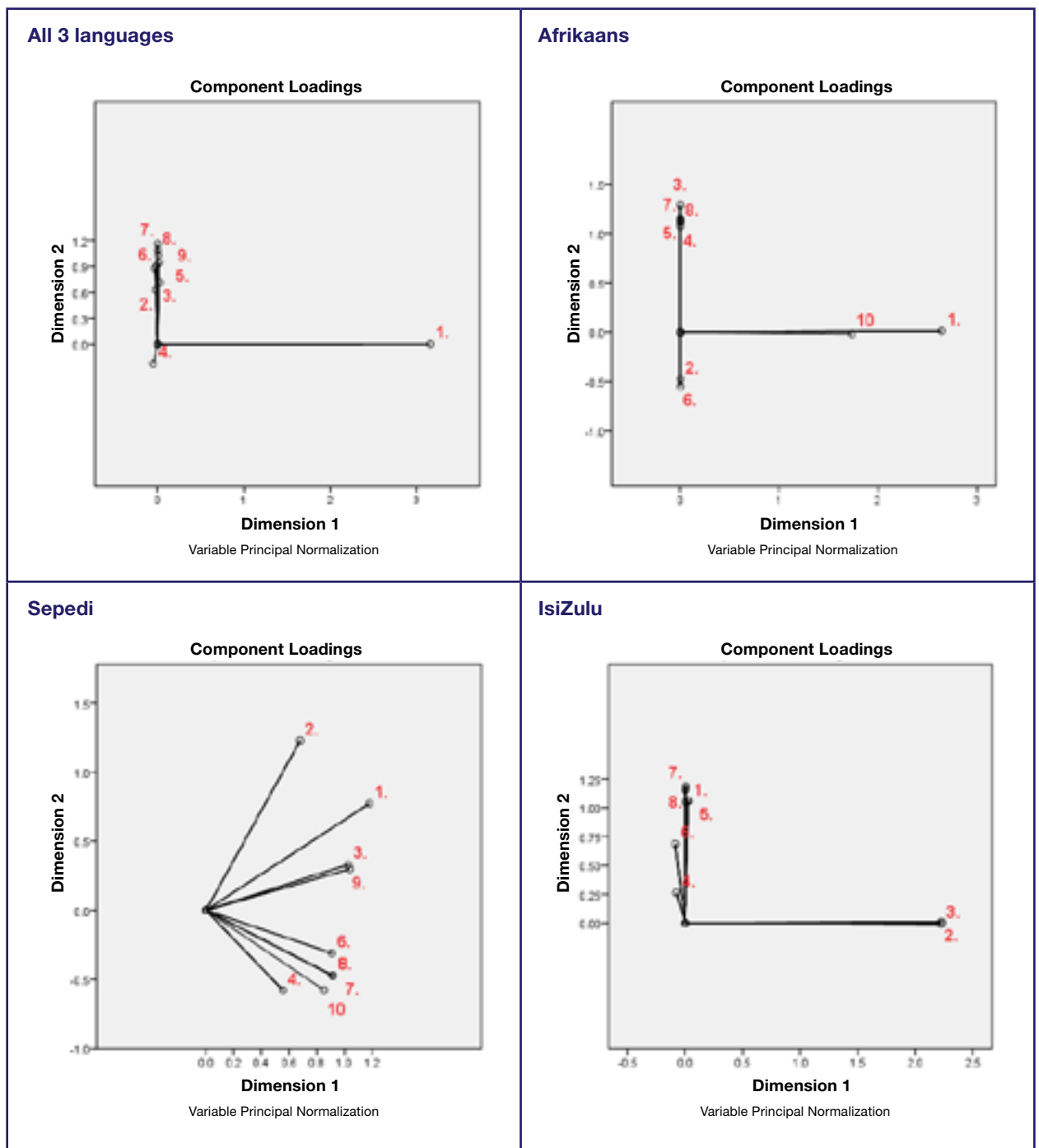


Figure 3. Categorical component analysis with different variables to the original questionnaire.

in an ordinal manner from the lowest to the highest ranking. ‘Somewhat bothered’ was left as ‘bothered’ which on the scale was less than ‘very bothered’. The Afrikaans version did not have the same challenge.

There were no single words in IsiZulu/Sepedi languages to describe some of the dental procedures e.g. root canal; crown; orthodontic braces/space maintainers; fissure sealants. An attempt was made to explain the terms in ‘phrases’ for ease of comprehension but short enough to not clutter the questionnaire.

Feedback from the Afrikaans speaking parents were that the word ‘herstelling,’ intended to mean a ‘dental filling’ was understood by others to mean ‘repair’ which might be confusing when relating to natural dentitions. It was decided that an explanation would be necessary during the interview process when applying the questionnaire to make sure it was understood.

Table 1 represents the characteristics of the pilot sample, which was composed of mostly employed female parents. All children were about 10 years old and mostly female. Most (61%) children had consulted the hospital for ‘non-emergency’ care. The ‘non-emergency’ care implied consultation for preventive and orthodontic treatment. There were significant differences in the self-rating of health between ‘very good to excellent’

and the lower ratings namely: poor-fair-good regarding items 1 and 3 in Table 2 (p<0.05).

The majority (58.5% [20.2% and 38.3%]) of parents rated their children’s oral health to be good to excellent which implied a good oral health related quality of life. This was in concord with impact scores calculated from the individual 10-item questions and the four dimensions of the PQOL scores. When the calculated score was low it indicated a good OHRQoL (1-4=good, 5-8= average, 9-12 = poor) Table 2 & Figure 2.

Internal consistency in the pre-final version was good with the Cronbach  $\alpha$  - score of 0.91. In order to Assessment of the structural validity of the tool required that it produced the same dimensions as the original four dimension POQL namely: physical, role, social and emotional functions. After categorical component analysis the pre-final SA tool produced multiple different dimensions unlike the original setting (Figure 3). There were two (Zulu), three (Afrikaans) and more than four (Sepedi) dimensions/components and all had different item loadings (Figure 3).

Construct validity refers to whether a scale or test measures the construct adequately. Table 3 depicts the measure of construct validity where the association between POQL scores and the responses to the type of

**Table 1.** Characteristics of the pilot sample.

Parents	Subgroups							
	Afrikaans Questionnaire (AQ)		Zulu Questionnaire (ZQ)		Sepedi Questionnaire (SQ)		Total	
<b>N</b>	30		33		31		94	
<b>Employment Status, % (n)</b>								
Unemployed	70	(21)	18.2	(6)	54.8	(17)	44	(47%)
Employed	30	(9)	81.8	(27)	45.2	(14)	50	(53%)
<b>Gender, % (n)</b>								
Female	83.3	(25)	60.6	(20)	67.7	(21)	66	(70%)
Male	16.7	(5)	39.4	(13)	32.3	(10)	28	(30%)
<b>Parent Age in years, Mean (SD)</b>	38.43	(9.01)	38.39	(6.01)	35.71	(6.44)	37.52	(7.3)
Children	Coefficients		Std. Err.		p value		[95% Conf. Interval]	
<b>N</b>	30		34		31		95	
<b>Child's Age Mean (SD)</b>	11	(1.8)	10.1	(1.8)	10.1	(1.8)	10	(1.8)
<b>Child's Gender</b>								
Female	23		21		10		54 (57%)	
Male	7		13		21		41 (43%)	
<b>Child's oral condition/reason for consultation</b>								
Emergency	7		19		11		37 (39%)	
Non-Emergency	23		15		20		58 (61%)	

**Table 2.** Self-rated oral health (Parent report on child).

	Poor-Fair	Good	Very Good-Excellent	Total	p-value
1. How would you rate your child's health in general?	19 (20.2%)	21 (22.3%)	54 (57.5%)	94	<0.05
2. In general, how would you rate the health of your child's teeth and mouth?	39 (41.5)	19 (20.2)	36 (38.3)	94	>0.05
3. Compared to one year ago, how would you describe the health of your child's teeth and mouth now?	20 (21.3)	12 (12.8)	62 (66)	94	<0.05

dental condition (non-emergency or emergency) was assessed. There was no difference in the quality of life when comparing emergency and non-emergency dental conditions.

## DISCUSSION

Improvements in the systems and information on quality of life methods have been good for both clinical dental research and in the evaluation of oral health programmes.<sup>18</sup> Availability of OHRQoL tools in non-South African languages might result in the exclusion of an important part of the population... in 2001 only 9.6% of South Africans were English first-language speakers.<sup>19</sup>

Such an exclusion due to language could result in systemic bias.<sup>15</sup> The present study sought to translate and adapt a paediatric oral health-related

quality of life (POQL) questionnaire into the South African languages of Sepedi, IsiZulu and Afrikaans.

Pilot studies are often essential and are therefore endorsed by scholars for several reasons, including development of a preliminary instrument.<sup>6,7</sup> Depending of the purpose of the study, a representative sample of thirty from the population of interest is usually regarded as a rational minimum recommendation for a pilot study where the objective is preliminary instrument development<sup>6</sup> or adaptation, as is in the case in the current study.

### Translation & adaptation

Cross-cultural adaptation looks at both language and culture issues in preparing a questionnaire for another setting. Translation of the integral meaning from the original English source questionnaire was achieved

**Table 3.** Construct validity item scales associated with a dental condition of all translated pre-final tools.

Dimensions in original questionnaire	Questionnaire item	Dental condition type	N	Mean rank	Level of significance
Physical functioning	1. Did your child have pain because of his or her teeth or mouth?	Non-Emergency	49	3.7	0.9
		Emergency	46	3.6	
		Total	95	3.6	
Physical functioning	2. Did your child have trouble eating any foods (hard/hot/cold) because of his or her teeth or mouth?	Non-Emergency	49	3.3	0.64
		Emergency	46	3.0	
		Total	95	3.2	
Role functioning	3. Did your child have trouble paying attention in school because of his or her teeth or mouth?	Non-Emergency	49	1.9	0.19
		Emergency	46	1.2	
		Total	95	1.6	
Role functioning	4. Did your child miss school because of his or her teeth or mouth?	Non-Emergency	49	1.4	0.37
		Emergency	46	1.9	
		Total	95	1.7	
Social functioning	5. Did your child not want to laugh or smile around others because of his or her teeth or mouth?	Non-Emergency	49	3.3	0.11
		Emergency	46	2.2	
		Total	95	2.8	
Role functioning	6. Did your child worry that he or she was not as good looking to others because of his or her teeth or mouth?	Non-Emergency	49	2.1	0.64
		Emergency	46	1.8	
		Total	95	2.0	
Physical functioning	7. Was your child unhappy with the way he or she looked because of his or her teeth or mouth?	Non-Emergency	49	3.7	0.35
		Emergency	46	3.0	
		Total	95	3.4	
Physical functioning	8. Was your child angry or upset because of his or her teeth or mouth?	Non-Emergency	49	3.2	0.26
		Emergency	46	2.4	
		Total	95	2.8	
Role functioning	9. Did your child feel worried because of his or her teeth or mouth?	Non-Emergency	49	3.9	0.3
		Emergency	46	3.2	
		Total	95	3.6	
Role functioning	10. Did your child cry because of his or her teeth or mouth?	Non-Emergency	49	4.0	0.82
		Emergency	46	3.8	
		Total	95	3.9	

with an acceptable degree of accuracy for all three target languages.

The internal consistency was good within the three languages, as shown by a satisfactory Cronbach's alpha of 0.91. That in the original source questionnaire was 0.86.<sup>5,17</sup>

The translation of the questionnaire experienced challenges in extracting the precisely the same meaning in the Sepedi and the isiZulu languages regarding the scaling of the responses from the lower order to the higher order rankings. There were discrepancies with regards the ordering of the responses from 'bothered a little bit' and 'somewhat bothered'.

The concepts seemed the same in the local dialect. Poor translation may lead to an instrument which is not equivalent to the initial instrument.<sup>15</sup> Equivalent ranking was achieved for the present pilot as direct verbatim translation was not critical. The aim was to write the response in a scaled manner from the lowest to the highest ranking order.

In addition, semantic equivalency was achieved on other parts of the questionnaire after compromises were made in explaining original English terms like "dentures, fissure sealant, crown, orthodontic braces" in phrases in the Sepedi and the isiZulu languages as there were no single word equivalents.

Explaining terms verbally in simple language proved to be helpful when translating an equivalent tool; Oral Impacts on Daily Performances (OIDP) into Afrikaans in Western Cape, SA<sup>21</sup>. However, in the current study, participants understood what was implied by these phrases and this result was considered satisfactory.

The subsequent step after translation and adaptation is conducting a psychometric properties test. An assumption is often made that equivalency between source and target instrument will ensure psychometric properties like validity and reliability at an item or scale level, but, according to Beaton et al., this is not necessarily the case.<sup>15</sup>

The pre-final versions in the present study did not display good structural validity. Treating the variables as ordinal, two to four variables clustering along two dimensions emerged when using categorical principle components. Assessment of the structural validity of the tool required that it produced the same dimensions as in the original<sup>5</sup> four-dimension POQL, namely: physical, role, social and emotional functions. The SA tool setting in fact produced multiple different dimensions after categorical component analysis unlike the original setting.

There were two dimensions in the isiZulu, three dimensions in the Afrikaans and more than four in the Sepedi tool and all had different item loadings (Figure 3). This result, however, should be regarded with caution as it could be due to only a few components loading because of the pilot sample size. This provides hope that in the broader studies the results could be different.

Alternatively, different structural validity could be caused by inherent differences in the cultural or contextual understanding of the concepts even after equivalent translation. For instance, items 7 and 8 in the original tool were assigned to the Social Functioning dimension and yet when one looks at the content of the questions they seem to measure emotions and therefore could have been thought of, in another culture and context, as measuring the Emotional Functioning dimensions.

By examining the relationship between the type of dental condition and the OHRQoL score using an analysis of variance, it is possible to establish the existence of a relationship between the OHRQoL and the construct, in order to assess construct validity.

Parents rated the oral health of their children to be good and this might be explained by the fact that most children did not consult for pain but rather for preventive visits and for orthodontic reasons. This rating was congruent with the good OHRQoL scores. The finding renders the tool as displaying poor construct validity for this pilot phase because it failed to elicit the changes different dental conditions may have on the OHRQoL. Perhaps in a different setting where patients have consulted for pain-related conditions, the tool may have teased out the differences on POQL scores. The POQL used in a setting of low-income and minority American setting proved to have good construct validity when applied to a larger sample.<sup>16</sup>

## CONCLUSION AND RECOMMENDATION

According to the literature, pilot studies are likely to be under-discussed and under-reported due to their very nature of being small studies.<sup>20</sup> However, it is equally important to ensure that lessons learned with respect to the pilot phases are shared, otherwise tools not properly developed may be applied for research. The piloted pre-final SA version tool displayed good internal consistency and thus is conceptually equivalent to the original POQL. The tool however produced multiple different dimensions after component analysis unlike the original tool.

In addition, the tool did not show good construct validity as it failed to elicit the differences in the quality of life status when comparing emergency and non-emergency dental conditions. It is recommended that future studies should look at psychometric properties and full scale validation with reliability testing and applicability of the version in a larger sample of primary school children. Thereafter, the tool may be used and compared with similar instruments to further validate it in the SA context.

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**Declaration**

There is no conflict of interest declared.

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# The use of cone beam computed tomography in establishing the etiology of an impacted tooth

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E Thomas<sup>1</sup>, MPS Sethusa<sup>2</sup>, R Singh<sup>3</sup>

## ABSTRACT

Cone Beam Computed Tomography (CBCT), a three-dimensional imaging modality, is considered a ground-breaking advance in the field of dental imaging. This case report illustrates how the use of CBCT enabled the correct diagnosis of the cause of the impaction of a central incisor in an orthodontic patient.

A 10-year-old male patient presented with the chief complaint of a clinically missing permanent upper right central incisor. After clinical examination and history taking, diagnostic radiographs such as orthopantomographs, lateral cephalograms and periapical radiographs were taken. On examination, the panoramic radiograph and lateral cephalogram demonstrated that the central incisor was impacted. The clinical signs, symptoms, and radiographic features indicated that an odontoma was causing the impaction. However, the presentation on the periapical radiographic presentation was suggestive of gemination, a developmental anomaly.

A CBCT scan was requested to confirm whether there were two structures (odontoma and impacted central) or one single structure (gemination). The CBCT scans helped in determining the correct etiology for the clinically missing central incisor and aided the clinician to arrive at the definitive diagnosis that a supernumerary tooth was responsible for the impaction. The scan also helped in identifying the optimal path for surgical removal of the supernumerary tooth.

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2. **M Peter S Sethusa:** Writing article - 20%
3. **Rajbaran Singh:** Advisor - 5%

## ACRONYMS

<b>ALARA Principle:</b>	As Low As Reasonably Achievable
<b>CBCT:</b>	Cone Beam Computed Tomography
<b>FOV:</b>	Field of Vision

## INTRODUCTION

Disruptions to normal development may lead to the apparent absence of a tooth or teeth from the dental arcade. Several reasons are discussed in the literature for “missing” teeth, including tooth agenesis, supernumerary teeth, tooth malformations or dilacerations, cysts or pathological entities such as odontomas in the eruption pathway, retained primary incisors, inadequate space in the arch and syndromic conditions.<sup>1,2</sup>

When there are several possible etiologies for a problem, determining the correct diagnosis can be challenging. Generating a differential diagnosis whereby one develops a list of possible conditions is an important step in management.

Clinical reasoning and diagnostic aids such as radiographs help to rule out some possibilities and contribute to the conclusion of a final diagnosis. In order to arrive at an accurate diagnosis and correct treatment plan, practitioners may rely on findings from imaging diagnostic aids such as orthopantomographs, peri-apicals and lateral cephalograms.<sup>3</sup>

Conventional radiographs are essentially two-dimensional (2D) representations of three-dimensional (3D) objects. These 2D images suffer from limitations such as image enlargement and structure overlap, leading to a wide differential diagnosis. Often, information gleaned from two-dimensional radiographs is insufficient and misleading, especially in cases where structures may overlap such as in supernumerary or impacted teeth.<sup>4</sup>

Two dimensional radiological presentations of dental anomalies and odontogenic tumours characterized by the presence of mineralized dental tissues sometimes present a diagnostic dilemma.<sup>5</sup> Cone beam computed tomography (CBCT) has emerged as a viable 3D imaging modality, providing a unique perspective in orthodontic diagnosis and treatment planning of clinically missing/impacted teeth. Images can be viewed in coronal, sagittal, oblique sections and various planes, thus offering optimal viewing and avoiding superimpositions.<sup>6</sup>

This case report highlights the superiority of CBCT images compared with conventional two-dimensional radiographs in the diagnosis of the etiology of an impacted central incisor.

In the present case, the findings of the panoramic radiograph and the lateral cephalogram suggested the presence of an odontoma while the periapical view indicated the developmental anomaly of gemination.

CBCT, however, revealed a supernumerary tooth lying in close proximity to the crown of the impacted central incisor tooth. CBCT narrowed the wide differential diagnosis for the etiology of a clinically missing upper right central incisor in this orthodontic patient to a supernumerary tooth.

### CASE REPORT

A 10-year-old male patient presented at the Department of Orthodontics, Sefako Makgatho Health Sciences University, South Africa, with the chief complaint of a missing upper right permanent central incisor. The medical history revealed that he was a healthy child.

The dental history reported that the upper right permanent central incisor had failed to appear, two years after the contralateral permanent incisor had fully erupted into the oral cavity. Intraoral examination confirmed that the upper right permanent central incisor was clinically missing.

The panoramic radiograph (Figure 1) revealed an impacted upper right permanent central incisor with a mass having the radiological density of a tooth-like structure that appeared to be superimposed at the incisal third of the permanent incisor tooth. Taking into account the dental history, clinical signs, symptoms and radiological features a diagnosis of "odontoma" was considered.<sup>7</sup>

The periapical radiographs (Figures 2 and 3) of the patient demonstrated an unerupted right central incisor showing features of coronal gemination. The incisor tooth displayed altered shapes of hard tissue and pulp.

Radiopaque enamel outlines and coronal invaginations were seen. There was a single pulpal chamber. Since the total count of teeth, including the impacted central, was normal, a diagnosis of gemination was made.

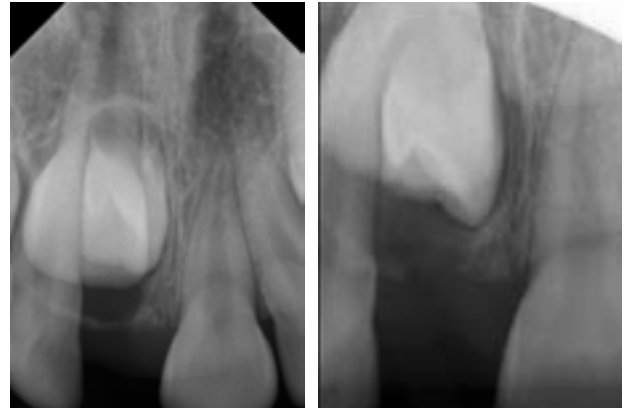


Figure 2 and 3. Periapical views of the central incisor region.

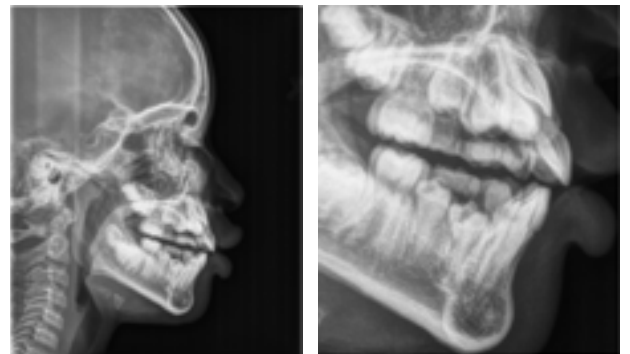


Figure 4. Lateral Cephalogram.

Figure 5. Magnified view of dentition.

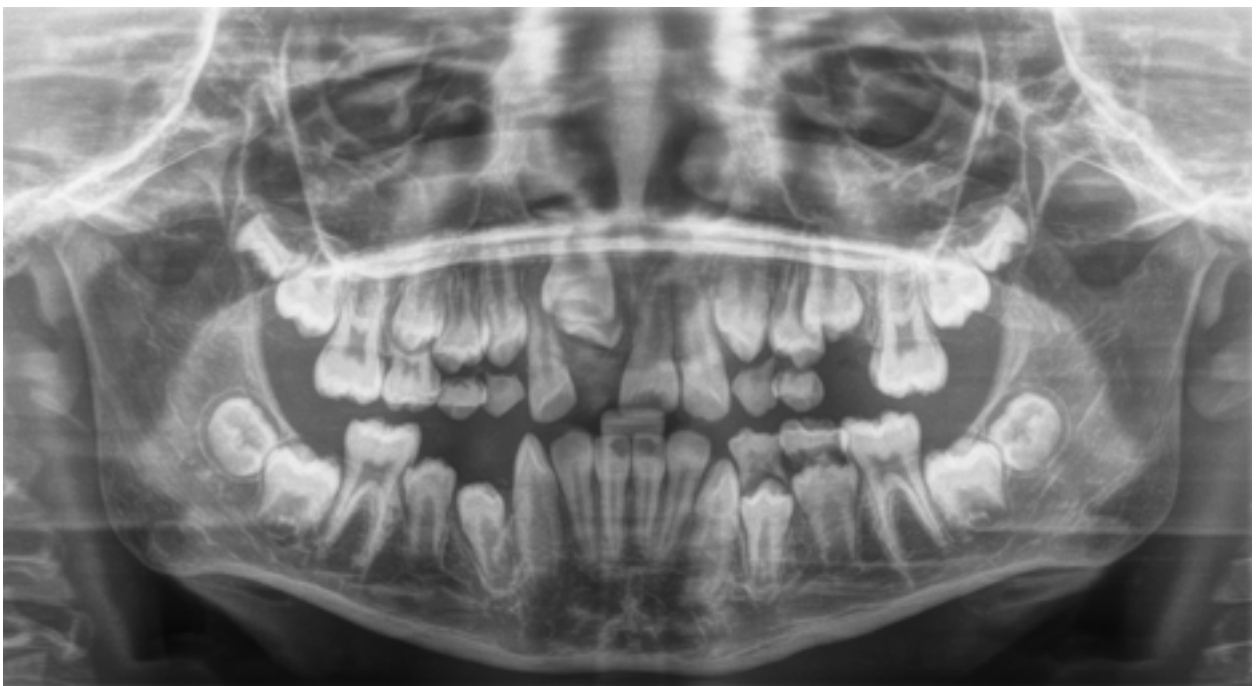


Figure 1. Panoramic radiograph. Note the mass overlying the incisal third of the crown of the 11.

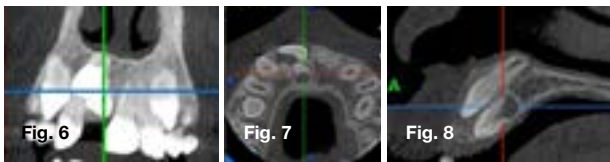


Examination of a lateral cephalogram (Figures 4 and 5) demonstrated, on the lingual aspect of the impacted tooth, a radio-dense bell-shaped structure with invaginations and a central radiopaque spherical mass. It was not clear whether it was attached to the tooth or not.

CBCT imaging was requested to identify whether there were two structures (odontoma and impacted central) or one entity (gemination).

Radiological investigation was performed with a CBCT utilizing the following protocol: 6 cm x 6 cm field of view (FOV), 110 kV, 17.73 mA, 5.4 seconds exposure time and 0.150 mm slice thickness. Axial, coronal and sagittal images were evaluated.

These CBCT sections (Figures 6, 7 and 8) demonstrated the appearance of a single, unilateral supernumerary tooth infero-palatal to an impacted right central incisor that had been displaced labially and superiorly. Both the supernumerary tooth and the impacted tooth were surrounded by individual pericoronal follicular spaces.



**Figure 6.** Axial image.

**Figure 7.** Coronal image.

**Figure 8.** Sagittal image.

CBCT proved that the differential diagnoses derived from conventional radiographs were inaccurate. It was actually a supernumerary tooth that was impeding the eruption of the right permanent central incisor.

The final diagnosis for the cause of the delayed eruption of the upper right permanent central was confirmed as a supernumerary tooth of the tuberculate variety after surgical intervention (Figures 9, 10 and 11).<sup>9</sup>



**Figure 9.** Surgical exposure of central incisor and supernumerary tooth.



**Figure 10.** Labial aspect of extracted supernumerary.

**Figure 11.** Lingual aspect.

## DISCUSSION

A correct diagnosis is the key to finalizing a correct treatment plan in the management of such cases. Accurate imaging and visualization are central to diagnostic and treatment planning processes.

Imaging techniques routinely used for diagnostic purposes in orthodontics include orthopantomographs and lateral cephalograms. The orthopantomograph enables the orthodontist to have a general overview of the dentition and supporting structures and helps to pinpoint anomalies or pathologies occurring in this region.

Although orthopantomographs are invaluable diagnostic tools, areas or structures outside the focal trough are prone to distortion. Other problems commonly encountered are magnification or overlapping of objects. The definition of structures in the panoramic x-ray is not as sharp as that seen on periapical or bitewing radiographs. As a result of these deficiencies, additional views may be required for patients presenting with a pathology in the incisor region.<sup>10,11</sup>

Lateral cephalograms are used to assess the dental, skeletal and soft tissue relations of an orthodontic patient. Lateral cephalometric analysis has been used widely in orthodontics as an investigative technique to evaluate growth and treatment responses.<sup>6</sup> The cephalogram also helps in the identification of anomalies or pathologies present in the jaws as well as impacted teeth. However, there are several disadvantages.

Cephalometric analyses are based on the expectation of excellent superimposition of the left and right sides at the mid-sagittal plane. Such perfect superimpositions are rarely seen due to slight facial asymmetry in individuals as well as faulty head positioning. Major errors are also encountered due to the ambiguity in locating anatomical landmarks due to poorly defined outlines and shadows.<sup>12</sup>

Periapical views of upper and lower teeth are usually taken in orthodontics to determine the root lengths, shape and form. A review of the literature shows that these features play a role in determining the susceptibility of incisors to root resorption.<sup>13</sup> Knowledge of these factors before commencing treatment helps the orthodontist to be prudent with the application of forces.

Therefore, periapical radiographs of the incisors of orthodontic patients are recommended before commencing treatment. Periapical views, however, are limited in terms of the possibility of an overlapping of the images of buccally or lingually impacted teeth, leading to incorrect interpretations.<sup>14</sup>

Imaging is a valuable diagnostic addition to the clinical assessment of an orthodontic patient. However, intra-oral imaging procedures such as periapical views and extra-oral procedures including panoramic x-rays and lateral cephalograms used individually or in combination suffer from the same inherent limitations of all two dimensional projections, namely magnification, distortion, superimposition and misrepresentation of structures.<sup>15</sup>

In this particular case, interpretation of all these two-dimensional conventional radiographs failed to produce a definitive diagnosis. The differential diagnosis varied from “odontoma,” a benign tumour, to “gemination,” a developmental anomaly.

The World Health Organization (WHO) classifies odontomas within the category of odontogenic tumours that are composed of epithelial and mesenchymal components of the dental apparatus with or without the formation of mineralized dental tissues.

These lesions are considered as hamartomas and not as true neoplasms.<sup>16,17</sup> Typically, they are divided into compound and complex odontomas.<sup>18</sup> Complex odontomas are less common than compound odontomas. A dilated odontoma has been described as yet another type of odontoma.<sup>16</sup> This is a single structure that may be a more severe form of *dens in dente*.

Odontomas are the most common type of odontogenic tumours and are generally painless and asymptomatic. The majority of odontomas appear before the age of 20, hence are discovered during childhood or adolescence. They are seen more frequently in the maxillary anterior region than in the mandible and are often associated with unerupted permanent teeth.<sup>19</sup> The canines, followed by upper central incisors and third molars, are the teeth most frequently impacted by odontomas.<sup>20</sup>

Odontomas develop and mature while the neighbouring teeth are forming and conclude their development once the development of the associated teeth is complete. Only rarely does an odontoma erupt into the oral cavity. If associated with an impacted tooth, odontomas are usually removed by surgical excision. They do not recur and after their removal, the impacted tooth usually erupts into the oral cavity on its own or otherwise may require orthodontic traction.

Radiologically, three stages can be seen in the development of an odontoma. In the first stage, the tumour appears radiolucent due to lack of calcification of dental tissues. In the intermediate stage, a partial calcification is noted and in the final stage the odontoma appears radiopaque with a radiolucent halo.<sup>21</sup> Compound odontomas are seen as calcified structures resembling teeth within a well-defined radiolucent lesion.<sup>5,7</sup>

A complex odontoma presents as a more or less amorphous mass with the radio-density of a tooth structure, but bearing no anatomical resemblance to a tooth, and is surrounded by a thin radiolucent area with a smooth periphery.<sup>5</sup> In some cases, the calcified matrix is predominant while in others there are islands of pulp tissue along with cords and buds.<sup>21</sup>

The dilated odontome is considered the most severe form of *dens invaginatus* or *dens in dente*. The former is characterized by the invagination or in folding of enamel surface into the interior of a tooth.<sup>22</sup> The invagination can occur either at the incisal edge or at the cingulum area. It is seen most frequently affecting the permanent maxillary lateral incisors followed by maxillary central

incisors, premolars and canines. They are very rarely observed in the posterior region. In its most affected form, the tooth is severely malformed. Radiologically, it presents with a circular or oval form and a radiolucent interior.<sup>16</sup>

A differential diagnosis, generated from assessment of the periapical X ray, was that of “gemination”. This dental anomaly occurs when a single tooth bud attempts to divide. This may result in the invagination of the crown with partial division. It can occur in both primary and permanent dentitions and is usually seen in the incisor region. It is commonly detected after the abnormal tooth erupts into the oral cavity.

Radiographic evaluation reveals alteration in the normal contour of the hard tissue - namely, clefts and invaginations in the enamel outlines and the pulp chamber is usually single and enlarged.<sup>16</sup> A geminated tooth in the anterior region may produce compromised esthetics.<sup>23</sup>

In addition, areas of invaginations are prone to caries and sometimes result in pulpal inflammation. In treatment, the crown may be reshaped or restored or left untreated with periodic reviews if esthetics is not a concern of the patient.<sup>16</sup>

In this case, traditional two-dimensional radiographs used as diagnostic aids, failed to provide a definitive, accurate diagnosis. Studies have shown that CBCT scans are useful in refining diagnoses and thus contribute significantly to a higher confidence level in a the diagnostic acumen of the clinician.<sup>24,25</sup> A correct diagnosis leads to a successful treatment plan and a gratified, contented patient.

Clinicians may request additional 3D images using CBCT if conventional radiographs fail to provide enough information for diagnosis, surgical intervention and orthodontic therapy.<sup>14</sup> Since CBCT has higher radiation doses, the basic principles to which an orthodontist should adhere before requesting cone beam computed tomography are:

1. CBCT examinations should not be used routinely and indiscriminately for all patients
2. A history and clinical examination must be conducted before doing a CBCT assessment.
3. CBCT assessments must be justified for each patient. CBCT images must provide new information when compared with that coming from conventional radiographs
4. CBCT field of view (FOV) should be controlled as much as possible. This helps to reduce the radiation dose and achieve the ALARA principle (As Low As Reasonably Achievable).<sup>14</sup>

In the present case, a CBCT scan revealed that it was a supernumerary tooth that was causing the impaction of the central incisor. Supernumerary teeth denote those formed in excess of the number found in normal series and are more prevalent in the permanent dentition. Most frequently found in the central incisor region, they might be associated with delayed eruption of the adjacent incisors.<sup>2,26,27</sup>

Supernumerary teeth in the permanent dentition are classified according to their position as mesiodens, paramolar or distomolar. Mesiodens are typically found between the maxillary central incisors. Mesiodens may be single or multiple, unilateral or bilateral, erupted or unerupted. Their orientation could be vertical, horizontal or inverted. Paramolar is a supernumerary molar found buccally or lingually in relation to the maxillary molars or in the buccal interproximal space between the second and third molars. Distomolar is a small and rudimentary molar located distal to the third molar.<sup>26,28</sup>

Supernumerary teeth are classified according to their morphology as conical, tuberculate, supplemental or odontoma.<sup>26,28</sup> Conical supernumerary teeth are small peg-shaped teeth with root formation ahead of or corresponding to that of permanent incisors. It is the most common supernumerary tooth in the permanent dentition. It is termed as a mesiodens and is present between upper central incisors and occasionally may be found high in the palate in an inverted or horizontal position.

Tuberculate teeth are supernumerary teeth, which are larger than the conical type and have more than one cusp or tubercle. They are short, barrel-shaped teeth with normal appearing crown and a rudimentary root. Root formation is delayed when compared with the permanent incisors. They are characteristically located on the palatal aspect of the permanent central incisors, are frequently associated with delayed eruption of the incisors and rarely erupt into the oral cavity.<sup>1</sup>

Supplemental teeth refers to duplication of teeth in the normal series and are found at the end of a tooth series. In the permanent dentition, they appear most commonly as extra maxillary and mandibular lateral incisors. Odontomas have no regular shape. This last category is not universally accepted as a supernumerary, however.<sup>28,29</sup>

Similarities concerning their topographic distribution, clinical features and pathologic manifestations between odontomas and supernumerary teeth have been quoted.<sup>17</sup> There appears to be some possibility of common genetic and immune-histochemical etiologic factors for these conditions. From a nosological point of view, odontomas and supernumeraries are classified as separate entities, but seem to be an expression of a similar process that is either malformative or hamartomatous.

Most supernumerary teeth are located in the anterior maxillary region.<sup>2,30</sup> They may remain asymptomatic without any clinical manifestations.<sup>27</sup> Sometimes malocclusions caused by supernumerary teeth, such as impacted teeth, crowding or diastema, particularly in the anterior region, may negatively affect the esthetics, mastication and speech of children, who might then become objects of ridicule in their peer groups, affecting their psychological development. Early detection, supervision and management of supernumerary teeth is crucial in avoiding these problems.<sup>31</sup>

Detection of supernumerary teeth is best achieved by a thorough clinical and radiographic examination.

The application of conventional radiographic techniques together with CBCT in order to determine the position of supernumerary and impacted teeth has been studied previously.<sup>32,33</sup>

The results show that both techniques are useful as initial diagnostic tools but the CBCT images provide more detailed information about the position of the teeth, the exact dimension of supernumerary and impacted teeth and the presence or absence of root resorption.<sup>25,33</sup> A frequent indication for CBCT in orthodontics is for eruptive disorders like impacted teeth and supernumerary teeth.<sup>14,34</sup> By using 3D visualization, CBCT provides information in all three planes and thus enhances diagnostic accuracy. This is an important attribute when contemplating surgical removal of supernumerary teeth which have resulted in impaction of neighboring permanent teeth. The need for accurate diagnostic 3D information also becomes apparent when considering the proximity of supernumerary teeth located in the anterior maxillary region to neighboring teeth and vital structures like the nasopalatine canal, nasal floor or the floor of the mouth.<sup>35</sup>

## CONCLUSION

It is recommended that in the case of eruptive disorders, including impacted teeth, it is advisable to investigate the etiology of the condition by detailed history taking, clinical examination and the critical assessment of diagnostic aids like radiographs. If conventional two-dimensional radiographs fail to provide a definitive diagnosis, then the use of CBCT scans is recommended.

CBCT scans should be used only when the potential benefits for diagnosis and treatment planning outweigh the potential risks of an increased radiation dose. In the present case, CBCT imaging led to a change in diagnosis and treatment planning and was justified. CBCT imaging also assisted the surgeon in determining the least invasive point of entry for removal of the supernumerary tooth.

## Acknowledgements

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# What's new for the clinician?

## - excerpts from and summaries of recently published papers

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Compiled and edited by V Yengopal

### 1. 6-mm vs 11-mm implants for full-arch rehabilitation of the edentulous mandible

L Guida, M Annunziata, U Esposito, M Sirignano, P Torrisi, D Cecchinato.  
Clinical Oral Implants Research. 2020; 31: 64-73.

The clinical use of dental implants in the rehabilitation of totally and partially edentulous patients represents a well-documented long-term and highly predictable procedure with almost 100% survival rates over long term periods (> 5 years).<sup>1</sup> One of the main limitations for correct implant placement, however, still remains the availability of a sufficient amount of bone at the implant site. When there is reduced bone height, standard length fixtures can be inserted only after advanced reconstructive surgical treatments, with a consequent increase in financial and biological demands on the patient (additional costs, longer treatment time, increased postoperative morbidity, and greater risk of complications).<sup>1</sup>

The use of short implants for the rehabilitation of atrophic sites in order to avoid the disadvantages of vertical bone augmentation procedures, has greatly expanded in recent years, with promising results.

Short implants offer benefits in terms of less invasive surgery, ease of handling, and reduced risk of damaging anatomical structures, thus supporting the concept of a "stress-minimizing surgery". However, the efficacy of short dental implants has been a matter of debate in the recent literature with mixed findings reported. Guida and colleagues from Italy (2020) reported on a randomized controlled clinical trial that sought to evaluate the efficacy of 6-mm-short implants compared with 11-mm-long implants supporting fixed full-arch mandibular prostheses in patients with a fully edentulous mandible, avoiding the need for bone augmentation procedures. The null hypothesis for this study was that there was no difference in terms of marginal bone level change between short and longer implants from prosthetic installation to one and three years of follow-up.

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#### MATERIALS AND METHODS

This study was designed as a multicentre parallel-group randomized controlled clinical trial (RCT) with a 1:1 allocation ratio. Patients were enrolled at the three involved centres. Inclusion criteria were aged between 18 and 75 years, total mandibular edentulism for at least eight months, sufficient amount of native bone (no previous bone augmentation procedures) in the recipient sites to allow the installation of five implants with length  $\geq 11$  mm and width 4 mm being circumferentially surrounded by  $\geq 1$  mm of peri-implant bone, systemic health, and compliance with good oral hygiene.

Exclusion criteria were any disease, medication or drug that could jeopardize healing, osseointegration or treatment outcome, severe bruxism or other parafunctional habits, unrealistic aesthetic demands. Smokers were not excluded, however, the smoking habit was registered as heavy smoker ( $\geq 10$  sig./day), light smoker ( $< 10$  sig./day), non-smoker, or former smoker.

Patient eligibility in terms of bone dimensions was determined on computer tomography (CT) scans, with the aid of an implant planning software (Simplant, Dentsply Sirona Implants). Thirty patients were selected in three study centres to receive a fixed full-arch mandibular rehabilitation supported by five inter-foraminal implants.

The primary outcome of the study was the radiographic marginal bone level change (MBLc) around 6-mm-short and 11-mm-long implants, evaluated from prosthetic installation to one and three years of follow-up.

The secondary outcomes included (a) implant survival rate, (b) prosthesis survival rate, and (c) biological or technical complications. Surviving implant or prosthesis were those still in function at the last follow-up.

Biological complications were considered peri-implant mucositis and peri-implantitis. Technical complications were considered prosthesis fracture, screw loosening or fracture, implant fracture and veneer fracture.

Eligible patients received a complete anamnestic and clinical examination; hopeless teeth were extracted; caries and periodontal lesions on the remaining teeth were treated. The prosthetic project was accurately planned on cast models mounted in an articulator. When possible, the previous denture was used as a reference.

The randomization and the allocation concealment were carried out using sealed opaque envelopes created following a computer-generated randomization list by a person not otherwise involved in the study. Such envelopes were consecutively opened at the leading center and communicated to the surgeon at the moment of the first surgery.

Surgeries were performed by expert clinicians and the surgical protocol was shared among all three centers. The implant positioning was carried out with the help of a computer-aided bone-supported surgical guide (Simplant, Dentsply Sirona). In the test group, 5 short (6-mm-length) implants were placed, while in the control group 5 long (11-mm-length) implants were used.

Minimal measurements of 3 mm of inter-implant distance and of 1 mm of bone at the buccal and lingual aspects were required, with no need for augmentation procedures (if augmentation was required, the patient would have been excluded from the study). If needed, an osteoplasty of the alveolar ridge was done by means of a carbide-cutting bur mounted on a straight surgical handpiece. The implant head was placed flush to the bone. At the end of the surgical procedure cover screws were positioned and a careful adaptation of the flaps by means of an accurate suture was assured in order to obtain primary closure and full periosteal coverage.

The patients were instructed to rinse with a chlorhexidine 0.12% mouthwash twice a day for two weeks and to avoid using the denture. Liquid and semisolid food was prescribed for the first postoperative week, after which the sutures were removed.

Two weeks after the surgery, the denture was properly relined, avoiding direct contact with the fixture until the second-stage surgery. Patients were controlled at four, eight and 12 weeks.

After three months of healing all implants were exposed by separated linear incisions, cover screws were removed and replaced by healing abutments. After one week, the final abutment was screwed on each implant and an abutment-level impression was registered. Expert clinicians followed all the prosthetic phases.

All patients received a fixed screw-retained full-arch prosthesis with distal cantilevers. It consisted of a cobalt-chrome framework, fabricated according to the Cresco method (Dentsply Sirona Implants) and covered by an acrylic veneer. The length of the bridge cantilevers was duly calculated to minimize implant overloading. All prosthetic procedures were made according to the Astra Tech Implant System procedures and products manuals.

Patients were instructed in proper hygiene measures, suitably designed on individual needs, including tooth brushing, interdental brushing, flossing, and rinses with a chlorhexidine 0.12% mouthwash. Patients were recalled every six months for professional supragingival infection control, including ultrasonic debridement and polishing.

Radiographs and clinical examinations of the restored segments were performed at baseline (permanent restoration placement), and after one and three years of loading. Marginal bone level change [MBLc] (primary outcome), implant survival rate, prosthesis survival rate, and biological/technical complications (secondary outcomes) were registered.

For MBLc measurements, peri apical radiographs were taken at the baseline and after one and three years of loading. Early or late (before and after prosthetic loading, respectively) implant losses were registered, as well as any other biological or technical complications which occurred during the study period.

## RESULTS

Thirty patients (15 per group) were enrolled and randomly allocated to the test and control groups. More female patients were enrolled in the test group ( $p = 0.02$ ), but there were no other inter-group differences at the baseline for any of the considered variables.

A total of 150 implants (5 per patient, 75 per group) were inserted. All patients were re-evaluated at one and three years of follow-up, from December 2012 (the first one-year follow-up visit) to March 2019 (the last three-year follow-up visit).

Between the one- and three-year follow-ups, one patient (control) did not attend control visits and another one (test) died, so that 14 test patients and 14 control patients were available to be evaluated at the three-year follow-up. No implant or prosthesis failure was registered (100% survival rate in both the test and control groups). In one patient (control), there was a wound dehiscence within the first two weeks of healing and the placement of healing screws on three exposed implants was anticipated.

In two patients (one test and one control), two implants per patient suffered, during the first year of function, from peri-implant mucositis, resolved by professional cleaning and 1% chlorhexidine gel application every week for one month. No other biological complications requiring additional chair-time were observed.

In three patients (test), a fracture of the acrylic veneer was registered and repaired. Three cantilever fractures happened in two control patients (after two years of function) and one test patient (after one year of function) and were repaired by laser welding after prosthesis removal. Two had natural teeth and one had a removable denture at the opposite arch. No other complications that might have required chair-time were observed. No significant inter-group differences for any of the registered complications were found.

No statistically significant difference in terms of MBLc between baseline and one- and three-year follow-up visits in both groups, as well as between test and control group at all follow-up visits was observed. There were no significant correlations between MBLc and any of the patients' demographic variables (centre, age, gender, and smoking habit) at any time point when each group was analysed separately and when data from both group were pooled together.

## CONCLUSION

The researchers concluded that short (6 mm) implants may be a reliable option when used in the rehabilitation of a total edentulous mandible, with clinical and radiographic outcomes, up to three years of loading, comparable to those of long implants (11 mm).

## Implications for practice

This study supports the concept of a minimally invasive, low-stress, simplified implant therapy, with absolute benefits for both patients and clinicians. However clinicians should note the strict patient selection criteria and the small sample size before applying these findings to all patients.

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1. Guida, L, Annunziata, M, Esposito, U, Sirignano, M, Torrisi, P, Cecchinato, D. 6-mm-short and 11-mm-long implants compared in the full-arch rehabilitation of the edentulous mandible: A 3-year multicenter randomized controlled trial. *Clin Oral Impl Res.* 2020; 31: 64-73.

## 2. Postoperative pain following endodontic irrigation using 1.3% versus 5.25% sodium hypochlorite in mandibular molars with necrotic pulps

MEHAA Mostafa, YAI El-Shrief, WIO Anous, MW Hassan, FTA Salamah, RM El Boghdadi, MAA El-Bayoumi, RM Seyam, KG Abd-El-Kader, SAW Amin. *International Endodontic Journal*, 2020; 53: 154-66.

Postoperative pain is common after root canal treatment and is mainly attributed to mechanical, chemical and microbiological factors. Several factors can influence post-endodontic pain including pre-treatment, intra-treatment or post-treatment factors.

Intra-treatment factors include the number of visits, the type of irrigant and/or intracanal medication, the root canal instrumentation technique and the root filling technique. Methods to prevent post-endodontic pain, thus, include the selection of instruments, instrumentation techniques, devices and the chemicals used during treatment.

Several irrigants have been used during root canal treatment of which sodium hypochlorite (NaOCl) is the most common, due to numerous advantages including its antimicrobial activity, antibiofilm activity and organic tissue dissolution potency. However, it also is an irritant to periapical tissues, especially at high concentrations, and can induce an inflammatory reaction even at concentrations as low as 0.5%.

Various concentrations of NaOCl are used by dental practitioners varying from 0.5% to ≈8% with a tendency towards using higher concentrations. The effect of different NaOCl concentrations on teeth with non-vital pulps is yet to be assessed.

Mostafa and colleagues (2020)<sup>1</sup> reported on a randomized clinical trial that sought to compare the effect of two NaOCl concentrations, 1.3% and 5.25%, on post-endodontic pain and on rescue medication intake in patients with non-vital pulps in mandibular molars, undergoing root canal treatment over two visits.

## MATERIALS AND METHODS

This was a prospective, two-arm, parallel-group, double-blind, single-centre, randomized, clinical trial. Eligible patients for inclusion in this study were systemically healthy subjects between the age of 25 and 45 years with a mandibular molar (first or second) with non-vital pulp with or without radiographic evidence of apical periodontitis; symptomatic and asymptomatic patients were included.

Patients were excluded if they were pregnant or lactating females; had a history of sensitivity or adverse reactions to any of the medications or materials used in this study; had acute periapical or periodontal abscess, or badly decayed crowns; were retreatment cases; or had severely curved root canals. Patients who took a preoperative premedication that could alter pain perception (e.g. analgesics) within at least 12 hrs. before treatment were also excluded. Of 463 patients assessed for eligibility, 308 were included.

The included patients had a diagnosis of symptomatic or asymptomatic mandibular molars with nonvital pulps, associated or not with radiographic evidence of apical periodontitis. After instruction, patients recorded their preoperative pain on a 0-10 numerical rating scale with 0 indicating 'No pain' and 10 indicating 'The worst pain.' The pain scores were categorized into four categories as follows: 0 = none, 1-3 = mild, 4-6 = moderate and 7-10 = severe. Included patients had a negative response to electric pulp sensitivity testing and cold thermal testing.

Definitive pulp status was confirmed during access cavity preparation through lack of bleeding. Patients with or without pain on percussion were included. Periapical

radiographs were taken to assess the status of the periapical structures; patients with normal structures or periapical radiolucency were included.

Root canal treatment was carried out in two visits using a standardized protocol. After access preparation in the first visit, each tooth was isolated using rubber dam and then patients were randomly assigned, according to the NaOCl concentration used, to either of the following groups: 1.3% NaOCl or 5.25% NaOCl. The patients and operators were unaware of the assigned group throughout the duration of the study.

The pulp chamber was filled with 3 mL irrigant. The patency of canals was established, and an initial glide path was prepared using size 10 and size 15 K-files. After coronal pre-flaring, the working length (WL) was determined using an apex locator and radiographically confirmed to be 0.5-1 mm short of the radiographic apex.

Root canals were mechanically prepared using a nickel-titanium rotary system (ProTaper Universal, Dentsply Sirona) in a torque-controlled endodontic motor according to the manufacturer's sequence and recommendations of speed and torque.

Syringe irrigation was done using 3 mL irrigant with a 27-gauge, notched-tip needle between each two consecutive instruments. Needle penetration depth in the canal was 3 mm shorter than the WL of the canal after preparing the canal to the master apical instrument as adjusted by rubber stoppers. The final flush was done using 5 mL saline.

At the end of the first visit, the canals were dried using paper points, a dry cotton pellet was placed in the pulp chamber, and the access cavity was sealed with a temporary filling (Cavit) without intracanal medication. In the second visit 7 days later, a rubber dam was placed and the temporary filling was removed.

Root canals were irrigated using the same irrigant concentration as on the first visit, and the canal walls were re-prepared using the instrument size last used on the first visit before the canals were dried. Canal filling was carried out using the modified single-cone technique with matched-size gutta-percha cones (ProTaper Universal) and an epoxy resin-based sealer (AH Plus).

The tooth was temporized using a cotton pellet and temporary filling. A postoperative periapical radiograph was taken for each patient and evaluated for the following features: the extent of root canal filling ('adequate filling' within  $\leq 2$  mm from the radiographic apex, 'underfilling' or 'overfilling'), the taper and width of filling ('overinstrumentation' was considered if the filling was wide and/or showed overflaring; 'underinstrumentation' was considered if the filling was thin and/or showed underflaring) and/or the presence of a fractured instrument, a ledge or a perforation; such data were recorded for each patient.

Each patient received a pain diary to record pain levels at the following time-points: immediately after instrumentation, three, 24, 48 hours and seven days after the first

visit and, on the second visit, immediately after root filling. Pain was assessed using a 0-10 numerical rating scale. Patients were asked to mark the number that represented their pain level. Patients were contacted by their operator at each time-point to check and to remind them to record their pain. After the first visit, each patient was dismissed with a capsule (containing powdered milk), as sham analgesic, to be taken in case of pain. If pain persisted, the patient was instructed to contact the operator who would then prescribe an analgesic (ibuprofen 600 mg). The patients were asked to record whether they took the sham only or the analgesic as well in the pain diary. The patients delivered their pain charts in the second visit after seven days.

## RESULTS

Of the 308 included patients, 178 were females and 130 were males. The age range was from 25 to 45 years with an overall mean age of  $31.87 \pm 5.82$  years. The study included 235 first and 73 second mandibular molars. 57% (175/308) of the patients had pain on percussion and 40.6% (125/308) had a periapical radiolucency. Both groups were similar regarding baseline data.

The 1.3% NaOCl group was associated with significantly less pain intensity than the 5.25% NaOCl group at all the time-points ( $P < 0.05$ ). For both groups, a significant decrease in pain intensity occurred immediately after treatment compared with preoperative pain ( $P < 0.05$ ). With 5.25% NaOCl, a significant rise in pain intensity ( $P < 0.05$ ) compared with preoperative pain occurred at three hours and continued through 24 hours ( $P > 0.05$ ) and then a significant decrease occurred at 48 hours compared with the 24 hour level ( $P < 0.05$ ), reaching the preoperative pain level ( $P > 0.05$ ).

A gradual decrease compared with the preoperative pain then occurred up to seven days ( $P < 0.05$ ); a significant rise, however, occurred after root filling compared with the seven days pain intensity ( $P < 0.05$ ). A significant rise in pain intensity occurred with 1.3% NaOCl at three hours compared with immediately after treatment ( $P < 0.05$ ), yet, it was significantly less than had been the pre-operative pain ( $P < 0.05$ ).

Pain remained at the same intensity from three to 24 hours after which it gradually declined until it reduced at seven days compared with preoperative pain ( $P < 0.05$ ) with no rise in pain level after root filling at seven days ( $P > 0.05$ ).

Overall, postoperative pain incidence was significantly associated with preoperative pain ( $P = 0.000$ , OR [95% CI]: 1.788 [1.459, 2.192]), periapical radiolucency ( $P = 0.015$ , OR [95% CI]: 1.282 [1.049, 1.568]) and analgesic intake ( $P = 0.000$ , OR [95% CI]: 2.477 [1.614, 3.803]); the other studied factors (gender, pain on percussion, sham intake) did not have an impact ( $P > 0.05$ ).

A total of 60 of 308 patients (23/154 in the 1.3% NaOCl group and 37/154 in the 5.25% NaOCl group) took the sham capsule. A total of 38 of 308 (9/154 in the 1.3% NaOCl group and 29/154 in the 5.25% NaOCl group) patients took the analgesic (600 mg ibuprofen).



Thus, of the 60 patients who took the sham capsule, 22 (22/60, ≈37%) patients did not require further analgesics. Using 1.3% NaOCl was associated with significantly less incidence of sham intake (23/154) compared with 5.25% NaOCl (37/154) (14.9% vs. 24%, respectively,  $P=0.044$ ). There was also significantly less incidence of analgesic intake with 1.3% NaOCl (9/154) compared with 5.25% NaOCl (29/154) (5.8% vs. 18.8%, respectively,  $P=0.001$ ).

For the 1.3% NaOCl group, overinstrumentation in a canal occurred in 12 cases, underinstrumentation in one case, overfilling in 10 cases and underfilling in one case. For the 5.25% NaOCl group, overinstrumentation occurred in four cases, underinstrumentation in two cases, overfilling in four cases and underfilling in two cases. No instrument fractures occurred in either group. No adverse effects were recorded by any patient throughout the trial.

## CONCLUSIONS

Using 1.3% NaOCl was associated with less intense and less frequent post-endodontic pain than that associated with 5.25% NaOCl in mandibular molars with non-vital pulps treated in two visits. The incidence of pain was reduced by up to 60% within the week post-instrumentation and 80% after root canal filling and the rescue analgesic intake reduced by about 70% when 1.3% NaOCl was used compared with the use of 5.25% NaOCl.

## Implications for practice

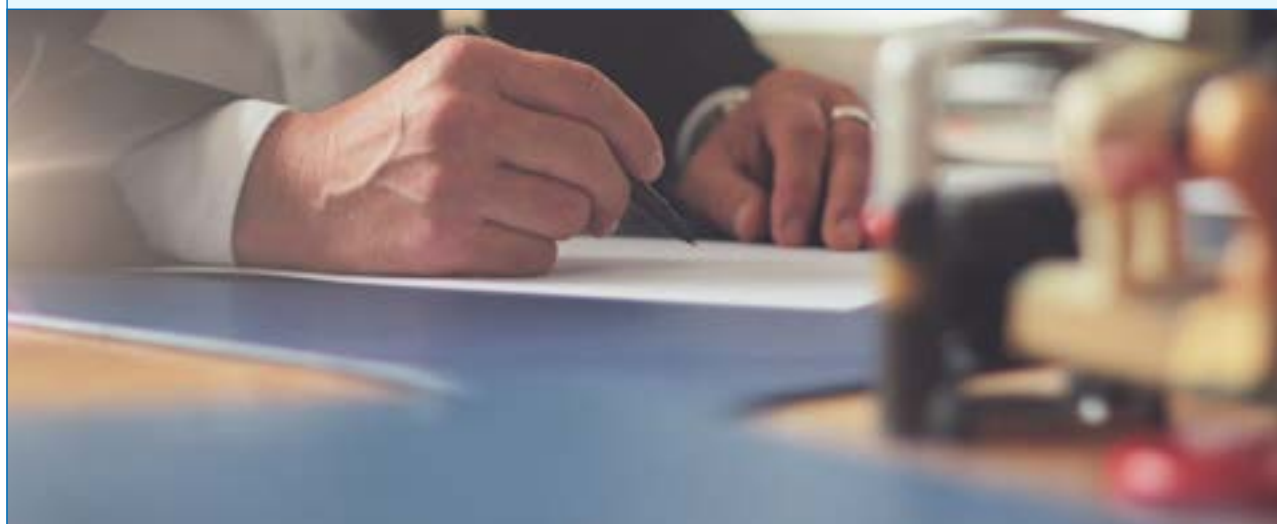
This trial provides evidence of superior patient-related outcomes achieved using the 1.3% NaOCl as an irrigant compared to the 5.25% NaOCl.

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## Do the CPD questionnaire on page 53

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.



### Online CPD in 6 Easy Steps

- 1 Go to the SADA website [www.sada.co.za](http://www.sada.co.za).
- 2 Log into the 'member only' section with your unique SADA username and password.
- 3 Select the CPD navigation tab.
- 4 Select the questionnaire that you wish to complete.
- 5 Enter your multiple choice answers. Please note that you have two attempts to obtain at least 70%.
- 6 View and print your CPD certificate.

# Maxillofacial Radiology 177

SADJ February 2020, Vol. 75 No. 1 p48

CJ Nortjé

This twenty seven year old mother presented at the Department of Maxillofacial Surgery with the main complaint of a throbbing pain on the right side of her face, experienced over the last three months. She also informed the clinician that she had delivered a baby son six months previously and that she was in good health. Clinical examination revealed that the 16 had extensive caries with an apical abscess. Advanced underlying periodontal disease was present in both jaws. No signs of mental retardation were observed. What are the important clinical and radiological findings and what is your provisional diagnosis?



Fig. 1



Fig. 2



Fig. 3

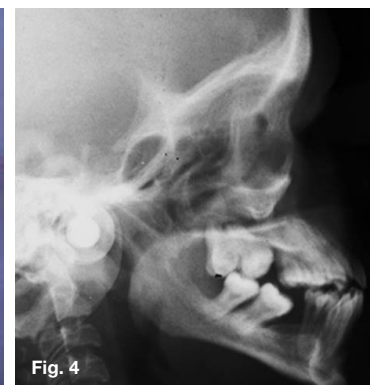


Fig. 4

## INTERPRETATION

The most important clinical findings are a short stature, an abnormally thick facial skin which shows excessive wrinkling (Fig. 1), which was also discernible in the fingers (Fig. 3). The panoromograph (Fig. 2) shows underlying periodontal disease and radiological features of apical infection on the 16. The lateral skull radiograph (Fig. 4) shows a normal sella turcica. A provisional diagnosis of pituitary dwarfism I was made. Pituitary dwarfism is a condition in which the growth of the individual is very slow or delayed, resulting in less than normal adult stature. There is decreased bodily growth due primarily to a deficiency of growth hormone (GH). The end result is a normally proportioned but little person, because the height and the growth of all other structures of the individual are decreased. It is estimated that between one in 14,000 and one in 27,000 babies born each year have some form of dwarfism.

In 2004, more than 20,000 children in the United States were receiving supplemental GH therapy. It is estimated that about one quarter had organic causes of GH deficiencies. There appears to be no racial or ethnic component to pituitary dwarfism, but males seem to be affected more often than females. Dwarfism with growth retardation becomes evident during the first two years of life. The voice may be shrill and piping. Mental retardation is normally not present. The basic defect is unknown but it is related to a deficiency of growth hormone. This condition is autosomal recessive and the life spans of the affected individuals probably does not deviate significantly from normal. Premature and excessive facial wrinkling plus shrill voice are cardinal features of this condition.

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# Constructing the consultation chair - balancing the four (E)-legs

SADJ February 2020, Vol. 75 No. 1 p49 - p52

LM Sykes<sup>1</sup>, JT Marais<sup>2</sup>

## INTRODUCTION

Reflecting on the past 80 years in dentistry with 20:20 vision, we observe a number of changes in materials, techniques, medicaments, facilities, patient desires, and treatment options. What has not changed is the duty of the clinician to “promote and safeguard the health of all patients, using their knowledge and conscience to fulfil this duty” (Declaration of Helsinki).

This philosophy is considered so sacrosanct that it has been incorporated into The Declaration of Geneva of the World Medical Association which states “The health of my patient will be my first consideration,” and the International Code of Medical Ethics which declares that “A physician shall act only in the patient’s interest when providing medical care which might have the effect of weakening the physical and/or mental condition of the patient.”

In practice, all healing carries the risk of harm, and almost every prophylactic, diagnostic, and therapeutic procedure involves certain risks and burdens. The onus is on the clinician to determine the most suitable and beneficial treatment option with the least risks for each patient. This is not always easy as there are a number of external factors that have to be considered.

The levels of training, skills and experience of dentists, their preferences, their ethical standards, the availability of materials and facilities, and the time and costs of treatment will all influence planning and decision making.

Of importance also to be taken into account are patient factors such as their level of education and understanding, family and peer pressure and their desire to conform to social media standards together with consideration of their actual needs versus their wishes and demands.

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### Author contributions:

1. **Leanne M Sykes:** Primary author - 70%
2. **Koos Marais:** Secondary author - 30%

## ACRONYM

**EBD:** Evidence Based Dentistry

This paper will look at different elements that may impact on treatment planning and clinical decision-making, using the analogy of a four-legged chair with seat and backrest.

The dentist is the carpenter whose aim it is to construct a well-balanced, comfortable, aesthetically pleasing, durable, and functional chair. The seat of the chair is the treatment plan, the most central element in the entire process. The four legs are the pillars that support the chair on which the patient will be sitting.

The legs are represented by the four “E” concept, these being Education, Evidence Based Dentistry, Experience, and Ethics. Each “E” has to be present and carefully balanced with the other three legs if the chair is to be comfortable and remain stable under load. The last element is the back of the chair. This represents the laws governing the practice of dentistry. It is generally not needed for the chair to function, but goes a long way to providing additional comfort, support, and a solid backing for the patient to lean on if needed. The dentist should always be aware of its presence, and ensure the chair design is in harmony with the back.

## 1. Education



The bulk of clinical decision-making and subsequent treatment is based on the education that the dentist received as an undergraduate student. However, science and technology are not static and there are ongoing and progressive changes taking place in all spheres of technology, dentistry included. Dentists are morally obliged to keep abreast of the latest developments and

to adapt their practices accordingly. Attendance at CPD courses and “hands-on skills training” have been made a legal requirement in medicine and dentistry through-out the world. Sadly, many of these programmes have become largely money-making ventures for the presenters and point collecting activities for the participants, rather than valid learning experiences.

There is little control over or monitoring of, the material that is presented at these courses, other than informal participant feedback. At a recent congress (2019), the opening speaker began his presentation on facial aesthetics by referring to measurements of facial profiles taken from a 1960's study done on Scandinavian patients. He used these as guidelines for work carried out on a very racially diverse South African population. Not only was the information dated, but also the so-called “ideal norms” were subjective, and unsuited to the local population. Not a single person in the audience challenged him.

So while it is a legal requirement for dentists to attend ongoing training, it is also incumbent upon them to ensure that they acquire valid and reliable education. They also need to stay current by reading peer-reviewed scientific literature and by following technological developments to learn about new materials and products that have become available. Of course they then need to implement the changes and adapt their practice accordingly (when necessary or indicated and not just because a company representative has offered them free samples of a new product to try out!).

One should be suspicious of a dentist who is still using all the same techniques and materials that he/she was taught years ago in dental school. That said, there are of course a number of situations where traditional, conservative management is still the best option. The aim of any treatment should be preservation and retention of what is, rather than restoration of what has been lost.

## 2. Experience

There is no substitute for experience. Every patient encounter is a learning exercise. Clinicians gain as much knowledge from their successes as from their failures, and both will influence how they approach the next similar patient situation.

Inevitably then, the “In my hands” approach to decision-making and treatment often becomes the norm for well-established practitioners. This stance has served them well for many years as evidenced by the number of successful cases they have treated. However, it also has the danger of leading to complacency, blinding them to the possibility that there may be newer and better ways of doing things. The wise dentist will know when it is time to consider abandoning one approach for another.

Conversely there may also be clinicians with little experience but a lot of zeal. They eagerly embark on testing out new products, instruments and free samples on their patients, and in effect turn them into walking human experiments. While their desire to remain current or to

aid progress is admirable, and it is known that much of medical progress is based on research involving experimentation on human subjects, the health and well-being of patients should never be put in jeopardy in the process.

The dentists may justify their actions if they have a truly strong conviction that they will be helping to improve prophylactic, diagnostic, or therapeutic procedures. Nobody can argue that even the best-proven medical science must continuously be challenged through research for optimal effectiveness, efficiency, accessibility, and quality, but, the well-being of patients should always take precedence over a clinician's interests, ambitions, (bank balances) and objectives, and of the needs of science and society.



## 3. Evidence Based Dentistry (EBD)

All clinical practice should be based on methods, materials, and procedures that have undergone extensive laboratory and / or clinical trials. The research must be based on good science, well controlled with suitably sized randomized samples, must have undergone rigorous scientific review and be evidence based. It may be difficult for practitioners focused on clinical commitment to judge the value of published research.

In 1992 Guyatt's proposal that there should be a formal means of evaluating the trustworthiness of research<sup>1</sup> led to the development of “The Evidence Ladder/Pyramid”. This grades the quality of research from highest to lowest as follows: high quality systematic reviews, large randomized trials with clear results; smaller randomized trials with uncertain results; non-randomized trials with contemporary controls; non-randomized trials with historical controls; cohort studies; case-controlled studies; dramatic results from uncontrolled studies; case series and lastly are reports or expert opinions based on clinical experience.<sup>2</sup>

Thus whenever clinicians are presented with a new material, device or technique, the onus is on them to examine all available evidence before blindly accepting and using it. In the absence of evidence or only company sponsored research, the claims must be viewed with circumspection if not suspicion, and it may be best to avoid the offerings until more credible results become available.

While EDB is the universally accepted “gold standard” in research, it has become almost impossible to secure ethical approval for clinical studies involving patients. This has led to the more recent trend of journals accepting case reports, and, to a greater extent, case series, for publication. It is a well-known fact that many groundbreaking discoveries have come about by chance. This makes it crucial for dentists to keep comprehensive, accurate, and clear patient records and to either document cases of interest, or at least to disseminate this information amongst their colleagues - especially if they notice a trend developing.

NB – this is **not** the same as, or an excuse to permit “experimenting” on patients, and leads to the fourth leg – that of ethical conduct.

#### 4. Ethics

There are a myriad of papers, books, guidelines, and opinion pieces related to ethical clinical practice. Most of them revolve around the four key elements proposed by Beauchamp and Childress in 2001.<sup>3</sup> These are 1. Patient autonomy (including understanding, education and consent), 2. Beneficence, 3. Non-maleficence and 4. Justice.

Essentially, ethics in dentistry is simply a matter of treating each patient in the same manner as you would like to be treated yourself, striving to maintain and promote health, choosing the treatment option that offers the most benefits and the least amount of risk or discomfort, and refraining from willfully inflicting harm or damage. The latter is not restricted to physical harm, but also includes the burdens of emotional stress, wasted time, financial costs, and having to endure pain and suffering. Thus we believe that ethical considerations should be the guiding factors when drawing up any set of treatment options and finally deciding on the most suitable treatment plan. And so we move up from the legs to address issues associated with the seat of the chair.

#### 5. The seat



The seat refers to the treatment options, plan, and execution. It forms the foundation for an optimal dentition that ideally the patient will be using for years to come and as such needs to be sturdy, comfortable, aesthetically pleasing, durable and suited to the overall

chair design. Not all seats can or will be made out of the same material or in the same manner, and may function slightly differently from each other.

Most seats are designed to make optimal use of the materials that the dentist had access to when the patient first arrived. This may be influenced by factors such as the desires and demands of the patient, the amount of time he/she is willing to contribute as well as the funds available for purchasing additional “building supplies”.

Some chairs may have to be made with compromised seats, especially if the dentist is presented with limited or poor quality material to work with initially. It may be possible to restore the seat with the limited supply of materials available, but the patient must be cautioned to use it with care. Some seats may be built as temporary measures until such time as the patients can afford more permanent materials, or used as diagnostic aids to evaluate the amount of load that they will need to carry. More complex seats will require regular maintenance, adjustments, professional cleaning, and repair. Finally, regardless of the design and type, all seats need daily home care by the patients. No chair should ever be delivered without the dentist taking the time to explain this process fully and clearly.

Some final design thoughts and guidelines – keep it simple; never discard or destroy any material that the patient arrived with, unless it is undoubtedly beyond saving; choose the most conservative design first, this allows one to opt for a more complex restoration at a later date; if in doubt about how to proceed, then don't make major or irreversible changes to the existing chair; never be tempted to choose a design that is based on personal interests, the desire to bolster sales of a product, or to swell your own pockets; at times, the best choice may be to do nothing and leave the existing chair to function as it has done; after all the patient came in using their current seat and it would be foolish to destroy that unless you are certain you can build a better one. You also have a right to refuse taking on a project when the patient has unrealistic demands. Perhaps the final guiding principle comes from 19<sup>th</sup>-century English surgeon Thomas Inman who said “Practice two things in your dealings with disease: either help or do not harm the patient”.<sup>4</sup>

#### 6. The backrest

At times it becomes necessary to sit back and reflect upon the success and comfort of the chair. In such cases the backrest becomes a type of concinnity, a skillful fitting together of parts, so that it offers benefits to both or either of the two parties, the patient and dentist. When the dentist has forgotten to provide a proper backrest in the form of legal and ethical requirements he or she may “fall off” the chair.

While all chairs have backrests, they are not always used, and many competent and experienced clinicians don't pay much attention to this aspect when planning and working on the other components. However, the patient's comfort will be vastly improved if they know

there is this extra support on which to lean should the need arise. That support/the backrest is the Law. It is generally only focused upon in situations where the patient is unhappy with other elements of the craftsmanship.



They may complain that the seat is uncomfortable or breaks frequently, that the legs are unstable, that they don't like the design, colour or materials used to make the chair, that their family feel the chair doesn't suit them, that they were not told about the different choices of design initially, that the dentist destroyed some of the seat material that could have been saved and re-used, that the chair looks and functions worse than when they brought it in for repair, or most commonly, when they believe they have been charged too much for the chair.

Generally, when a dispute arises, independent expert witnesses will assess the case. They will be experienced colleagues of good repute. It is never easy to criticize another dentist's work. There are often many sides to each complaint, and very often a number of extenuating circumstances that impacted on the treatment outcome. Their judgement is usually made using the Reasonable Man Rule – i.e. what would a reasonable clinician, under the same circumstances, have done in a similar situation for their patient? The ruling will depend on whether the witness believes the dentist acted in a reasonable manner.

However, there is one major lapse in this approach. It usually involves debating the technical and legal aspects of the treatment and its outcomes. There is seldom consideration of all four legs of the chair. Has the dentist remained current in Education or were dated materials and procedures used? Did the treatment conform to that advocated by the best practice approach of EBD? Was the dentist Experienced enough to undertake the work? And finally did the dentist act Ethically? The latter may have a strong influence on whether the verdict is guilty or innocent. **For example:** the witness needs to differentiate between a cautious "wait and see" approach and supervised neglect; or between an adverse event and gross negligence. A further complication is that the way they view these issues may be subject to their own practice philosophy and thus be subjective and open to bias.

Other ethical issues which should be debated revolve around frequency, magnitude, and intent. Once-off events where the intention was good may be condoned, however repeat offenders with malicious intentions need to be admonished.

So, in conclusion, perhaps we in the dental profession need to re-look at how we go about constructing our consultation chairs and assemble our treatment planning and execution according to our own adapted version of the legal rule. Ours can be called "The Reasonable Ethical Man Rule"

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# CPD questionnaire

This edition is accredited for a total of 3 CEUs: 1 ethical plus 2 general CEUs

## GENERAL

### Self-reported oral hygiene practices and oral health status among dental professionals

- Identify the INCORRECT statement.  
Dental health education:
  - can help improve individual, group and community well-being
  - tends to shape behavioural patterns, which begin with change in attitude and transformation in conduct
  - requires the healthcare sector to invest more towards increasing awareness and helping educate individuals about oral hygiene measures
  - is independent of systemic or mental health
- Identify the CORRECT statement.  
A reported reason for oral health neglect among dental practitioners is:
  - Fear of cross infection resulting from the dental treatment
  - Dental treatment that was considered urgent
  - Cost of consultation and treatment from colleagues
  - Time constraints and limitations
- Identify the CORRECT statement.  
Considering the oral health of the oral healthcare practitioner:
  - Tooth loss is inevitable, which implies that maintaining good oral hygiene only delays tooth loss.
  - Oral hygiene neglect may lead to dental caries, gingival inflammation and eventual tooth loss.
  - Neglect of oral hygiene has a negligible impact on the quality of life and expectancy
  - Oral diseases resulting from poor oral hygiene may lead to the suppression of various systemic diseases

### Dental biomaterials: challenges in the translation from lab to patient

- Identify the CORRECT answer.  
An example of a natural polymer is:
  - Polyamide
  - Polyethylene
  - Sodium alginate
  - Poly(D,L-lactide-co-glycolide)
- Identify the CORRECT answer.  
A disadvantage of controlled drug delivery systems that hinders clinical translation is:
  - Bioavailability
  - Cytotoxicity
  - Early onset of action
  - Low manufacturing costs

- Identify the CORRECT answer.  
Which of the following is NOT an example of *in vitro* studies:
  - Cell differentiation assays
  - Nano indentation tests
  - Quantitative attachment tests
  - Histopathological tests
- Identify the CORRECT answer.  
Which of the following is a commercial challenge to successful clinical translation of stem cells?
  - Genetic and phenotypic instability
  - Capacity to generate adult phenotypes
  - Limited positive cell therapy outcomes
  - Tumorigenicity risks
- Identify the CORRECT answer.  
An inventor may not patent a product that:
  - Is novel
  - Has been discussed with a research supervisor
  - Has been presented at a local conference
  - Has been tested in a laboratory
- Bioactive materials interact directly with their surrounding environment:
  - True
  - False

### Cross-cultural adaptation of the Paediatric Oral Health-Related Quality of Life (POQL) tool in South Africa - a pilot project

- Identify the INCORRECT statement.  
The measurement of the OHRQoL of developing children is important because:
  - The measurement allows for evaluation of child's oral health status and treatment efficiency
  - Children are a major focus of dental public health and they have more oral diseases
  - Children are vulnerable and have no rights regarding their health care
  - The measurement offers an invaluable opportunity to hear and understand their voice and viewpoints
- What type of analysis was as used to determine structural validity of the POQL?
  - Exploratory factor analysis
  - Confirmatory factor analysis
  - Principal component analysis
  - All of the above

12. How many of the respondents in the study were female?
- Thirty-eight
  - Seventy-six
  - Fifty-three
  - Seventy

13. Identify the CORRECT answer. A Cronbach  $\alpha$ -score of 0.91 confirms that the study had good:
- Internal validity
  - Internal consistency
  - Construct validity
  - Item consistency

#### The use of cone beam computed tomography in establishing the etiology of an impacted tooth

14. Identify the CORRECT answer. The characteristic clinical signs and symptoms presented by an Odontoma are:
- It is painless and symptomatic
  - It is often discovered before the age of 20
  - It is associated with unerupted permanent teeth
  - It rarely erupts into the oral cavity
  - All of the above

15. Identify the CORRECT answer. Extra-oral radiographic images routinely used in orthodontic patients are:
- Panoramic radiographs and lateral cephalograms
  - Panoramic radiographs, occlusal radiographs
  - Panoramic radiographs and CBCT scans
  - Lateral cephalograms and periapicals

16. Identify the CORRECT answer. Lateral cephalograms may be used to evaluate:
- growth
  - treatment changes
  - impactions
  - All of the above

17. Identify the CORRECT answer. CBCT has the following advantages over when compared with conventional radiographs:
- A three dimensional view of objects are obtained
  - Images can be viewed at various planes
  - Restricting field of vision helps to reduce the radiation dose
  - All of the above

18. Identify the CORRECT answer. Tuberculate teeth are an example of:
- Dens in dente*
  - Supernumerary teeth
  - Odontomas
  - None of the above

#### Maxillofacial Radiology Case 177

19. Mental retardation is a common finding in Pituitary dwarfism.
- True
  - False
20. Dwarfism with growth retardation becomes evident during the first two years of life of Pituitary dwarfs.
- True
  - False

#### ETHICS

#### Constructing the consultation chair - balancing the four (E)-legs

21. Identify the CORRECT statement. Consent is:
- not needed for minor dental procedures
  - not needed if working on minors
  - not needed if patients request the treatment themselves
  - not static and may be renewed or retracted if circumstances change
22. Identify the CORRECT statement. For consent to be valid the patient needs to:
- understand all risks and benefits
  - be able to afford the time and costs of treatment
  - be fully informed about alternatives
  - only answers a) and c) above
  - answers a), b) and c) are correct
23. Identify the CORRECT statement. The International Code of Medical Ethics declares that:
- "Only a physician shall act in the patient's interest when providing medical care which might have the effect of weakening the physical and/or mental condition of the patient"
  - "A physician shall act in the patient's interest only when providing medical care which might have the effect of weakening the physical and/or mental condition of the patient"
  - "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and/or mental condition of the patient"
  - "A physician shall act in the patient's interest when providing medical care which might only have the effect of weakening the physical and/or mental condition of the patient"
24. Identify the INCORRECT statement. Ethics embodies:
- i). Patient autonomy (including understanding, education and consent), ii). Beneficence, iii). Non-maleficence and iv). Justice.
  - Treating patients as you would like to be treated yourself
  - Choosing the treatment option that offers the most benefits to patient and practice
  - Determining treatment decisions based on the costs incurred in providing treatment
  - Refraining from wilfully inflicting harm or damage
25. Identify the INCORRECT statement. In determining whether ethical principles have been transgressed, the following factors may be taken into account:
- Was the practitioner guilty of supervised neglect... or simply overcautious?
  - The age of the patient, older persons being more critical of treatment
  - Was the event the result of negligence or was it an unfortunate adverse incident?
  - Is the event an isolated occurrence or part of repeated actions?



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