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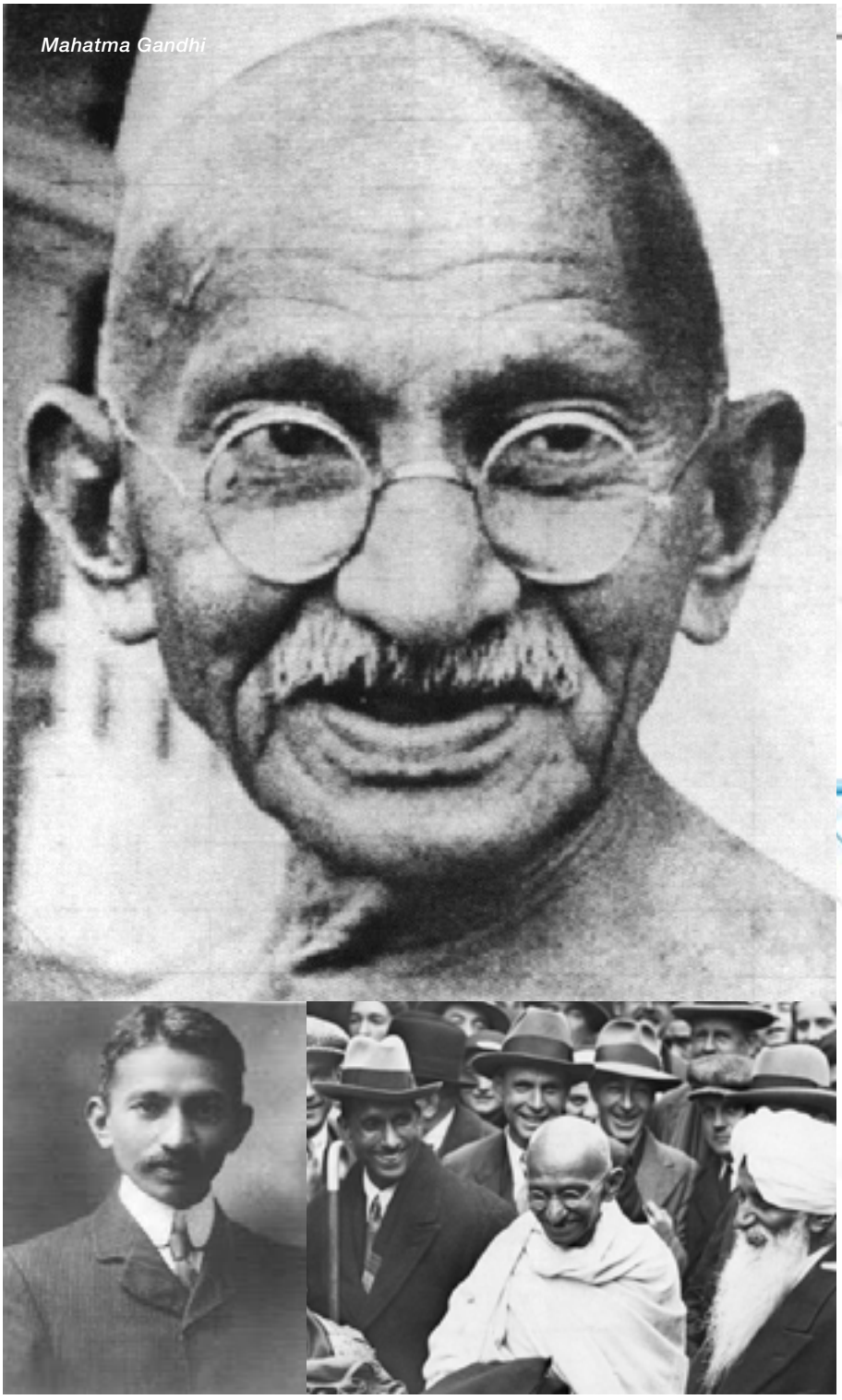

Mahatma Gandhi: It's true, Gandhi had a set of false teeth. He only used them when he ate, at all other times he kept them in a pocket in his loincloth. This is why in many of his photos, he does not have teeth. Also known as Mohandas, Gandhi was incredibly tiny. This is because of his commitment to Vegetarianism and his tendency to fast. He played a major role in worldwide societal development, nonviolence, and civil disobedience in a century filled with war and tragedy.

Source: https://mahatmagreatsoul.weebly.com

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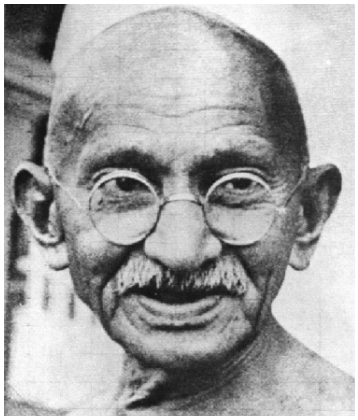
Our Front Cover for this Issue…

Teeth have on occasion been central to historical, social and humorous events. The **Front Cover** in 2019 will reflect some of these **Famous Teeth.**



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Power: the inputs, the outputs

SADJ March 2019, Vol. 74 No. 2 p51

WG Evans

Power, the word on the lips of every South African today... Power, the motive essential to everyday dentistry... but also how appropriate that the lips are mentioned... how about the **power** of a **smile!** Frustration must have been rampant amongst the profession as the lights went out, the loss of power translating into the loss of time, of service, of money. Stymied were our efforts at producing the Smile that indeed has Power. Meg Selig, psychologist and author, lists several benefits lending Power to a smile... and starts by citing research which shows that Smiling may make you look younger! Not only younger but thinner! She surmises that since a smile lifts the corners of the mouth and the cheeks, a more youthful appearance is produced.[1]

A sense of well being, an elevation of mood, projecting an aura of likeability, attractiveness and competence… all in the Power of exercising mainly the Levator anguli oris, together with Risorius and Zygomaticus minor. Seems a fine bargain... no wonder our patients are eager to achieve that Smile! But the claim for the Power of a smile goes further... apparently a smile can predict fulfilment in marriage, can predict life span and even when you force a smile, it can lead to good things!

Figure 1. Pedal driven drill from the 19th century.
Image source: https:www.liveauctioneers.com

WG Evans: Managing editor, **Email:** bill.evans@wits.ac.za

It appears that the song "Smile and the world smiles with you" indeed carries great truth, **but** in order to produce that smile the Dentist requires Power. That energy was supplied originally by muscle action... the bow drill was used some 7000 years ago in the Indus Valley to drill teeth... cavity preparations of up to 3,5 mms depth have been proved to have been produced by rotating drills.[2]

Mechanical drills such as used in woodwork were in favour in the 18th century in Europe, whilst a clockwork drill was invented by George Harrington in 1864 ...somewhat faster but noisy... and called Erado! Pneumatic drills operated by foot activated bellows followed, and the pedal driven drill arrived in Dentistry in 1871 (James Morrison, inventor).

The first Power drill, motivated by electricity, was patented by Green in 1875. From here developments to faster and more efficient instruments followed apace ...literally, for the air turbine produced speeds of rotation enormously faster than the fastest electric drill… 400,000 rpm vs 3000 rpm.

Today the turbine can rotate at an impressive 800,000 rpm! The first generation air turbine was the initiative of a group of New Zealand scientists who were granted a patent in 1949. The first commercially distributed air turbine was the familiar Borden, introduced by Dentsply in 1957. (I was the first patient at the Wits Dental Hospital to undergo cavity preparation with a Borden, a box which was attached to the cervical arm of the chair... and we produced an exposure! Not an occasion for a smile!).

That Dentistry is a profession wrought by stress is again proven in a paper appearing in the Journal this month. The study went further to identify coping mechanisms amongst the subjects. Exercise and Rest were the most commonly relied upon as stress relievers. Recent experience with load shedding will certainly have raised the already high levels of stress… and may have offered practitioners plenty of opportunities for both these stress breakers.

The profession has a real opportunity to exercise the Power of the discipline when the World Oral Health Day is celebrated on 20th March. The Association has planned a series of events to mark this special event… and details appear in the following pages.

Power has both input and output roles in Dentistry... perhaps a focus on the positives of the output - the Power of a Smile… may offset the frustrations of the (interrupted) input!

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A dental and oral imperative: World Oral Health Month

SADJ March 2019, Vol. 74 No. 2 p52 - p53

Head Office, SADA

As on the thirteenth day of February this year, the population of South Africa was officially recorded as 57,814,097. Let us assume that each citizen has 15 teeth… a moderate estimate, but, accounting for children with deciduous dentition, for adults who are already edentulous, that may be a fair guess.

That assumption translates into just on 870 million teeth being used on a daily basis in South Africa. We have some 6500 dentists registered with the HPCSA... and, again an assumption... say 500 are not actually in practice. A quick calculation, assuming all else is equal, …results in the conclusion that each practising dentist has responsibility for some 145,000 teeth!

It is all very well to play with statistics, the harsh reality is that the fight against dental disease is not being won. A recent study showed that amongst children attending immunization clinics around Johannesburg, there was a 60% occurrence of caries.. and that 90% of the affected children had received no treatment.[1] If that is the case in an urban community alert enough to ensure immunization for their children, it may be assumed that much more dire statistics await us elsewhere in the country.

Oral diseases remain a major public health concern affecting 3.9 billion people.[2] Dental caries which is largely preventable **through proper self-care and regular dental check-ups**, together with managing risk factors, remains the most common oral disease, affecting 60-90% of school children and a vast majority of adults.[3] It is about five times as common as asthma and seven times as common as hay fever.

On the horizon may be some positive opportunities... It is that exciting time of the year when oral health professionals give back to the communities that are under their care. Yes, it's time to celebrate World Oral Health Day (WOHD), which is on the 20th March.

WOHD is the largest global awareness campaign on oral health and an opportunity for the profession to raise awareness of the global burden of oral diseases, and to engage and work with stakeholders to reduce the overall oral disease burden.

Of course there is a most relevant factor which focusses our attention on March 20th, World Oral Health Day. It is embodied in **the most recent definition of Oral Health which moves away from the normative, paternalist view of oral health, and places the patient at the centre of how they view oral health.** Therefore, we are in a partnership with our patients to ensure that they achieve and maintain optimal oral health. It is indeed clear that the primary responsibility for oral health care rests with every individual, every citizen, every patient.

Certainly, the Dental Profession should be seen to take a leading role in guiding the population to better oral health, but in the long run, the oft-quoted saying "Oral Disease is preventable" is the foundation on which should be built the desired enhancement of the oral health of the community. The opportunity to emphasise the critical importance of oral care is provided by the FDI (The World Dental Federation) who have seized a day when across the world, oral care will hold centre stage.

The South African Dental Association is a committed member of the world team, and will strive to secure the attention of all people to spend the time and energy to preserve their natural dentition.
The 2019 Theme is :

Say Ahhh… Action on Mouth Health.

The WOHD theme '**Say Ahh**', started with **Think Mouth, Think Health** as the first sub-theme. It empowered people to keep a healthy mouth, helping them to maintain their general health and well-being. A healthy mouth and a healthy body go hand in hand. Maintaining a healthy mouth is crucial to keeping it functioning correctly and for maintaining overall health and quality of life.

The theme focuses on four main messages:

1. Oral health is much more than a nice smile.
2. Oral health and general health have a two-way relationship.
3. The mouth cannot be isolated from the rest of the body.
4. Oral health professionals play a key role in providing this information and guidance on how to prevent, manage and treat oral diseases and in making people understand the benefits to their general health and well-being.

South Africa intends to participate in the Day, and the Dental Association is planning a variety of activities.

Early announcement of the Day is a critical requirement and a Press Release has been prepared for circulation to all South African Newspapers:

WORLD ORAL HEALTH DAY: 20 MARCH 2019

Say Ahh: Act on Mouth Health

Oral health is multi-faceted and includes the ability to speak, smile, smell, taste, touch, chew, swallow and convey a range of emotions through facial expressions with confidence, and without pain, discomfort and disease of the craniofacial complex.[4] Oral diseases, such as tooth decay and gum disease, are widespread and preventable. Through proper self-care and regular dental check-ups, together with managing risk factors, good oral health and general health can

be secured.

It's never too early or too late to start looking after your oral health. Just like other major diseases, prevention, early detection and treatment are key to ensuring the best outcomes and reducing the risk for oral diseases and associated health complications. People can 'Act on Mouth Health' by adopting good oral hygiene habits; eating a healthy diet, particularly one low in sugar; quitting tobacco use; and avoiding excessive alcohol consumption.

Oral diseases and tooth loss impact both children and adults - they should not be considered as unavoidable consequences of population ageing. Oral health professionals play a key role in providing information and guidance on how to prevent, manage and treat oral diseases and in making people understand the benefits to their general health and well-being.

World Oral Health Day (WOHD) is celebrated on 20 March each year and is the largest global awareness campaign on oral health and an opportunity for all stakeholders to Say Ahh: Act on Mouth Health and make a commitment to oral health. Safeguarding oral health can help ensure people have good quality of life into old age.

Prepared by: Dr Khanyi Makwakwa, FDI Liaison, South Africa

Other media exposure for the World Oral Health Day in South Africa involves:

- Full page advertisements in You and Drum Magazines.
- Full page advertisement in Mother & Child Magazine as well as the Editorial.
- Clicks Radio: Members of the Committee of the Young Dentists Council will be addressing Oral Health on the Clicks Radio station, every day from 18 - 21 March with a 30 minute slot.

Schools

- Each SADA Branch will nominate five schools to visit in partnership with Colgate. Oral Health packs will be delivered to Grade R to Grade 3 children. The intention is to reach 7500 children in SA.
- SADA Head Office staff are to visit 15 additional schools, also in partnership with Colgate.

Campaigns

- Sefako Makgatho University is actively involved in school visits with an ongoing outreach programme.
- All other Dental Schools are invited to be part of the Day and are encouraged to initiate outreach programmes.

Social Media

- Temporary Tattoos to be printed (SADA Logo and "Say Ahh") and handed out to Dental Students. Students will take Selfies and will circulate these with the WOHD slogan.

SADA Communique

- Printable WOHD posters and suggested activities on how to celebrate WOHD will be included in forthcoming Communiques.

Unilever will actively partner with SADA in projects currently undergoing planning.

We should encourage our patients and the communities in which they live that it is never too early or too late to start looking after oral health. Prevention, early detection and treatment are key to ensuring the best outcomes and reducing the risk for oral diseases and associated health complications. They should be enabled to **'Act on Mouth Health'** by adopting good oral hygiene habits; eating a healthy diet, particularly one low in sugar; quitting tobacco use; and avoiding excessive alcohol consumption,.

The Association applauds all those supporting and participating in the programmes.

Challenge

How many of those 870 million teeth can be saved?

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Christopher C Rachanis

15th October 1929 to 18th February 2019

SADJ March 2019, Vol. 74 No. 2 p54

Dentistry lost an icon when Chris Rachanis passed away. Being dual qualified in Medicine and Dentistry, Chris was able to bring clear perspectives to Oral Medicine, as will readily testify the literally hundreds of Wits graduates who sat at his feet absorbing insights into his cherished field.

But it did not stop with undergraduates for Chris was well known for his willingness to help all members of the oral health team ...dentists, doctors, hygienists, therapists… who held him in high esteem, appreciated his expertise and valued his generous friendship.

Dr Rachanis was schooled at Parktown Boys High and Benoni High Schools, and entered a prolonged academic career when he registered for a BA degree at Wits. Over the next several years he graduated BA, BSc, BDS at Wits (1957) and then travelled to England to complete the double with an MB BCh from Sheffield, followed by a Fellowship from the Royal College of Surgeons, Glasgow in 1971. A perennial student indeed!

Between 1960 and 1975, Chris held posts at several hospitals in the United Kingdom, notably the London Hospital where he was a lecturer in Oral Medicine, Periodontology and Oral Pathology from 1969 to 1974.

On his return to South Africa he lasted only a few months as a Casualty Officer at the Johannesburg Hospital before academe again beckoned. Wits Dental welcomed him in 1976 and became his academic home for the next forty years! He worked closely with Professor Mervyn Shear and Professor John Lemmer ...an impressive team indeed!

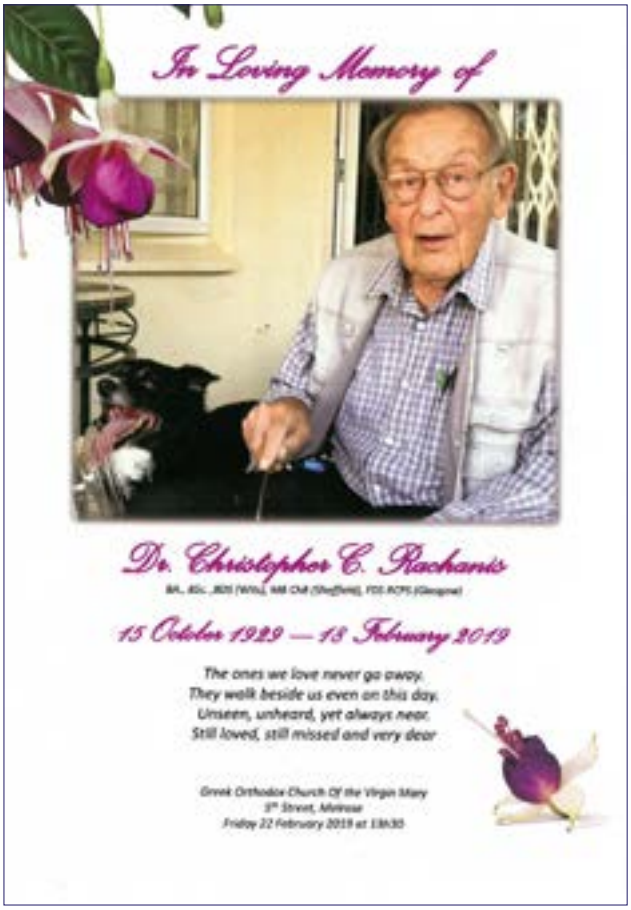
The familiar figure of Dr Rachanis in the clinic… constantly involved in ensuring patients were properly diagnosed, that students understood and recognized the oral medicine presented, that his cheerful good humour spread content across the room. Always so willing to share of his extensive knowledge, Chris happily undertook additional after hours seminars and tutorials to help his students.

He published several papers but it was the personal delivery that Chris really enjoyed and he received many invitations to deliver papers at congresses and courses, travelling to branch meetings across and beyond South Africa. He developed particular acumen in the scourge of HIV and contributed to the management of the dreaded disease in our country.

A dedicated and green fingered gardener, a Doberman and Collie enthusiast, an avid reader of the literature… and in his latter years, a computer addict.

Christopher C Rachanis
December 2013

Johan Langenneger, a friend of many years, delivered a moving tribute to Chris at the funeral service, recalling just how much Chris had missed his wife, Colleen, who passed away some six years ago. Johan closed with the words... “Goodbye Chris, we will never forget you”.



Perceptions of stress among dentists: an investigation of stress management among dental practitioners in South Africa

SADJ March 2019, Vol. 74 No. 2 p55 - p61

S Bhat[1], N Nyathi[2]

ABSTRACT

Introduction: Stress among dentists has been well documented in international research papers, with many reporting high levels. However, there is insufficient information on perceived stress among South African dentists.

Aims and objective: The aim of this research was to investigate the level of stress among South African dentists in general, to identify high occupational stressors and the choices of stress-relieving mechanisms by the dentists.

Method: An anonymous online cross-sectional questionnaire was undertaken using non-probability sampling, and was distributed via social media and e-mail. The questionnaire was divided into four parts: demographic information; Work Stress Inventory for Dentists (WSID); Perceived Stress Scale (PSS); and finally, a checklist of the stress- relieving coping mechanisms commonly used.

Results: A significant positive correlation was found between general stress and all the work-related factors. 44%-56% of dentists identified 'being perceived as an inflictor of pain'; 'coping with difficult' and 'uncooperative patients' as major (high/great deal of stress) work stressors.

Results: This study found that most of the dental participants were highly stressed. Since many participants indicated patient-relations as being highly stressful it is recommended that ways be sought to improve dentist-patient relationship which may help with how dentists appraise situations at work as stressful.

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1. **Shubha Bhat:** *BDS (MEDUNSA), MBA (UCT),* Urgent Care Dentist, Service Rendering Department, Tygerberg Oral Health Centre (Young Author. DOB: 10/APRIL/1988).
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Author contributions:
1. **Shubha Bhat:** principal researcher/author, writing article, statistical analysis, distribution of questionnaire, responsible for compliance with HREC (Human Research Ethics Committee, UCT).
2. **Nceku Nyathi:** Research supervisor, active mentorship.

ACRONYMS

PSS:	The Perceived Stressed Scale
WSID:	Work Stress Inventory for Dentists

INTRODUCTION

Many people choose the profession of dentistry because of the prestige and rewards offered in the long-term career. Dentists play an important role in society, and often the career brings excellent above-average remuneration and a chance to help others.[1]

Although a career in dentistry is rewarding, it can also be a highly stressful profession. A study done in the UK showed that 86% of dentists found their lives to be highly stressful.[2] This is mainly because dentists are in direct contact with anxious patients, a management challenge which often requires a high level of patience.[3–5]

Patients who have higher dental anxiety perceive their dentists to have more negative attributes and the converse applies among patients who have lower dental anxiety.[6] Dentists have to ensure that patients are calm before, during and after treatment. This often requires dentists to play two roles: that of a psychotherapist and that of a manually skilled clinician,[7] Research has shown that a patient-dentist relationship has a direct impact on the physical quality of treatment.[8] Thus, how dentists experience and manage anxious patients plays a pivotal role in the success of the practice.

There is a one-on-one relationship between the patient and the dentist; this places pressure on the dentist as the clinician who is faced with challenges that require making independent decisions, unlike when working in a group or teams[9] and thus dentistry is considered a "lone" profession.[10] Furthermore, dentists quite often have to deal with incompetent staff, intrusive insurance enquiries and the running of the practice/(business) or department.[11]

Stress/burnout that is experienced in one part of one's life, will more often than not have an influence in other areas too, spreading to other aspects of personal life.[12] It is important for both dental students and dentists to be very aware of these stressors which are associated with the occupation, in order that they may live a more fulfilling professional life.[13]

It has been well documented in South Africa that there is a limited number of dental professionals, and dentistry is considered a scarce skill in South Africa. According to statistics published in May 2016 by the Health Professions Council of South Africa, only 6147 dentists were registered.[14] The population of South Africa, according to the World Bank, was around 56 million in 2016.[15] The low ratio of dentists to the population indicates that many people in South Africa do not have sufficient access to dental care, a situation which places considerable mental and physical pressure on dentists. These pressures may contribute to low job satisfaction, affect the way dentists run their businesses and influence the quality of relationships they have with their patients.[16]

There is not much in the literature about the coping strategies used by dentists. According to Alexander (2001): "In one study, 24 percent of the dentists surveyed said they did nothing, 32 percent said they used physical activity to de-stress, and 13 percent reported they just "coped." Only 10 percent said they took any time off from the practice, and only six percent had a hobby".[17] Another study surveyed 700 dentists and found that interacting with people, taking part in sport and forgetting about work were the top three coping strategies used by New Zealand dentists.[16] The least used coping strategies were smoking, recreational drugs and prescribed drugs.

Although perceived stress among dentists has been studied in other countries, further research on the topic is required in South Africa.[18] Therefore, the aim of this study was to investigate the level of general stress among South African dentists, the various contributors to high levels of work stress, and to understand what coping mechanisms dentists practiced. This will assist dental students and dentists to become more aware of the occupational issues that they may encounter, or indeed are currently facing, and to provide information on more effective coping strategies that may help them to enjoy a fulfilling professional and personal life.

METHOD

The study was conducted in a limited research time and therefore a non-probability sampling approach (snowballing, purposeful and convenience) was used in surveying general dental practitioners living in South Africa. However, the sample was wide, consisting of general dental practitioners with various lengths of experience working in the private or public sectors, and practising in rural, small-town or urban centres within the country. All were registered with the Health Professions Council of South Africa (HPCSA).

Google forms were used to create a modified questionnaire that was distributed via e-mail, Dental Facebook pages, WhatsApp and LinkedIn. All response buttons were activated for each question on the Google forms, making it mandatory for all participants to answer all questions.

The responses were confidential and the researchers did not collect identifying information such as names, email addresses or IP addresses. In addition, the questionnaire complied with the latest version of The Department of Health, Ethics in Health Research: Principles, Structures and Processes (2015). The study was approved by the Human Ethics Committee of the Faculty of Health Sciences, University of Cape Town. A total of 151 questionnaires were received.

Measures

The study was based on a deductive approach, determining the choice of the following standardised sections in the questionnaires:

1. The demographic information: The questionnaire started off with eight demographic questions (age; sex; relationship status; children; area of work- rural, small-town or urban; province; the sector of work and number of years of experience).

2. The Perceived Stressed Scale (PSS): This is composed of 10 questions that measured the overall perception of stress within the last month.[19]

3. Work Stress Inventory for dentists (WSID)[5]:
This was developed to identify specific work stressors experienced by general dental practitioners.[5] The original WSID consisted of 30 items divided into five factors labelled as: 'time and scheduling pressures'; 'pay-related stressors'; 'patients' unfavourable perception of dentists'; 'staff and technical problems'; and 'problems dealing with patients'. WSID Factor 2 (pay-related stressors) was slightly modified to accommodate the South African context by eliminating two questions which were: 'working constraints set by NHS' and 'the piecework system of payment'.

The final questionnaire used for the study therefore consisted of 28 items. PSS used the ordinal Likert scale ranging from 0-4 (0: no stress to 4: very high-stress) and WSID used the Likert Scale ranging from 1 (no stress) to 5 (a great deal of stress) to measure negative or positive thoughts and feelings.

4. Stress-Coping strategy checklist: This section consisted of 12 activities, participants being given the choice to check multiple options that most describe their strategies in managing their stress.

The data (PSS, WSID, and Stress-Coping strategy checklist) were analysed by descriptive analysis which was computed via IBM SPSS 23 statistics software. The descriptive statistics include cross tabulations, frequency distributions, standard deviation and means, as well as a classification of data of frequencies for non-parametric variable analyses; correlations; t-test for two categories and ANOVA for three or more categories, with the alpha level set at 0.05. For both PSS and WSID, the higher the total score, the higher the levels of stress.

RESULTS

Demographic information

Of the 151 respondents, 54% (n= 81) were female and 46% (n=70) were male. Most participants were between 26-40 years of age, making up 58.9% (n=89) of all respondents. A higher proportion of respondents had a significant other (79%; n=119), had less than five years

of work experience (33.1%; n=50), worked in private practice (67%; n=101), lived in urban areas (61%; n=92) and had children (53%; n=81). Gauteng Province is the home of three of the four dental academic institutions and is the most populated province in South Africa, so it is no surprise that the highest number of participants (35%; n=53) came from this Province.

Perceived Stress Scale (PSS)

A higher stress score indicates higher stress levels, which are associated with an increased susceptibility to stress-induced illness such as depression or burnout.[20] Table 1 is used to interpret, analyse and discuss the PSS section of the results.

Table 1. PSS score interpretation.[20]

Total Score	Perceived Stress Level	Health Concern Level
0-7	Much lower than average	Very Low
8-11	Slightly lower than average	Low
12-15	Average	Average
16-20	Slightly higher than average	High
21 and over	Much higher than average	Very High

The relationship between the individual and the overall PSS score

The mean total PSS score of all 151 dentists is 19.3 (SD=7.9) with a median of 19 which indicates a high health concern and a slightly higher than average perceived stress level.

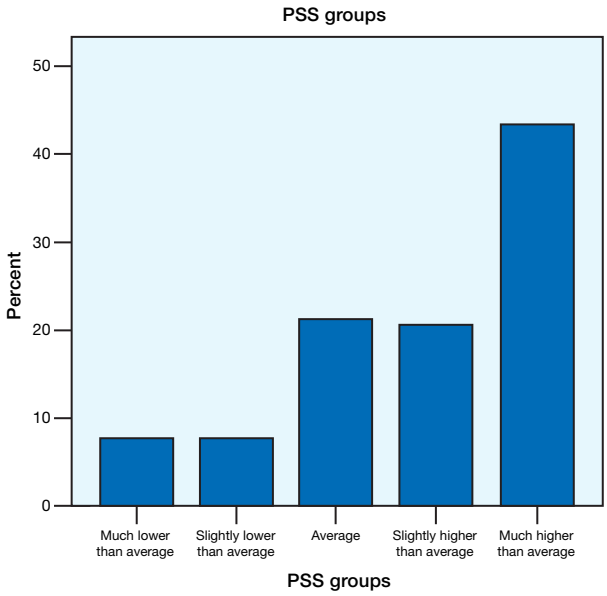

Figure 1. Bar graph showing perceived stress levels among South African dentists

Figure 1 shows 44% of dentists scored much higher than average which was also the highest score level among the five perceived stress levels and 21% (slightly higher) than average.

Table 2 demonstrates that most of the dentists fairly often felt that things were going their way (62; 41.1%) and felt that they were on top of things (65; 43%).

Table 1. Dentists' responses showing percentage and number of participants per item.

	Variable	Mean	SD	Median	Inter-quartile range
1. In the last month, how often have you been upset because of something that happened unexpectedly?	3	27	71	31	19
	2.0%	17.9%	47.0%	20.5%	12.6%
2. In the last month, how often have you felt that you were unable to control the important things in your life?	12	42	36	34	27
	7.9%	27.8%	23.8%	22.5%	17.9%
3. In the last month, how often have you felt nervous and "stressed"?	5	25	47	33	41
	3.3%	16.6%	31.1%	21.9%	27.2%
4. In the last month, how often have you felt confident about your ability to handle your personal problems?	5	27	44	51	24
	3.3%	17.9%	29.1%	33.8%	15.9%
5. In the last month, how often have you felt that things were going your way?	6	17	50	62	16
	4.0%	11.3%	33.1%	41.1%	10.6%
6. In the last month, how often have you found that you could not cope with all the things that you had to do?	20	33	53	30	15
	13.2%	21.9%	35.1%	19.9%	9.9%
7. In the last month, how often have you been able to control irritations in your life?	6	37	41	43	24
	4.0%	24.5%	27.2%	28.5%	15.9%
8. In the last month, how often have you felt that you were on top of things?	7	20	43	65	16
	4.6%	13.2%	28.5%	43%	10.6%
9. In the last month, how often have you been angered because of things that were outside of your control?	8	40	44	39	20
	5.3%	26.5%	29.1%	25.8%	13.2%
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	23	49	33	25	21
	15.2%	32.5%	21.9%	16.6%	13.9%

Also, one third of dentists fairly often (51; 33.8%) felt confident about their ability to handle their personal problems and almost never (49; 32.5%) felt difficulties were piling up so high that they could not overcome them. Whereas almost half of the respondents said they were sometimes (71; 47%) and fairly often (31; 20.5%) upset because of something that happened unexpectedly, and a good number of dentists very often (41; 27.2%) and sometimes (47; 31.3%) felt nervous and stressed.

The relationship between PSS scores and demographic variables

The study indicated that female dentists were found to have greater perceived stress scores (20.8) than male dentists (17.5). There was a significant difference found between male and female dentists in the total mean PSS score ($p< 0.05$).

The maximum mean PSS score (21) was observed in dentists who have 5-10 years of dental experience and the least mean PSS score (17) was found in those who have had more than 15 years of dental experience. Even so, the difference between the means of the four categories of years of dental experience (<5 years, 5-10 years, 10-15 years, >15 years) was found not to be significant ($p>0.05$).

Dentists who have children reported a lower mean PSS score (18) than dentists who didn't have children (20.6). It was observed that there was a significant difference in mean PSS scores between dentists who had children and those who didn't ($p<0.05$). The study also showed that male dentists are significantly more likely to have children than female dentists (Chi-square= 7.501; $p<0.05$).

It may be deduced from the data in Table 3 that there is a negative correlation between PSS scores and: age ($r=-0.171$), gender ($r=-0.206$), dentists' parental status ($r=-0.166$), and experience ($r=-0.148$). Apart from dental experience ($p>0.05$), all else showed significant differences in correlation ($p<0.05$).

Table 3. Correlation between: PSS scores and age; PSS scores and gender; and PSS scores and dentist that have children or not.

		Total PSS
How many years of experience do you have?	Pearson Correlation	-.148
	Sig. (2-tailed)	.070
	N	151
What is your age?	Pearson Correlation	-.171*
	Sig. (2-tailed)	.036
	N	151
Do you have children?	Pearson Correlation	-.166*
	Sig. (2-tailed)	.042
	N	151
What is your gender?	Pearson Correlation	-.206*
	Sig. (2-tailed)	.011
	N	151

Correlation is significant at the 0.05 level (2-tailed).*

Work Stress Inventory for Dentists (WSID)

Interpretation of the scores: WSID identifies stressors that are perceived to be highly stressful among dental professionals, therefore the data for both 'high-stress and great deal of stress' have been added to identify most stressful stressors.

The researchers looked at each of the 28 items from the WSID to evaluate the percentage of work stressors which dentists reported as the most stressful ('High-stress' and a 'Great deal of stress' indicates that the participant ticked no. 4 and no. 5 respectively on the Likert Scale). Of the 28 items, the ten items which dentists stated to be the most stressful are shown in Table 4.

Table 4. The 10 most stressful work events rated by dentists.

	n	Percentage
1. Being perceived as an inflictor of pain	85	56.3%
2. Coping with difficult, uncooperative patients	79	52.3%
3. Quoting fees and collecting payments	76	50.3%
4. Lack of patient appreciation and awareness of the complex nature of the job	75	49.7%
5. Earning enough money to meet your lifestyle needs	67	44.4%
6. Equipment breakdowns and defective materials	67	44.4%
7. Treating extremely nervous patients	66	43.7%
8. Feeling underrated by patients	66	43.7%
9. Working under constant time pressures	62	41.1%
10. Running behind schedule	61	40.4%

Correlation is significant at the 0.05 level (2-tailed).*

'Being perceived as an inflictor of pain' was rated as most stressful by 56.3% (n=85) of dentists, followed by 'coping with difficult, uncooperative patients' (n=79; 52.3%); 'quoting fees and collecting payments' (n=76; 50.3%); 'lack of patient appreciation and awareness of the complex nature of the job' (n=75; 49.7%); 'earning enough money to meet your lifestyle needs' (n=67; 44.4%); 'equipment breakdowns and defective materials' (n=67; 44.4%); 'treating extremely nervous patients' (n=66; 43.7%); 'feeling underrated by patients' (n=66; 43.7%); 'working under constant time pressures' (n=62; 41.1%); 'running behind schedule' (n=61; 40.4%). In addition, 'maintaining high levels of concentration for long periods and with few breaks' was also reported by 40.4% of dentists (Factor 1) as a most stressful event.

Table 5 shows the mean for each of the five dental stress factors. Of these, those related to patients' unfavourable perceptions of dentists have the highest mean work stress scores of 3.2 (SD=1.355), second to those related to problems dealing with patients (mean=3.06, SD=1.054). Staff and technical problems have the least mean work stress scores of 2.95 (SD=1.264).

Table 5. Average mean for each work-stress factor.

Stress Factors	Mean	Std. Deviation
1. Time and scheduling pressures	2.98	1.274
2. Pay related stressors	2.97	1.302
3. Patient's unfavourable perception of dentists	3.20	1.355
4. Staff and technical problems	2.95	1.264
5. Problems dealing with patients	3.06	1.054

The relationship between WSID scores and demographic variables.

With regards to gender, female dentists experienced a significantly ($p<0.05$) higher mean work stress score than did male dentists (90.59, 78.23, respectively).

We looked at 'equipment breakdowns and defective materials' ($r=-0.08$; $P>0.05$); 'treating extremely nervous patients' ($r=0.04$; $P>0.05$) and 'actually making mistakes' ($r=-0.122$; $P>0.05$) with age and experience, and found the relationships to be weak with no statistical significance.

The relationship between PSS scores and WSID scores

Perceived overall stress was significantly highly correlated with all the five work factors: time and scheduling pressures ($r=0.49$; $p<0.01$), pay related stressors ($r=0.45$; $p<0.01$) patient's unfavourable perceptions of dentists ($r=0.62$; $p<0.01$), staff and technical problems ($r=0.48$; $p<0.01$), and problems dealing with patients ($r=45$; $p<0.01$) (Table 6).

Table 6. Correlation between work stress factors and total PSS scores.

Work Stress Factors		Total PSS
Time and scheduling pressures	Pearson Correlation	.486**
	Sig. (2-tailed)	.000
	N	151
Pay-related stressors	Pearson Correlation	.448**
	Sig. (2-tailed)	.000
	N	151
Patient's unfavourable perceptions of dentists	Pearson Correlation	.624**
	Sig. (2-tailed)	.000
	N	151
Staff and technical problems	Pearson Correlation	.483**
	Sig. (2-tailed)	.000
	N	151
Problems dealing with patients	Pearson Correlation	.454**
	Sig. (2-tailed)	.000
	N	151
Correlation is significant at the 0.01 level (2-tailed).**		

Coping strategies

Participants were requested to tick multiple strategies that helped them to cope with their stress levels. Of the 12 coping strategies or mechanisms, exercise (n=97; 64%) and resting (n=95; 63%) were the most frequently selected by the respondents. Almost 50% of the respondents said that forgetting about work helped them cope with stress and 46% of respondents said that interactions with people assisted them in times of stress. Only 15% of respondents resorted to alcohol, 3.3% resorted to recreational drugs and 13% resorted to smoking to relieve their stress (Figure 2).

Figure 2. Frequency of responses for the various stress coping mechanisms

There is no significant difference found between genders for the following coping strategies: alcohol consumption, resting, interacting with people and for smoking. However, there was a significant difference found between the genders with regards to the coping mechanism of exercising (Chi-square=10.205; $p<0.05$), indicating that male dentists were more likely to exercise than female dentists.

Since many participants ticked 'interaction with people' as a way of reducing their stress, the authors wanted to know if the area (rural, small town or urban) in which dentists worked had an impact on whether they interacted with people or not. The study found that there was no significant difference (Chi-square=.792; $p>0.05$).

DISCUSSION

Perceived general stress among dentists

The results highlight the fact that dentists experienced slightly higher than average overall stress scores, indicating that dentists do experience a high perceived level of stress, with mean PSS scores also shown to be much higher than the mean PSS scores observed among US population.[21] The study found that a large proportion of dentists recorded much higher than average (44%) and slightly higher than average (21%) stress scores, indicating that 65% of participants experienced high-stress levels, which meant that they had a high susceptibility to stress-induced illness such as depression or burnout.[20] This finding agrees with results from Möller & Spangenberg who that found that 40% of dentists experienced extremely high-stress levels.[18]

When looking at the individual demographic characteristics, it was found that female dentists experienced significantly higher levels of reported stress than did male dentists. This indicated that female dentists overall perceived life situations as more stressful than male dentists. Although the study by Möller, & Spangenberg[18] used a different scale to measure stress, they reported that there was no significant difference in stress levels found between the two genders.[18] However, their study

was done 10 years ago and 52% of the present respondents have less than 10 years of dental experience, which may indicate the presence of a trend among newer graduates. Also, Möller and Spangenberg[18] included only 13% of female respondents, which may have made it more difficult to detect significant differences. Another important issue to note is that there is a larger number of female dental graduates in South Africa now than in 1996. Reports state that almost 80% of dentists graduating between 1985 and 1994 were male. This, however, changed significantly between 1995-2004, with the proportion of female dental graduates rising to 46%.[22] Although random sampling was applied - offering an equal probability for any dental participant to be chosen for participation in the study - this could explain why the 1996 study had a low count of female dental practitioners.[18]

The lowest overall stress score was also among dentists who had had the most years of dental experience (>15 years). However, a closer look showed that there was no statistical correlation between dental experience and perceived overall or general stress. Overall perceived stress is highly likely to occur in dentists of various experience and dentists who have the most dental experience, stress less for reasons other than longevity in the profession.

The present study found a significant difference in stress experience between dentists who have children and those who don't, those with children reporting significantly less general stress than did those without children. This study also found that male dentists were significantly more likely to have children than would female dentists. One possible explanation for this comes from a study done in 1997 by De Wet, Truter and Ligthelm who found that when South African female dentists had children, they worked significantly fewer hours per week than did their male counterparts.[23] It may be that male dentists were less involved with their children and relied more on their spouses. In addition, the study found that female dentists could afford to work for fewer hours because they were not the breadwinners, which may also have contributed to their lower levels of parental stress.[23] However, the present study did not look at the working hours or family dynamics of each participant, opening the opportunity for new studies on stress and dental families in South Africa.

Occupational stressors for dentists

'Being an inflictor of pain' and 'coping with difficult, uncooperative patients' were also identified in much of the literature as top high stressors. [4,16,24–26] These factors, 'being an inflictor of pain' and 'coping with difficult patients', were also reflected in another study, which concluded that large numbers of the dentists found these stressors to be intensely stressful in South Africa.[23] 'Running behind schedule' was ranked by more than 60% of dentists as a top high stressor in many studies.[8,24,26,27] However, in the present study it was ranked as the 10th highest work stressor, with 40% of respondents rating the item as causing a high-stress/great deal of stress.

Of the five work factors, 'staff and technical problems' caused the least amount of stress among the surveyed dentists. Also, reporting under this factor, almost 60% of dentists responded that 'interpersonal problems with work colleagues' gave them no stress/little stress. Relationships with their work colleagues were low on their list of stress causes. Similarly, this confirms a previous South African study,[18] and the investigation which found office management to be the lowest cause of stress levels among Saudi Arabian dentists.[28]

The factors that caused the highest amounts of stress were related to an unfavourable perception of the dentist and problems dealing with patients. This agrees with Kay & Lowe's study which found that UK dentists attributed patient demand as the highest work stress factor.[2] However, this is in contrast to a paper reporting on stress among Yemeni dentists which found the patient-related factor to be the lowest cause of stress.[25] Another discovery was that the lowest mean score for work stress factor (staff and technical problems) found in the present study were similar to the highest mean scores for work stress factors found in both the Yemen and in Saudi Arabia.[25,28] South African dentists in this study certainly perceived dentistry to be a highly stressful profession.

With regards to gender, not only were the mean general stress scores higher for female dentists than for male dentists, but also were the mean work stress scores. Female dentists perceive dentistry as being significantly more stressful than do male dentists. This corroborates findings in a UK study,[24] whilst no differences in gender were found among Southern Thailand dentists.[29]

No significant relationship was found when observing the correlation between the number of years of dental experience and the three work stressors (equipment breakdowns, making mistakes or treating extremely nervous patients). However, this contrasts with a previous South African study.[18]

An important finding was that high overall perceived stress in a dentist's life were strongly associated with all five work stress factors (time and scheduling pressures, pay-related stressors, patients' unfavourable perceptions of dentists, staff and technical problems, and problems dealing with patients). Although further studies are required to determine the cause and effect, dentistry is indeed a work related stressful profession among the South African dentists who participated in this study, in concord with UK dentists.[24]

Coping strategies used among dentists

In contrast to other studies[25,28,29] a high proportion of South African dentists, especially males, reported that they exercised (This may explain why males experienced significantly less stress than female dentists!).

More New Zealand dentists working in major cities reported interacting with people as a strategy for coping with their stress than did those working in other areas.[16] The present investigation found no significant differences between these groups. Dentists are not restricted from interacting with people, wherever the venue. This study found that 15% of dentists consumed alcohol as a form of stress relief. This is much less than the report of a previous South African study[18] that more than 40%

of dentists drank alcohol to relieve their stress levels. This seems to indicate that the number of dentists who drink alcohol to relieve their stress has diminished. These data reflect a marked reduction in dependency on alcohol.

LIMITATIONS

Firstly, in recognition of the constraints of time, non-probability sampling (convenience or purposive) was used rather than random sampling, therefore resulting in the situation where each member of the dental population did not get an equal chance of being picked.[30] Hence it will not be possible to draw inferences from the study on the general population.

Secondly, this is a cross-sectional study i.e. observing a section of the dental population at one point in time, therefore a cause-and-effect relationship cannot be determined.[24] This is also one of the limitations of the PSS scale i.e. it measures stress levels within the preceding month.

CONCLUSIONS

The dentists in this study had a much higher than average overall perceived stress score and these were shown to be associated with high work stress levels. This confirms the findings of the previous South African study[18] and many others[5,16,18,24,28,29,32] that dentistry is a highly stressful profession.

The occupational stressors identified as highly stressful were patient related matters, indicating the need to improve dentist-patient relationships. It is therefore recommended that good patient communication skills are taught at undergraduate level and are reinforced throughout a dentist's career.

Most dentists in this study chose to manage their stress by exercising, resting, forgetting about work and interacting with people. Since many of the dentists in this study were found to be highly stressed, it is recommended that they seek healthier coping strategies and improve their dentist-patient relationship. Overall, this study indicated the stressful nature of the dental profession, therefore interventions are desirable to help dentists lessen stress in the work environment.

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Does additional information provided by cone beam computed tomography (CBCT) and a consequent modification of surgical technique reduce the possibility of inferior alveolar nerve injury? A pilot study

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ABSTRACT

Objectives

To compare the incidence of inferior alveolar nerve injury after lower third molar extraction between two groups who had undergone differing preoperative diagnostic radiological assessments.

Material and methods

A pilot study was conducted comparing potential surgical complications between two groups before surgical removal of lower impacted third molars. The patients (n=93) were divided into two groups: panoramic x-ray and Cone-beam computed tomography group (n=38) and the panoramic x-ray group (n=55). Post-operative complications in each group were recorded a week after surgery. Multivariate logistic regression was used to determine the association between the incidence of nerve injury and other variables.

Results

The inferior alveolar nerve was exposed during the procedure in only six patients (6.45%) and thirteen patients (13.98%) had transient paraesthesia a week post-surgical extraction. In twelve patients (92.30%) sensation fully recovered within the first month after the procedure with one patient (1,08%) having paraesthesia after six months post-extraction.

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ACRONYMS

CBCT:	Cone Beam Computed Tomography
IAN:	Inferior Alveolar Nerve
L3M:	Lower Third Molars
PGC:	Pell and Gregory Classification

Conclusions

Additional information gathered from Cone-beam computed tomography and precautionary measures taken during surgery did not reduce the incidence of IAN injury.

Keywords

Cone-beam computed tomography, paraesthesia, lower third molar, inferior alveolar nerve.

INTRODUCTION

Surgical removal of impacted lower third molars (L3Ms) is one of the most commonly performed procedures in oral surgery. The indications for the procedure include the following: recurrent pericoronitis, interference with reduction of fractures, preparing for orthognathic surgery, carious lesions, and pathology associated with impacted L3Ms. The complications of this procedure include damage to the inferior alveolar nerve (IAN) with subsequent neurosensory impairment of the lower lip and chin.[1]

A panoramic radiograph is generally mandatory before surgical removal of L3Ms. Various signs have been described on the panoramic image that may indicate a close proximity of the L3M roots to the inferior alveolar canal.[2-4] A study by Hasengwa et al.[5] however, suggests that a panoramic radiograph alone does not provide sufficient information to confirm the relationship between an impacted tooth and the mandibular canal. These authors recommend that additional radiography be used, namely cone beam computed tomography (CBCT), the gold standard for accurate evaluation of these relationships.[6]

The main advantage of CBCT scans is that they provide three-dimensional views with lower radiation exposure. However, they are very costly.[7]

Apart from proximity issues, other risk factors associated with the surgical procedure that have been cited in the literature include inadequate experience of the surgeon, elderly patients with fully developed roots, deep impaction,[8] and intraoperative exposure of the IAN.[9]

A few studies have reported an association between the Pell and Gregory classification (PGC) and the likelihood of an IAN injury.[8] Several studies suggest that the use of CBCT scans in patients with radiographic signs of close proximity of the root of an impacted wisdom tooth to the mandibular canal may be instrumental in reducing the risk of an IAN injury.[10,11] However, a study by Sanmarti-Garcia[6] reported that this does not necessarily apply.

Hence there are conflicting reports in the dental literature on whether the preoperative use of CBCT aids the surgeon in reducing the prevalence or severity of an IAN injury.[6,10,11] The aim of this study was to determine whether having a preoperative CBCT scan had any influence on the incidence and evaluation of an IAN injury caused during L3M extraction. A comparison was made of two groups of patients who had had differing radiological examinations but showed similar radiologic signs indicating proximity between tooth roots of the L3M and the mandibular canal.

The study firstly determined the incidence of IAN injuries in patients treated at the Maxillofacial and Oral Surgery Department. The objective then was to assess the utility of CBCT in providing preoperative information which could prevent the occurrence, or decrease the severity, of an IAN injury that may occur during an extraction of a L3M that is seen on a panelipse to be in close relation to the mandibular canal.

MATERIALS AND METHODS

Study Population

A pilot study was conducted from January 2014 to December 2014 on patients presenting for surgical extraction of symptomatic impacted L3M's at the Maxillofacial and Oral Surgery Department at the University of the Witwatersrand. All eligible participants were aged 18 years or older and had panoramic radiographs which depicted signs that suggested close proximity between the tooth roots and the mandibular canal.

Patients presenting with any pathology (granuloma, cysts or tumours) associated with the root of an impacted L3M and with L3M mandibular fractures were excluded. Informed consent was obtained from all volunteers, and the Human Research Ethics Committee of the University of the Witwatersrand (M130915) granted ethical permission for the study.

Patients were randomly allocated to one of the following two groups: a control group (panelipse only) or an intervention group (panelipse and CBCT). Sealed envelopes containing cards with either "panelipse only" or "panelipse and CBCT" were placed in a box. Each patient was requested to pick up an envelope that would allocate him/her to a group.

Data collection

A data collection sheet was used to record the required information, which was categorized into preoperative, operative, and postoperative data. Recorded preoperatively were data on: gender, age, tooth number, depth and orientation of the impacted L3M. Two calibrated radiologists assessed the pan and the CBCT scans.

The inter-examiner agreement was assessed using the Kappa statistic, with an overall value of 0.7-0. 8 for panoramic x-ray films and 0.8 -0.9 for the CBCT scan. The depth and orientation of the impactions were recorded using PGC and Winters' classification.

Intraoperative data that was recorded included the surgical procedure performed on each tooth, any complications, the experience of the surgeon in years, and exposure of the IAN.

Additional information acquired from the CBCT was used in the endeavour to prevent injury to the IAN. The surgical procedures were recorded as follows: intra-alveolar dental extraction (extraction); whether or not a flap was raised (F); elevation of the tooth (E); bone removal (B); and tooth sectioning / odontectomy (D). At the postoperative stage recorded data included neurosensory disturbance, infections, alveolitis, and any other complications.

All patients underwent surgical removal of the tooth, performed using a buccal approach, under local anaesthesia by an oral and maxillofacial surgeon and registrars (residents). In patients with the inferior alveolar canal located on the buccal side to the L3M, the surgeon luxated the tooth in a buccal direction, thus rotating the apex in a lingual direction.

When the inferior alveolar canal was located lingually to the L3M the surgeon luxated the tooth in a lingual direction, thereby rotating the tooth in the direction opposite to the inferior alveolar canal.[12]

Another surgeon who was blinded to both the preoperative and intraoperative data of the control and intervention groups, reviewed all patients. The patients had a postoperative review appointment a week after the surgery to assess any postoperative complications.

Neurosensory disturbances of the lip and the chin were first assessed through self-reported outcomes. Subjective and objective assessments were performed with the light touch test (with von Frey fibres) and a two-point discrimination threshold in patients complaining of neurosensory disturbance.[13]

Statistical analysis

The collected data were statistically analyzed using the SPSS version 19 for Windows (IBM SPSS, Chicago, IL, USA). Descriptive statistics were used to summarize all measurements. The association be tween categorical variables was tested with Fisher's exact test. A Mann-Whitney nonparametric test was used to compare ages between the two groups.

A P-value <0.05 was considered statistically significant. Multivariate Logistic regression was used to determine the association between nerve injury and other variables. The odds ratio was used to determine the strength of the association.

RESULTS

The study involved 93 patients, 52 (55.91%) women and 41 (44.09%) men (Table 1). The age range of the patients was between 23 and 32 years with a median of 27 years. Thirty-eight patients (40.86%) had both a panelipse and a CBCT scan taken, while 55 (59.14%) had only a panelipse taken. The majority of patients had level 1A and 2A impactions, only three having 2C impactions, according to the PGC classification.

The distribution of patients in relation to the radiographic signs of root proximity to the inferior alveolar canal is shown in Table 1. Twenty-eight patients (30%) were treated by an oral and maxillofacial surgeon, while 65 (70) were treated by residents. Thirteen patients (13.98%) had transient paraesthesia a week after surgical extraction, eight in the intervention group (21.05%) and five in the control group (9.09%). Eleven were treated by residents. Twelve patients recovered from this paraesthesia within the first month after the procedure. One patient (1.08%) continued to have paraesthesia after six months.

Fisher's exact test (Table 2) showed a statistically significant association between an IAN injury and the depth of the impaction (p=0.036), the surgical procedure (p=0.007) and the nerve exposure (p=0.034).

Even though only three patients were affected, the bivariate and multivariate logistic models showed that nerve exposure (OR: 7.7; 95% C.I: 1.36 – 43.46; p= 0.021); (OR 17.30; 95% C.I: 2.10-142.50; p=0.008) and PGC classification (2C) (OR: 24; 95% CI 1.46-394; p=0.026); OR: 40.41; 95% CI 1.71-951.85; p= 0.22) had significant associations with IAN injury. (Table 3).

DISCUSSION

Inferior alveolar nerve injury is a serious complication of the surgical removal of an impacted L3M. The incidence of IAN injury ranges from 0.5% to 17%,[14] with a 14% prevalence.[6] Permanent injury has been reported as 0.12% of cases.[13] An IAN injury may be perceived as tingling, numbness, or as a burning, painful sensation affecting the lower lip, chin, and teeth or labial gingiva.[4] A study by Ghaeminia et al. reported a 17% incidence of transient injury.

Table 1. Demographic characteristics of the participants

Characteristics	Frequency (%)
Gender	
Male	41 (44.09)
Female	52 (55.91)
Age Median (IQR)	27 (23 – 32)
Sign	
IWL	46 (49.46)
RR	28 (30.11)
DR	9 (9.68)
DC	4 (4.30)
NC	6 (6.45)
CBCT	
No	38 (40.86)
Yes	55 (59.14)
Winters Classification	
MA	39 (41.94)
V	30 (32.26)
H	24 (25.81)
Pell Gregory	
1A	26 (27.96)
2A	34 (36.56)
1B	17 (18.28)
2B	11 (11.83)
2C	3 (3.23)
3A	2 (2.15)
Tooth	
Right Side	45 (48.39)
Left Side	48 (51.61)
Complications	
None	73 (78.49)
Pain	1 (1.08)
IAN	13 (13.98)
Septic Socket	4 (4.30)
Dry Socket	2 (2.15)
Work Experience	
5 – 15 years	65 (69.89)
15+	28 (30.11)
Surgical Procedure	
Extraction	9 (9.68)
FE	28 (30.11)
FBE	2 (2.15)
FBD	54 (58.06)
Nerve Exposure	
No	87 (93.55)
Yes	6 (6.45)

Acronyms

IQR = interquantile range
IWL = Interruption of white line
RR = Root radioluscency
DR = Diversion of the root
DC = diversion of the cana
NC = narrowing of the canal
MA = Mesio-angular impaction
V = Vertical impaction
H = Horizontal impaction
FE = flap raised and elevation of the tooth
FBE = Flap raised, bone removal and elevation of the tooth
FBD = Flap raised, bone removal and dentectomy (sectioning of the tooth).

Table 2. Relationship of the variables between IAN and risk factors

Factors	IAN (n=13)	Other Complications (n=80)	p-value
Gender			
Male	7 (17.07)	34 (82.93)	0.445
Female	6 (11.54)	46 (88.46)	
Age Median (IQR)	25 (24 – 28)	28 (22 – 32)	0.257
Sign			
IWL	6 (13.04)	40 (86.96)	0.812
RR	5 (17.86)	23 (82.14)	
DR	1 (11.11)	8 (89.89)	
DC	1 (25.00)	3 (75.00)	
NC	0 (0.00)	6 (100.00	
CBCT			
No	5 (13.16)	33 (86.84)	0.850
Yes	8 (14.55)	47 (85.45)	
Winters Classification			
MA	4 (10.26)	35 (89.74)	0.480
V	4 (13.33)	26 (86.67)	
H	5 (20.83)	19 (79.17)	
Pell Gregory			
1A	2 (7.69)	24 (92.31)	*0.036
2A	3 (8.82)	31 (91.18)	
1B	2 (11.76)	15 (88.24)	
2B	3 (27.27)	8 (72.73)	
2C	2 (66.67)	1 (33.33)	
3A	1 (50.00)	1 (50.00)	
Tooth			
Right Side	6 (13.33)	39 (86.67)	
Left Side	7 (14.58)	41 (85.42)	
Work Experience			
5 – 15 years	11 (16.92)	54 (83.08)	0.180
15+	2 (7.14)	26 (92.86)	
Surgical Procedure			
Extraction	0 (0.00)	9 (100.00)	
FE	0 (0.00)	28 (100.00)	
FBE	0 (0.00)	2 (100.00)	*0.007
FBD	13 (24.07)	41 (75.93)	
Nerve Exposure			
No	10 (11.49)	77 (88.51)	*0.034
Yes	3 (50.00)	3 (50.00)	

* p>0.05
** Mann Whitney t-test for equality of age between the two groups

Table 3. Bivariate and Multivariate logistic regression model

Factors	p-value	Bivariate Logistic model OR & 95% CI	p-value	Multivariate logistic model OR & 95% CI
Gender				
Male		1		
Female	0.447	0.63 (0.19-2.06)		
Age Median (IQR)	0.204	0.93 (0.84-1.04)		
Sign				
IWL		1		
RR	0.574	1.45 (0.40-5.28)		
DR	0.874	0.83 (0.09-7.89)		
DC	0.518	2.22 (0.20-25.00)		
NC		1		
CBCT				
No		1		
Yes	0.850	1.12 (0.34 – 3.74)		
Winters Classification				
MA		1		
V	0.693	1.35 (0.31-5.89)		
H	0.252	2.30 (0.55-9.61)		
Pell Gregory				
1A		1		1
2A	0.875	1.16 (0.18-7.51)	0.762	0.73 (0.10-5.44)
1B	0.655	1.6 (0.20-12.60)	0.994	0.99 (0.09-10.39)
2B	0.133	4.5 (0.63-31.95)	0.380	2.67 (0.30-23.83)
2C	*0.026	24 (1.46-394)	*0.022	40.41 (1.71-951.85)
3A	0.119	12 (0.53-273)	0.235	180.15 (0.03-953178.2)
Tooth				
Right Side		1		
Left Side	0.862	1.11 (0.34-3.59)		
Work Experience				
5 – 15 years	0.226	2.65 (0.55-12.83)		
15+		1		
Nerve Exposure				
No		1	1	
Yes	*0.021	7.7 (1.36 – 43.46)	*0.008	17.30 (2.10-142.50)

*p>0.05
**Mann Whitney t-test for equality of age between the two groups

Acronyms
IQR = interquantile range
IWL = Interruption of white line

In the current study, transient injury occurred in 13.98% of cases and reduced to 1% after one month. Since the resolution of neurosensory disturbances occurred within four weeks after the procedure, neuropraxia was the most likely cause of transient sensory disturbance in this study.

Most studies consider diversion of the nerve canal and darkening of the roots of teeth as being significantly associated with an IAN injury.[1-2,14] Other associated factors such as the interruption of the white line[2,5] and narrowing of the canal[16] show a close association with an IAN injury. In this study, none of these panoramic signs were associated with an IAN injury. However, the results of this study are skewed since most patients had an interruption of the white line and radiolucency of the roots. Further studies are needed to investigate the infrequent radiographic signs. Few studies have reported an association between the depth of an impacted tooth and an IAN injury.[8,12,15] This study showed a statistically significant association between depth of impaction and IAN injury, probably because in deeper vertical impactions part of the tooth structure is below the level of the mandibular canal or the whole tooth may be lying along the length of the canal in horizontal impactions.

This study also found a significant association between nerve exposure and an IAN injury, which is in accord with the findings described in other reports.[5,10,13] However, according to Ghaeminia et al.[1] there is no correlation between nerve exposure and sensory

nerve impairment. Neurological disturbances in patients with nerve exposure are likely to be caused by nerve compression by the tooth or fragment of bone that was covering it and the nerve stretching that occurs when dissecting it out from overlying structures.

The study also showed that a surgical procedure that involves raising of the mucoperiosteal flap, bone removal, and sectioning of the tooth (FBD) is more likely to predispose patients to an IAN injury.

The association between FBD and IAN injury was statistically significant, with $p<0.05$. This finding is in agreement with the findings of a study by Blondeau and Daniel,[8] which also found that ostectomy and odontectomy (sectioning of the impacted tooth) were strongly associated with an IAN deficit.

A study by Hasengwa et al.[5] also found that ostectomy was associated with neurosensory disturbances. It is not surprising that ostectomy and odontectomy are associated with neurological deficits since these procedures are performed in deep impactions.

Some studies reported an association between the experience of the surgeon and an IAN injury.[8,13] On this point, our study is in agreement with a study by Hasengwa et al.[5] which also found no association between experience and IAN injury. The difference between this study and a report by Cheung et al.[13] is that in this series, specialists were removing deeper impactions that had a higher risk of an IAN injury.

CONCLUSION

The results of this study indicate that the use of information gleaned through a CBCT does not reduce the incidence of nerve injury during surgical removal of L3Ms. An extensive procedure involving removal of bone, odontectomy and manipulation of anatomical structures at varying depths of the tooth impaction (PGC 2B, 2C, and 3A) will largely influence the occurrence of an IAN injury during surgical extraction of L3Ms.

The significance of this finding is that the surgical procedure predisposes the patients to the risk of nerve injury, and the patients should always be informed of this risk. However, the outcome of this study needs to be confirmed with larger sample sizes that may include many cases of impactions at deep depths, where the surgical procedure is extensive and exposure of the nerve is likely to occur.

Conflict of interest: We have no conflicts of interest to declare.

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Ethical approval: Data collection and the methods used in present study were approved by the Human Research Ethics Committee of the University of the Witwatersrand (M130915).

Informed consent: Informed consent was obtained from all volunteers.

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Comparison of two light guide tips used to photo-polymerize two dental composites. An *in-vitro* study

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ABSTRACT

Introduction

Manufacturer-made light guide (MMLG) tips of light emitting diodes (LEDs) are frequently damaged. Could custom-made light guide (CMLG) tips be suitable replacements?

Aims

1.) To compare compressive fracture strengths of resin-based composite specimens photo-polymerized/cured with a CMLG tip (acrylic-glass) and a MMLG tip (fibre-optic), used interchangeably on a poly-LED curing unit.
2.) To compare the costs of the CMLG tip and the MMLG tip.

Methods

Two groups of 20 composite cylindrical specimens (4 mm diameter, 4 mm length) were made in teflon moulds. Each light tip cured ten micro-hybrid Z100™ and ten nano-filled Filtek™ Supreme XTE specimens, (60 seconds each side). Storage was in distilled water at 37°C (±2°C) for 48 hours. Compressive strength testing (MPa) was done at a crosshead speed of 0.5 mm/min using a Bencor Multi-T device in an Instron machine. Student's paired t-test and intra-class correlation coefficients (ICC) were applied for analysis and agreement testing. Relative costs of both light guide tips were determined and compared.

Results

Only the Z100™ groups showed significant differences in compressive fracture strength (p = 0.001). The CMLG tip was cheaper.

Discussion

The CMLG tip was preferred for photo-curing Filtek™ Supreme XTE resin based composite.
The MMLG tip was preferred for photo-curing Z100™ resin based composite.

Conclusions

The CMLG was suitable for curing preclinical Z100™ and Filtek™ Supreme XTE resins and was substantially cheaper than the MMLG tip.

ACRONYMS

CMLG:	Custom-Made Light Guide
LCU:	Light Curing Unit
LED:	Light Emitting Diode
MMLG:	Manufacturer-Made Light Guide

INTRODUCTION

The use of a manufacturer-made Poly Light Emitting Diode (LED) LCU for the photo-polymerization (curing) of light cured resin based composites is well known to the dental profession.[1-7] Polymerization of a resin based composite depends on an adequate output of light (minimum irradiance between 300-400 mW/cm^2).[4] The output depends on the condition of the internal filter, condition and type of reflector, condition of the bulb LED and the condition and type of the light guide tip. Other factors include appropriate wavelength range and the exposure time of the light to the surface of the composite.[2] It is also imperative that the irradiance wavelength of these LED dental curing units is compatible with the photo-initiator present in the resin based composite restoration.[8-12] The amount of photo-initiator activated depends on the concentration in the material as well as the number and energy of the photons (wavelength of the curing light) to which the material is exposed. The most common photo-initiator today is camphorquinone which has a peak activity at around 470 nanometers.

The LED light guide tip forms part of the LCU and is responsible for the transmission, distribution and dispersion of light energy from the LED source to the surface of the resin based composite restoration.[13-17] The transmission distribution and dispersion across the face (surface) of the light guide tip has a great impact on the polymerization kinetics of resin based composites.[14,15,18,19] These factors can affect the polymerization shrinkage, associated stresses, micro-hardness,

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depth of cure, degree of conversion and water sorption of water soluble resin based composites, effects that may result in post-operative sensitivity, micro-leakage and restoration failure.[14,15,20-23] It is therefore important that the light guide tip remains undamaged, clean and unobstructed so that it functions at an optimal level. MMLG tips are known to cure resin-based composites adequately.[1-5] However they are extremely fragile and easily damaged by dental students performing pre-clinical restorative dental procedures.

Replacement of these damaged MMLG tips can be extremely expensive for dental schools and the ordering process can be a lengthy and arduous task. The delay also results in undergraduates having to share a LCU for pre-clinical procedures, compromising the efficiency of their pre-clinical education.

The efficacy of a CMLG tip (similar to the shape and dimensions of a MMLG tip) that allows the curing of a resin based composite to the status of sufficient compressive strength, similar to the compressive strength fracture of a human molar (305 MPa[24]) has not been investigated. This may be an alternative option, offering a suitable and inexpensive solution.

Therefore the aims of this study are;

i.) To evaluate the compressive fracture strength (MPa) values of specimens of two resin-based composite specimens (microhybrid Z100™ and nanofilled Filtek™ Supreme XTE) photo-cured with either a CMLG tip or a MMLG tip.

ii.) To compare the costs of the CMLG tip and the MMLG tip.

MATERIALS AND METHODS

Technical specifications of the LED Unit

The LED curing unit used for this study was a Light SLC-VIIIc (Hangzhou corporation, Zhejiang Province, China). The unit had an AC 90 adapter using a power source that delivered between 220V and 230V at a frequency that varied between 50Hz and 60Hz. The power intensity (fast mode) of the LED unit was measured at 600 mw/cm^2, using a radiometer as a guide.

The optical specification of the wavelength, as indicated by the manufacturer, was between 430nm and 490nm. These specifications ensured that the LED unit would be effective with both the resin based composite specimens and that the photo-initiator (camphoroquinone) present in the specimens would be activated.

Specimens were cured using the same LCU, the same power source and at the same room temperature of 18°C. The light intensities through the CMLG tip and through the MMLG tip were tested, using the radiometer, before each specimen was cured, ensuring that curing was effected under the same conditions.

Technical specifications of the light guide tips

The MMLG tip was fibre-optic and the CMLG was acrylic-glass. The light guide tips were 8mm in diameter and 10cm in length, with a 145° curved angle closer to the flat, polished tip.

Specifications of the radiometer

The radiometer used was a DEMETRON Model 100 Curing Radiometer (Demetron Research Corporation, Danbury, CT, USA). The radiometer reading instructions were listed on the rear surface of the radiometer as follows:

Readings under 200: Do not use the curing light, refer to instructions (for the curing light).

Readings in between 200-300: Increase the curing time.

Readings above 300: Use the curing light recommended time indicated by the manufacturer.

Technical specifications of the composite specimens

In this study one group of 20 composite cylindrical specimens (4 mm in diameter and 4 mm in length) were made of Filtek™ Supreme XTE (3M ESPE Dental Products, St Paul, MN, USA). The other group of 20 composite specimens (4mm in diameter and 4mm in length) were made from Z100™ (3M ESPE Dental Products, St Paul, MN, USA). The twenty composite specimens in each group were prepared using a machined teflon mould 4 mm in length and 4 mm in diameter.

Manufacturing of the CMLG tip and resin based composite specimens:

1. A custom mould made from polysiloxane lab putty (COLTENE, Essex, United Kingdom), was manufactured by taking an impression of the MMLG tip (Figure 1a) so that the dimensions and angles of the MMLG tip could be accurately transferred to the CMLG tip.

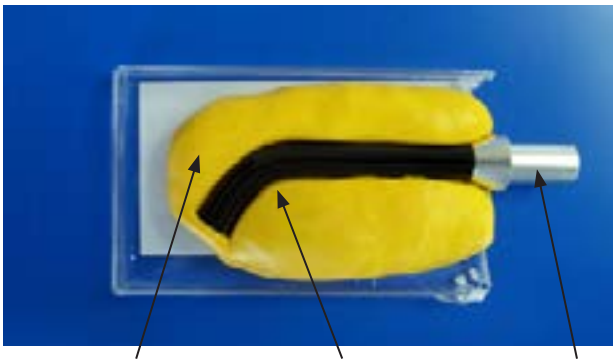

Figure 1a. Lab-putty impression of a MMLG fibre-optic tip with removable steel coupling.

2. A 2m rod made of acrylic-glass (Plexiglas, Bedfordview, South Africa), 8mm in diameter, was sectioned into 10cm rods using a diamond disc on a straight hand-piece.

3. Each 10cm acrylic glass rod was heated in a Bunsen burner flame (Science World, Parow Cape Town, South Africa) so it could be shaped into a 145 degree angle at the front end, using as a guide a custom

mould made from polysiloxane lab putty (Coltene, Essex, United Kingdom) so the rod could be used as a light guide (Figure 1b).

The glass rod has a melting temperature of 130°C. Extreme care was taken when shaping the light guide tip to avoid melting the rod. The light intensity of the CMLG tip was tested with the radiometer, before and after the structural reshaping.

There was no change in the transmission and intensity of the light. The CMLG rod was then finished (pumice and water) and polished (acrylic polish) in a Gamberini Polishing Machine (Gamberini corporation, Cambridgeshire, United Kingdom).

The smoothness of the surface of each end of the CMLG tip was evaluated using a Profilometer (Mitutoyo, Tokyo, Japan). The average of the Ra values (roughness coefficient) recorded were 0.259 which is well below the standard reference calibration value of 2.97 (according to the manufacturer) indicating high quality, polished surfaces at both ends of the CMLG tip.

Figure 1b: Lab-putty mould used as a guide when shaping the CMLG acrylic-glass tip into a 145 degree angle.

4. The CMLG was fitted into the removable steel coupling that connected to the LED SLC-V IIIc Dental Curing Light (Hangzhou corporation, Zhejiang Province, China).

   The CMLG tip was tested with the radiometer before each specimen was cured to ensure that light transmission was optimal to activate the photoinitiator and thus to cure each composite specimen.

5. Filtek™ Supreme XTE (A1) (3M ESPE) and Z100™ (A1) (3M ESPE) composite were severally packed into and cured (2 mm increments) in machined circular teflon moulds (Figure 2) that were placed on a clear glass mixing slab.

   The moulds were covered with a Mylar (Du Pont, Wilmington, USA) polyester strip, and light cured (60 seconds) on both sides to form cylindrical composite specimens (4mm in diameter, 4mm in length).

   The flat face of the light guide tip was positioned directly over the polyester strip and onto the Teflon mould on both sides of the specimen. The distance between the tip face and the composite specimen was less than 0.5mm. The specimens were subsequently stored in distilled water at 37°C for 48 hours.

Figure 2: Composite specimens packed into Teflon moulds.

6. Two groups of twenty composite specimens (n = 40) were made using the Teflon moulds.

7. Ten Z100™ specimens were light-cured using a CMLG tip and ten Z100™ specimens with the MMLG tip

8. Ten Filtek™ Supreme XTE specimens were light-cured using a CMLG tip and ten Filtek™ Supreme XTE specimens with a MMLG tip.

9. The compressive strength of the specimens was determined, with the specimens mounted in a Bencor Multi-T device (Danville Engineering, San Ramon CA, U.S.A) placed in an Instron machine (Norwood Corporation, Massachusetts, U.S.A), at a crosshead speed of 0.5mm/min (Figure 3). Maximum compressive load (compressive strength) was measured in MPa at fracture of each specimen.

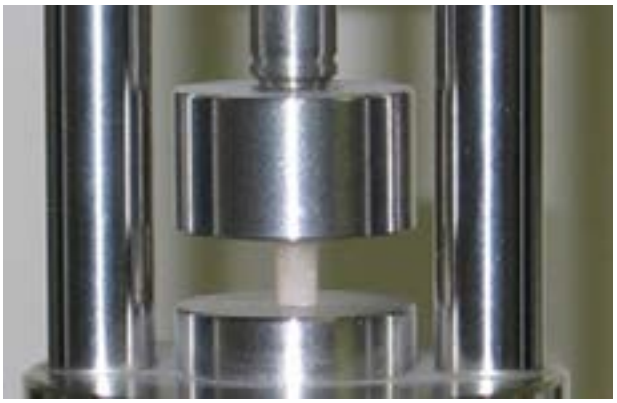

Figure 3: Instron machine with composite specimen mounted in a Bencor Multi-T device.

Results were compared and analysed using a Student's paired t-test. Agreement amongst the compressive fracture (MPa) values in each group was assessed with the intra-class correlation coefficient (ICC), a descriptive statistic that is a general measurement of agreement. The results for both specimens are presented in Tables 1 and 2, which reflect a summary of the analyses.

The calculation of the cost difference of each light guide tip was determined by comparing the quote from the manufacturer for the MMLG tip with the total costs involved in the manufacturing of the CMLG tip.

In this study the results of the specimens photo-cured with the MMLG tip acted as the control. The assumption is that MMLG tip, functioning optimally and used with a suitable LCU, will cure Z100™ and Filtek™ Supreme XTE resin specimens to an adequate degree. The mean compressive strength (MPa) value of the resin specimens photo-cured with the MMLG tip also served as the mechanical standard against which the mean compressive strength value (MPa) of the resin specimens photo cured with the CMLG tip were compared.

RESULTS

A) Compressive fracture strengths; Z100™ composite

There were significant differences (p=0.001) between the values of the mean compressive strengths (MPa) of the specimens in the Z100™ group. The mean compressive fracture strength at break for the specimens cured with the CMLG tip was **265.73 MPa** and the mean compressive strength at fracture strength at break for the specimens cured with the MMLG tip was **348.47 MPa**.

The coefficient of variation (CV) for specimens in the Z100™ group was low (CMLG: 46%; MMLG: 33%) indicating consistency amongst the specimens within the group.

However, agreement amongst the MPa values assessed with the ICC, determined in a mixed-effects regression analysis, was found to be 0.58 implying moderate to poor agreement between the MPa values (since $0 \leq ICC \leq 1$ with ICC = 1 being perfect agreement).

Table 1. Summary of the results for Z100™ group

Z100™ results	CM specimens	MM specimens	Difference (CM-MM)	p-value
Median	256.28	369.13	-54.67	
25th percentile	143.36	270.66	-150.34	
75th percentile	377.93	400.18	-35.31	
Mean	265.73	348.47	**-82.74**	p=0.001
Standard deviation	121.15	114.35	82.38	
Minimum	76.22	175.49	-213.66	
Maximum	439.73	556.03	44.78	
Coefficient of variation (CV)	46%	33%		
CV (CM) = SD/Mean = 46%, CV (MM) = SD/Mean = 33%.				

B) Compressive fracture strengths; Filtek™ Supreme XTE composite

There were no significant differences (p = 0.147) between the mean compressive fracture strength (MPa) values of the specimens in the Filtek™ Supreme XTE group. The mean compressive fracture strength at break for the Filtek™ Supreme XTE specimens cured with the CMLG tip was **330.33 MPa** and the mean compressive fracture strength at break for the Filtek™ Supreme XTE specimens cured with the MMLG was **285.62 MPa**.

The coefficient of variation (CV) for the Filtek™ Supreme XTE group was low (CM: 28%; MM: 33%) indicating consistency amongst the specimens within the group.

However agreement amongst the MPa values was assessed with the ICC, determined in a mixed-effects regression analysis, and was found to be 0.27, implying poor agreement between the MPa values (since $0 \leq ICC \leq 1$ with ICC = 1 being perfect agreement).

Table 2. Summary of the results for Filtek™ Supreme XTE group

Filtek™ Supreme XTE results	CM specimens	MM specimens	Difference (CM-MM)	p-value
Median	358.66	287.96	68.76	
25th percentile	254.53	234.84	-28.65	
75th percentile	392.19	344.07	113.59	
Mean	330.33	285.62	**44.72**	p=0.147
Standard deviation	94.02	70.68	97.46	
Minimum	174.70	175.51	-154.08	
Maximum	477.86	385.98	153.82	
Coefficient of variation (CV)	28%	33%		
CV (CM) = SD/Mean = 28%, CV (MM) = SD/Mean = 33%.				

C) Comparative costs

The CMLG tip cost R 5 to manufacture and was significantly cheaper than the MMLG tip which cost R 1145 to purchase. Two hundred and thirty CMLG tips could be manufactured for the price of a single MMLG tip. Therefore in the event of breakage of or damage to a MMLG tip, a CMLG tip is the preferred option for replacement.

DISCUSSION

The conditions and specifications of an LCU and a light guide tip that allows adequate photo-polymerisation of resin based composite restorations is well known to the profession.[24-30] These conditions and specifications have to be operating optimally, together with the appropriate light curing techniques, in order for the resin based composite restorations to be successfully cured.[4,14,23,24,29-37]

The wavelength of the LCU used in this experiment initiated activation of the photo-initiator in both resin specimens. The radiometer was used to test each light guide tip before each specimen was made, to ensure that the light intensity was sufficient to photo-polymerize each resin specimen. Light guide tips are an important part of the LCU since they are responsible for delivering (guiding) light from the LCU to the surface of the resin based composite. Compressive strength tests have been used previously to compare different MMLG tips.[24]

Resin based composites that are placed accurately under the appropriate conditions and cured adequately using appropriate techniques have a compressive strength that is able to resist the compressive forces of occlusion.[24] The compressive fracture strength of a human molar is approximately 305 MPa.[24] This value was used as the mechanical standard to compare the compressive fracture strengths (MPa values) of the Z100™ and Filtek™ Supreme XTE resin based composite specimens.

The mean MPa value for the Z100™ specimens light cured with the CMLG tip was 265.73 and the mean MPa value for the specimens cured with the MMLG tip was 348.47 MPa. The mean MPa of the Z100™ specimens cured with the MMLG tip exceeded the mechanical standard of 305 MPa indicating that the MMLG tip should be preferred for photo-polymerizing Z100™ resin specimens.

The mean MPa value for the Filtek™ Supreme XTE specimens light cured with the CMLG tip was 330.33 MPa and the mean MPa value for the specimens cured with the MMLG tip was 285.62 MPa. The mean MPa of the Filtek™ Supreme XTE specimens cured with the CMLG tip exceeded the mechanical standard of 305 MPa indicating that the CMLG tip should be preferred for photo-polymerizing Filtek™ Supreme XTE resin specimens.

The results indicate that the consistency of the specimens made and the repeatability of the study design was excellent (Coefficient of variation was <50% in both groups). However the measured agreement amongst the compressive fracture (MPa) values in each group of specimens photo-cured with both light guide tips, was moderate to poor (ICC=0.58 for Z100™ and 0.27 for Filtek™ Supreme XTE). The reasons for this poor agreement may be speculated as: 1) A small sample size and 2) uncontrollable variables within the resin, the light guide tips and the electricity supply, such as; i) the unknown quantity of the photo-initiator within each resin composite; ii) damage to the light guide tip such as breakage of the fibre-optic bundles and undetected light guide tip fractures and iii) electricity supply having a variable/ inconsistent line voltage. This may have resulted in partial curing and under-polymerization of the resin specimens[36] within each group, resulting in compressive fracture strength values (MPa) that have poor agreement.

The radiometer gauge indicated that the CMLG tip guided light from the LCU to the surface of each resin specimen slowly and gradually (the gauge of the radiometer moved at a slow and steady speed from 0 to 600 mw/cm^2 that took approximately 5 seconds) until the maximum intensity was reached and sustained during the photo-activation process.

The radiometer gauge indicated that the MMLG tip guided light from the LCU to the surface of the resin specimens rapidly (the gauge of the radiometer moved with a sudden rapid surge from 0 to 600 mw/cm^2 that took approximately one second) until the maximum intensity was reached and sustained during the photo-activation process.

The mean MPa values of Z100™ and Filtek™ Supreme XTE groups suggest that the Z100™ specimens (cured with the MMLG tip) responded to the sudden rapid progress to maximum light intensity compared with the Filtek™ Supreme XTE specimens (cured with the CMLG tip) that "preferred" the gradual steady progress to maximum light intensity. Further studies are required to confirm these assumptions. The CMLG tip emitted very little heat energy, when touched with a forefinger, compared with the MMLG tip that emitted a substantial amount of heat energy, enough to cause tactile discomfort when touched.

The acrylic glass of the CMLG tip allowed heat to dissipate as light travelled along its length compared with the fibre-optic MMLG tip that did not allow heat to dissipate as light travelled along its length. The reasons for the different heat energy emissions and heat dissipations form each light guide tip was beyond the scope of this experiment and the aims of this study. Follow up studies will determine the reasons for this occurrence.

A comparison of the cost of each light guide tip indicate that the cost of the CMLG tip was significantly cheaper than the MMLG tip. The CMLG tips were easier to replace, available immediately and did not require a waiting period for delivery. The replacement process became extremely efficient. Students were allowed to progress efficiently with their pre-clinical training educational process.

CONCLUSION

The CMLG tip was preferred for curing Filtek™ Supreme XTE resin composite and the MMLG tip was preferred for curing Z100™ resin composite. The CMLG tip was suitable for curing pre-clinical Z100™ and Filtek™ Supreme XTE resin based composite restorations. Further studies are required to determine whether the CMLG tip is suitable for clinical use on patients to cure Filtek™ Supreme XTE resin based composite restorations. The CMLG tip was easier to replace and is more cost efficient than the MMLG tip.

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Conflict of interest

No conflict of interest declared.

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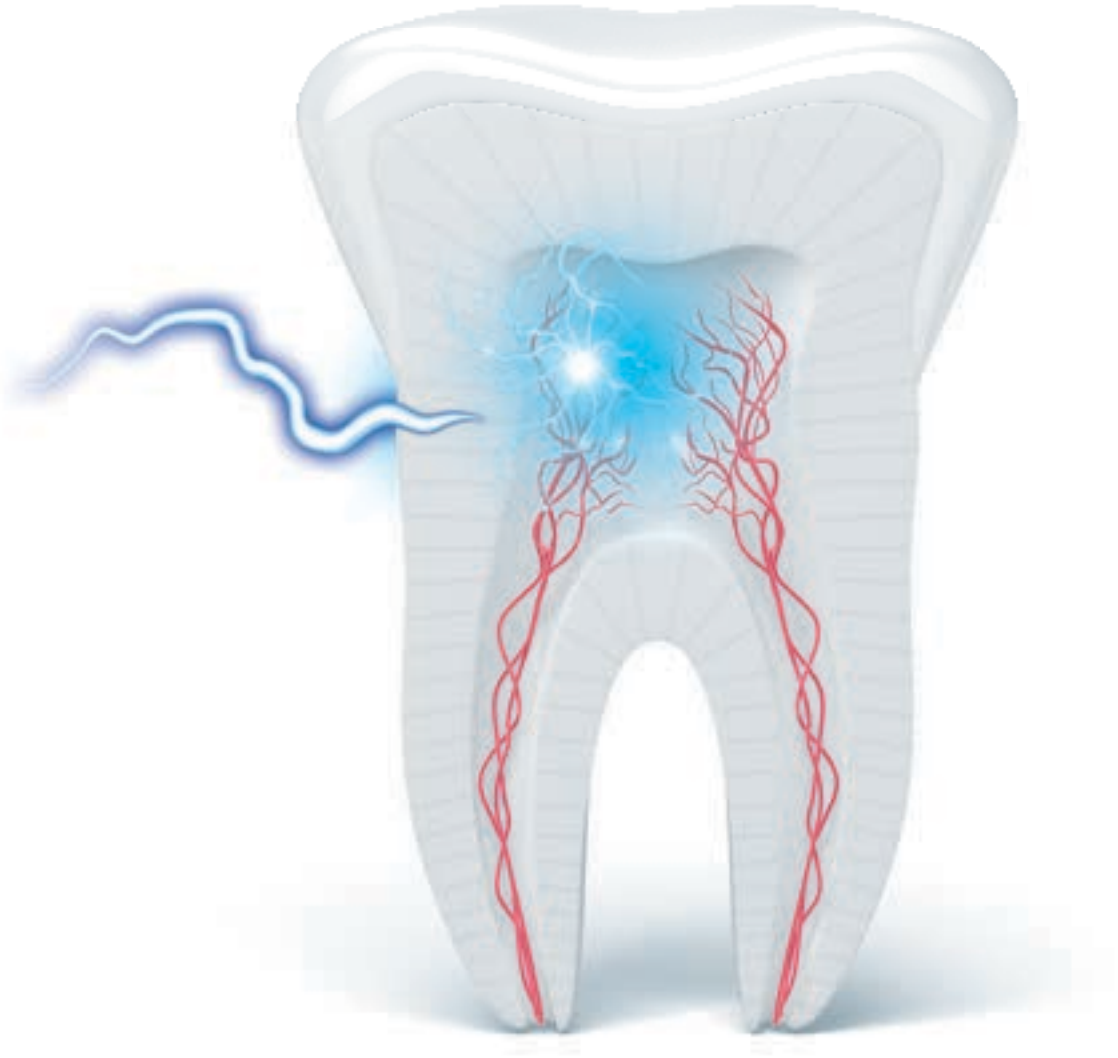

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Labelling of fluoridated toothpaste in South Africa

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SUMMARY

Introduction
Product labelling is essential for education and protection of consumers and is fundamental to product quality.

Aim
To evaluate the labelling of commercially available fluoridated toothpastes in South Africa (SA). To determine compliance with the South African National Standard (SANS).

Design & methods:
A national, cross-sectional survey of 300 fluoridated toothpastes (12 brands, nine paediatric and 29 adult toothpaste types). Labels were appraised relative to a key identifier, product descriptor, country of production or distributor address, content description, batch identification, and expiry date.

Results
None demonstrated full compliance with SANS 1302:2008 (edition 1.1). Nearly three quarters of the labels (n=38; 71.05%) adhered to five of the six marking requirements, while the least compliant provided only product name and distributor address, neither of which has any bearing on consumer education, health benefits or product safety. SANS 1302:2008 omits labelling requirements considered mandatory by the ISO11609:2010 guideline in terms of consumer protection, but all the toothpastes displayed partial compliance with these omitted variables.

Conclusion
The quality of information provided is satisfactory due to partial compliance with the internationally accepted ISO11609:2010 framework, but there is a need for more stringent regulation and the ISO 11609:2010 framework should be adopted within SA.

Keywords
Labelling, standards, compliance.

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ACRONYMS

CTFA:	Cosmetics, Toiletries and Fragrance Association of South Africa
FDA:	Federal Drug Administration
ISO:	International Organisation for Standardisation (International Standards Organisation)
SANS:	South African National Standards

BACKGROUND AND INTRODUCTION

It is generally accepted that the preventive-therapeutic efficacy of the fluoridated toothpastes are reliant on the fluoride content. Systematic reviews of the literature have concluded that a minimum concentration of fluoride of 1000ppm be present in the formulation if caries is to be inhibited.[1,2] Moreover, this fluoride needs to be chemically soluble in the formulation.[3]

Other factors relevant to toothpaste quality include the packaging and the marking practices. Packaging is fundamental in protecting the product against contamination from micro-organisms, moisture and dehydration while appropriate labelling that does not confuse or mislead by implication, provides a platform for effective communication with and education of, the consumer.

The major objective of the present study was to analyse labelling practices in terms of the information provided by the label and to assess the degree of conformity with prescribed marking regulations as stipulated by guidelines of the South African National Standards (SANS 1302:2008) and the International Organisation for Standardisation (ISO 11609:2010).

These documents were used as the benchmark for comparison even though their listed standards are not law and their application not mandatory. The recommended regulations are definitive for what may be regarded as acceptable and to which, at a minimum, manufacturers should adhere.

South African National Standard – Toothpaste (1302:2008; ed. 1.1)[4]

The SANS 1302:2008 (edition 1.1) guidelines pertaining to toothpastes was ratified by the National Committee of the South African Bureau of Standards SC271B, Cosmetics – Toothpastes, and was published in June 2008, superseding SANS 1302:1980 (edition 1). According to this standard, toothpaste is to be packaged in leak-proof, collapsible tubes bearing the total nominal volume or in the case of composite packs (i.e. two or more toothpastes of

equivalent or differing net volume(s) and in which the tubes are separated from one another) the total nominal volume of the pack. Permissible volumes include 15ml, 35ml, 50ml, 75ml, 100ml, 125ml, 150ml, 175ml and 200ml.

Additionally, individual and composite packs are to be packaged in such a manner that affords protection against contamination and damage during transportation, handling and storage.

In terms of tube labelling, apart from nominal volume, the name of the toothpaste, the name and contact details of the manufacturer or responsible distributor, a description of content, batch number and, if the product is fluoridated, the phrase, "Fluoride Toothpaste" or "Fluoride Dental Crème" is to be displayed. This phrase is to be marked in a durable and intelligible manner with a font size of 3mm and must be readily visible against the background. Similarly all marking requirements, excluding batch identification, as stipulated for the tube are to be applied in the labelling of the outer carton, packaging of composite packs and bulk packages.

International Organisation for Standardisation - ISO 11609:2010 Dentifrices[5]

In addition to all packaging and labelling norms prescribed in SANS 1302:2008, the International Organisation for Standardisation document (ISO 11609:2010) includes further labelling specifications, namely, expiry date, chemical form of fluoride, total fluoride concentration and a cautionary note regarding use in paediatric consumers. This last provision can be regarded as mandatory in terms of product safety and health benefits and therefore is a fulfilment of the objective of full consumer protection.

Unlike SANS requirements, ISO labelling regulations pertain to the tube alone. These standards typically refer to the tube as the primary package (i.e. the container in direct contact with the product and retained by the consumer following purchase). The primary package is thus paramount in communicating with the consumer. Notably, two further declarations, omitted from both the SANS and ISO frameworks, but frequently applied by manufacturers in the labelling of toothpastes are storage instructions and guidelines for use. Due to their importance with respect to consumer protection these variables were included in the quality assessments of labelling practices in the present study.

AIMS AND OBJECTIVES

The aim of the present study was to evaluate toothpaste packaging and labelling practices and the extent of the provision of consumer information. In order to achieve this aim, the objectives were: (i) to determine whether packaging and labelling practices on the sample aligned with SANS 1302:2008; (ii) to determine whether labelling practices on the sample complied with ISO 11609:2010 and (iii) to evaluate the quality of the information provided on toothpaste packaging.

METHODOLOGY

Fluoride toothpaste samples and sample size

A convenience sample of commercially available paediatric and adult fluoridated toothpastes, excluding herbal brands and those claiming to have tooth-whitening properties, were purchased off the shelf of a Dis-Chem outlet located in metro Cape Town. The toothpastes sampled in this manner were used to formulate a 'gold standard' list (Table 1) which guided the collection of further samples from other retailers in the five provinces included in the study. A total of 300 fluoridated toothpastes (n=300) were conveniently purchased across 10 sampling sites – from a major pharmaceutical outlet (Dis-Chem) and a food retailer (Pick 'n Pay) located in each of five metropolitan municipalities (Cape Town, Durban, Port Elizabeth, Pretoria and Gauteng) of South Africa.

Each toothpaste sample was assessed for conformity with the packaging and marking regulations/variables stipulated in SANS 1302:2008 (ed. 1.1).[4] The norms prescribed by this documentation were identified as variables 1 to 8 (Table 2).

As per ISO 11609:2010, labels were also studied for information on the chemical form of fluoride, the fluoride concentration, and the expiry date.[5] If the fluoride concentration was expressed as a percent of volume (%w/v) or weight (%w/w), the value was converted to parts per million (ppm). Any additional information provided by manufacturers (e.g. descriptive name of the abrasive, agent, storage instructions, guidelines for use) and deemed essential in terms of consumer protection, were also recorded.

A number of variables, including toothpaste brand and name, nominal volume, manufacturer or distributor contact details, content description and the presence of the phrase 'fluoride toothpaste' were identical for the same toothpaste types irrespective of sampling site. Hence, to improve ease of interpretation, the data obtained was reported, wherever possible, in terms of the 'gold standard' list alone. This produced an effective total sample of 38 toothpastes. Toothpaste types were then codified from 1 to 38 (Table 1).

RESULTS

Locally manufactured and distributed products comprised 60% of the total initial sample (n=300).

Compliance with SANS 1302:2008 (Table 1 & 2)

All toothpastes (n=300) complied with variables 1, 4 and 6 - being contained within "leak- proof", collapsible tubes, presenting with a brand name/key identifier and bearing a manufacturer or distributor address respectively (Table 2). Likewise, all samples, excluding the toothpaste codified 10 were packaged in individual outer cartons (Variable 2). The packaging of toothpaste 10 was restricted to a tube alone and it may be assumed that this compromises the degree to which the toothpaste is protected against contamination and

degradation under normal conditions of transportation, handling and storage. The absence of an outer carton for this product was taken into account in the calculation of box marking statistics.

According to SANS documentation it is only necessary for batch identification (Variable 3) to be displayed on the primary package. Nearly 85% of the toothpastes sampled (84.67%; n=300) presented with a tube batch identification, but 90,33% of boxes also had this information, although not required by SANS (Table 2, Variable 3).

Less than ten percent of toothpastes, codified 7,14,26 (n=38) did not display the nominal volume (Variable 5). Quantity was still however declared in terms of weight in grams, with weights of 70g, 125g and 115g reflected respectively.

The 'content description' regulation (Variable 7) implies through use of the term 'description' that a listing of all ingredients in conjunction with an explanation of the concentration and function of each ingredient be provided. Space limitations imposed by the outer carton and tube in conjunction with requirements that all information be presented in a visible and legible manner meant that for most toothpastes sampled, content 'description' was confined to a constituent list and frequently an indication of the active ingredient, the chemical form of fluoride and the concentration.

The presence of these elements (i.e. constituent list that included the abrasive agent as well as chemical form and concentration of fluoride) was regarded as conformance with this variable.

A majority, 89.47% of the sample (n=38), provided an ingredients list (Table 2) on the outer carton. Non-observance was noted for toothpastes 7,10, 11 and 24 (Table 1). Samples 7 and 10 declared no information with respect to formulation and as a result gave no indication of the abrasive agent and fluoride content or chemical form, stating only that fluoride was present, while samples 11 and 24 did not stipulate fluoride concentration.

Table 1: Fluoridated toothpaste types and compliance with sans marking guidelines per product

		Sample Size (n) = 38							
Toothpaste Type Code	Fluoridated Toothpaste Samples	Batch Identification Tube Only	Product Name	Nominal Volume	Manufacturer Address	Content Description	Product Descriptor	Number of Regulations Applied	% Compliance per Product
1	Aquafresh Milk Teeth 0-3yrs	1	1	1	1	1	0	5	83.3
2	Aquafresh Little Teeth 4-6yrs	1	1	1	1	1	0	5	83.3
3	Aquafresh Big Teeth >6yrs	1	1	1	1	1	0	5	83.3
4	Colgate 0-2yrs	0	1	1	1	1	0	4	66.7
5	Colgate 2-5yrs	1	1	1	1	1	0	5	83.3
6	Colgate >5yrs	1	1	1	1	1	0	5	83.3
7	Dis-Chem Dentalmate Kids	0	1	0	1	0	0	2	33.3
8	Elgydium Kids 2-6yrs	1	1	1	1	1	0	5	83.3
9	Mentadent P Kids	1	1	1	1	1	0	5	83.3
10	Nature Fresh Junior Toothpaste	1	1	1	1	0	0	4	66.7
11	Aquafresh all-in-one Protection	1	1	1	1	0	0	4	66.7
12	Aquafresh Extreme Clean	1	1	1	1	1	0	5	83.3
13	Aquafresh Ultimate	1	1	1	1	1	0	5	83.3
14	Close Up Deep Action	1	1	0	1	1	0	4	66.7
15	Colgate Active Salt	1	1	1	1	1	0	5	83.3
16	Colgate Gel	1	1	1	1	1	0	5	83.3
17	Colgate MaxFresh	0	1	1	1	1	0	4	66.7
18	Colgate Maximum Cavity Protection	0	1	1	1	1	0	4	66.7
19	Colgate Sensitive Multiprotection	1	1	1	1	1	0	5	83.3
20	Colgate Sensitive Pro-Relief	1	1	1	1	1	0	5	83.3
21	Colgate Total 12	0	1	1	1	1	0	4	66.7
22	Colgate Pro-Gum Health	0	1	1	1	1	0	4	66.7
23	Colgate Triple Action	1	1	1	1	1	0	5	83.3
24	Dis-Chem Dentalmate	1	1	1	1	0	0	4	66.7
25	Elgydium Sensitive	1	1	1	1	1	0	5	83.3
26	Enamel Care	1	1	0	1	1	0	4	66.7
27	GUM Caries Protect	1	1	1	1	1	0	5	83.3
28	Mentadent P Gel Protection	1	1	1	1	1	0	5	83.3
29	Mentadent P Micro Granules	1	1	1	1	1	0	5	83.3
30	Mentadent P Protection	1	1	1	1	1	0	5	83.3
31	Mentadent P Sensitive	1	1	1	1	1	0	5	83.3
32	Oral B Pro-Expert	1	1	1	1	1	0	5	83.3
33	Pepsodent	1	1	1	1	1	0	5	83.3
34	Pepsodent Complete 8	1	1	1	1	1	0	5	83.3
35	Sensodyne Cool Gel	1	1	1	1	1	0	5	83.3
36	Sensodyne Multi Care	1	1	1	1	1	0	5	83.3
37	Sensodyne Rapid Action	1	1	1	1	1	0	5	83.3
38	Sensodyne Repair & Protect	1	1	1	1	1	0	5	83.3
	Total Compliant per Regulation	32	38	35	38	34	0		
	Proportion Compliant per Regulation	84.2	100	92.1	100	89.5	0		

As abrasives influence fluoride bioavailability and the rate of fluoride release, reflection of the abrasive agent in the list of ingredients is of paramount importance.[6-9] Nearly all (94.7%) of the toothpastes sampled (n=38) displayed the abrasive name in listing of the constituents, although not designating it as the abrasive, so that recognition by the lay person may be difficult.

No toothpastes were found to conform to the Variable 8 product descriptor regulation in marking of the tube (i.e. presence of the phrase 'fluoride toothpaste' with a font size of 3mm and in a colour distinct from the background). Eight (n=38), however, did meet specifications in marking of the outer carton and included toothpastes 9, 15-19, 21 and 23, with the Colgate brand demonstrating greatest compliance.

Compliance with SANS 1302:2008 (Table 1 & 2)

In contrast to the ISO 11609:2010 guidelines,[5] a number of frank omissions are evident from theregulations of SANS 1302:2008 (edition 1.1).[4] These omissions pertain to key information, namely, expiry date, chemical form of fluoride, total fluoride concentration, cautionary note regarding use in paediatric consumers, storage instructions and guidelines for use, the provision of which can be regarded as mandatory in terms of product safety and health benefits and therefore in the fulfilment of full consumer protection.

Take note that the two latter variables, storage instructions and guidelines for use are also absent from the ISO11609:2010 framework. Each sample was also evaluated in terms of these omitted variables (Table 3).

As is evident from Table 3, application of the 'additional' ISO labelling regulations (i.e. those not mentioned within SANS) in marking of the primary package is widely divergent with positive results ranging from 65.8% (n=38) for the cautionary note regarding use in paediatric consumers to 99% (n=300) for 'expiry date'. The 1% failing to present an expiry date may be accounted for by the fact that ISO11609: 2010 guidelines only require that an expiry date be reflected if the product stability is less than 30 months.[5]

Table 2: Total sample compliance with sans packaging and marking guidelines

Sample size (n) = 300					
Variables				**Number Compliant**	**Percentage Compliance**
1	Collapsible, "leakproof" tubes:			300	100
2	Presence of outer carton			299	99
3	Batch/Lot Identification:	Box		271	90.3
		Tube		254	84.7
"Gold Standard" Sampling List: Sample size (n) = 38					
4	Toothpaste Brand & Name:			38	100
5	Nominal Volume (ml):			35	92.1
6	Address Manufacturer/Distributor:			38	100
7	Content Description:			34	89.4
8	Product Descriptor - Phrase "Fluoride Toothpaste":	Box	Present	22	57.9
			Font size 3mm	8	21.1
			Distinct	16	42.1
			All Applied	8	21.1
		Tube	Present	24	63.2
			Font size 3mm	0	0
			Distinct	24	63.2
			All Applied	0	0
		Both		0	0

*As variables 4 to 8 are identical for the same toothpaste brands and types across the sampling range, statistics pertaining only to the gold standard sampling list are reflected. As the outer packaging or carton is typically discarded after purchase, results relative to tube labelling are highlighted, emphasizing the significance of the primary package in communicating with, education and therefore protection, of the consumer.

Table 3: Compliance with ISO 11609:2010 marking guidelines

Sample size (n) = 300				
Variables			**Number Compliant**	**Percentage Compliance**
1	Stability/Expiry Date	Box	232	77.3
		Tube	297	99
"Gold Standard" Sampling List: Sample size (n) = 38				
2	Chemical Form of Fluoride		36	94.7
3	Total Fluoride Concentration		34	89.5
4	Safety Notice re. use in Paediatric Consumers	Box	35	92.1
		Tube	25	65.8
		Both	25	65.8
Additional information provided by manufacturers not covered in SANS 1302:2008 and ISO11609:2010 Frameworks.				
5	Directions for use	Box	26	68.4
		Tube	18	47.4
		Both	13	34.2
6	Storage Instructions	Box	12	31.6
		Tube	10	26.3
		Both	10	26.3

*As variables 2 to 5 are identical for the same toothpaste brands and types across the sampling range, statistics pertaining only to the gold standard sampling list are reflected. As the outer packaging or carton is typically discarded after purchase, results relative to tube labelling are highlighted, emphasizing the significance of the primary package in communicating with, education of and therefore protection of the consumer.

ISO labelling regulations pertain to the tube alone. Only 77.3% of toothpastes sampled displayed an expiry date in marking of the outer carton. Products lacking a stability declaration on the box included those codified 7, 9, 10,17, 22, 24 as well as a number of samples of toothpaste 15.

DISCUSSION

Batch identification

As demonstrated by the results in relation to batch identification (Variable 3) it was found, paradoxically, that fewer of the sampled toothpastes presented with a tube batch identification as opposed to the representation on the box, not actually a requirement. Non-compliance was primarily attributed to the illegibility of this information with numbers being smudged on the outer box or tube, or the imprint being superimposed onto the corrugated terminal tube seal.

Product descriptor and content description

In the interests of protecting the consumer against harm from the product and ensuring that intended health gains are attained, appropriate labelling that includes a readily visible product descriptor ('fluoride toothpaste') and quantity declaration of not only total, but also bioavailable fluoride content, is imperative.

Not all (total) fluoride incorporated into a toothpaste is available in soluble (bioavailable) form. A proportion is insoluble/inactive and does not contribute to caries inhibition or management.[7,10] It is therefore obligatory that not only the total but also the active/bioavailable content be declared in the labelling of a product and that the bioavailable concentration exceed 1000ppm F in order for health benefits to be realized.[3]

In the present study, a minority of toothpastes (8), manufactured predominantly by Colgate were the only samples found to conform with the product descriptor regulation (Variable 8) in labelling of the outer carton. None, however, were found compliant in marking of the tube. With respect to content description (Variable 7), no declarations were made with respect to total soluble (potentially bioavailable) fluoride content.

Two probable explanations as to why bioavailable content is not declared in marking of the packaging could firstly be due to the fact that regulating authorities fail to recognise or adequately define differing fluoride species. This is supported by the fact that the SANS 1302:2008 (edition 1.1) provides guidance only with respect to an analysis of total fluoride content[4] while the Medicines and Related Substances Act 101 of 1965 (R510) merely prescribes the maximum total fluoride concentration (1500ppm) that a toothpaste may contain.[11] Secondly, fluoride bioavailability decreases over time in response to chemical incompatibility between toothpaste constituents[7] and the ambient conditions under which the toothpaste is stored and handled,[6] rendering any declaration in terms of fluoride bioavailability of questionable integrity.

Anti-caries efficacy is reliant on soluble/bioavailable fluoride content. Recommended then is that this minimum total soluble/available fluoride concentration be declared on the label in conjunction with storage instructions,[9,12] This would accord with the Federal Drug Administration's (FDA) anti-caries monograph which stipulates that manufacturers should formulate toothpastes in such a manner as to ensure maintenance of a minimum available fluoride content for the duration of a product's shelf-life, when stored and handled appropriately. It may, however, be anticipated that if this recommendation is to be met, additional analyses would need to be undertaken by manufactures, new formulations may need to be developed and labels would need to be updated, all procedures having significant financial implications.

Listing of the bioavailable fluoride content is a complex issue, although it is essential in terms of consumer protection. Regulating authorities would need to clearly define and acknowledge the presence of differing fluoride species. Manufacturers would have to hold a complete understanding of fluoridated toothpaste chemistry (i.e. the interaction of fluoride with other constituents of the toothpaste formulation and the impact of environmental conditions on these processes). These provisions would allow for the formulation of amendments to existing, or the generation of new, standards/norms and policies.

The majority of samples provided a content description or rather a listing of ingredients (Table 2) in marking of the outer carton.

Understandably, full content description (i.e. listing of constituents in conjunction with their function) is best practice in empowering consumers to make informed choices, but this may be impractical in terms of packaging. It is therefore advisable that in order to avoid misinterpretation that wording of the standard be amended to a 'complete listing of ingredients' that must include a statement with regards to the chemical form of fluoride, fluoride content declaration and designation of abrasive agent(s). Alternatively, to consider regulations in terms of product information sheets/inserts. Provision of such sheets would however markedly increase costs and the benefits in terms of consumer protection would have to be offset against affordability. Additionally, ISO 11609: 2010 standards require only that "a complete listing of ingredients according to the International Nomenclature of Cosmetic Ingredients (INCI)" be reflected.[5] Toothpastes are indeed classified as cosmetic products within the South African context, and hence the use of this INCI phrasing may result from the fact that the SANS regulates packaging and marking subject to the 'Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972; Regulation R1555). In the preface of this document, included within the list of definitions, 'describe' is said to include 'to advertise or label'[13].

Extensive evidence, dating as far back as the first clinical trials undertaken to evaluate the anti-caries efficacy of fluoridated toothpastes, has demonstrated

that abrasives influence fluoride bioavailability and the rate of fluoride release in response to chemical incompatibility between these components.[6-9]

Recent analytical studies have also repeatedly demonstrated that fluoride bioavailability declines markedly over time especially in toothpastes formulated with a calcium-containing abrasive as opposed to a silica-based abrasive or when subjected to excessive temperatures.[6,8,14]

In the interests of consumer protection and the realisation of intended health gains it is therefore imperative that consumers be educated with respect to abrasive agents in the toothpaste formulation, be alerted to the fact that anti-caries efficacy declines over time and markedly so with improper handling and storage. This highlights a need for identifying the abrasive agent(s) and legibly displaying the expiry date and storage instructions on the label.

The present study found that over three quarters of the toothpastes sampled displayed the abrasive in listing of the constituents together with an expiry date, while less than a third displayed storage instructions in marking of either the tube or outer carton.

Expiry

As fluoride bioavailability is reliant on product age and is a measure of efficacy it is fundamentally important that the stability of the toothpaste be specified through provision of an expiry date and it is for this reason that this variable, although not mentioned in the SANS parameters, receives special mention.

Declaration of an expiry date is preferable as opposed to a date of manufacture as the layperson is not necessarily aware that toothpastes have a shelf life and that the normal duration for which a product may be considered viable and safe for use is two years.

Additionally, conflicting information presents within the literature with respect to product stability.
Some researchers refer to a three-year shelf life[6], while the ADA (American Dental Association) stipulates a two-year product stability.[15]

South African Statutory Requirements

Some marking regulations omitted from the SANS guidelines in contrast to ISO, may be accounted for by a clause which has been inserted into the edition 1.1 SANS 1302:2008 documentation, immediately below the heading, “4. Packing and Marking,” which stipulates that all packing and marking practices must comply with current national legislation, namely the ‘Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972; Regulation R1555), the primary statute regulating the sale, manufacture, import and export of these substances.[13] In recent years, especially since the ratification of the Consumer Protection Bill (Act No. 68 of 2008) in April 2010 and its coming into operation in March 2011, consumer rights and protection have garnered increasing attention.[16] In association with this upsurge, amendments to the ‘Foodstuffs, Cosmetics and Disinfectants Amendment Act, 2007 (Act No. 39 of 2007) and food labelling regulations (R146 of 2010) have been promulgated which focus, in particular, on revisions to labelling regulations, recognizing that adequate marking is a means of empowering the consumer to make informed choices and respecting his/her right to autonomy.[17,18]

The Cosmetics, Toiletries and Fragrance Association of South Africa (CTFA) states that in keeping with ‘new’ cosmetics labelling legislation, certain compulsory information, namely, brand name, product descriptor, directions for use, cautionary statements, ingredient listing and quantity declaration, be displayed in the marking of a product.[19] Once again, no mention is made with respect to product stability/expiry, declaration of the active ingredient/s and concentration thereof, all of which are paramount to consumer safety.

As food, cosmetics and disinfectants are regulated under the same Act it is noteworthy that the ‘new’ Food labelling regulations, R146 (2010), do require that an expiry/use-by date be conspicuously displayed.[18] Regulations pertaining to permissible fluoride content are also found in the Medicines and Related Substances Act 101 of 1965 (R510) which state that fluoride concentration shall not exceed a mass fraction of 0.15%.[11] This controls manufacture and formulation, but there is no mention made as to representation on the label. No reference is made within this Act with respect to the different fluoride ion species or chemical form of fluoride.[11]

According to the CTFA, South Africa ascribes to the European Regulations and Ingredient Annex to facilitate import and export. This provides an additional explanation as to why toothpaste labelling practices do not conform completely to SANS parameters and local legislation, but also partially adhere to ISO11609:2010 specifications.[19]

Appropriate packaging and marking is a complex process when one considers the multitude of Acts and associated amendments governing the sale, manufacture and advertisement of toothpastes, compounding the difficulties associated with comprehending the intricacies of legal discourse therein.

In summary, the SABS regulates packaging and marking as well as quantity declarations subject to the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972; Regulation R1555)[13] and the Trade Metrology Act (Act No. 77 of 1973)[20] respectively, while fluoride content is managed in accordance with the Medicines and Related Substances Act (Act 101 of 1965; Regulation R510).[11]

Additionally the National Consumer Commission over-sees improvements to standards of consumer information and the prohibition of unfair marketing practices, such as ambiguous and misleading labelling and advertising.[21] A feasible recommendation, therefore, is that all regulations pertaining to

manufacture, marking and packaging be clearly and comprehensibly documented in bullet format within SANS guidelines in a manner that provides no leeway for misinterpretation and as a result protects both the consumer against harm from the product as well as the manufacturer/distributor from legal liability.

Despite these statutory requirements, the South African cosmetics industry is self-regulated meaning that manufacturers and/or distributors are responsible for 'in-house' quality assurance.[19] Periodic inspection by external authorities, such as SANS, must occur but the continued sale of products despite non-compliance, demonstrates an inability of authorities to impose restrictions.

Reasons cited for non-compliance with food labelling laws (R146) include a lack of awareness around labelling regulations or a misinterpretation of certain aspects of the provisions, purposeful disregard of legislative details in an attempt to remain competitive, high costs associated with compliance due to required laboratory testing and/or assistance provided by consultants and lawyers in legal interpretations, large expenses incurred in updating and changing labels and poor enforcement of regulations.[22]

As foodstuffs and cosmetics are regulated subject to Act 54 of 1972, all reasons discussed in terms of food labelling non-compliance are applicable to this research context as well. Lack of awareness and misinterpretation of legislation may stem from the fact that as a large proportion of toothpastes are imported, manufacturers lack familiarity with local laws (although it is anticipated that the major brands would have 'in-house' legal departments) and due to the multitude of acts governing marking procedures. Editing labels in an effort to achieve compliance is not only expensive but runs the risks of altering the key identifier by which the consumer recognises the product, reducing sales and competitive advantage, meaning that norms are ignored.

CONCLUSION

Partial compliance with marking requirements of SANS 1302:2008 (edition 1.1) was observed for all toothpastes sampled. That standard may, however, be regarded as weak as marking requirements with respect to information which is considered mandatory in terms of consumer protection, are omitted. On the other hand, a large number of manufacturers conformed to the ISO11609:2010 framework, which includes labelling regulations pertaining to this essential information and even went further in providing additional information, not regulated by either of the SANS or ISO marking criteria. Hence, the quality of consumer information provided on most toothpastes was evaluated as satisfactory.

In the interests of consumer protection, it is viable to recommend that at a minimum, SANS documentation be revised to align with ISO guidelines or alternatively to accept the complete adoption and implementation of the ISO framework within the South African context. The ISO framework does includes labelling regulations (omitted from current SANS) pertaining to information which may be considered mandatory in terms of consumer protection and attainment of intended health gains. However, this standard may also be regarded as suboptimal due to the omission of norms relating to the designation of abrasive agent, the recognition and quantity declaration of differing fluo-ride species (total, soluble/bioavailable and insoluble), directions for use and appropriate storage instructions. Optimally, therefore, it is advisable that in addition to adoption of the ISO framework within the South African context, that national standards and policies be amended to embrace these variables as well.

In a consumer-centric environment in which labelling regulations are set to become more stringent and consumers more educated with respect to their rights, consumer protection (against harm and the realisation of intended health benefits) as well as legal accountability should provide sufficient motivation for manufacturers to become compliant with South African legislation, and with local and international standards.

Ethical considerations

The authors have no conflict of interest to declare. Ethical approval was granted by the Senate Research Committee of the University of the Western Cape. (Project registration number 15/1/7)

This survey was undertaken during 2014/15 and it may be that the labels for certain of the toothpastes referred to herein have been updated.

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Comparison of efficiency of ozone and chlorhexidine subgingival irrigation in orthodontic patients for controlling gingival inflammation

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ABSTRACT

Aim

To compare the clinical effects of subgingival irrigation with ozonated water to the effects of chlorhexidine solution on gingivitis in orthodontic patients and to correlate the clinical effects with the MCP-1 activity in gingival crevicular fluid (GCF).

Objective

Correlate the inflammatory marker monocyte chemoattractant protein (MCP-1) in GCF with clinical parameters viz. gingival index (GI), plaque index (PI), gingival bleeding index (GBI), probing pocket depth (PPD).

Materials and method

A double-blind clinical study of subgingival irrigation was conducted in a split-mouth design on 30 subjects for 28 days. Clinical parameters (plaque index, gingival index, gingival bleeding index, probing pocket depth) and MCP-1 enzyme activity were measured at baseline followed by subgingival irrigation with 0.01 mg/l of ozonated water on right maxillary quadrants and 0.02% of chlorhexidine solution on left maxillary quadrants. These parameters were again assessed on 14th and 28th day.

Results

Significant ($P<0.01$) reduction of all the clinical parameters and GCF MCP-1 activity after subgingival irrigation with both solutions. Ozonated water showed a highly significant reduction of clinical parameters and MCP-1 activity.

Conclusion

Subgingival ozone irrigation can be an effective method to reduce gingival inflammation in orthodontic patients.

Keywords

Gingival inflammation, Ozonated water, Chlorhexidine solution, MCP-1.

ACRONYMS

Elisa:	Enzyme-Linked Immunosorbent Assay
GBI:	Gingival Bleeding Index
GCF:	Gingival Crevicular Fluid
MCP-1:	Monocyte Chemoattractant Protein
PI:	Plaque Index
PPD:	Probing Pocket Depth

INTRODUCTION

Fixed orthodontic appliance treatment tends to promote dental plaque accumulation and gingival inflammation, related to the difficulties posed in maintaining optimal oral hygiene. In time, plaque accumulation around orthodontic appliances may lead to gingivitis, enamel decalcification and white spot lesion formation.[1-4]

In order to overcome these problems, numerous preventive strategies are used and recommended in the literature.[5-7] These strategies are mainly focused on the elimination of the cariogenic microflora or the mechanical removal of the plaque.[8]

Ozone therapy is amongst these strategies and nowadays the ozone treatment is gaining wider acceptance in dentistry. In the field of orthodontics, ozone gas has been tested for its anticariogenic effect, for its effect on the shear bond strength of orthodontic brackets to enamel and on the presence of gingival inflammation.[9-11]

The aim of the study was to compare the clinical effects of subgingival irrigation with ozonated water to those seen with chlorhexidine solution irrigation on gingivitis in patients with fixed orthodontic appliances and also to correlate the clinical effects with the MCP-1 activity in the GCF.

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MATERIALS AND METHODS

Study sample

A total of 30 subjects aged between 21-23 were enrolled in the study. The participants had no relevant medical history and had not taken antibiotics nor used antibacterial mouth rinse within the last month. The inclusion criterion was having been under fixed orthodontic appliance treatment for a minimum of three months.

The participants were informed about the study well in advance and informed consent was obtained. Ethical clearance was granted by the Ethical Committee of the C.K.S. Theja Institute of Dental Sciences & Research, Tirupati.

Method

This study was conducted for 28 days. The study period was divided into three-time intervals i.e. baseline (day 0), day 14, day 28. A split-mouth design was used in this study of subgingival irrigation. The right and left maxillary quadrants were irrigated with ozonated water and chlorhexidine solution respectively and were designated as the experimental and control sides respectively.

Clinical procedure

At the baseline, clinical parameters such as plaque index,[12] gingival index[13] and gingival bleeding index[14] were recorded at distofacial, facial, mesiofacial and the entire lingual gingival marginal surfaces of all the teeth present. The probing pocket depth was also determined, using William's periodontal probe for the same surfaces. The value was registered to the nearest millimetre boundary/division. All the recordings of clinical parameters were made by the same calibrated examiner, who was blinded as to the treatment condition. GCF samples were collected from both sides of each maxillary quadrant followed by subgingival irrigation.

Ozone irrigation

The right half of the upper quadrant was irrigated with 0.01 mg/l ozonated water that was released from a dental jet (Kent Ozone Dental jet TY- 820, Pure Water House, Bangalore, India). The device released a single pulsating stream of ozonated water from the nozzle. The speed and pressure of the flow could be varied from 350 to 500 kPa with an ozone output of 0.082 mg/h, at a noise output of <70 dB and a water outflow of ≥450 ml. A 22-gauge blunt needle was bent and attached to the tip of the nozzle of the device. The crevice was irrigated with ozonated water by inserting the needle 3mm subgingivally. A stop clock was used to set the irrigation time to 15sec at each site. A total time of 5-10 min was spent for the irrigation for each patient.

Chlorhexidine irrigation

The other half of the quadrant were irrigated with 0.2% chlorhexidine solution released from a "Water Pik". A 22-gauge blunt needle was bent and attached to the tip of the nozzle of the device. Irrigation was done at the low-pressure setting.

GCF sampling procedure

GCF was collected using 1-3µl calibrated volumetric microcapillary pipettes obtained from Sigma Aldrich Chemical Company, USA (Catalog No.p0549). By placing the tip of the pipette extracrevicularly (unstimulated) for 5-20 minutes and referring to the calibration on the micropipette, a standardized volume of 2µl GCF was collected using from each test site. After collection, the samples were stored in a refrigerator at -20°C in the Department. of Anthropology, Tirupati for subsequent biochemical analysis.

Patient's instructions

After irrigation, the patients were directed to follow oral hygiene habits regularly, using a standard Ortho toothbrush and paste provided to each. The patients were instructed to report on the 14th and 28th day following irrigation treatment.

Quantification of inflammatory mediators - MCP-1 by enzyme-linked immunosorbent assay

The assay was based on Sandwich Elisa. Capture antibody was coated on an Elisa plate and stabilized by coating stabilizer. Standards and samples containing antigen were added to the wells and incubated. During incubation, antigen and antibody complexes were formed. This complex was detected by using biotin-labelled tracer antibody conjugated with streptavidin-horse radish peroxidase.

Addition of a tetramethylbenzidine (TMB) substrate produced colour which could be monitored at a wavelength of 450nm by the ELISA reader. A calibrated standard curve, plotted with optical density values of the standards, was used to approximate the concentrations of MCP-1 in the tested samples.

Statistical analysis

Statistical data was subjected to: an Independent t-test to compare the data between test and control samples at various durations, a Pearson correlation test to correlate between clinical and biochemical parameters, and an ANOVA test to analyze the differences among group means. For all the tests, $P \leq 0.05$ was considered statistically significant.

RESULTS

The results of the study are reported in Tables 1-13. The interpretation of clinical and microbial data was done on the information gathered at baseline and on the 14th and 28th days. A significant reduction was observed for all the clinical parameters with both ozone and chlorhexidine irrigation (Tables 1-3).

A higher percentage of reduction of PI (71.4%), GI (74.6%) and GBI (93%) was observed with ozone irrigation as compared with chlorhexidine. No such drastic reduction in PPD was observed when a comparison was made between the data of the experimental and control sides taken on the 14th and 28th days (Table 4).

Besides affecting the clinical parameters, ozonated water irrigation also caused significant reduction in the GCF MCP-1 enzyme activity from baseline to 14th day, from 14th to 28th day and also from baseline to 28th day. The percentile reduction of MCP-1 (57.9%) using ozone was appreciable as compared with chlorhexidine (45.7%) from baseline to the 28th day. (Table 5)

Results also showed a statistically significant positive correlation between the concurrent changes of clinical parameters and MCP-1 values on both sides.

Table 1. Mean Plaque Index (PI) on experimental side and control side at three time intervals

Day	Side	No. of Samples	Mean	S.D	% Reduction	t Value	p Value
Day 0	Experimental	30	2.243	0.143	-	1.026	0.078**
	Control	30	2.127	0.293	-		
Day 14	Experimental	30	1.190	0.214	46.8	-10.709	0.000*
	Control	30	1.670	0.212	21.2		
Day 28	Experimental	30	0.647	0.161	71.4	-7.977	0.000*
	Control	30	0.997	0.199	53.3		

*significant; **non-significant.

Table 2. Mean Gingival Index (GI) on experimental side and control side at three time intervals

Day	Side	No. of Samples	Mean	S.D	% Reduction	t Value	p Value
Day 0	Experimental	30	2.130	0.149	-	1.110	0.137**
	Control	30	2.040	0.271	-		
Day 14	Experimental	30	1.200	0.087	43.6	13.083	0.000*
	Control	30	1.660	0.175	18.6		
Day 28	Experimental	30	0.540	0.210	74.6	8.449	0.002*
	Control	30	1.030	0.241	49.5		

*significant; **non-significant.

Table 3. Mean Gingival Bleeding Index (GBI) on experimental side and control side at three time intervals

Day	Side	No. of Samples	Mean	S.D	% Reduction	t Value	p Value
Day 0	Experimental	30	13.030	7.699	-	-0.340	0.471**
	Control	30	12.870	6.703	-		
Day 14	Experimental	30	4.500	2.874	65.4	-7.895	0.000*
	Control	30	10.130	3.857	21.2		
Day 28	Experimental	30	0.870	1.634	93.0	-7.319	0.000*
	Control	30	5.470	3.711	57.4		

*significant; **non-significant.

DISCUSSION

This double-blind prospective clinical study was carried out to evaluate and compare the clinical effects on gingivitis of a single subgingival irrigation with 0.01mg/1 ozonated water with effects associated with 0.2% chlorhexidine irrigation in patients with fixed orthodontic appliances and also to correlate the clinical parameters with the MCP-1 activity in GCF.

The results showed significant reduction for all the clinical parameters from baseline to 14th day, from 14th to 28th day and also from baseline to 28th day on both the ozonated water irrigated side ($p<0.01$) and the chlorhexidine irrigation side ($p<0.01$). The results followed an expected pattern as seen in the study conducted by Dhingra and Vandana.[11] Schlagenhauf et al.[15] showed that ozonated water was highly effective in killing both Gram +ve and -ve oral microorganisms *in vitro*.

However, the statistical comparisons showed that the ozonated water- irrigated side experienced a highly significant reduction of mean PI, GI, GBI scores, whilst the mean PPD score showed no significant change. A higher % reduction of PI, GI, GBI was also reported by Kshitish and Laxman,[16] who compared the effects of ozone to chlorhexidine in patients with chronic and aggressive periodontitis. Furthermore, they reported that the percentile reduction of *Actinobacillus actinomycetem-comitans* (Aa) (25%) using ozonated water was appreciable as compared with no change in Aa occurrence using chlorhexidine solution.

The possible mechanism for the reduction in the PI and gingival inflammation associated with subgingival ozone irrigation may be the antibacterial effect on the plaque microorganisms or may be by disruption of subgingival plaque rather than an instant killing of microorganisms. Huth et al.[17,18] showed that NF-*K*b activity in oral cells in periodontal ligament tissue from the root surfaces of periodontally damaged teeth was inhibited following incubation with aqueous ozone (20µg/ml), suggesting that it has an anti-inflammatory capability.

Although there was a significant reduction in GBI % scores in this study at both 14th and 28th days indicating that reduction was maintained throughout the study duration of 28 days, it cannot be assumed that GBI scores would have been maintained had the duration of the study been longer. A prolonged observation period will allow a better estimation of the effect of the extinction.

The significant reduction in probing depth seen at 14th day (33.4%) and 28th day (44%) on both sides could have resulted from a reduction in gingival inflammation.

The MCP-1 marker in GCF was selected because its activity may increase around teeth wearing orthodontic appliances even if they do not undergo orthodontic movement, possibly as a consequence of gingival inflammation produced by the presence of plaque re-tentive appliances.[19]

Table 4. Mean Probing Pocket Depth (PPD) on experimental side and control side at three time intervals

Day	Side	No. of Samples	Mean	S.D	% Reduction	t Value	p Value
Day 0	Experimental	30	2.600	0.621	-	0.000	1.000**
	Control	30	2.600	0.621	-		
Day 14	Experimental	30	1.730	0.538	33.4	0.000	1.000**
	Control	30	1.730	0.538	33.4		
Day 28	Experimental	30	1.430	0.626	45	0.000	1.000**
	Control	30	1.430	0.626	45		

*significant; **non-significant.

Table 5. Mean LDH Values (mU/sample) in GCF on experimental side and control side at three time intervals

Day	Side	No. of Samples	Mean	S.D	% Reduction	t Value	p Value
Day 0	Experimental	30	416.643	28.376	-	-0.553	0.584**
	Control	30	419.307	28.779	-		
Day 14	Experimental	30	291.643	21.197	30	-21.765	0.000*
	Control	30	366.723	7.679	12.6		
Day 28	Experimental	30	151.077	14.105	63.7	-17.641	0.000*
	Control	30	227.363	17.723	45.7		

*significant; **non-significant.

There was indeed a significant reduction in in MCP-1 enzyme activity from baseline to the 14th day, from 14th to 28th day and also from baseline to 28th day in both the ozone and chlorhexidine irrigation sites. The baseline GCF MCP-1 levels on experimental and control sides were 38.93 pg/µl and 39.71 pg/µl respectively.

Table 6. Results of Pearson's Correlation test between GCF- LDH & Clinical parameters on experimental side – **Day 0**

	N	GI	PI	GBI	PPD	LDH
GI	30	1.000	0.543 0.002	0.624 0.003	0.565 0.003	0.704 0.000
PI	30	0.543 0.002	1.000	0.489 0.003	0.376 0.038	0.633 0.000
GBI	30	0.624 0.003	0.489 0.034	1.000	0.511 0.004	0.429 0.027
PPD	30	0.565 0.003	0.376 0.038	0.511 0.004	1.000	0.378 0.039
LDH	30	0.704 0.000	0.633 0.000	0.429 0.027	0.378 0.039	1.000

Table 7. Results of Pearson's Correlation test between GCF- LDH & Clinical parameters on experimental side – **Day 14**

	N	GI	PI	GBI	PPD	LDH
GI	30	1.000	0.195 0.302	0.174 0.359	0.267 0.154	0.762 0.000
PI	30	0.195 0.302	1.000	0.042 0.825	0.061 0.750	0.116 0.541
GBI	30	0.174 0.359	0.042 0.825	1.000	0.247 0.188	0.276 0.140
PPD	30	0.267 0.154	0.061 0.750	0.247 0.188	1.000	0.215 0.255
LDH	30	0.762 0.000	0.116 0.541	0.276 0.140	0.215 0.255	1.000

Table 8. Results of Pearson Correlation test between GCF- LDH & Clinical parameters on experimental side – **Day 28**

	N	GI	PI	GBI	PPD	LDH
GI	30	1.000	0.454 0.041	0.584 0.051	0.744 0.042	0.941 0.000
PI	30	0.454 0.041	1.000	0.620 0.042	0.867 0.032	0.695 0.039
GBI	30	0.584 0.051	0.620 0.042	1.000	0.897 0.000	0.782 0.001
PPD	30	0.744 0.042	0.867 0.032	0.897 0.000	1.000	0.818 0.025
LDH	30	0.941 0.000	0.695 0.039	0.782 0.001	0.818 0.025	1.000

Table 9. Results of Pearson Correlation test between GCF- LDH & Clinical parameters on control side – **Day 0**

	N	GI	PI	GBI	PPD	LDH
GI	30	1.000	0.301 0.150	0.246 0.159	0.402 0.028	0.978 0.000
PI	30	0.301 0.105	1.000	0.594 0.001	0.506 0.004	0.336 0.069
GBI	30	0.246 0.159	0.594 0.001	1.000	0.666 0.000	0.316 0.089
PPD	30	0.402 0.028	0.506 0.004	0.666 0.000	1.000	0.420 0.021
LDH	30	0.978 0.000	0.336 0.069	0.316 0.089	0.420 0.021	1.000

Table 10. Results of Pearson Correlation test between GCF- LDH & Clinical parameters on control side – **Day 14**

	N	GI	PI	GBI	PPD	LDH
GI	30	1.000	0.573 0.001	0.546 0.002	0.502 0.004	0.980 0.000
PI	30	0.573 0.001	1.000	0.364 0.048	0.362 0.049	0.539 0.002
GBI	30	0.546 0.002	0.364 0.048	1.000	0.553 0.002	0.890 0.001
PPD	30	0.502 0.004	0.362 0.049	0.553 0.002	1.000	0.499 0.005
LDH	30	0.980 0.000	0.539 0.002	0.890 0.01	0.499 0.005	1.000

Table 11. Results of Pearson Correlation test between GCF- LDH & Clinical parameters on control side – **Day 28**

	N	GI	PI	GBI	PPD	LDH
GI	30	1.000	0.369 0.045	0.789 0.051	0.477 0.003	0.948 0.000
PI	30	0.369 0.045	1.000	0.741 0.063	0.583 0.001	0.863 0.001
GBI	30	0.789 0.051	0.741 0.063	1.000	0.607 0.000	0.634 0.004
PPD	30	0.477 0.003	0.583 0.001	0.607 0.000	1.000	0.489 0.006
LDH	30	0.948 0.000	0.863 0.001	0.634 0.004	0.489 0.006	1.000

Table 12. ANOVA for experimental side

		Mean value	F value	P value
GI	Between sides	19.164	778.283	0.000*
	Within sides	0.025		
PI	Between sides	19.770	642.918	0.000*
	Within sides	0.031		
GBI	Between sides	1170.233	50.007	0.000*
	Within sides	23.402		
PPD	Between sides	11.011	29.536	0.000*
	Within sides	0.373		
LDH	Between sides	529548.211	1093.013	0.000*
	Within sides	484.485		

*significant

Table 13. ANOVA for control side

		Mean value	F value	P value
GI	Between sides	7.746	139.576	0.000*
	Within sides	0.055		
PI	Between sides	9.694	167.627	0.000*
	Within sides	0.058		
GBI	Between sides	1244.933	50.762	0.000*
	Within sides	24.526		
PPD	Between sides	11.011	29.536	0.000*
	Within sides	0.373		
LDH	Between sides	295142.299	737.053	0.000*
	Within sides	400.435		

*significant

These results were in concord with Yu et al.[20] who found that MCP-1 is expressed in inflamed gingival tissue as it plays an important role in the recruitment of monocytes and the amplification of inflammatory signals in bacterially induced inflammation. The GCF MCP-1 levels

in our study reduced significantly from 38.93 pg/µl to 16.36 pg/µl at 28th day after ozone irrigation ($p<0.01$) and from 39.71 pg/µl to 21.53 pg/µl on control side ($p<0.01$).

When the effects of the irrigants were compared, the data of the ozonated water showed a highly significant reduction in MCP-1 concentration ($p<0.01$). Concurrently, changes in GCF MCP-1 values and the clinical parameters and PPD between baseline and 28th day, evaluated using Spearman's correlation coefficient, were also seen to exhibit a significant correlation on both experimental and control sides.

At the end of one month, reduction of gingival inflammation in orthodontic patients was appreciable with a single subgingival irrigation of 0.01 mg/l ozonated water as compared with 0.2% chlorhexidine. Thus, subgingival ozone irrigation can be an effective method that can be performed during monthly visits on orthodontic patients to reduce the gingival inflammation.

Considering the limitation of this study in terms of short duration, ozone can be considered as a promising anti-inflammatory agent in periodontal therapy. Further long-term studies are required to adequately assess the efficacy of ozone with respect to the frequency and duration of application.

Conflicts of interest

None

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Applicability of the McNamara analysis in a sample of adult Black South Africans

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SUMMARY

Introduction
Cephalometric norms have been established for the McNamara analysis for different age, racial and ethnic groups.

Aim
To establish McNamara cephalometric norms for a sample of Black South African adults and to compare with Caucasian norms.

Methods
Thirty lateral cephalograms of a sample of eligible untreated Black adult subjects was retrieved from archives in the Department of Orthodontics at the Medunsa Oral Health Centre. They were traced and digitized using Dolphin Imaging® computer software. The McNamara analysis was performed. The one sample *t*-test was performed to compare study values with McNamara norms. The two sample *t*-tests were used to determine statistical differences between the data for genders.

Results
The mean age of the study subjects was 24 years (SD=3.9). Two-thirds of the linear measurements were significantly higher than the McNamara norms. The angular measurements of female subjects were significantly higher than McNamara's reference values.

As regards gender differences, almost two-thirds of male linear measurements were higher than females, and the differences were statistically significant in half of the measurements. In contrast, though all higher, female angular measurements showed no statistically significant differences.

Conclusion
Gender and racial differences exist in cephalometric norms measured using the McNamara analysis.

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INTRODUCTION

Radiographic cephalometry is a vital tool for clinical and research orthodontics.[1] Since its introduction by Broadbent[2] in 1931, numerous cephalometric analyses have been described over the years. These analyses are frequently used by orthodontists and maxillofacial surgeons for diagnosis, treatment planning, growth analysis and evaluation of treatment results.[3]

The McNamara[4] analysis is a popular example, composed of eight linear and three angular measurements. The analysis provided a method that is simultaneously sensitive not only to the position of the teeth within a given jaw bone but also to the relationship of the two jaws, as well as the relationship between the jaws and cranial base.[4] The relative positions of the maxilla and mandible, maxillary and mandibular lengths, the height of the face and the position of the incisors are described. It was developed for conventional orthodontic patients as well as for those with skeletal discrepancies requiring orthognathic surgery or growth modification.[5]

Studies have established McNamara norms for various population groups, the data having been found to vary amongst different age, racial and ethnic groups.[6-11] Whilst Barter et al.[12] established norms for Black South African children aged between 11 and 16 years, no McNamara norms for Black adults are available in the literature. This study seeks to determine these values for an adult Black South African sample.

MATERIAL AND METHODS

The study was approved by the Medunsa Research and Ethics Committee (MREC) of the University of Limpopo, Medunsa Campus, South Africa (Project number: MREC/D/213/2012). The study material consisted of lateral cephalograms and study models of untreated Black adult subjects retrieved from the archives in the Department of Orthodontics, University of Limpopo, Medunsa Campus.

A total of 30 lateral cephalograms and study models (12 men and 18 women) were selected for this study. The criteria for selection were the following: Skeletal

Class I; acceptable soft tissue profile[12]; Dental Class I; normal overjet and overbite; no severe crowding; no crossbites; no missing teeth except the third molars; and, no history of orthodontic treatment or orthognathic surgery.

All radiographs had been taken with the Frankfort horizontal plane parallel to the floor, the teeth in centric occlusion and the lips at rest. The analog cephalograms were taken with the Siemens, Orthopantomogram 10® while the digital radiographs were obtained using the Kodak 8000C® X-ray machine. The analog cephalograms were digitized using Vidar Sierra Advantage® X-ray film digitizer. A ruler from the Dolphin software programme was attached to each cephalogram during the digitization process (Figure 1). The calibrations on the ruler served as a reference to enable adjustment for magnification of the image.[8]

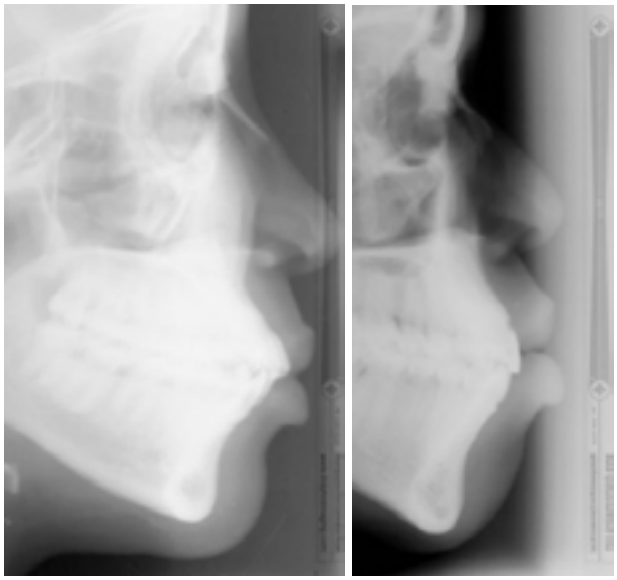

Figure 1: Digitized analog lateral cephalogram with a Dolphin ruler in place.

Dolphin Imaging 11.5 Premium® cephalometric analysis computer software was used to trace and analyze the cephalograms. The landmarks and measurements for assessing skeletal classification and soft tissue profile are shown in Figure 2, and those for the McNamara[4] (1984) analysis are illustrated in Figure 3. All measured variables of the McNamara analysis are shown in Table 1.

To determine the errors associated with landmark identification and measurements, five radiographs were randomly selected, retraced and re-measured by the principal investigator (intra-examiner reliability/error), as well as by the supervisor (inter-examiner reliability) two weeks after the initial measurements. The Pearson Correlation coefficient test was performed to determine intra- and inter-examiner reliability. Arithmetical means and standard deviation were calculated for all variables. A Shapiro-Wilk test was carried out to objectively assess the normality of distribution of the measured variables.

The mean values obtained from the sample for all the variables were compared with the McNamara[4] norms (Ann Arbor sample) by a one-sample *t* test. The mean values for male and female subjects were compared by a two-sample *t* test. The level of significance was set

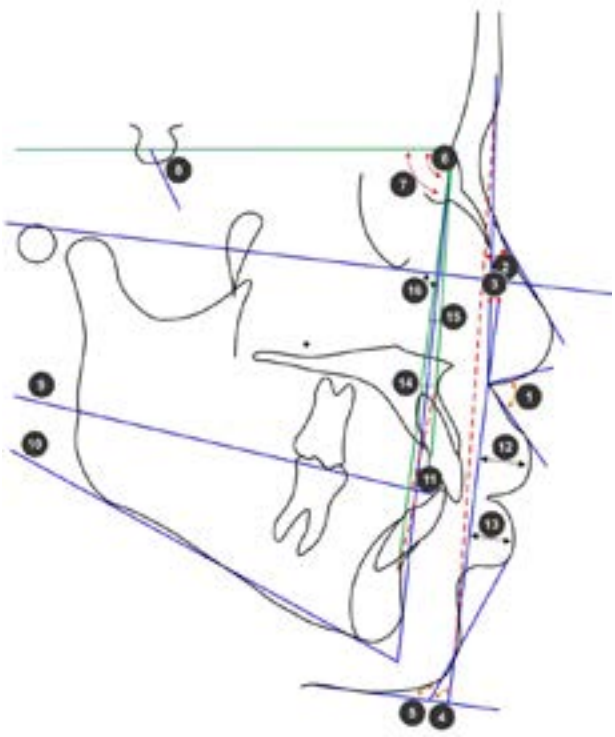

Figure 2: Linear and angular measurements to verify that a patient had skeletal Class I pattern and acceptable soft tissue profile 1) nasolabial angle, 2) nasofacial angle, 3) facial contour angle, 4) lower face-throat angle, 5) lower lip-chin-throat angle, 6) SNB, 7) SNA, 8) Y-axis, 9) occlusal plane, 10) mandibular plane angle, 11) Wits, 12) B-line upper lip, 13) B-line lower lip, 14) convexity, 15) ANB 16) face-plane.

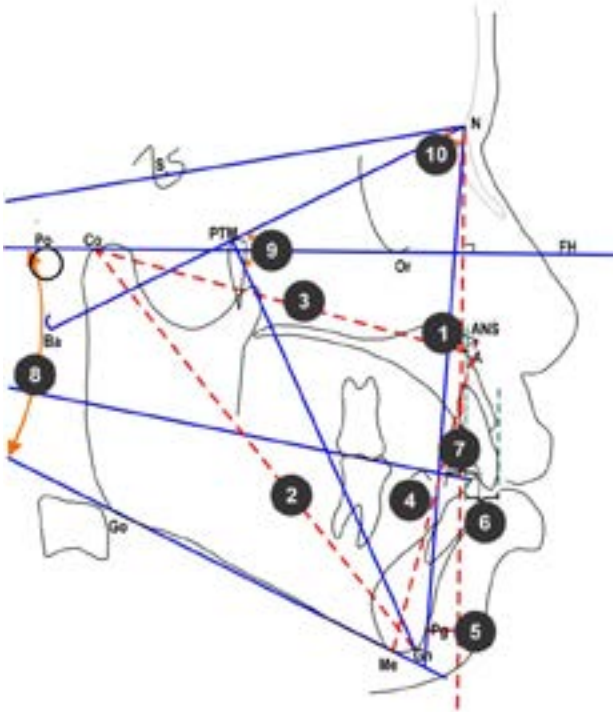

Figure 2: Landmarks, linear and angular measurements used for McNamara (1984) analysis 1) Distance from Point A to nasion perpendicular line, 2) Distance from condylion to gnathion, 3) Distance from condylion to Point A, 4) Distance from anterior nasal spine to menton, 5) Distance from point pogonion to the nasion perpendicular, 6) Distance from labial surface of upper incisor to Point A vertical, 7) Distance from tip of lower incisor to A-Pogonion line, 8) Angle between FH plane and Go-Me line, 9) Angle formed by intersection of N-Ba and PTM-Gn lines, 10) Angle formed by intersection of SN and NA lines.

at $p \leq 0.05$. All statistical analyses were performed under the advice of a statistician and were processed using the Statistical Analysis System (SAS) 9.2 computer software programme.

Table 1. Different linear and angular measurements of McNamara (1984)

Measurements	Definition
Maxilla to cranial base	
Nasion perpendicular to point A (mm)	Distance from Point A to nasion perpendicular line
SNA angle	Angle formed by intersection of SN and NA lines
Mandible to maxilla	
Effective mandibular length (mm)	Distance from condylion to gnathion
Effective midfacial length (mm)	Distance from condylion to Point A
Maxillomandibular differential (mm)	Midfacial length subtracted from mandibular length
Lower anterior facial height (mm)	Distance from anterior nasal spine to menton
Mandibular plane angle	Angle between FH plane and Go-Me line
Facial axis angle	Angle formed by intersection of N-Ba and PTM-Gn lines
Mandible to cranial base	
Pogonion to nasion perpendicular (mm)	Distance from point pogonion to the nasion perpendicular
Dentition	
Upper incisors to point A vertical (mm)	Distance from labial surface of upper incisor to Point A vertical
Lower incisors to A-Po line (mm)	Distance from tip of lower incisor to A-Pogonion line

RESULTS

The sample demographics are illustrated in Table 2.

There was no statistically significant difference between the ages of male and female subjects. The Shapiro-Wilk test revealed that more than 90% of the variables were normally distributed ($p > 0.05$). The intra- and inter-examiner reliability tests showed the correlation coefficient exceeded 0.8 indicating that the method of measurement was reliable and reproducible.

Gender differences in the study sample

Table 3 shows a comparison of the measured variables between male and female subjects. The mean values for four linear measurements (effective mandibular length; effective mid-facial length; maxillomandibular differential; and anterior lower facial height) were significantly larger in males than in females. The other four linear measurements (nasion perpendicular to Point A; pogonion to nasion perpendicular; upper incisor to Point A vertical; and lower incisors to A-Po line) and three angular measurements (SNA; mandibular plane; facial axis angle) showed no statistically significant difference between male and female subjects.

Comparison between study and Ann Arbor male sample

Table 4 shows a comparison of the measured variables between the study and the Ann Arbor male sample. The mean values for two linear measurements (upper

Table 2. Sample distribution by age and gender

Sample (n)	Number	Mean age (years)	SD	Median	Minimum	Maximum	p-value
Males	12	25.1	5.09	24.0	20	39	0.294
Females	18	23.3	2.81	23.0	20	29	
Total	30	24	3.90	23.5	20	39	

SD = standard deviation; p-value level of significance □ 0.05.

Table 3. Comparison of measured variables between males and females of the study sample

Parameters	Male Mean	Female Mean	Mean difference	t-value	*p*-value	95% CI for mean difference
Maxilla to cranial base						
Nasion perpendicular to point A (mm)	1.32	3.84	2.53	1.89	0.0693	-0.214 – 5.269
SNA angle (°)	83.23	85.81	2.58	1.81	0.0807	-0.336 – 5.492
Mandible to maxilla						
Effective mandibular length (mm)	129.63	123.50	6.13	-3.50	0.0016	-9.717 – -2.542
Effective midfacial length (mm)	98.51	95.53	2.98	-2.55	0.0164	-5.379 – -0.591
Maxillomandibular differential (mm)	31.12	28.03	3.09	-2.97	0.0060	-5.219 – -0.959
Lower anterior facial height (mm)	77.08	73.65	3.43	-2.05	0.0499	-6.855 – -0.001
Mandibular plane angle (°)	22.60	23.43	0.83	0.69	0.4981	-1.651 – 3.315
Facial axis angle (°)	-1.45	0.27	1.73	1.60	0.1209	-0.485 – 3.937
Mandible to cranial base						
Pogonion to nasion perpendicular (mm)	-3.43	-0.77	2.67	1.14	0.2650	-2.136 – 7.469
Dentition						
Upper incisors to point A vertical (mm)	8.45	9.59	1.15	1.65	0.1107	-0.279 – 2.571
Lower incisors to A-Po line (mm)	6.47	7.26	0.79	1.08	0.2893	-0.707 – 2.285

CI = confidence interval; *p*-value level of significance ≤ 0.05; t = value of statistical test

incisors to point A vertical and lower incisors to A-Po line) were significantly larger in the study than for those of the Ann Arbor male sample.

The mean value for one angular measurement (facial axis angle) was found to be significantly smaller in the study sample than in the Ann Arbor sample. The mean values for the other six linear measurements (nasion perpendicular to point A; effective mandibular length; effective midfacial length; maxillomandibular differential; lower anterior facial height; and, pogonion to nasion perpendicular) and two angular measurements (SNA and mandibular plane angle) were not statistically significant.

Comparison between study and Ann Arbor female sample

Table 5 shows the comparison of the measured variables between the study sample and Ann Arbor female sample.

The mean values for six linear measurements (nasion perpendicular to Point A; effective mandibular length; effective midfacial length; lower anterior facial height; upper incisors to Point A vertical; and, lower incisors to A-Po line) and one angular (SNA angle) measurement were significantly larger in the study sample than in the Ann Arbor females. The mean values for the other two linear measurements (maxillomandibular differential and pogonion to nasion perpendicular) and two angular measurements (facial axis and mandibular plane angles) were not statistically significant.

DISCUSSION

This study set out to establish McNamara norms for a population of adult Black South Africans, compare that data with Ann Arbor population norms, and examine for gender differences in the measurements.

Table 4. Statistical comparison of linear and angular measurements between study and Ann Arbor male sample

Parameters	Study sample (n = 12)			Ann Arbor sample (n = 38)	*p*-values
	Mean	t-value	95% CI of mean	Mean	
Maxilla to cranial base					
Nasion perpendicular to point A (mm)	1.32	1.89	-1.02 – 3.65	1.1	0.8419
SNA angle (°)	83.2	1.81	80.55 – 85.92	83.9	0.5957
Mandible to maxilla					
Effective mandibular length (mm)	129.6	-3.50	126.2 – 133.1	132.3	0.1172
Effective midfacial length (mm)	98.5	-2.55	96.47 – 100.6	99.8	0.1934
Maxillomandibular differential (mm)	31.1	-2.97	29.12 – 33.12	32.5	0.1561
Lower anterior facial height (mm)	77.1	-2.05	73.68 – 80.47	74.6	0.1367
Mandibular plane angle (°)	22.6	0.69	20.56 – 24.63	21.3	0.1888
Facial axis angle (°)	-1.5	1.60	-3.17 – 0.26	0.5	**0.0290**
Mandible to cranial base					
Pogonion to nasion perpendicular (mm)	-3.4	1.14	-7.16 – 0.29	-0.3	0.091
Dentition					
Upper incisors to point A vertical (mm)	8.5	1.65	7.06 – 9.83	5.3	**0.0004**
Lower incisors to A-Po line (mm)	6.5	1.08	4.94 – 7.99	2.3	**0.0001**

CI = confidence interval; *p*-value level of significance ≤ 0.05; t = value of statistical test

Table 5. Statistical comparison of linear and angular measurements between study and Ann Arbor female sample

Parameters	Study sample (n = 18)			Ann Arbor sample (n = 38)	*p*-values
	Mean	t-value	95% CI of mean	Mean	
Maxilla to cranial base					
Nasion perpendicular to point A (mm)	3.84	1.89	2.09 – 5.60	0.4	**0.0007**
SNA angle (°)	85.8	1.81	84.06 – 87.56	82.4	**0.0007**
Mandible to maxilla					
Effective mandibular length (mm)	123.5	-3.50	121.4 – 125.6	120.2	**0.0036**
Effective midfacial length (mm)	95.5	-2.55	94.00 – 97.06	91.0	**0.0001**
Maxillomandibular differential (mm)	28.0	-2.97	26.77 – 29.29	29.2	0.0661
Lower anterior facial height (mm)	73.7	-2.05	71.74 – 75.56	66.7	**0.0001**
Mandibular plane angle (°)	23.4	0.69	21.80 – 25.06	22.7	0.3602
Facial axis angle (°)	0.3	1.60	-1.23 – 1.77	0.2	0.9203
Mandible to cranial base					
Pogonion to nasion perpendicular (mm)	-0.8	1.14	-4.03 – 2.49	-1.8	0.5126
Dentition					
Upper incisors to point A vertical (mm)	9.6	1.65	8.78 – 10.40	5.4	**0.0001**
Lower incisors to A-Po line (mm)	7.3	1.08	6.46 – 8.05	2.7	**0.0001**

CI = confidence interval; *p*-value level of significance □ 0.05; t = value of statistical test.

Four linear measurements relating maxilla to the mandible demonstrated a statistically significant difference between the male and female sample. The effective mandibular length, effective mid-facial length, maxillomandibular differential and lower anterior facial height values in males were significantly larger than in females. These findings were in agreement with several other studies.[4,6-8,10,11]

These findings are an indication that male subjects have larger mandibular and maxillary skeletal structures than females. This finding could be related to the well-known time differences in craniofacial growth; male subjects grow for a longer period of time and therefore have larger maxillary and mandibular skeletal structures than females.[13-15]

No statistically significant difference was found in the two angular measurements for vertical dimension, linear measurement for the position of the mandible and linear measurement of the positions of the upper and lower incisors. However, the female sample demonstrated a more vertical tendency as measured by the mandibular plane angle, a more protrusive mandibular position and more protrusive upper and lower incisor positions. These findings are similar to data previously reported with regard to the vertical dimension,[4,6,8,10] the mandibular position,[8] and the upper[4,6] and lower[4,6] incisors position.

These findings were in agreement with those of a number of researchers for both upper and lower incisor positions.[6-8,10] Furthermore, the findings in this study concur with those of other studies with regards to the facial axis angle.[6,11]

The other eight variables showed no statistically significant differences between the two groups. However, the mean values for the effective mandibular length, effective maxillary length and pogonion to nasion perpendicular were larger in the Ann Arbor male sample. On the contrary, the mean values of the nasion perpendicular to point A and mandibular plane angle were larger in the Black male sample. Similar findings have been reported for effective mandibular and maxillary lengths.[6,7,10,11] Additionally, larger lower anterior facial height values have also been found.[6,8,10]

The results of the current study suggest that Black subjects have protrusive upper and lower incisors (bimaxillary protrusion) as well as an increased lower anterior facial height. A combination of increased lower facial height with relatively shorter maxilla and mandible (a finding in the current study although not statistically significant) further suggests that Black subjects of the present study have a tendency to downward and backward rotation of the mandible and a convex facial profile compared with Caucasians.

Comparison between study sample and Ann Arbor male sample

Only three variables (facial axis angle; upper incisor to Point A vertical; lower incisor to APO line) were found to be significantly different between the current study and the Ann Arbor sample. The facial axis angle in the present study sample was smaller (more negative, i.e. -1.5° versus 0.5°) than that of the Ann Arbor sample. The mean value of upper incisors to Point A vertical in this study was 3.2 mm larger compared with the Ann Arbor male sample. The lower incisor to APO measurement was 4.2 mm greater than the McNamara norms.

Comparison between study sample and Ann Arbor female sample

A comparison of the female results showed that the values of seven (7) out of eleven (11) variables were statistically significantly larger in the present study compared with the McNamara norms. These variables are: SNA angle; nasion perpendicular to point A; effective mandibular length; effective maxillary length; lower anterior facial height; upper incisors to point A; and lower incisors to APO. Except for the Saudis[8] mandibular and maxillary lengths, the values from the present study revealed larger figures than any reported previously (Table 6).

Table 6. Mean values of variables comprising the McNamara analysis of adult samples from different population groups

Authors	McNamara		Miyajima et al.		Basciftci et al.		Al-Barakati and Talic		Nahidh		Gu et al.		Present study	
Year	1984		1996		2004		2007		2010		2011		2014	
Country	USA		Japan		Turkey		Saudi Arabia		Iraq		China		South Africa	
Gender	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
Sample	38	73	26	28	50	55	36	29	33	42	25	40	12	18
NP-A (mm)	1.1	0.4	2.5	2.3	0.7	0.2	-2.0	-0.2	1.6	0.7	1.0	0.0	1.3	3.8
SNA (°)	83.9	82.4	82.2	82.1	83.3	81.9	-	-	83.8	81.8	85.1	83.6	83.2	85.8
Co-Gn(mm)	134.3 [132.3]*	120.2	125.5	118.8	126.4	117.8	133.4	124.9	121.4	111.0	125.4	119.4	129.6	123.5
Co-A (mm)	99.8	91.0	91.4	86.3	95.1	90.4	101.7	98.2	93.2	85.5	92.0	87.5	98.5	95.5
MM diff (mm)	34.5 [32.5]**	29.2	34.1	32.5	31.3	27.4	31.8	26.8	28.2	25.7	33.4	31.9	31.1	28.0
LAFH (mm)	74.6	66.7	75.1	72.7	75.1	68.3	76.1	68.9	68.8	63.4	74.9	69.4	77.1	73.7
FMPA (°)	21.3	22.7	22.3	26.1	-	-	24.9	25	21.7	23.9	-	-	22.6	23.4
FAA (°)	0.5	0.2	-4.2	-3.5	-1.3	-1.0	2.8	2.9	-0.6	-0.2	-5.4	-2.2	-1.5	0.3
Pog-NP (mm)	-0.3	-1.8	0.3	-1.7	-1.5	-1.8	-6.1	-5.9	-0.1	-1.4	-3.2	-6.6	-3.4	-0.8
UI-PA Vert (mm)	5.3	5.4	5.7	6	-	-	6.2	4.3	6.4	5.9	5.2	4.5	8.5	9.6
LI-A-Pog (mm)	2.3	2.7	4	4.9	2.6	2.3	4.4	3.6	4.0	4.0	4.1	4.1	6.5	7.3

* and ** are revised values for effective mandibular length and maxillomandibular differential respectively (McNamara & Brudon, 2001).

The current findings with regard to the position of maxilla differ from the results of other studies that found the SNA to be smaller than that of the McNamara norms.[6,7,10] Similar results of smaller mean values of point A to nasion perpendicular were reported in two studies.[8,11]

A similar trend of smaller values than the McNamara norms was found with regard to effective mandibular and maxillary lengths.[6,7,10,11] By contrast, several studies reported greater values than the McNamara norms for the lower anterior facial height,[6-8,11] upper incisor to point A vertical[6,10] and lower incisors to APO.[6,8,10,11]

The interpretation of the current findings suggests that the Black female subjects had prognathic maxillae (larger SNA and nasion perpendicular to point A), larger mandibles (effective mandibular length) and maxillae (effective maxillary length), longer lower anterior facial height and procumbent upper (upper incisors to point A vertical) and lower incisors (lower incisors to APO). In addition, the mandible was also protrusive, even though the values were not statistically significant.

These findings further suggest that a combination of larger maxilla, protrusive maxilla and maxillary incisors together with larger mandible, protrusive mandible and mandibular incisors (bimaxillary skeletal and dental protrusion) is a characteristic feature of the current female study subjects.

Bimaxillary protrusion has been established as a common feature among the general Black population as well as among Black South African subjects.[16-20] Our study sample subjects, therefore, appear to have facial features shared with other Black individuals from other parts of the world.

Limitation of the study

The sample size in this study was small. However, it was representative of the target population. A large number of significance tests were also carried out on the data. These two factors increase the possibility of making type I and II errors.

CONCLUSION

Within the limitations of the current study, the following conclusions can be drawn:

- There are significant gender differences in the study sample, with male subjects having significantly larger mandibles, maxillae and lower anterior facial height structures.
- The present male study subjects demonstrated a significantly smaller facial axis angle, and significantly more procumbent upper and lower incisors compared with the Ann Arbor sample.
- The females from this study were found to have significantly larger and protrusive maxillae, significantly larger but non-significantly protrusive mandibles, significantly greater lower anterior facial heights, and significantly procumbent upper and lower incisors compared with the Caucasian Ann Arbor sample.
- The Ann Arbor (McNamara) norms may be applicable to the male study sample except for the facial axis angle, upper incisors to Point A vertical and lower incisors to A-Po line measurement. The Ann Arbor norms are, however, not applicable to the female study sample.
- A more comprehensive survey including a larger sample drawn from a wider population is indicated to confirm the results of this study.

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

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1. Root surface alterations following manual and mechanical scaling: A comparative study

M Maritato, L Orazi, D Laurito, et.al. Int J Dent Hygiene. 2018; 16: 553-8.

Periodontitis and gingivitis are common inflammatory conditions affecting the oral cavity. These conditions can be managed in nearly all cases when proper plaque control is practiced, requiring professional cleanings in the form of scaling and polishing and daily brushing and flossing. Scaling and root planing involve both the cleaning and smoothing of the root surface. In the past, the removal of dental plaque, calculus and altered cement was performed using hand-held instruments only, for example sickle, curettes, chisel, files and hoes.[1]

Sonic and ultrasonic scalers are referred to as power-driven scalers and are currently used for scaling and root planing in conjunction with, or as an alternative to, hand-held instruments. There is still some controversy about the effectiveness of available treatment options. According to some authors, ultrasonic scalers leave more contaminated cementum on the root surface compared with curettes, and hence consider the power driven scalers as adjuncts to hand instruments for tooth surface debridement.[1]

Further concern has been raised concerning the effects of periodontal instrumentation on root surfaces as several studies on plaque accumulation have found a positive correlation between root roughness and plaque growth, with a greater amount of plaque on rougher than on smooth surfaces.[1] Maritato and colleagues (2018)[1] reported on an *in vitro* study that sought to analyse the morphological changes and the roughness on the root surfaces of extracted teeth treated with hand curette and with two different mechanical ultrasonic devices.

MATERIALS AND METHODS

Twenty-four extracted monoradicular human teeth were selected for the study. Inclusion criteria were the following: teeth extracted as a result of severe periodontal disease (probing depth >6mm), tooth mobility (grade II or grade III), no root decay and no history of periodontal treatment over the past six months. All specimens were washed and cleaned to remove any residual soft tissue attached to the root surface. Calculi were not removed during the sample preparation. After embedding in plaster casts, the samples were randomly divided into four groups (n=six teeth per group) and the middle third of the mesial and distal root surfaces of each tooth were instrumented with the following devices:

- **Group A:** Piezoelectric ultrasonic device *Piezon Master 400* with scaler tip "A"
- **Group P:** Piezoelectric ultrasonic device *PiezoSmart®* alone with a scaler tip "P1"
- **Group C:** Gracey curette 7/8 alone
- **Group AC:** Piezoelectric ultrasonic device *Piezon Master 400* with scaler tip "A" followed by Gracey curette 7/8

Each sample was instrumented until a smooth, calculus-free surface was obtained. One single operator performed the tests to ensure the same working conditions and consistency in applied pressure during scaling. Subsequently, 5 × 5mm sections of each surface were cut (thus obtaining n=12 sections per group) and sent for surface analysis.

After instrumentation, nine specimens per group were randomly selected for topographic analysis using a white light interferometer. The data was enhanced digitally and different amplitude parameters were evaluated: S_a, average surface height deviation amplitude (arithmetic mean of the distances between the points of the surface and a medium reference plane); S_t, distance between the highest peak and the deepest valley within the measured area; S_q, root-mean-square roughness (mean square of the distances between the points of the surface and a medium reference plane).

For each parameter, the arithmetic mean, the standard deviation and maximum and minimum values were recorded. Finally, three specimens for each group were analysed using a scanning electron microscope (SEM).

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RESULTS

Interferometric analysis with a three-dimensional mapping revealed the residual roughness of the samples. The most pronounced roughness alterations were observed in Group C (S_a = 24.98 µm). Group AC also showed significant surface alterations (S_a = 14.48 µm), while the piezoelectric ultrasonic scalers used in groups A and P produced moderate peaks and less surface modifications than the first two groups (S_a = 8.99 and S_a = 4.45 µm, respectively). Statistically significant differences were found for S_a and S_q between groups C and P (P = .036 and .023, respectively). For the SEM analysis, samples treated by hand curette (Group C) revealed a non-homogeneous surface with some deeper and smooth portions. In the group treated with the combined technique (Group AC), some areas were characterized by major substance loss and no well-defined borders, presumably due to hand instrumentation. The root surfaces presented, however, a more homogeneous morphology compared with Group C. Finally, samples treated by piezoelectric ultrasonic devices (groups A and P) presented only superficial grooves distributed unevenly, within an almost uniform cementum layer.

CONCLUSION

The results of this study indicate that both mechanical and hand professional instrumentation can have an impact on the tooth surface. Hand curettes produced the most remarkable surface alterations, modifying the root morphology and roughness, while piezoelectric devices showed a limited but still present impact on root surfaces. Both interventions thus showed evidence of a negative impact on the integrity of the root surfaces.

Implications for practice

The clinical implications of this and other *in vitro* studies can be questioned and the study is far from giving a definitive answer to the question about the most effective periodontal instrumentation. However, clinicians should be aware that, based on the current knowledge, both manual and mechanical devices could eventually damage the root surface as a result of improper use.

In this study, piezoelectric instrumentation has been demonstrated to preserve root morphology to a greater extent than the use of manual curettes although all the tested instruments produced surface alterations.

Reference

1. Maritato M, Orazi L, Laurito D, et.al. Root surface alterations following manual and mechanical scaling: A comparative study. Int J Dent Hygiene 2018; 16: 553-558.

2. A comparative evaluation of three obturation techniques in primary incisors

JEJ Akhil, B Prashant, KK Shashibushan. Clin Oral Invest. 2019; 23: 689-96.

Dental caries continues to be one of the most common oral conditions that affects young children in both developed and developing countries. Primary teeth are needed as they act as a natural space maintainer, thereby preventing detrimental psychological effects, aiding in proper mastication, phonation, swallowing, aesthetics, and preventing the development of aberrant oral habits due to loss of teeth.[1]

Pulp treatment to preserve the primary tooth is becoming more common as more parents become aware of the need to keep the primary teeth in the oral cavity for as long as is possible/needed. A three-dimensional (3-D) fluid tight seal is essential in an aseptically prepared root canal to prevent recurrence of infection.[1] This is difficult to achieve due to varied morphologies of primary teeth such as thin ribbon-shaped and lateral branching canals, apical ramifications, and connecting fibrils.[1] Different obturation materials and techniques are used to obtain a proper apical seal with fewer voids.[1] Zinc oxide eugenol paste (ZOE), calcium hydroxide $Ca(OH)^2$ paste, iodoform, and/or a combination of these are the most commonly used obturating materials in primary teeth. However, none meet all the criteria for an ideal filling material.[1] The success of pulpectomy depends on appropriate case selection and usage of ideal obturating materials with proper technique of obturation.[1]

Various obturating techniques like endodontic pressure syringe, lentulospiral, mechanical syringe, incremental filling technique using endodontic finger or hand plugger, jiffy tube, tuberculin syringe, reamer technique, insulin syringe technique, pastinject, cotton pellet, paper point, small amalgam plugger or condenser, disposable injection technique and navitip technique have been used to obturate primary teeth root canals.[1]

Obturation quality of *in vivo* or *in vitro* techniques can be evaluated using radiographs, fluid filtration, bacterial leakage, dye penetration, radio isotopes, microscopic analysis, clearing technique and digital radiography methods like radiovisiography (RVG) or cone beam computed tomography (CBCT). However, there is no literature available regarding the evaluation of obturation quality using three different obturation techniques such as lentulospiral, insulin syringe, and endodontic plugger with a two-dimensional (2-D) digital intra-oral receptor (DIOR) (Vatech, Ez Sensor) and CBCT (Planmeca, Promax® 3D Classic). Akhil and colleagues (2019)[1] reported on an *in-vitro* study using DIOR and CBCT that sought to evaluate and compare the obturation quality, based on the assessment of underfilling, optimal filling, over-filling, and the location of voids in primary incisors among the three obturation techniques.

MATERIALS AND METHODS

Thirty-three extracted single-rooted primary incisor teeth having full root length were collected. Any teeth with signs of root canal obstruction, gross decay or fracture were excluded. Collected teeth were cleaned and stored in saline until use. Access was gained with carbide bur and pulpectomy was performed by a single trained operator. The canals were dried using sterile absorbent paper points.

After the canal preparation, the apical foramen was covered by a ball of red wax measuring approximately 4–5 mm in diameter, to create a halo anatomical apical space around each root apex. This served as a collection area for any extruded canal filling material, simulating identical environment as *in vivo* conditions. The apical parts of the roots were then mounted in the centre of cold-cured acrylic resin blocks. Later, 33 teeth were randomly selected with 11 teeth in each obturating group. The prepared root canals were filled with slow-setting ZOE. A creamy consistency was achieved by mixing one volume unit of powder and two volume unit of liquid on a dry glass slab at room temperature for 45 seconds. Obturation was done 1 mm short of radiographic apex.

Group 1: lentulo spiral method

A lentulospiral file (21 mm, Dentsply, Maillefer) was mounted on a rotary slow-speed handpiece (1000 rpm), which was adjusted in clockwise rotation initially to pick up the freshly mixed ZOE. After insertion into the canals, it was operated in a counter clockwise direction. This procedure was repeated 3–5 times until the canal orifices were visibly filled.

Group 2: insulin syringe method

An insulin syringe (size 30 gauge) loaded with ZOE was inserted into the canal. ZOE was compacted into the canal by pressing the plunger. The needle was then gradually withdrawn from the canal while the material was still being dispensed.

Group 3: endodontic plugger method

An endodontic finger plugger (35 size, 21 mm) corresponding to the last instrument size was used to incrementally plug the mix into the canal until it was visibly filled near the orifice.

To control paste delivery in all groups, a rubber stopper was placed around each instrument at a distance determined by preoperative measurements. In all groups, when the canals were visibly filled, a wet cotton pellet was used to lightly tamp the material into the canal. Later, the access cavity was filled with a thick mixture of ZOE. All the samples were stored in 37 °C in 100% relative humidity for a day and thereafter scanning was performed.

The quality of the obturation, measured as optimal filling, underfilling, overfilling, and voids (presence and location), was evaluated with DIOR. Radiographic evaluation was done in both bucco-lingual and mesio-distal directions using a paralleling cone technique. Obturated canals were assessed on the basis of presence and number of voids in each third of the root canal (coronal, middle, apical). All the results were reviewed by the second evaluator.

The obturation quality of the filled root canals was recorded, according to the distance of the ZOE filling from the apex using Coll and Sadrian criteria as follows:

- **Score-1 (under filling):** canal filled more than 2 mm short of the apex.
- **Score-2 (optimal filling):** canal having zinc oxide eugenol ending at the radiographic apex or up to 2 mm short of apex.
- **Score-3 (over filling):** any canal showing zinc oxide eugenol outside the root apex.

RESULTS

The quality of obturation was significant (P = 0.02) between the three tested groups with Fisher's exact test in both DIOR and CBCT. The highest optimal filling was found with lentulospiral (90.9%) followed by endodontic plugger (81.8%) and the least was in insulin syringe (63.6%) on both DIOR and CBCT evaluations.

Among the three obturation techniques, statistically significant differences in the number of voids were seen in DIOR (in the apical one third of root, P = 0.02) and in CBCT (apical one third of the root, P = 0.04 and in the total length of the root, P = 0.03)

The highest number of voids was seen in lentulospiral technique followed by endodontic plugger and the least seen in insulin syringe in both DIOR and CBCT. On comparing the number of voids in obturated root canals between the data provided by DIOR and by CBCT, using a paired t test for different obturation techniques, DIOR showed statistically more number of voids at coronal one third of root in lentulospiral group (P < 0.001), middle one third of root in insulin syringe (P = 0.001) group, and total length of the root in lentulospiral (P = 0.04) and insulin syringe (P = 0.02) groups.

CONCLUSION

The study concluded that lentulospiral was effective in terms of optimal length of root canal filling in primary incisors when compared with insulin syringe and endodontic plugger group. The insulin syringe technique resulted in the least number of voids compared with endodontic plugger and lentulospiral groups. Both DIOR and CBCT were effective in determining the length of obturation. However, for void detection, DIOR performed better than CBCT.

Implications for practice

In day to day practice, DIOR provides a more easily accessible, less expensive, low radiation operational method compared with CBCT. This helps in gaining more confidence for the clinician in a 2-D imaging technique.

Reference

1. Akhil JEJ, Prashant B, Shashibushan KK. Comparative evaluation of three obturation techniques in primary incisors using digital intra-oral receptor and CBCT—an *in vitro* study. Clin Oral Invest 2019; 23: 689-96.

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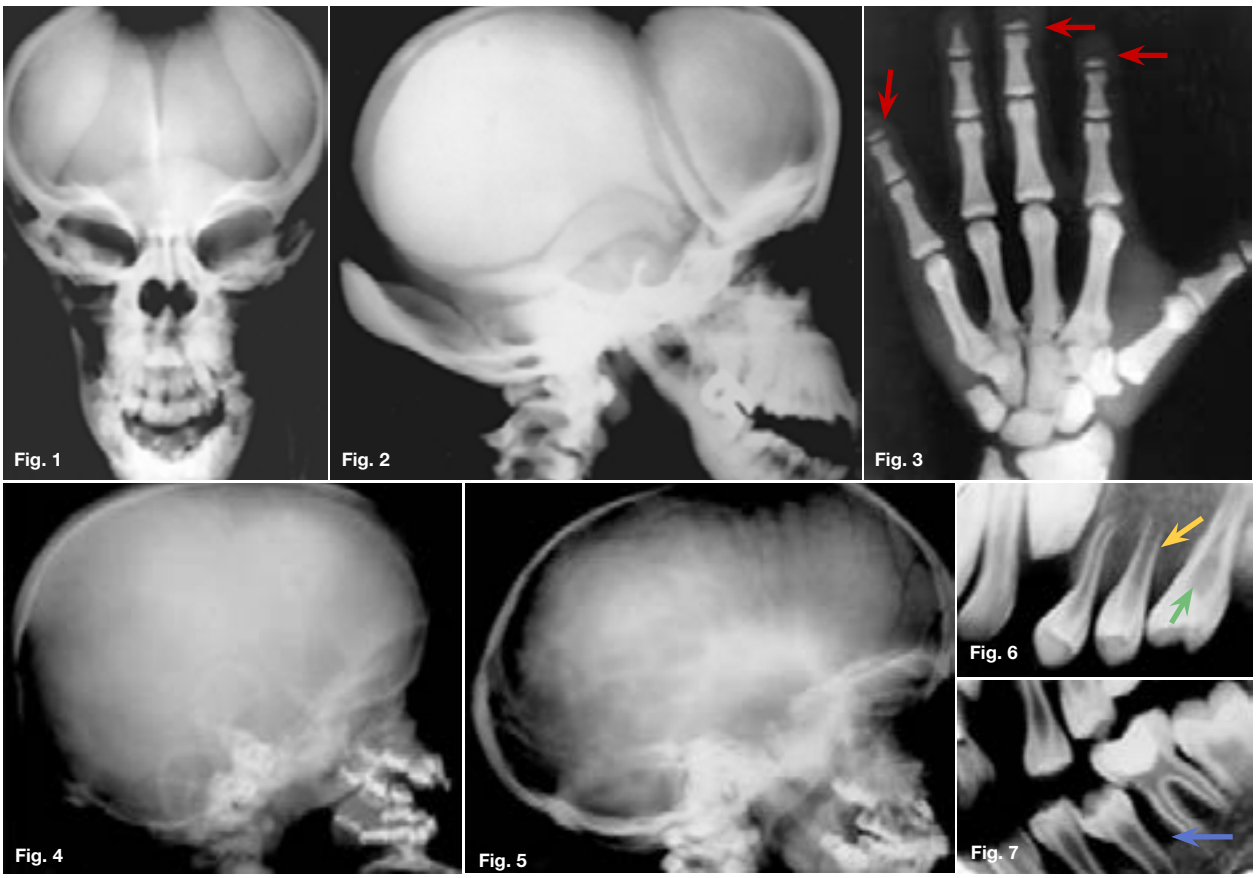
Maxillofacial Radiology 168

SADJ March 2019, Vol. 74 No. 2 p97

CJ Nortjé

Below are cases of two very rare genetic disorders. Figures 1, 2 & 3 are of an inherited form of dwarfism associated with fragile bones, while Figures 4, 5, & 6 are cases of metabolic disturbances affecting the skull, jaws and teeth. Describe the important radiological features discernible and what are your diagnoses?



INTERPRETATION

Postero-anterior skull (Fig. 1) and lateral skull radiographs (Fig. 2) showing open anterior fontanelle, dense bones and small maxillary sinuses. In addition, Figure 2 also demonstrates obtuse mandibular angles. The hand-wrist radiograph (Fig. 3) shows incomplete terminal phalanges (red arrows). A diagnosis of Pyknodysostosis was made which is a genetic lysosomal disease characterized by short stature, increased density of the bones, and brittle bones. Other features may include underdevelopment of the tips of the fingers with absent or small nails, an abnormal collarbone (clavicle), distinctive facial features including a large head with a small face and chin, underdeveloped facial bones, a high forehead, and dental abnormalities. These patients are predisposed to osteomyelitis. The diagnosis of Pyknodysostosis is based on physical features and X-ray findings. Figure 4 is a lateral skull radiograph of a patient presenting with bulging of the frontal region of the skull and showing attenuation of the outlines of the dental crypts which is suggestive of a child with vitamin D deficiency. This deficiency results in rickets in childhood and is one of the causes of osteomalacia in adults. Vitamin D acts to increase intestinal calcium uptake, bone calcium mobilization reabsorption. Hypovitaminosis D leads to nondeposition of calcium salt in bone matrix. Figure 5 is a lateral skull radiograph showing generalized radiolucency while figures 6 & 7 are intra-oral and bitewing radiographs of the same patient showing large pulp cavities (green arrow) and attenuation of the lamina dura and dental crypts (yellow arrow). There is also lack of mineralization of the alveolar crest bone (blue arrow). These radiological features are suggestive of Vitamin D–resistant rickets which is an isolated renal tubular defect inhibiting reabsorption of inorganic phosphates, resulting in hypophosphaturia which is inherited as an X-linked dominant trait. The full manifestation of vitamin D-resistant rickets is rickets or osteomalacia non-respondent to vitamin D therapy, as vitamin D metabolism is normal. However, there is diminished intestinal calcium and phosphate absorption. Patients with the milder form may be slightly shorter than normal siblings, with no other manifestation. Females with vitamin D resistant rickets tend to show fewer signs and symptoms than do their brothers.

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Reference

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http://dx.doi.org/10.17159/2519-0105/2019/v74no2a9

Rules of conduct

SADJ March 2019, Vol. 74 No. 2 p98-p99

WG Evans

The Medical and Dental Council publishes Rules of Conduct[1] which cover all the registered professions. In an endeavour to clarify how the Rules may be applied, a series of case examples were published by T Verschoor.[2] Although that publication appeared in 1990, the examples cited remain relevant to the Rules as they have been amended to date.

The cases summarised below demonstrate how the Council interprets the Rules... and also how members may transgress.

RULE 6 - Itinerant practice

A practitioner may conduct a regularly recurring itinerant practice at a place where another practitioner is established if, in such itinerant practice, such practitioner renders the same level of service to patients, at the same fee as the service which he or she would render in the area in which he or she is conducting a resident practice.

Case: Dentists intended to use a caravan for the delivery of dental services at distant towns at regular intervals.

Ruling: It was decided this was permissible provided that a full professional service was rendered and that only towns having no resident dentist were visited.

RULE 9 - Covering

A practitioner shall employ as a professional assistant or locum tenens, or in any other contractual capacity and, in the case of locum tenens for a period not exceeding six months, only a person - (a) who is registered under the Act to practise in independent practice; (b) whose name currently appears on the register kept by the registrar in terms of section 18 of the Act; and (c) who is not suspended from practising his or her profession. [Subrule (1) substituted by GN R68/2009] (2) A practitioner shall help or support only a person registered under the Act, the Pharmacy Act, 1974 (Act No. 53 of 1974), the Nursing Act, 1978 (Act No. 50 of 1978), the Social Service Professions Act, 1978 (Act No. 110 of 1978), the Dental Technicians Act, 1979 (Act No. 19 of 1979), or the Allied Health Professions Act, 1982 (Act No. 63 of 1982), if the professional practice or conduct of such person is legal and within the scope of his or her profession.

Case: A dentist wished to make use of a non-professional hypnotist in his practice.

Ruling: It was decided that the Councils ethical rules prohibit the use of unregistered persons for the purposes of hypnosis during professional treatments.

WG Evans: Managing editor, **Email:** bill.evans@wits.ac.za

Case: A dentist's wife placed and cemented crowns on a patient's central incisors.

Ruling: The dentist was found guilty of disgraceful conduct. He was suspended from practice for six months, which suspension was conditionally deferred for three years.

RULE 10 - Supersession

A practitioner shall not supersede or take over a patient from another practitioner if he or she is aware that such patient is in active treatment of another practitioner, unless he or she - (a) takes reasonable steps to inform the other practitioner that he or she has taken over the patient at such patient's request; and (b) establishes from the other practitioner what treatment such patient previously received, especially what medication, if any, was prescribed to such patient and in such case the other practitioner shall be obliged to provide such required information.

Case: A dentist had over twenty years continually held various Provincial maxillo-facial posts. He had dealt with patients suffering jaw fracture cases being referred to him by private practitioners.

The dentist had the opinion that as the patient had been referred to him, treatment could proceed with no consultation with the dentist of the patient. He requested a ruling from the Council.

Ruling: It was decided that he should firstly ask a patient who his dentist was. if the patient had his own dentist, he then had to decide in consultation with the latter whether to continue treatment or to refer the patient to his own dentist.

RULE 16 - Certificates and reports

(1) A practitioner shall grant a certificate of illness only if such certificate contains the following information - (a) the name, address and qualification of such practitioner; (b) the name of the patient; (c) the employment number of the patient (if applicable); (d) the date and time of the examination; (e) whether the certificate is being issued as a result of personal observations by such practitioner during an examination, or as a result of information which has been received from the patient and which is based on acceptable medical grounds; (f) a description of the illness, disorder or malady in layman's terminology with the informed consent of the patient: Provided that if such patient is not prepared to give such consent, the practitioner shall merely specify that, in his or her opinion based on an examination of such patient, such patient is unfit to work; (g) whether the patient is totally indisposed for duty or whether such patient is able to perform less strenuous duties in the work situation; (h) the exact period of recommended sick leave; (i) the date of issue of the certificate of illness; and (j) the initial and surname in block letters and the registration number of the practitioner who issued the certificate.

(2) A certificate of illness referred to in subrule (1) shall be signed by a practitioner next to his or her initials and surname printed in block letters. (3) If preprinted stationery is used, a practitioner shall delete words which are not applicable. (4) A practitioner shall issue a brief factual report to a patient where such patient requires information concerning himself or herself.

Case: A dentist submitted a medical certificate he had completed himself as a claim for sick benefits from a provident fund. He claimed falsely that he had been examined by a physician and had been advised that he would be unable to practice for a period as a result of backache.

Ruling: It was decided that the practitioner was guilty of disgraceful behaviour. He was suspended from practice for six months.

Being alert to the Rules of Conduct is a prerequisite to proper ethical practice.

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CPD questionnaire

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GENERAL

Labelling of fluoridated toothpaste in South Africa

1. Identify the INCORRECT answer. Quality control for fluoride toothpastes would include:
   A. fluoride content of at least 1000ppm
   B. chemically soluble fluoride
   C. packaging which protects against micro-organisms, moisture and dehydration
   D. a foaming ingredient to enhance fluoride uptake

2. Identify the INCORRECT answer. The SANS 1302: 2008 (edition 1.1) guidelines stipulate the following conditions for the packaging of fluoride toothpaste:
   A. Must be in leak-proof, collapsible tubes bearing a notation of the total nominal volume
   B. May be packaged in volumes of 15ml, 35ml, 50ml, 75ml, 100ml, 125ml, 150ml, 175ml and 200ml
   C. If packaged in composite packs, the tubes are to be separated from each other
   D. The tube must be labelled "Fluoride Toothpaste" in red letters at least 3mm in height

3. Identify the INCORRECT answer. The bioavailability of fluoride in tooth pastes is complex because:
   A. fluoride bioavailability decreases over time in response to chemical incompatibility between toothpaste constituents.
   B. fluoride content cannot be accurately measured
   C. the ambient conditions under which the toothpaste is stored and handled affect fluoride bioavailability
   D. differing fluoride species would have to be defined and acknowledged

Perceptions of stress among dentists: An investigation of stress management among dental practitioners in South Africa

4. Identify the INCORRECT statement.
   The study found that:
   A. female dentists were found to have greater perceived stress scores (20.8) than male dentists (17.5)
   B. maximum mean PSS score (21) was observed in dentists who have 5-10 years of dental experience
   C. least mean PSS score (17) was found in those who have had more than 15 years of dental experience
   D. dentists who have children reported a higher mean PSS score (20.6) than dentists who didn't have children (18)

5. Identify the CORRECT statement. The top factors inducing stress amongst the study group included:
   A. financial factors, family factors, time schedule factors, equipment factors
   B. peer factors, financial factors, time schedule factors, equipment factors
   C. patient factors, financial factors, time schedule factors, equipment factors
   D. time schedule factors, patient factors, financial factors, staffing factors

6. Identify the CORRECT statement. Amongst the coping strategies reported by participants in the study, alcohol was acknowledged to be used by:
   A. 11% of the sample
   B. 15% of the sample
   C. 25% of the sample
   D. 5% of the sample

Comparison of two light guide tips used to photo-polymerize two dental composites. An *in-vitro* study

7. Identify the CORRECT statement.
   The output depends on:
   A. the condition and type of reflector, the condition of the internal filter, the ambient temperature and the condition and type of the light guide tip
   B. the condition of the internal filter, condition and type of reflector, condition of the bulb LED and the condition and type of the light guide tip
   C. the condition of the internal filter, condition and type of reflector, condition of the bulb LED and how forcefully the tip is placed in contact with the composite
   D. the curvature of the light guide tip, the condition and type of reflector, condition of the bulb LED and the condition and type of the light guide tip

8. Identify the INCORRECT statement.
   A. The CMLG tip guided light from the LCU to the surface of each resin specimen in a single burst
   B. The MMLG tip guided light from the LCU to the surface of the resin specimens rapidly
   C. The CMLG tip emitted very little heat energy
   D. The MMLG tip that emitted a significant amount of heat energy

ACRONYMS

CMLG:	Custom-made Light Guide
LCU:	Light Curing Unit
MMLG:	Manufacturer-made Light Guide

9. The most common photo-initiator today is camphorquinone which has a peak activity at around 470 nanometers.
   A. True
   B. False

Does additional information provided by cone beam computed tomography (CBCT) and a consequent modification of surgical technique reduce the possibility of inferior alveolar nerve injury? A pilot study.

10. Identify the CORRECT answer. Fisher's exact test (Table 2) showed a statistically significant association between an injury to the inferior alveolar nerve and:
    A. the depth of the impaction (p = 0.036), the surgical procedure (p = 0.007) and the nerve exposure (p = 0.034)
    B. the depth of the impaction (p = 0.036), the presence of an assistant surgeon (p = 0.007) and the nerve exposure (p = 0.034)
    C. the surgical procedure (p = 0.007), the nerve exposure (p = 0.034) and the size of the molar (p = 0.036)
    D. the surgical procedure (p = 0.007), the age of the patient (p = 0.036) and the nerve exposure (p = 0.034)

11. Identify the CORRECT answer.
    In this study, the surgeon:
    A. luxated the tooth in a direction away from the lingual nerve
    B. luxated the tooth in a direction towards the lingual nerve
    C. luxated the tooth in the direction of least resistance
    D. luxated the tooth vertically whatever the relation to the lingual nerve

Comparison of efficiency of ozone and chlorhexidine subgingival irrigation in orthodontic patients for controlling gingival inflammation

For questions 12 -15 please identify the CORRECT answers.

12. Applications of ozone in dentistry:
    A. Immuno stimulant
    B. Analgesic
    C. Antimicrobial agent
    D. All the above

13. The methods of collecting Gingival Crevice Fluid include:
    A. Gingival washing technique
    B. Capillary tube method
    C. Paper strip insertion method
    D. All the above

14. The properties of chlorhexidine include:
    A. Antimicrobial
    B. Anti plaque
    C. Anti gingivitis agent
    D. All the above

15. Which of the following bacteria is lethal to *actenomyceten comitans*.
    A. Streptococcus salivarius
    B. Streptococcus mutans
    C. Streptococcus mitis
    D. Streptococcus sanguinis

Maxillofacial Radiology Case 168

16. Incomplete terminal phalanges are a feature of Pyknodysostosis.
    A. True
    B. False

17. Females with Vitamin D resistant rickets show fewer signs and symptoms as their brothers.
    A. True
    B. False

Clinical Windows

18. The results of the Maritato et al. study showed that only mechanical hand scaling could have an impact on the tooth surface.
    A. True
    B. False

19. In the Akhil et al. study, the highest number of voids was seen in lentulospiral technique.
    A. True
    B. False

20. In the Akhil et al. study, the Insulin syringe technique resulted in least number of voids compared with endodontic plugger and lentulospiral group.
    A. True
    B. False

ETHICS

21. The HPCSA Rules require that standards of practice are maintained whether in a central or a branch practice.
    A. True
    B. False

22. The HPCSA Rules provide that a locum tenens need not hold the right to practice independently.
    A. True
    B. False

23. The HPCSA Rules stipulate that if a person who is registered under the Act requests assistance, that assistance may be given only if the person has acted legally within the scope of the profession.
    A. True
    B. False

24. Identify the INCORRECT statement. A dentist who takes over treatment previously being undertaken by another practitioner may request records from that practitioner provided:
    A. the patient has requested that the treatment be taken over
    B. the situation is explained to the patient
    C. he/she has taken reasonable steps to ensure that the first practitioner is informed of the situation
    D. the patient gives assurance that all fees owing to the previous dentist have been paid

25. A practitioner issuing a medical certificate must state on the certificate whether he/she has personally examined the patient or whether the (medically sound) information has been provided by the patient.
    A. True
    B. False

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