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Comparing Obturation Quality and Preparation Times of Different Pulpectomy Preparation Techniques in Primary Molars – an In Vitro Study.

May 2023

SUPERVISOR: Prof M Vorster

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Declaration

I, Ilana Middleton, declare that this dissertation entitled "**Comparing Obturation Quality and Preparation Times of Different Pulpectomy Preparation Techniques in Primary Molars – an In Vitro Study**", which I herewith submit to the University of Pretoria in fulfilment of the requirements for the degree MSc(Dent), is my own original work, and has never been submitted for any academic award to any other institution of higher learning. All sources cited or quoted in this research paper are indicated and acknowledged with a comprehensive list of references.

May 2023

Quote

"The joy of the Lord is my strength."

Nehemiah 8 verse 10

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- Our **magnificent God,** with You nothing is impossible.

Abstract

The purpose of this in vitro study was to evaluate and compare obturation quality and preparation times after root canal shaping between manual, rotary and reciprocating files during pulpectomy treatment in primary molars.

Sixty extracted, human, primary mandibular second molars were randomly divided into three experimental instrumentation groups, Group 1: Manual stainless steel (ss) K-files (ISO size 20-35), Group 2: Rotary ProTaper Gold SX file and Group 3: Reciprocating WaveOne Gold Medium file. The mesiobuccal root canals of all the teeth were prepared and obturated with an iodine paste, Vitapex. The obturation quality was assessed using post-operative radiographs and a scoring criteria classified as “Good”, “Average”, “Poor” or “Failed”. Preparation times were recorded in seconds with a digital stopwatch and compared between different preparation groups.

The quality of obturation results showed superior obturation quality in the ProTaper Gold SX and WaveOne Gold Medium groups. Although the ProTaper Gold SX group performed the best, no statistically significant difference was observed between the ProTaper Gold SX and WaveOne Gold Medium groups. The ss K-file group resulted in the most “Poor” and “Average” outcomes.

The results of the preparation times showed the mean preparation time values within the ss K-file group to be significantly higher (186.4 s) than preparation time values within both the ProTaper Gold SX (29.6 s) and WaveOne Gold Medium groups (30.5 s). The preparation times of samples in the ProTaper Gold SX group and the WaveOne Gold Medium group did not differ significantly.

Within the limitations of this study, it can be concluded that the preparation times with the ProTaper Gold SX and WaveOne Gold Medium groups were statistically significantly faster than the manual ss K-file group. Rotary and reciprocating file instruments are also effective alternatives to conventional manual preparation with ss K-files. Rotary and reciprocating file instruments resulted in better obturation quality during pulpectomy treatment in primary molars compared to manual instrumentation. Thus, it can be concluded that the rotary and

reciprocating file systems results in the fastest preparation time as well as superior obturation quality.

Keywords: Pulpectomy, Obturation Quality, Preparation Time, ProTaper Gold SX, WaveOne Gold Medium.

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Chapter 1: Introduction

Background and rationale of the study:

Paediatric dentistry and root canal treatment specifically, is an integral, yet challenging aspect of dental practice. Pulpectomy treatment is aimed at preserving primary teeth, therefore avoiding extraction and subsequent space loss of teeth with irreversible pulpitis or necrotic pulps due to trauma or carious lesions.[1, 2]

Successful pulpectomy treatment in primary teeth relies largely on the mechanical cleaning ability of the root canal instrument, which aids in the removal of infected dentine and debris. Proper shaping of the canal will facilitate disinfection of the canal through irrigation with a disinfecting agent in order to ultimately obturate the root canal.[3]

The ideal pulpectomy preparation method remains controversial. Most dental practitioners use manual preparation with stainless steel (ss) K-files although rotary systems have been proven successful in treating primary root canals.[4, 5] The disadvantage of using manual ss K-files is that it is a time consuming procedure with an increased risk of procedural errors.[6] As a result of these challenges, dentists often avoid performing pulpectomy procedures on primary teeth and may rather opt for extraction in these cases. Although extraction is an acceptable alternative, pulpectomy treatment is still considered the ideal as premature extraction of primary teeth might lead to space loss and the need for future orthodontic treatment.[2]

The ultimate goal for an endodontic obturation is to create a bacteria-tight seal from the coronal opening of the canal to the apical termination. The quality of obturation is thus paramount to the long term success of the procedure.[7]

Pulpectomy treatment in children can be a challenging and stressful procedure for the child, parent and the dental operator. A decrease in chair time can eliminate or reduce the need for lengthy or multiple appointments, especially in uncooperative children.[8] Due to the complex internal anatomy of root canal systems of primary molars, canal preparation is the most time consuming aspect of a pulpectomy procedure.[9] Therefore a novel technique that produces well obturated canals in the shortest possible chair time, needs to be investigated.

Aim

The aim of this in vitro study was to compare obturation quality and preparation times of different pulpectomy preparation techniques in primary molars and to determine which preparation technique enables the best obturation quality in the shortest preparation time.

Objectives

1) To evaluate and compare the obturation quality of the canals after root canal preparation using the three different preparation techniques.

2) To give recommendations on which technique resulted in the best obturation quality.

3) To evaluate and compare the root canal preparation times of the three different preparation techniques.

4) To give recommendations on which technique resulted in the shortest preparation time.

Null hypothesis

1) There will be no difference in the obturation quality between the three different preparation techniques used.

2) Root canal preparation times will be similar using the three different preparation techniques.

Potential value of the study

To recommend which file preparation system produces the best obturation quality in the shortest time during pulpectomy treatment in primary molars.

Study design

This study is a comparative, cross-sectional study.

General methodology

Sixty extracted, human, primary mandibular second molars were selected of which the mesiobuccal canal of each tooth was prepared with three different preparation techniques. The mesiobuccal canals were used in this study for purpose of standardisation. The messiobuccal canals were selected as they are the most severely curved canals in mandibular primary molars and most challenging in terms of canal negotiation. The root canals were randomly divided into three experimental instrumentation groups using Research Randomizer software (n=20).

Canal shaping was done with manual ss K-files ISO size 20-35 (Dentsply Sirona, Ballaigues, Switzerland), the rotary NiTi ProTaper Gold SX file (Dentsply Sirona) and the reciprocating NiTi WaveOne Gold Medium file (Dentsply Sirona).

Group 1: Root canals prepared with manual ss K-files (n=20);

Group 2: Root canals prepared by the ProTaper Gold SX rotary file (n=20);

Group 3: Root canals prepared by the WaveOne Gold Medium reciprocating file (n=20).

In order to evaluate the shaping ability of the different preparation groups with a high degree of reliability, Vitapex (Neo Dental Chemical Products Co., Ltd, Tokyo, Japan) was chosen as the obturation material of choice.[10] After preparation, all the canals were obturated with Vitapex using the same technique in order to evaluate the obturation quality between the different groups. Obturation quality was evaluated by means of digital radiographs in order to give a recommendation on the ideal file preparation instrument with the best obturation outcome. A new method using an adjusted/ combined scoring criteria for each canal was used to evaluate and assess the presence of voids and the extent of fill according to the specific criteria.[11-13]

Presence of voids:

Score 1: Entire canal perfectly filled, well adapted to the root canal with no voids.

Score 2: Imperfectly-condensed root canal filling with irregularities of less than 0.25 mm.

Score 3: Imperfectly-condensed root canal filling with irregularities of 0.25 mm – 1 mm.

Score 4: Poorly-condensed root canal filling with irregularities of more than 1 mm.

Extent of fill:

Grade A: Less than half of the root canal length was filled.

Grade B: More than half the root canal length was filled but not optimal.

Grade C: Optimal filling (canal filled within 0 – 1 mm from the apex).

Grade D: Overfilling of the root canal to an acceptable standard (Less than 1 mm through the apex).

Grade D+: Extreme overfill, not acceptable (More than 1 mm through the apex).

The presence of voids (Score 1 – 4) and the extent of fill (Grade A – D+) were combined in order to grade the samples. Each case was graded as "Good", "Average", "Poor" or "Failed" in a combined scoring system as set out in the table below:

Table 1: Combined Scoring Criteria

Obturation quality:	**Presence of voids and extent of fill combined criteria:**
Good	1 C, 2 C, 1 D, 2 D
Average	3 C, 4 C, 3 D
Poor	1 B, 2 B, 3 B, 4 D
Failed	1 A to 4 A, 1 D+ to 4 D+, 4 B

The rationale behind the combined scoring criteria was to evaluate the obturation quality in combination with the lack or presence and size of voids and the extent of fill as both contribute to treatment outcomes.

Canal preparation times were measured with a digital stopwatch and recorded in seconds.

Layout of dissertation:

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Literature review.

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Manuscript 1: "**Evaluation of Obturation Quality after Pulpectomy Treatment in Primary Molars using Different Preparation Techniques."** (Submitted to Journal of Indian Society of Pedodontics and Preventative Dentistry April 2023)

Manuscript 2: "**A Comparison of Preparation Times between Manual, Rotary and Reciprocating Files during Pulpectomy Treatment of Primary Molars."** (Submitted to Journal of Indian Society of Pedodontics and Preventative Dentistry April 2023)

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Chapter 2: Literature Review

The preferred treatment option to preserve primary teeth with pulpal necrosis or irreversible pulpitis is a pulpectomy procedure.[1] The internal anatomy and morphology of the root canal system of primary molars are complex, which makes root canal treatment of primary teeth challenging.[2] Due to the difficulty of the procedure, dental practitioners often opt for extraction rather than performing a pulpectomy. The retention of primary teeth is however of paramount importance as primary teeth aid in mastication and function, prevent speech problems and aberrant tongue movement, improve aesthetics and prevent psychological effects due to premature tooth loss.[3] It also guides the eruption of permanent teeth and act as natural space maintainers in the arch.[4]

The most important objective in pulpectomy treatment is to eliminate all the microorganisms in the root canal system which is achieved through the complete removal of residual necrotic material, vital tissues, debris and infected dentine.[5] Another important goal is to create the ideal shape for irrigation, creating space for instruments and obturation materials while still preserving the dentine and retaining the integrity of the root.[6] The success of a pulpectomy therefore depends on proper cleaning and shaping of the root canal which will lead to optimal obturation of the canals. Manual stainless steel (ss) K-files, and to a lesser degree, rotary nickel-titanium (NiTi) files are currently used to perform pulpectomy treatments in primary teeth.

The use of manual ss K-files (Figure 1) has been the “gold standard” in the preparation of root canals during a pulpectomy treatment. Manual ss K-files are however more rigid and the stiffness of these files might cause many aberrations, irregularities and ledges in the root canal after filing, compromising optimal obturation.[7] Preparation with manual ss K-files are

also more time consuming and iatrogenic, procedural accidents occur more often, compared to rotary counterparts.[8]

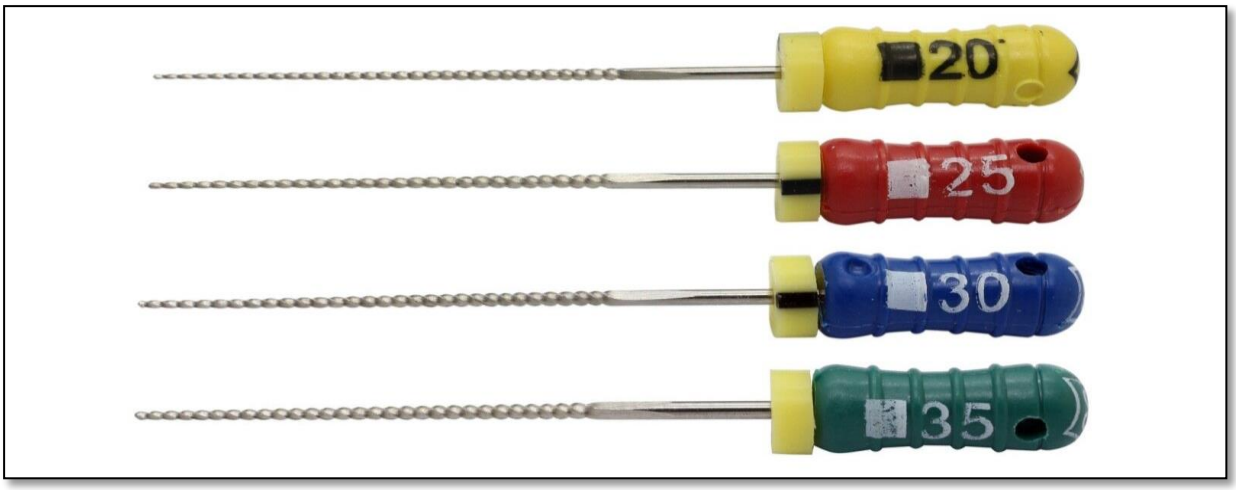

Figure 1: Stainless steel K-files (ISO size 20-35) (Dentsply Sirona)

Since the 1960s, root canal instruments made from stainless steel (ss) alloy were used to perform endodontic treatment. Stainless steel instruments had a high incidence of distortion and fractures due to limited flexibility. These problems created the need for a more flexible instrument leading to the introduction of NiTi instruments in endodontics. The advantages of NiTi instruments include an increase in flexibility, super elasticity, a significant reduction in preparation times and better anatomically shaped root canal treatments.[9]

Attention has been drawn to investigate other options such as the use of NiTi rotary or reciprocating instruments in the treatment of primary molars. There are no known studies evaluating obturation quality and canal preparation times using the ProTaper Gold SX instrument (Dentsply Sirona, Ballaigues, Switzerland) or the WaveOne Gold Medium instrument (Dentsply Sirona), as single-files for pulpectomies, up to date.

Rotary biomechanical preparation of primary teeth during a pulpectomy was first described by Barr *et al.*[10] in 2000 using the ProFile system (Dentsply Sirona) with a taper of 4%. NiTi

instruments are specifically designed so that the flexibility allows to closely follow the original canal shape.[11] Barr *et a*l.[10] concluded that the use of NiTi rotary files in primary teeth resulted in a uniform and predictable obturation which is cost effective. Several other studies have also concluded that rotary files create a smooth, predetermined funnel-like shape without the risk of ledge formation and canal transportation.[11-13] Subsequent to that, several studies have been done using rotary files to prepare canals in primary teeth.[9, 14, 15]

According to Kuo *et al.*[14] the ideal technique for successful pulpectomy treatment is to have appointments with limited chair-time. Successful cleaning of the root canal system without damage to the underlying tooth germ or root structure, whilst maintaining function until it is naturally shed should be acheived.[14]

In 2006, Kuo *et al.*[14] used the SX file from the ProTaper Universal system (Dentsply Sirona) to prepare the coronal portion of the canal, followed by the ProTaper Universal S2 (Dentsply Sirona) file for final canal preparation. This study concluded that the taper of the ProTaper Universal S2 file was not sufficient for a primary tooth due to the root already undergoing physiological resorption. Kuo *et al,*[14] reported that NiTi rotary files must be designed specifically for primary teeth to prevent lateral perforations, as primary teeth have narrower, curved, ribbon-shaped canals increasing the risk of lateral perforation. The need for an alternative rotary file with a more appropriate length, taper and tip size was identified.[14]

The ProTaper Universal SX file (Figure 2) is 19 mm long and has a tip size of 0.19 mm with a variable taper ranging from 3.5%-19%. Furthermore, the quality of obturation results showed superior obturation quality in the ProTaper Gold SX and WaveOne Gold Medium groups. Although the ProTaper Gold SX group performed the best, no statistically significant difference was observed between the ProTaper Gold SX and WaveOne Gold Medium groups.

The ss K-file group resulted in the most "Poor" and "Average" outcomes.[16] The file has the largest taper of all the files in the ProTaper Universal system with cross-sectional diameters of 0.50, 0.70, 0.90 and 1.10 mm at D6, D7, D8 and D9 respectively. At D14 the diameter ends at 1.20 mm.[16] A case report (2011), using only the ProTaper Universal SX file, proved to be a successful option for a single-file pulpectomy preparation. In this report the ProTaper Universal SX file produced adequate chemo-mechanical preparation of the canals and satisfactory obturation after shaping and disinfection. The duration of the appointment was also shortened when using the single-file system, which is ideal, especially in children.[15]

ProTaper Gold instruments (Dentsply Sirona) were introduced with exactly the same geometry as ProTaper Universal instruments, but offer an increased flexibility due to the proprietary advanced metallurgy. The ProTaper Gold instrument also has a shorter handle (11 mm compared to the traditional 13 mm) which gives it improved accessibility to primary teeth in younger patients with limited mouth opening and smaller mouths.[17]

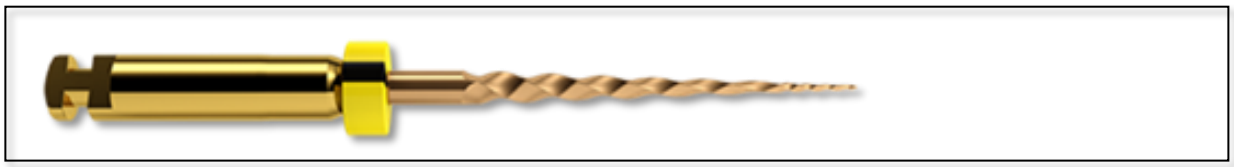

Figure 2: ProTaper Gold SX file (Dentsply Sirona)

A study done by Katge *et al.*[18] in 2014 is the only study, to the researchers' knowledge, that was done where a reciprocating file system was compared to manual ss K-files and a rotary file system. For the rotary system, The ProTaper Universal SX was inserted into the canal to about 3 mm beyond the root canal orifice and the ProTaper Universal S2 file was inserted and used to prepare the root canal up to the full working length. For the reciprocating file system, the conventional M-wire WaveOne Small instrument (21/06) was used with the crown-down

technique. The study only evaluated the preparation times and cleaning efficacy, but not the obturation quality after preparation.[18]

The WaveOne Gold file system was introduced in 2011 and is designed with a parallelogram-shaped cross-sectional diameter which limits the engagement of the files and dentine to only one or two points of contact at any given stage of canal preparation. This improves the safety of the files with less taper-lock and screw-in effect. The file's cross-sectional design also allows for more debris extrusion during canal preparation. The file is designed with a progressively decreasing percentage taper from D14 - D16 to preserve pericervical dentine.[17] WaveOne Gold files engage at a counter-clockwise angle of 150° and a clockwise disengaging angle of 30°. After three cutting cycles a file rotates one complete circle. This unique movement, according to Ruddle,[17] is a major advantage due to the safety of the files when compared to continuous rotating files. The files advance more readily to the desired working length without excessive inward pressure and debris extrusion from the canal is also enhanced.

There are four WaveOne Gold files (Dentsply Sirona) in the system: Small (20/07) (Figure 3), Primary (25/07) (Figure 4), Medium (35/06) (Figure 5) and Large (45/05) (Figure 6).

According to the manufacturer, the Primary (25/07) file is suitable for shaping most root canals in permanent teeth, but will not be suitable for primary teeth due to the narrow canals of primary teeth. It was decided to use the Medium (35/06) file due to its tip size corresponding to that of the prescribed manual technique of using a ss K-file up to size 35.[19]

- Small (yellow) – ISO 20 tip size with 7% taper (D1–D3) – used as bridging file when the Primary file does not seem to progress passively.

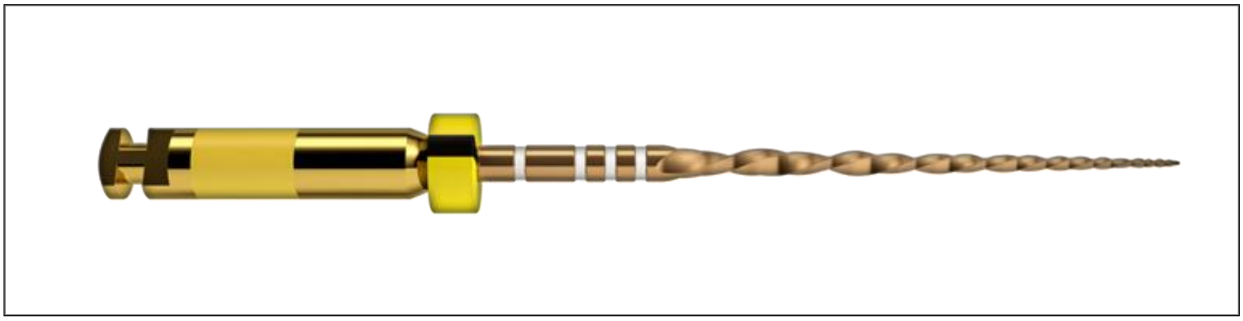

Figure 3: WaveOne Gold Small file (20/07) (Dentsply Sirona)

- Primary (red) – ISO 25 tip size with 7% taper (D1–D3) – used in 80% of cases from orifice to apex in permanent teeth.

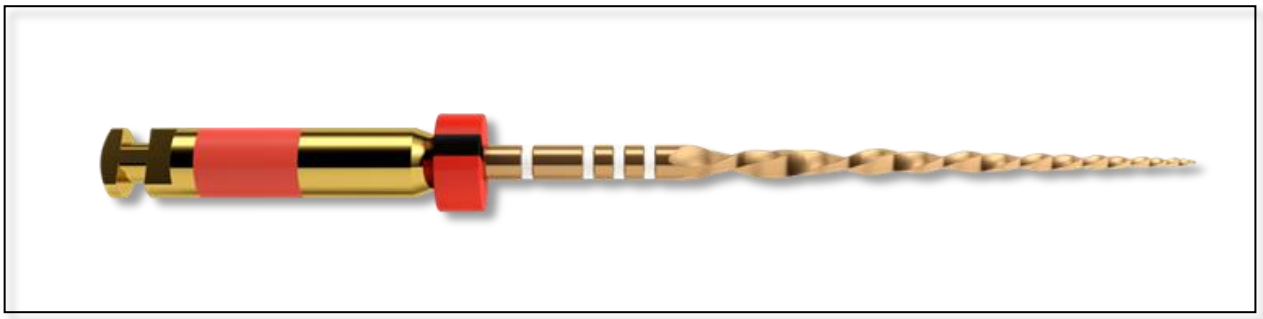

Figure 4: WaveOne Gold Primary file (25/07) (Dentsply Sirona)

- Medium (green) ISO 35 tip size with 6% taper (D1–D3) – used when the Primary file does not cut sufficient dentine or the apex is larger than ISO size 25.

- The Medium (35/06) file was used in this study, due to its tip size corresponding to that of the prescribed manual technique of using a ss K-file up to size 35.[19]

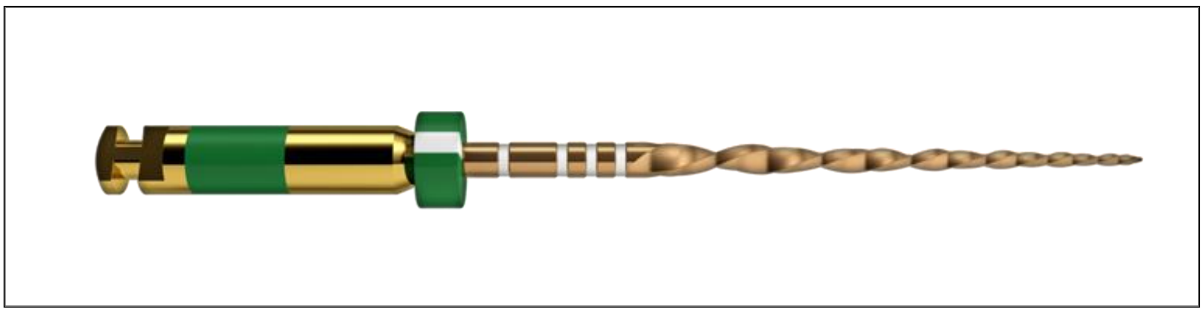

Figure 5: WaveOne Gold Medium file (35/06) (Dentsply Sirona)

- Large (white) ISO 45 tip size with 5% Taper (D1–D3) – used when the apex is larger than ISO 35 and not enough cutting was done with the Medium file.[20]

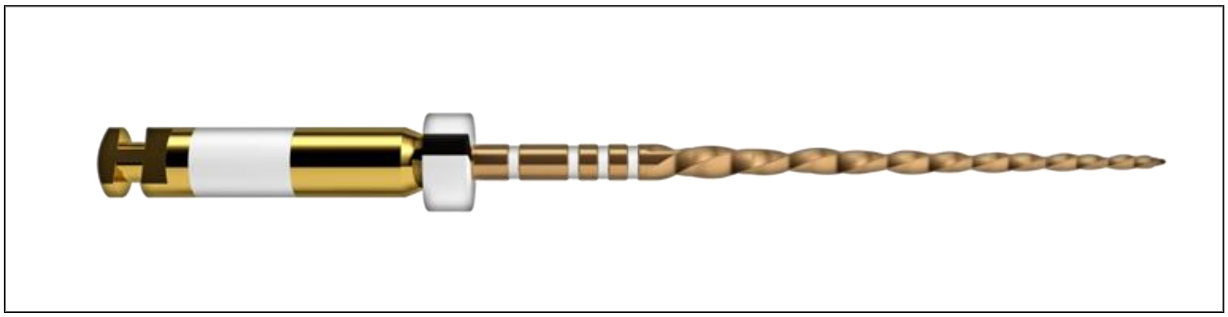

Figure 6: WaveOne Gold Large file (45/05) (Dentsply Sirona)

Distinctively, the WaveOne Gold files exhibit less memory effect than M-Wire or conventional NiTi instruments and display super elasticity.[21] This gives them the benefit of being pre-curved before canal preparation (and retaining their shape) and respecting canal anatomy better. According to the manufacturer, the WaveOne Gold Primary file is 80% more flexible and 50% more resistant to cyclic fatigue compared to its WaveOne predecessor. The gold wire, of the WaveOne Gold instruments, is a super-metal manufactured at the phase-transition point between martensite and austenite finished by thermal processing and post-machining procedures.[21]

A study done by Mittal *et al.*[22] in 2015 concluded that the taper and metallurgy affects the shaping and cleaning which might improve obturation quality.

Many studies have been done in primary teeth comparing manual and rotary preparation techniques to determine which technique results in the best obturation quality[2, 3, 7, 23], but there has been no study conducted to compare obturation quality when comparing manual ss K-files with rotary and reciprocating files in primary molars. Hence, these three groups were investigated in this study.

The quality of obturation is paramount to the long-term success of the procedure. The root canal should be optimally filled without under filling or overfilling the canal.[24] The ultimate goal for an endodontic obturation is to create a bacteria-tight seal from the coronal opening of the canal to the apical termination.[24] Endodontic failures usually occur due to a few factors including; persistence of bacteria in the canals, inadequate filling due to poorly shaped or cleaned canals, overfilling of materials through the apex, poor coronal seal, unprepared canals and procedural errors.[25]

If the obturation is inadequately filled with a presence of voids or under filled, it has been reported that there is an increased incidence of reoccurring abscess formation and periapical disease post-treatment.[26]

Overfilling of the primary tooth canals is a common finding, especially when root resorption has already started to take place. Overfilling of root canals can lead to the irritation of the surrounding periapical tissues and cause deflection of the permanent successor. If deflection of the permanent successor occurs, it will defeat the purpose of doing a pulpectomy as the main goal of performing a pulpectomy is to maintain function and space, by not extracting the primary tooth, and allowing normal growth and physiological root resorption.[27]

Zinc oxide eugenol is widely used for obturation in primary teeth[24,28] but various disadvantages such as slow resorption, irritation to surrounding periapical tissues and

deflection of permanent erupting teeth because of the material's hardness (especially when overfilled) have been noted.[29] Zinc oxide eugenol also has limited antibacterial properties and because of all these shortcomings it is not the ideal obturation material.[28]

Properties of an ideal obturation material for primary teeth include; the material should be resorbable at the same rate as the root of the primary tooth, anti-bacterial, be harmless to the permanent tooth germ or surrounding tissues and also resorb if extruded through the apex.[27] In order to evaluate the shaping ability of the different preparation groups with a high degree of reliability, Vitapex (Neo Dental Chemical Products Co., Ltd, Tokyo, Japan) was chosen as the obturation material of choice, which is a premixed calcium hydroxide and iodoform paste.[27]

Figure 7: Vitapex paste (Neo Dental Chemical Products Co., Ltd, Tokyo, Japan)

Hence, this study was performed with the aim to compare obturation quality, with Vitapex as obturation material, between different canal shaping groups. Canal shaping was done with manual ss K-files (ISO size 20-35), the rotary ProTaper Gold SX file and the reciprocating WaveOne Gold Medium file.

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Chapter 3: Manuscript 1

Obturation Quality after Pulpectomy Treatment in Primary Molars using Different Preparation Techniques

Abstract

Background: Obturation quality is important in pulpectomy treatment, as it contributes significantly to the success of the root canal treatment.

Aim: To evaluate the quality of obturation after root canal shaping with manual, rotary, and reciprocating files during pulpectomy treatment in primary molars.

Settings and Design: This study was a randomized, cross-sectional study.

Methods: Sixty extracted, human, primary mandibular second molars were randomly divided into three experimental groups. Group 1: Manual stainless steel (ss) K-files (ISO size 20-35) (n = 20), Group 2: Rotary ProTaper Gold SX file (n = 20), and Group 3: Reciprocating WaveOne Gold Medium file (n = 20). The mesiobuccal root canals of all the teeth were prepared and obturated with Vitapex. Obturation quality was assessed using post-operative radiographs and scored as “good”, “average”, “poor” or “failed”.

Statistical analysis: The data were descriptively analyzed. The obturation outcomes (“good”, “average”, “poor” or “failed”) were compared between the three instrumentation groups using the Fisher Exact test. Statistical significance was set at $p < 0.05$.

Results: Superior obturation quality results were observed in teeth that were prepared using the ProTaper Gold SX and WaveOne Gold Medium files, with most teeth being scored as “good”. Although the ProTaper Gold SX group had the best obturation quality, no significant difference was observed between the ProTaper Gold SX and WaveOne Gold Medium groups. Teeth prepared using the ss K-files had the most “poor” and “average” obturation quality scores ($p < 0.05$).

Conclusion: Rotary and reciprocating file systems are efficient alternatives to conventional manual preparation, with superior obturation outcomes after pulpectomy treatment in primary molars.

Key message: Obturation quality is important in pulpectomy treatment, as it is one of the major factors that determines the success of the root canal treatment. Rotary and reciprocating file systems are efficient alternatives to conventional manual filing in terms of obturation quality after pulpectomy in primary molars.

Keywords: Obturation quality, Protaper Gold SX, WaveOne Gold Medium

Introduction

Pulpectomy is the preferred treatment option to preserve primary teeth with pulpal necrosis or irreversible pulpitis [1]. Primary teeth guide the eruption of permanent teeth and act as natural space maintainers in the dental arch [2]. Primary teeth also aid in chewing, prevent speech problems and aberrant tongue movement, improve aesthetics, and prevent psychological effects due to premature tooth loss. The retention of primary teeth is therefore of paramount importance [3]. Pulpectomy treatment in primary molars is challenging due to complex internal anatomy and morphology, and due to the process of physiological root resorption [4]. The outcome and overall success of pulpectomies are often considered unpredictable and depend on various treatment- and patient-related factors [5]. Dental practitioners might therefore refrain from performing these treatments despite the importance of preserving primary teeth.

The objective of pulpectomy treatment is to completely remove residual necrotic material, vital tissues, debris, and infected dentine from the root canal system and replace this with inert obturation material [6]. During pulpectomy, dental practitioners have to create space for instrumentation, attain an ideal shape for irrigation, and obturation while still retaining the integrity of the root and preserving dentine [7]. For pediatric patients, root canal preparation is usually performed using manual stainless steel (ss) K-files, and to a lesser degree, rotary nickel-titanium (NiTi) files.

The use of manual ss K-files has been the “gold standard” for preparing root canals during pulpectomy treatment in children [8, 9]. However, preparation with hand instruments is more time consuming and iatrogenic, procedural accidents such as canal transportation, ledging, zipping, and apical blockage often occur due to the inflexibility of ss K-files [10]. To overcome these challenges, much attention has been given to other options such as NiTi rotary and reciprocating instruments for treating primary teeth. The advantages of NiTi instruments include increased flexibility, super elasticity, a significant reduction in preparation times, and better anatomically shaped root canals [11].

In pulpectomy treatment, high quality obturation often determines the long term success of the procedure. As the aim of pulpectomy is to fill the root canal with inert obturation material, high quality obturation implies optimal filling without under filling or overfilling [12]. The ideal obturation material for primary teeth should have the same resorption rate as that of the original root, be anti-bacterial, be harmless to the permanent tooth germ and surrounding tissues, and also resorb if extruded through the apex [13]. In this study, the authors wanted to evaluate the shaping ability of different instrumentation types with a high degree of reliability. Vitapex (Neo Dental Chemical Products Co., Ltd, Tokyo, Japan), a premixed calcium hydroxide and iodoform paste, was chosen as the obturation material as it meets the criteria for an ideal obtuartion material [13].

In pediatric patients, pulpectomy treatment is often avoided due to the complexity of the procedure and the need for longer chair times when using manual instruments. In a previous study, the authors compared the preparation times when using ss K-files (ISO size 20-35), the rotary ProTaper Gold SX file (Dentsply Sirona, Ballaigues, Switzerland), and the reciprocating WaveOne Gold Medium file (Dentsply Sirona) and found that manual preparation was much slower than when using rotary or reciprocating files.

In this study, the authors compared the obturation quality, with Vitapex as obturation material, between different canal shaping instruments. Canal shaping was done with manual ss K-files (ISO size 20-35), the rotary ProTaper Gold SX file, and reciprocating WaveOne Gold Medium file.

Methods

In this randomized comparative cross-sectional study, 60, extracted, human, primary mandibular second molars were selected, of which the mesiobuccal canals were prepared. The inclusion criteria were root canals clearly visible on pre-preparation radiographs, roots that were intact and measured 8 mm or more from the cemento-enamel junction, and an apical

foramen size of no bigger than 0.3 mm [10]. We excluded teeth with sclerosed mesiobuccal canals or canals that had been previously accessed endodontically [10].

Sixty root canals were randomly divided into three instrumentation groups (K-file, ProTaper Gold SX, and the WaveOne Gold Medium groups) using Research Randomizer software (n = 20).

The teeth were coded and placed in a simulated jaw to replicate the clinical setting. Before cavity access and canal preparations, periapical pre-operative radiographs were taken. Coronal access was prepared using a high-speed hand piece and a diamond fissure bur. An Endo-Z bur (Dentsply Sirona) was used to ensure straight-line access to all root canals. A size 10 ss K-file was used to locate mesiobuccal canals and to negotiate to patency. One mm was subtracted from the length of the canal measured to the major apical terminus under 10 times magnification using a dental operating microscope (Zumax Medical Co, Ltd, Suzhou, China) to determine working length [14]. The size 10 ss K-file was moved in and out of the root canal with amplitudes of 1–2 mm up to working length for all 60 root canals to create an initial, manually reproducible micro glide path. A size 15 ss K-file was used in a similar manner once the size 10 ss K-file moved more freely up to working length. A final reproducible glide path was confirmed when the size 15 ss K-file could reach full working length, pulled back 4 mm and pushed back with light finger pressure without any interference or blockages [14]. After the glide path was confirmed, preparation of root canals was performed using one of three different instrumentation types.

K-file group: Root canal preparation was done by the conventional step-back method using pre-curved ss K-files from size 20 to 35 up to working length with the quarter-turn-pull technique (n = 20).

ProTaper Gold SX group: Root canal preparation was done using the ProTaper Gold SX file with rotation up to working length according to manufacturer's instructions (n = 20).

WaveOne Gold Medium group: Root canals were enlarged using the WaveOne Gold Medium file with reciprocation up to working length according to the manufacturer's instructions (n = 20).

The 40 mesiobuccal canals that were prepared using the rotary and reciprocating files, were all prepared using a 16:1 speed reducing hand piece (X-Smart Endo motor, Dentsply Sirona). Throughout the instrumentation process, each canal was irrigated with 5 ml of 3% sodium hypochlorite solution, and RC Prep (Premier, Pennsylvania, USA) was used as a lubricant. The flutes of the files were cleaned of debris after each insertion. The rotary and reciprocating files were used only once to prepare the canal before being discarded.

After final irrigation, the canals were dried with matching paper points. After canal preparation, a bubble of red wax was placed around the apex of each root to create a halo space around the apex, preventing unnecessary extrusion of the obturation material through the apex. The roots were then mounted in plaster molds to obturate the prepared canals [15]. Obturation was done with Vitapex according to the manufacturer's instructions. A post-operative radiograph was taken to evaluate obturation quality. An adjusted scoring system was used to evaluate the obturation quality for each canal based on previous methods described in literature [16-18]. Two evaluators blinded to the groups assessed the presence of voids and extent of fill based on the following criteria to limit bias and ensure reliability of results.

Presence of voids:

Score 1: Entire canal perfectly filled, well adapted to the root canal with no voids

Score 2: Imperfectly-condensed root canal filling with irregularities of less than 0.25 mm

Score 3: Imperfectly-condensed root canal filling with irregularities of 0.25–1 mm

Score 4: Poorly-condensed root canal filling with irregularities of more than 1 mm

Extent of fill:

Grade A: Less than half of the root canal length was filled

Grade B: More than half the root canal length was filled but not optimal

Grade C: Optimal filling (canal filled to within 0–1 mm from the apex)

Grade D: Overfilling of the root canal to an acceptable standard (< 1 mm through the apex)

Grade D+: Extreme overfill, not acceptable (> 1 mm through the apex)

The presence of voids (Score 1–4) and the extent of fill (Grade A – D+) were combined to grade obturation quality (Table 1). Each tooth was graded as “good”, “average”, “poor” or “failed”.

Table 1: Scoring criteria for obturation quality in pulpectomy of primary molars

Obturation quality score	**Presence of voids (1–4) + extent of fill (A–D+)**
Good	1C, 2C, 1D, 2D
Average	3C, 4C, 3D
Poor	1B, 2B, 3B, 4D
Failed	1A to 4A, 1D+ to 4D+, 4B

Statistical analysis

The analysis was descriptive and inferential, and all analyses were performed using SAS (SAS Institute Inc, Cary, NC, USA), Release 9.4. The obturation outcomes (“good”, “average”, “poor” or “failed”) were compared between the three instrumentation groups using the Fisher Exact test.

Results

The obturation outcomes observed across the three instrumentation groups differed significantly ($p = 0.016$). This was followed up by pair wise comparisons for each obturation outcome.

The proportion of “good” obturation outcomes observed with the ProTaper Gold SX group (65%) was significantly higher than observed in the K-file group (25%, p = 0.025) but was similar to the proportion of “good” outcomes observed in the WaveOne Gold Medium group (55%, p = 0.748). The proportion of “average” obturation outcomes was similar across the three groups (Table 2). The proportion of “poor” obturation outcomes was significantly higher in the K-file group (40%) than that observed in the ProTaper Gold SX group (5%; p = 0.020). No other significant differences were observed (Table 2).

Table 2: Obturation quality observed following root canal preparation using three different instrumentation types

Obturation quality	**Frequency (%)**		
	K-file group	**ProTaper Gold SX group**	**WaveOne Gold Medium group**
Good	5 (25)	13 (65)	11 (55)
Average	4 (20)	2 (10)	-
Poor	8 (40)	1 (5)	3 (15)
Failed	3 (15)	4 (20)*	6 (30)
Total	**20 (100)**	**20 (100)**	**20 (100)**

***2 of these failed cases were lateral perforations caused by the preparation technique.**

Discussion

In this simulation study, the obturation quality obtained was assessed when using three different preparation instrumentation types to prepare root canals during pulpectomy treatment. The authors found that manual preparation resulted in more “poor” obturation outcomes than the outcomes observed using rotary files which is similar to several other studies [3, 9, 19, 20]. No significant differences in obturation quality was observed when preparing primary teeth using rotating or reciprocating files.

Obturation quality is a key factor that influences the long term success of a pulpectomy [21]. This quality depends on effective mechanical cleaning and shaping of the root canal. During canal preparation, it is essential to remove micro-organisms, debris and residual pulp while preserving the original shape of the canal [22-24]. The prognosis of a pulpectomy also depends on the length of the root canal filling [12, 24, 25] and the presence and size or absence of obturation material voids [17, 20]. The presence of voids can lead to leakage and the possibility of retained micro-organisms leading to reoccurring abscess formation and periapical disease after treatment [17, 26]. Under filling and extreme overfilling of root canals have also been proven to cause treatment failure [3, 22]. Whereas optimally filled or slightly overfilled root canals have been proven successful when obturating with a resorbable paste, such as Vitapex [13, 27].

Ultimately, endodontic obturation aims to create a bacteria-tight seal from the coronal opening of the canal to the apical termination [12]. Endodontic failures usually occur when bacteria persist in the root canal, filling is inadequate due to poorly shaped/cleaned root canals, materials overflow through the apex, poor coronal seal, unprepared canals, and procedural errors [23]. Overfilling of root canals is a common finding, especially when root resorption has already started to take place. Excessive overfilling of root canals can lead to the irritation of the surrounding periapical tissues and cause deflection of the permanent successor. Deflection of the permanent successor defeats the purpose of a pulpectomy, which is to maintain function and space, by not extracting the primary tooth, and allowing normal growth and physiological root resorption [13].

Different techniques have been proposed for mechanical preparation of root canals, although manual filing is still the “gold standard.” Manual filing using ss K-files has limitations, as these files are more rigid causing aberrations, irregularities, and ledges in the root canal making optimal obturation difficult [28]. Our findings are in agreement with many other studies [10, 11, 20, 28], as the authors also found that manual ss K-files resulted in inferior obturation quality than that observed in the other instrumentation groups, including rotary and reciprocating files.

Manual filing resulted in the highest number of “poor” and “average” obturation quality outcomes. To improve obturation quality, dental practitioners may prefer to prepare canals with rotary or reciprocating file systems.

NiTi rotary files create a predetermined conical shaped canal. These files are specifically designed to be super flexible to closely follow the original canal shape, resulting in uniform and predictable obturation [29]. Several studies have concluded that NiTi rotary files create a smooth, predetermined, funnel-like shape without the risk of ledge formation and canal transportation [5, 30, 31]. The use of NiTi rotary files, designed for permanent teeth, in primary teeth raises concerns because primary teeth have narrower, curved roots, and ribbon-shaped canals increasing the risk of lateral perforation [32]. Subsequently NiTi rotary files should be designed specifically for primary teeth to prevent lateral perforations [32]. In the present study, two lateral perforations were observed, both caused by the ProTaper Gold SX file. These lateral perforations might be explained by the larger taper of the ProTaper Gold SX file, ranging from 3.5%–19%. This file has the largest taper of all the files in the ProTaper Gold system with cross-sectional diameters of 0.50, 0.70, 0.90, and 1.10 mm at D6, D7, D8, and D9 respectively [33]. Many practitioners already have endodontic armamentarium including the ProTaper Gold system which they use for pulpectomies in primary teeth to prevent additional expenses. In our study, the ProTaper Gold SX resulted in the best obturation quality with the most “good” outcomes.

Obturation quality is affected by the taper and metallurgy of instruments which affects shaping and cleaning [34]. The three instruments tested in our study, included the ProTaper Gold SX, WaveOne Gold Medium, and manual ss K-files, which differed in both metallurgy and taper. Many studies have been done in primary teeth comparing manual and rotary preparation techniques to determine which technique results in the best obturation quality [3, 4, 20, 28], but there has been no study comparing obturation quality when using manual, rotary files, and reciprocating files in primary molars. Hence, these three groups were investigated in our study.

In 2014, Katge, et al. [35] also investigated canal preparation using three different file systems but they only evaluated preparation times and cleaning efficacy, but not obturation quality. This is the only study, to the researchers' knowledge, that was done where a reciprocating file system was compared to manual ss K-files and a rotary file system. One case report done in 2011 concluded that the ProTaper Universal SX file (Dentsply Sirona) produced adequate chemo-mechanical preparation of canals and satisfactory obturation after shaping and disinfection [36]. We also tested the WaveOne Gold file system, which has a parallelogram-shaped cross-sectional diameter which limits the engagement of the file and dentine to only one or two points of contact at any given stage of canal preparation. This improves the safety of the file with less taper-lock and screw-in effect. The file's cross-sectional design also allows for more debris extrusion during canal preparation. The file is designed with a progressively decreasing percentage taper from D14–D16 to preserve dentine [33]. The WaveOne Gold file engages at a counter-clockwise angle of 150° and a clockwise disengaging angle of 30°. After three cutting cycles the file rotates one complete circle. This unique movement, according to Ruddle [33] is a major advantage due to the safety of the file when compared to continuous rotating files. The file advances more readily to the desired working length without excessive inward pressure and debris extrusion from the canal. There are four WaveOne Gold files in different sizes and lengths: small (20/07), primary (25/07), Medium (35/06), and large (45/05). According to the manufacturer, the primary (25/07) file is suitable for shaping most root canals in permanent teeth but will not be suitable for primary teeth due to the increased taper of primary canals. In this study, the Medium (35/06) file was used due to its tip size corresponding to that of the prescribed manual ss K-file size of 35 [5].

Obturation quality was assessed by using post-operative radiographs, which are two-dimensional images of three-dimensional objects. This was done in a simulated setting, and the findings of this study may differ in a clinical setting. Obturation quality is likely to be affected by a wide range of factors that were beyond the scope of this study.

Rotary and reciprocating file systems perform better than manual instrumentation in terms of obturation quality, but our results suggest that there is a need to create a dedicated file for pulpectomy in primary teeth. The file should have a smaller taper to prevent lateral perforations. More research should also be done on other file systems already used by practitioners for permanent teeth, to recommend the “ideal” file for pulpectomy in primary teeth.

Conclusions

Based on the results of this study, the authors conclude the following:

1. Rotary and reciprocating file systems are efficient alternatives to conventional manual filing in terms of obturation quality after pulpectomy in primary molars.
2. The rotary ProTaper Gold SX file showed superior obturation quality followed by the reciprocating WaveOne Gold Medium file and then conventional ss K-files.
3. The K-file group resulted in the most “poor” and “average” outcomes.
4. There was no significant difference in “failed” outcomes between all three groups.
5. Although further clinical studies are recommended, we conclude that both ProTaper Gold SX and WaveOne Gold Medium files might be viable instrumentation options in the preparation of primary molars during pulpectomy treatment.

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Bridging Text

The first manuscript, "**Obturation Quality after Pulpectomy Treatment in Primary Molars using Different Preparation Techniques"** submitted to the Journal of Indian Society of Pedodontics and Preventative Dentistry in April 2023, provides the findings on obturation quality evaluated after preparation using different preparation techniques. A manual, rotary and reciprocating technique was used to prepare the root canals. Post-operative radiographs were taken after obturation with Vitapex and a recommendation was made as to which preparation techniques showed superior quality obturation. The authors are not aware of any current research evaluating obturation quality between these three preparation groups. During the next phase of the study, where preparation times between the three different preparation groups were compared, the final manuscript with the title "**A Comparison of Preparation Times between Manual, Rotary and Reciprocating Files during Pulpectomy Treatment of Primary Molars**" was also submitted to the Journal of Indian Society of Pedodontics and Preventative Dentistry in April 2023.

Chapter 3: Manuscript 2

A Comparison of Preparation Times between Manual, Rotary and Reciprocating Files during Pulpectomy Treatment of Primary Molars

Abstract

Background: Preparation times are important in pulpectomy treatment of primary teeth, as they affect the overall duration of treatment and subsequent patient comfort. Reducing preparation time without compromising quality of treatment can improve patient satisfaction and increase the efficiency of dental clinics.

Aim: To compare preparation times using manual, rotary, and reciprocating files during pulpectomy treatment of primary molars.

Settings and Design: This study was a randomized, cross-sectional study.

Methods: The study was performed on 60 extracted human primary mandibular second molars. Only mesiobuccal canals were prepared using one of three preparation techniques; each preparation technique group comprised 20 canals. Canal preparations were performed by a single, skilled operator using stainless steel (ss) K-files (ISO size 20-35), a ProTaper Gold SX file, and a WaveOne Gold Medium file following glide path preparation. Preparation times were recorded in seconds (s) with a digital stopwatch.

Statistical analysis: Preparation times were compared using analysis of variance (ANOVA) and the Kruskal-Wallis analysis of variance, where appropriate.

Results: The mean preparation time using the ss K-files was significantly longer (186.4 s) than when using the ProTaper Gold SX (29.6 s) or WaveOne Gold Medium files (30.5 s) ($P < 0.001$). Similar preparation times were recorded when using the ProTaper Gold SX and WaveOne Gold Medium files ($P = 0.939$).

Conclusion: Preparation times with the ProTaper Gold SX and WaveOne Gold Medium files were significantly faster than when using the ss K-files to prepare the canal for pulpectomy. Similar preparation times were noted when using the rotary and reciprocation instrumentation groups ($P > 0.05$).

Keywords: Pulpectomy, Preparation time, ProTaper Gold SX, WaveOne Gold Medium, Single-visit pulpectomy

Short/Running Title: Comparing Canal Preparation Times in Primary Molars.

Key message: Preparation times were significantly shorter using the rotary ProTaper Gold SX or reciprocating WaveOne Gold Medium single-files, compared to traditional manual instrumentation in pulpectomy of primary molars. This may lead to reduced chair time in children.

Introduction

Pulpectomy treatment in children can be challenging for dental operators and stressful for children and parents. Decreasing chair time can reduce dental anxiety and eliminate the need for multiple appointments, especially for uncooperative children. Chair time should also be as short as possible when performing treatment under general anesthesia and when multiple treatments are required [1]. Pulpectomy treatment in primary teeth is described as the removal of the coronal and radicular pulp in primary teeth with pulp necrosis or irreversible pulpitis due to caries or trauma [2]. Pulpectomy is indicated when teeth cannot be restored by a conventional restoration or pulpotomy treatment [3]. Although tooth extraction is an acceptable alternative, pulpectomy treatment is still considered the ideal, since teeth will be retained for space maintenance, aesthetics, and function [4].

Aside from the time element, pulpectomy treatment in children remains challenging due to the difficulty level. The internal anatomy of root canal systems of primary molars is complex, which adds to the difficulty of the treatment [5]. Conventionally, root canal systems are prepared using manual stainless steel (ss) K-files, which have been shown to take much longer than rotary instrumentation. In 2000, Barr, et al. [6] were the first to compare the preparation times between nickel-titanium (NiTi) rotary files and ss K-files for pulpectomy in primary teeth, and they concluded that NiTi rotary instrumentation was faster. Other studies have also concluded that rotary instrumentation is faster than manual ss K-files in primary teeth [1, 7-10]. In 2014, Katge, et al. [11] concluded that the reciprocating file system was even faster than the rotary file system. In their study, they compared instrumentation time and cleaning efficacy of primary teeth using the WaveOne Small file (Dentsply Sirona, Ballaigues, Switzerland), ProTaper Universal SX and S2 files (Dentsply Sirona), and ss K-files.

In the present study, preparation times were compared using three different preparation techniques. The ProTaper Gold SX file (Dentsply Sirona) was selected as a rotary single-file [12], the WaveOne Gold Medium file (Dentsply Sirona) as the reciprocating single-file. Stainless steel K-files (ISO size 20-35) were used in the manual preparation group in

accordance with the prescribed manual technique [7].The ProTaper Gold SX file is 19 mm long and has a tip size of 0.19 mm with a variable taper ranging from 3.5%–19% [13]. The ProTaper Universal SX (Dentsply Sirona) file has been described as a successful option for single-file pulpectomy preparation, resulting in shorter appointments [12].

The ProTaper Gold rotary file has the exact same geometries as the ProTaper Universal file, but the ProTaper Gold offers increased flexibility due to proprietary advanced metallurgy. The ProTaper Gold file has a shorter handle which improves accessibility to primary teeth in younger patients who have smaller mouths [14].

WaveOne Gold is a reciprocating NiTi file system, cutting in a counterclockwise motion. The files are designed with a progressively decreasing percentage taper to preserve pericervical dentin [15]. The WaveOne Gold series consists of four files in assorted lengths: Small (20/07), Primary (25/07), Medium (35/06), and Large (45/05). According to the manufacturer, the Primary (25/07) file is suitable for shaping most root canals in permanent teeth, but will not be suitable for primary teeth due to the increased taper of primary root canals [15]. It was decided to use the 21 mm Medium (35/06) file due to its tip size, which is the same as the prescribed manual technique of using a K-file up to ISO size 35 [7].

In the current study, the authors investigated which preparation technique would result in the fastest preparation time to limit clinical chair time in pediatric patients.

Methods

Sixty, extracted, human primary mandibular second molars were selected and the mesiobuccal root canal of each tooth was prepared using one of the three preparation techniques. Only teeth with intact roots, measuring 8 mm or more from the cemento-enamel junction, and an apical foramen size of no bigger than 0.3 mm, were used. Root canals had to be clearly visible on the prepreparation radiographs [4]. Primary mandibular second molars with sclerosed mesial canals or canals that were previously accessed endodontically, were

excluded from the study [4]. Teeth were coded and randomly divided into three treatment groups using Research Randomizer software (n = 20).

The teeth were placed in a simulated jaw to replicate the clinical setting. Periapical, preoperative radiographs were taken before preparing the root canal. Coronal access was prepared using a high-speed hand piece and a fissure diamond bur. An Endo-Z bur (Dentsply Sirona) was used to ensure straight-line access to all canals. The mesiobuccal canals were explored with a size 10 ss K-file and negotiated to patency. Working length was determined by subtracting 1 mm from the length of the canal measured to the major apical terminus under 10 times magnification using a dental operating microscope (Zumax Medical Co, Ltd, Suzhou, China) [16].

An initial, manually reproducible micro glide path was prepared by moving the size 10 ss K-file in and out of the root canal with amplitudes of 1–2 mm up to working length for all 60 canals. Once the ss K-file moved more freely up to working length, a size 15 ss K-file was used in a similar manner. A final reproducible glide path was confirmed when the size 15 ss K-file could be placed at working length, pulled 4 mm backwards and pushed back to full working length using light finger pressure without any interference or obstruction [16].

K-file group: Root canals (n = 20) were enlarged using 21 mm pre-curved size 20, 25, 30, and 35 ss K-files up to working length with the quarter-turn-pull technique.

ProTaper Gold SX group: Root canals (n = 20) were enlarged using the ProTaper Gold SX file in rotation up to working length according to the manufacturer's instructions.

WaveOne Gold Medium group: Root canals (n = 20) were enlarged using the 21 mm WaveOne Gold Medium file in reciprocation up to working length according to the manufacturer's instructions.

A 16:1 speed reducing hand piece (X-Smart Endo motor; Dentsply Sirona) was used for canal preparation for the rotary and reciprocating groups. The flutes of the files were cleaned of debris after each insertion. Throughout the instrumentation process RC Prep (Premier,

Pennsylvania, USA) was used as lubricant and 5 ml of 3% sodium hypochlorite as irrigation solution per canal prepared. Each rotary and reciprocating file was only used once to prepare one canal before being discarded. Canal preparation times were measured with a digital stopwatch and recorded in seconds. The preparation time included active instrumentation as well as the time required for changing instruments, cleaning the flutes of the instruments and irrigation of the canal. The preparation time did not include glide path preparation. The same operator prepared all the canals and a different operator recorded time in seconds with a digital stopwatch.

Mean and standard deviations (SDs) were determined for each group, and the analysis of variance (ANOVA) was used to compare the mean preparation times for the three groups, with pairwise comparisons to detect between group differences. Median values of the three groups were compared using the nonparametric Kruskal-Wallis analysis of variance.

Results

The mean and SD values for the preparation times of the three different groups are presented in Table 1.

Table 1. Preparation times during pulpectomy using three different preparation techniques.

	Preparation time (s)		
Statistical measure	**K-file group**	**ProTaper Gold SX group**	**WaveOne Gold Medium group**
n	20	20	20
Mean (SD)	186.4[a] (62.0)	29.6[b] (11.6)	30.5[b] (10.5)
Median (IQR)	188 (135–245)	28 (22–32)	31 (25–34)
Minimum / Maximum	81/308	16/54	9/54

Mean values with the same superscript letters were not statistically different at P > 0.05.

The mean preparation time using ss K-files (186.4 s) was significantly longer than when using the ProTaper Gold SX files (29.6 s; P < 0.001) and WaveOne Gold Medium files (30.5 s; *P* < 0.001). The mean preparation time using the ProTaper Gold SX files (29.6 s) and the WaveOne Gold Medium files (30.5 s) did not differ significantly (P = 0.939).

The median values of the three preparation groups were also compared using the nonparametric Kruskal-Wallis analysis of variance which was found to be significant ($P < 0.001$).

Discussion

This study compared preparation times using manual, rotary and reciprocating files during pulpectomy treatment. Reducing the duration of treatment in children is important as anxiety is lessoned [17, 18]. According to Kuo, et al. [8], a successful pulpectomy procedure for primary teeth is characterized by appointments with limited chair time and successful cleaning of the root canal system without damaging the underlying tooth germ or root structure, whilst maintaining function until the tooth is naturally shed. Our findings support previous studies that report reduced preparation times using rotary or reciprocating files, in particular ProTaper Gold SX and WaveOne Gold Medium files.

Pulpectomy treatment aims to effectively clean, disinfect, and fill the root canal system [18]. Shaping and cleaning of canals is a complex, time consuming component of the procedure. The “gold standard” of canal preparation has traditionally been manual preparation using ss K-files [8, 18] but this has proven to be more time consuming, subsequently increasing anxiety and behavior management problems in children [17].

Several studies have compared the preparation times using manual and rotary files in primary teeth with all studies concluding that manual files take longer than rotary files [6, 8, 12, 17, 18]. We observed that the preparation time when using manual ss K-files was significantly slower than when using the rotary ProTaper Gold SX or reciprocating WaveOne Gold Medium files. Katge, et al. [11] were the first to compare preparation times using manual, rotary, and reciprocating files in primary teeth. In their study, using reciprocating files took less time than both rotary and manual files [11], which is in contrast to our findings that similar preparation times were observed using the rotary ProTaper Gold SX and reciprocating WaveOne Gold Medium files. These contrasting results could be explained by the fact that we used a single

file protocol, while Katge, et al. [11] used a two file protocol (ProTaper Universal SX and S2). We used a single file protocol for both the ProTaper Gold SX and WaveOne Gold Medium files similar to that reported by Mhatre, et al. [12], suggesting that preparation time may be more influenced by the number of instruments used during a single procedure rather than the type of instrument. Our findings support the use of a single-file system (rotary or reciprocation) in primary teeth instead of multiple files or preparation using manual ss K-files.

Further studies should be done to investigate the effect of these systems on remaining dentin thickness, obturation quality and cleaning efficiency as the authors of this study only evaluated preparation times.

Conclusion

Based on the results of this study, the following conclusion can be made: Preparation times using both rotary and reciprocating single-files were significantly shorter than when using traditional manual instrumentation during pulpectomy treatment in primary molars. This may reduce chair time for pediatric patients.

Acknowledgements

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Chapter 4: Discussion and Recommendations

The aim of this study was to compare preparation times and obturation quality between three different pulpectomy preparation techniques in primary molars. According to Kuo *et al.*[1] pulpectomy treatment should be done in the shortest chair time while effectively shaping and cleaning the root canal system. Obturation quality is also a critical factor in the long term success of a pulpectomy treatment in primary molars.[2] Quality of obturation is a direct result of proper mechanical shaping of the root canal system. Maintaining the original canal anatomy is paramount during shaping and cleaning with the ultimate goal of complete disinfection.[3-5] Shaping of the root canal system of primary teeth is a difficult and time consuming component of pulpectomy treatment possibly increasing anxiety in young patients.[6] The "gold-standard" in practice still being preparation by means of ss K-files.[1, 7]

Obturation quality, and ultimately the long-term prognosis of pulpectomy treatments in primary teeth, depends on the length of the root canal filling[5, 8, 9] as well as the presence and size of voids in the obturation material.[10, 11] The latter potentially leading to leakage and microbial contamination and ultimately periapical disease post-treatment.[11, 12] Literature has reported that both underfilling and extreme overfilling of root canals can potentially cause treatment failure.[3, 6] The aim of obturation is to therefore have canals that are optimally or slightly overfilled when using a resorbable paste, such as Vitapex during obturation.[13, 14]

The first component of this MSc project evaluated preparation time. Preparation time using manual K-files resulted in significantly slower preparation time compared to both the rotary ProTaper Gold SX group and the reciprocating WaveOne Gold Medium group.

Several studies evaluating preparation times of manual and rotary files in primary teeth reported similar results.[1, 6, 7, 15, 16]

When evaluating preparation time, Katge *et al*.[17] found the reciprocating WaveOne Small file (21/06) of the conventional WaveOne system, to prepare root canals faster than both rotary (ProTaper Universal SX and S2 was used) and manual ss K-files during pulpectomy treatment in primary teeth. In the current study the author found no statistically significant difference between the preparation times of the rotary ProTaper Gold SX group and the reciprocating WaveOne Gold Medium group. The study by Katge *et al.*[17] used a two file protocol in rotation

motion while the current study used a single file protocol, possibly explaining the opposing findings. In this current study, the researcher therefore recommends the use of a single-file system (rotary or reciprocation) in primary teeth instead of a multiple file system or manual ss K-files in the preparation of root canals in primary teeth.

The second phase of this MSc project evaluated the effect of above-mentioned preparation techniques on obturation quality. Manual ss K-files are rigid, potentially causing aberrations, irregularities and ledges compromising obturation quality.[18] A study done by Mittal *et al.*[19] showed that the taper and metallurgy affects the shaping and cleaning of root canals, potentially also affecting the obturation quality. Many studies evaluating obturation quality in pulpectomy treatment on primary teeth, comparing manual and rotary NiTi preparation techniques have been done[6, 10, 18, 20], but none according to the researcher up to date compared obturation quality between manual, rotary and reciprocating files in primary molars as performed in this MSc study. Katge *et al.*[17] compared a reciprocating file system to manual ss K-files and a rotary file system when evaluating the preparation times and cleaning efficacy, however, obturation quality was not evaluated.[17]

In this present study the manual ss K-file group performed inferior when evaluating obturation quality compared to the rotary and reciprocation groups. The highest number of "Poor" and "Average" obturation quality outcomes were reported in the manual preparation group. The findings are in agreement with many other studies comparing manual ss K-files to rotary file systems when evaluating obturation quality in primary teeth.[10, 18, 21, 22]

Kuo *et al,*[1] recommends NiTi files specifically designed for shaping primary teeth in order to accommodate the specific anatomy of these root canals in order to accommodate physiological resorption. This results in a less procedural accidents and a more predictable, smooth and uniformed obturation.[15, 23-25]

A concern regarding the use of NiTi rotary files in primary teeth, is the risk of perforations due to its increased and perhaps unsuitable taper and diameter design.[1] This was also a concern raised in this current study where two lateral perforations occurred when using the ProTaper Gold SX file. This is most probably due to the large (3.5-19%) aggressive taper of the ProTaper Gold SX file.[26]

Significant differences in terms of obturation quality were reported when comparing manual files to both rotary and reciprocating files. These findings are congruent with results observed in similar studies performed in primary teeth.[6, 7, 10, 27] The researcher further reported no statistically significant differences in obturation quality between the rotary and reciprocating files. To the researcher's knowledge this is a novel finding contributing to the body of evidence in literature.

A few limitations were observed in this study. Assessment of the obturation quality of a three-dimensional object with a two-dimensional image, is the first limitation of this study. A second limitation is the in vitro design of this study and the researcher therefore recommends further clinical investigations to evaluate the effect of these systems clinically. Lastly, the researcher also acknowledges the fact that numerous other file systems should also be evaluated before making recommendations on the "ideal" file system for pulpectomy treatment in primary molars, as numerous preparation systems exist on the market and newer systems are continuously being launched. Some dedicated pulpectomy file systems has emerged on the market after the research of this project has commenced and should therefore also be evaluated and researched.

In summary, the results of this study indicate that rotary and reciprocating single file systems prepare root canals of primary teeth faster than manual ss K-files. Superior obturation quality is also observed from the groups prepared with rotary and reciprocating files, compared to manual ss K-file preparation. The researcher also acknowledges the fact that the effect of all the mentioned preparation groups and systems on remaining dentine thickness, transportation and centering ability should also be evaluated and taken into consideration before final recommendations can be made on the ideal instrumentation system for pulpectomy treatment in primary molars.

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Chapter 5: Conclusions

Within the limitations of this study, the following can be concluded:

- Rotary and reciprocating file systems are efficient alternatives to conventional manual filing for canal preparation when evaluating obturation quality after pulpectomy treatment in primary molars.
- The rotary ProTaper Gold SX file canal preparation showed superior obturation quality followed by the reciprocating WaveOne Gold Medium file and then conventional ss K-files.
- The K-file group resulted in the most “Poor” and “Average” outcomes.
- There was no statistically significant difference in “Failed” outcomes between all three groups.
- Preparation times using both rotary and reciprocating single-files were significantly reduced when compared to traditional manual ss K-file instrumentation during pulpectomy treatment in primary molars. This might be beneficial in the reduction of chair time when treating paediatric patients.
- Although further clinical studies are recommended, the authors conclude that both ProTaper Gold SX and WaveOne Gold Medium files might be viable instrumentation options in the preparation of primary molars during pulpectomy treatment.
- The null hypothesis is therefore rejected.

Chapter 6: Appendices

Appendix 1:

Informed consent

ORAL AND DENTAL HOSPITAL

Dear Patient,

The personnel and students of Oral and Dental Hospital of the University of Pretoria (which is a teaching hospital) appreciate your confidence in us for dental treatment. Although we strive to complete treatment as speedily as possible, our primary task is the training of students. For this reason, the treatment of patients will necessarily be more time-consuming compared to the private sector.

The student who is responsible for your treatment is dependent on your promptness, co-operation and availability. While we strive to train students to treat you in the best possible manner, we kindly request your indulgence with the progress of your treatment plan. We would appreciate you informing us of any unfavourable circumstances. In this way we shall be able to improve our service to you.

Refusal by a patient to be treated by a particular student/dentist to whom he/she is allocated, is not acceptable. In such circumstances, further routine treatment for a patient will be refused. We appreciate your co-operation in this regard. If you have any enquiries, please discuss it with a lecturer/dentist on duty.

The Oral and Dental Hospital is a service rendering unit which is part of the University of Pretoria. Research, apart from teaching, is aimed at the continuous improvement of dental treatment and dental materials. The teaching and research that is done, is partly dependent on obtaining suitable material from our patients. We kindly request that you study the consent form below and if you approve, to please complete it. Should you have any enquiries, please feel free to discuss it with a lecturer/ dentist on duty.

CONSENT

By this I,(full names and surname) _____ (patient/parent/guardian) grant permission to be treated by the Oral and Dental Hospital. I realise that the Oral and Dental Hospital of the University of Pretoria is a teaching hospital and, as such, part or all of my treatment may be given by a student. I realise that information and materials, e.g. extracted teeth, obtained from me during dental procedures may be used for dental training and/or research. I understand that, in the case of my information or materials being used in research, that research will be approved in advance by the Research Ethics Committee of the Faculty of Health Sciences of the University of Pretoria. In the event of such research being of a genetic nature (i.e. if my genetic material is studied in the research), the researchers will ask my permission to use my material before they do so. I understand that, if I refuse to give permission for my information or materials to be used in research, this will not in any way affect the treatment I receive at the Oral and Dental Hospital. I understand that, in addition to research, the Oral and Dental Hospital from time to time will audit its patient records as part of the clinical audit process. My permission is granted on the understanding that in all circumstances my identity will remain confidential (secret) and that all my personal details will be dealt with confidentially.

Name: _____

Signature: _____

File No: _____

University of Pretoria

PO Box 1266, PRETORIA 0001

Republic of South Africa

Appendix 2:

University of Pretoria Research Ethics Approval and extensions:

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 22 May 2002 and Expires 03/20/2022.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 03/14/2020.

3 June 2019

Approval Certificate
New Application

Ethics Reference No.: 272/2019
Title: Comparing Obturation Quality and Preparation Times of Different Pulpectomy Preparation Techniques in Primary Molars – an In Vitro Study

Dear Dr I Hanger

The **New Application** as supported by documents received between 2019-04-30 and 2019-05-29 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 2019-05-29.

Please note the following about your ethics approval:

- Ethics Approval is valid for 1 year and needs to be renewed annually by 2020-06-03.
- Please remember to use your protocol number (272/2019) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:

- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

Dr R Sommers
MBChB MMed (Int) MPharmMed PhD
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

Research Ethics Committee
Room 4-60, Level 4, Tswelopele Building
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UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
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Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 22 May 2002 and Expires 03/20/2022.
- IORG #: IORG0001762 OMB No. 0990-0279 Approved for use through February 28, 2022 and Expires: 03/04/2023.

20 July 2020

Approval Certificate
Annual Renewal

Ethics Reference No.: 272/2019
Title: Comparing Obturation Quality and Preparation Times of Different Pulpectomy Preparation Techniques in Primary Molars – an In Vitro Study

Dear Dr I Hanger

The **Annual Renewal** as supported by documents received between 2020-06-19 and 2020-07-15 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 2020-07-15.

Please note the following about your ethics approval:
- Renewal of ethics approval is valid for 1 year, subsequent annual renewal will become due on 2021-07-20.
- Please remember to use your protocol number (272/2019) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

Dr R Sommers
MBChB MMed (Int) MPharmMed PhD
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

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Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 22 May 2002 and Expires 03/20/2022.
- IORG #: IORG0001762 OMB No. 0990-0279 Approved for use through February 28, 2022 and Expires: 03/04/2023.

15 April 2021

Approval Certificate
Annual Renewal

Ethics Reference No.: 272/2019
Title: Comparing Obturation Quality and Preparation Times of Different Pulpectomy Preparation Techniques in Primary Molars – an In Vitro Study

Dear Dr I Hanger

The **Annual Renewal** as supported by documents received between 2021-03-17 and 2021-04-14 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2021-04-14 as resolved by its quorate meeting.

Please note the following about your ethics approval:

- Renewal of ethics approval is valid for 1 year, subsequent annual renewal will become due on 2022-04-15.
- Please remember to use your protocol number (272/2019) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

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We wish you the best with your research.

Yours sincerely

Professor Werdie (CW) Van Staden
MBChB MMed(Psych) MD FCPsych(SA) FTCL UPLM
***Chairperson**: Faculty of Health Sciences Research Ethics Committee*

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

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Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 22 May 2002 and Expires 03/20/2022.
- IORG #: IORG0001762 OMB No. 0990-0279 Approved for use through February 28, 2022 and Expires: 03/04/2023.

Faculty of Health Sciences **Research Ethics Committee**

17 March 2022

Approval Certificate
Annual Renewal

Dear Dr I Hanger,

Ethics Reference No.: 272/2019 – Line 3
Title: Comparing Obturation Quality and Preparation Times of Different Pulpectomy Preparation Techniques in Primary Molars – an In Vitro Study

The **Annual Renewal** as supported by documents received between 2022-03-10 and 2022-03-16 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2022-03-16 as resolved by its quorate meeting.

Please note the following about your ethics approval:
- Renewal of ethics approval is valid for 1 year, subsequent annual renewal will become due on 2023-03-17.
- Please remember to use your protocol number (272/2019) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

On behalf of the FHS REC, Dr R Sommers
MBChB, MMed (Int), MPharmMed, PhD
Deputy Chairperson *of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria*

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

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Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 18 March 2022 and Expires 18 March 2027.
- IORG #: IORG0001762 OMB No. 0990-0278 Approved for use through August 31, 2023.

Faculty of Health Sciences **Research Ethics Committee**

23 March 2023

Approval Certificate
Annual Renewal

Dear Dr I Hanger,

Ethics Reference No.: 272/2019 – Line 4
Title: Comparing Obturation Quality and Preparation Times of Different Pulpectomy Preparation Techniques in Primary Molars – an In Vitro Study

The **Annual Renewal** as supported by documents received between 2023-03-01 and 2023-03-15 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2023-03-15 as resolved by its quorate meeting.

Please note the following about your ethics approval:
- Renewal of ethics approval is valid for 1 year, subsequent annual renewal will become due on 2024-03-23.
- Please remember to use your protocol number (272/2019) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

_____
On behalf of the FHS REC, Professor C Kotzé
MBChB, DMH, MMed(Psych), FCPsych, Phd
***Acting Chairperson**: Faculty of Health Sciences Research Ethics Committee*

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

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Appendix 3: RESCOM Approval

Chairperson:
Prof LM Sykes
Members:
Prof SM Dawjee
Dr P Brandt
Prof A Bhayat
Dr S Naidoo
Dr T Madiba
Dr C Davidson
Secretary:
Ms C Swart

RESCOM

School of Dentistry
Faculty of Health Sciences

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Fax:012 323 0561
E-mail:
leanne.sykes@up.ac.za
christa.swart@up.ac.za

Prof JG White 2019-04-18
Acting CEO/Chair of the School of Dentistry.

Dear Professor

PROTOCOL APPROVAL: DENT 2019/9

Name: Dr I Hanger

Title: "Comparing obturation quality and preparation times of different pulpectomy preparation techniques in primary molars – an *in vitro* study".

The protocol attached hereto was evaluated by the Research Committee of the School of Dentistry. The Research Committee recommends the approval of the title and the protocol.

Yours sincerely

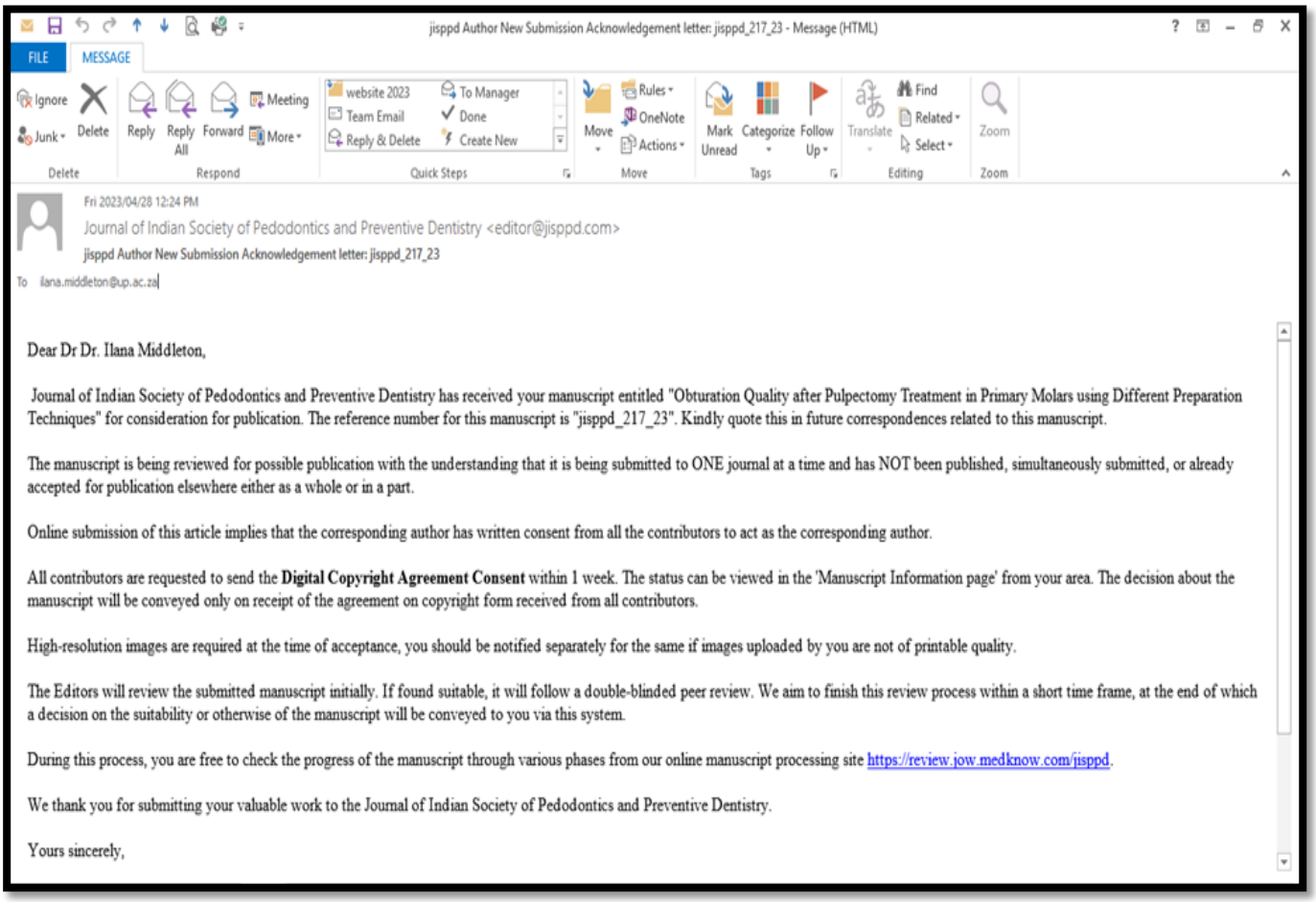
PROF L SYKES
CHAIRPERSON: RESEARCH COMMITTEE

Protocol approved/~~not approved~~

PROF JG White
Acting CEO/ CHAIR OF THE SCHOOL OF DENTISTRY

Appendix 4:

Proof of submission of Manuscript 1



jisppd Author New Submission Acknowledgement letter: jisppd_217_23 - Message (HTML)

FILE MESSAGE

Ignore Junk Delete Reply Reply All Forward Meeting More Delete Respond website 2023 Team Email Reply & Delete To Manager Done Create New Quick Steps Move Rules OneNote Actions Move Mark Unread Categorize Follow Up Tags Translate Find Related Select Editing Zoom Zoom

Fri 2023/04/28 12:24 PM

Journal of Indian Society of Pedodontics and Preventive Dentistry <editor@jisppd.com>

jisppd Author New Submission Acknowledgement letter: jisppd_217_23

To ilana.middleton@up.ac.za

Dear Dr Dr. Ilana Middleton,

Journal of Indian Society of Pedodontics and Preventive Dentistry has received your manuscript entitled "Obturation Quality after Pulpectomy Treatment in Primary Molars using Different Preparation Techniques" for consideration for publication. The reference number for this manuscript is "jisppd_217_23". Kindly quote this in future correspondences related to this manuscript.

The manuscript is being reviewed for possible publication with the understanding that it is being submitted to ONE journal at a time and has NOT been published, simultaneously submitted, or already accepted for publication elsewhere either as a whole or in a part.

Online submission of this article implies that the corresponding author has written consent from all the contributors to act as the corresponding author.

All contributors are requested to send the **Digital Copyright Agreement Consent** within 1 week. The status can be viewed in the 'Manuscript Information page' from your area. The decision about the manuscript will be conveyed only on receipt of the agreement on copyright form received from all contributors.

High-resolution images are required at the time of acceptance, you should be notified separately for the same if images uploaded by you are not of printable quality.

The Editors will review the submitted manuscript initially. If found suitable, it will follow a double-blinded peer review. We aim to finish this review process within a short time frame, at the end of which a decision on the suitability or otherwise of the manuscript will be conveyed to you via this system.

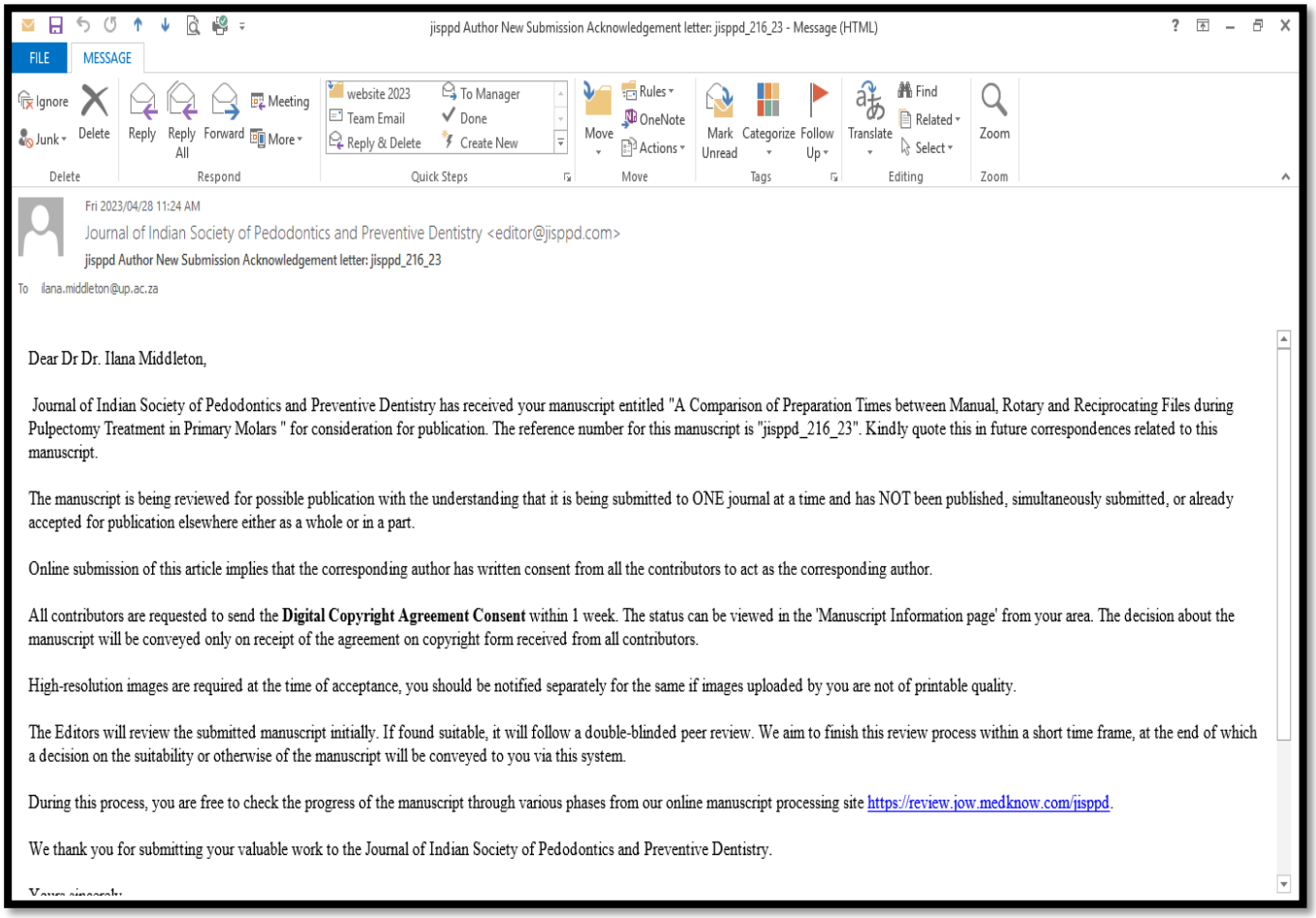
During this process, you are free to check the progress of the manuscript through various phases from our online manuscript processing site https://review.jow.medknow.com/jisppd.

We thank you for submitting your valuable work to the Journal of Indian Society of Pedodontics and Preventive Dentistry.

Yours sincerely,

Appendix 5

Proof of submission of Manuscript 2



jisppd Author New Submission Acknowledgement letter: jisppd_216_23 - Message (HTML)

FILE MESSAGE

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Fri 2023/04/28 11:24 AM

Journal of Indian Society of Pedodontics and Preventive Dentistry <editor@jisppd.com>

jisppd Author New Submission Acknowledgement letter: jisppd_216_23

To ilana.middleton@up.ac.za

Dear Dr Dr. Ilana Middleton,

Journal of Indian Society of Pedodontics and Preventive Dentistry has received your manuscript entitled "A Comparison of Preparation Times between Manual, Rotary and Reciprocating Files during Pulpectomy Treatment in Primary Molars " for consideration for publication. The reference number for this manuscript is "jisppd_216_23". Kindly quote this in future correspondences related to this manuscript.

The manuscript is being reviewed for possible publication with the understanding that it is being submitted to ONE journal at a time and has NOT been published, simultaneously submitted, or already accepted for publication elsewhere either as a whole or in a part.

Online submission of this article implies that the corresponding author has written consent from all the contributors to act as the corresponding author.

All contributors are requested to send the **Digital Copyright Agreement Consent** within 1 week. The status can be viewed in the 'Manuscript Information page' from your area. The decision about the manuscript will be conveyed only on receipt of the agreement on copyright form received from all contributors.

High-resolution images are required at the time of acceptance, you should be notified separately for the same if images uploaded by you are not of printable quality.

The Editors will review the submitted manuscript initially. If found suitable, it will follow a double-blinded peer review. We aim to finish this review process within a short time frame, at the end of which a decision on the suitability or otherwise of the manuscript will be conveyed to you via this system.

During this process, you are free to check the progress of the manuscript through various phases from our online manuscript processing site https://review.jow.medknow.com/jisppd.

We thank you for submitting your valuable work to the Journal of Indian Society of Pedodontics and Preventive Dentistry.

Yours sincerely