Evaluation of Root Canal Transportation, Centering Ratio and Remaining Dentine Thickness in Curved Root Canals Prepared with WaveOne Gold in Combination with Different Glide Path Techniques

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Dissertation submitted in partial fulfilment of the Degree of
MSc (Dent)
at the
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NOVEMBER 2017

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“Remember how far you’ve come, not just how far you have to go. You are not where you want to be, but neither are you where you used to be.”

- Rick Warren

Declaration

I, Martin Vorster, declare that this dissertation entitled, **"Evaluation of Root Canal Transportation, Centering Ratio, and Remaining Dentine Thickness in Curved Canals Prepared with WaveOne Gold in Combination with Different Glide Path Techniques"**, which I herewith submit to the University of Pretoria in partial 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.

1 November 2017

SIGNATURE **DATE**

Acknowledgements

I would like to extend my heartfelt appreciation to the following people:

- **Prof Peet van der Vyver – supervisor**, Department of Odontology, University of Pretoria, Pretoria, South Africa for his guidance, mentorship and his ceaseless passion towards the dental profession.

- **Dentsply Sirona** for sponsoring the materials needed for this study.

- **Prof F A de Wet,** for his guidance and support.

- **Prof H S Schoeman**, Statistician/Owner from Clinstat CC, Pretoria.

- **Ms Clarisa Sutherland,** for her assistance with the micro-CT analysis.

- **Barbara English** for her assistance in language editing.

- **Mr Jacobus Hoffman,** technician at NECSA for his assistance with the micro-CT Imaging.

- **NECSA,** for the use of the facility.

- My beautiful daughters **Lisa** and **Mia**. You are my inspiration.

- My **father, mother and sister** for their endless love and support.

- My **Creator and heavenly Father**. In You I live, move and have my being.

Summary

The aim of this *in vitro* study was to investigate various glide path preparation instruments followed by root canal preparation with the reciprocating Primary WaveOne Gold instrument in curved mesial root canals of extracted human mandibular molars. Micro Computed Tomography (micro-CT) was used. Canal transportation, centering ability and effect on remaining dentine thickness were evaluated over the apical, midroot and coronal levels (3 mm, 5 mm and 7 mm from the root apex). In addition, preparation times for glide path preparation and final canal preparation with the Primary WaveOne Gold instrument were also recorded and compared.

Sixty curved mesio-buccal root canals were randomly divided into four groups. These groups were Group 1: no further glide path preparation (n=15); Group 2: glide path enlarged with the use of pre-curved size 10,15 and 20 stainless steel K-files (n=15); Group 3: manual glide path enlargement with a size 10 K-file and further preparation with rotary PathFiles no.1-3 (n=15); and Group 4: manual glide path enlargement with a size 10 K-file and further preparation with the reciprocating WaveOne Gold Glider (n=15).

Micro-CT was used to scan teeth before and after glide path preparation. The final canal preparation was done with the Primary WaveOne Gold instrument after which all 60 specimens were scanned again by means of micro-CT.

The three-dimensional images obtained before instrumentation, after glide path preparation and again after final canal preparation with the Primary WaveOne Gold instrument were reconstructed and interpreted. Centering ratio values, canal transportation, remaining dentine thickness as well as glide path and final canal preparation times were recorded and compared

between the four glide path groups with the use of a one-way analysis of variance (ANOVA) for parametric and Kruskal-Wallis H test for non-parametric comparisons. Statistical significance was set at $p < 0.05$.

PathFiles performed most favourably when mean centering ratios were compared over all three levels from the root apex. However, no statistically significant difference in the mean centering ratios was found after glide path preparation when K-files, PathFiles and the WaveOne Gold Glider were compared. Mean combined transportation over the apical, midroot and coronal levels after glide path preparation was statistically significantly higher in the K-file preparation groups compared to the PathFile and WaveOne Gold Glider groups.

There was no statistically significant difference in the mean combined centering ratios or transportation values of the various glide path groups in combination with the Primary WaveOne Gold instrument over the apical, midroot and coronal levels. Although not statistically significant, the highest mean transportation values were seen in the group where no glide path was prepared prior to final canal preparation with the Primary WaveOne Gold Instrument.

All glide path groups performed similarly in evaluation of preservation of dentine when they were used in combination with the Primary WaveOne Gold instrument. Not having a prior glide path resulted in the most dentine thickness reduction after final canal instrumentation with the Primary WaveOne Gold instrument.

Glide path preparation was statistically significantly fastest with the use of the WaveOne Gold Glider ($p<0.0001$). Having no prior glide path preparation resulted in statistically slower final canal preparation in combination with the

Primary WaveOne Gold instrument compared to the other three glide path preparation groups (K-files, PathFiles and WaveOne Gold Glider) ($p<0.0001$).

The findings of this study suggest that glide path preparation before final instrumentation with the Primary WaveOne Gold instrument is advised for minimising canal transportation, achieving the most favourable centering ability, and preserving remaining dentine thickness most favourably. When the mean combined centering ratio values were compared over all three levels after glide path preparation, PathFiles seemed to perform best, although not to a statistically significant extent. Glide path preparation with WaveOne Gold Glider and final preparation in combination with the Primary WaveOne Gold instrument produced the fastest preparation times.

Keywords: Glide path, reciprocation, centering ability, transportation, remaining dentine thickness, preparation times, WaveOne Gold Glider, WaveOne Gold, PathFiles, K-files.

List of Abbreviations

%	-	Percentage
2D	-	Two dimensional
3D	-	Three dimensional
ANOVA	-	Analysis of Variance
CT	-	Computed Tomography
CBCT	-	Cone Beam Computed Tomography
CEJ	-	Cemento- Enamel Junction
CW	-	Clockwise
CCW	-	Counter Clockwise
D	-	Distal
D0	-	Distance 0 mm from instrument tip
D16	-	Distance 16 mm from instrument tip
ISO	-	International Organization of Standardization
M	-	Mesial
Micro-CT	-	Micro-Computed Tomography
MIXRAD	-	Micro-focus X-ray radiography and Tomography facility
mm	-	Millimeter
M-Wire	-	Memory Nickel-Titanium Wire
NaOCl	-	Sodium Hypochlorite
NECSA	-	Nuclear Energy Corporation of South Africa
NiTi	-	Nickel-Titanium
n	-	Number/s
s	-	Second/s

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Chapter 1: Introduction and Literature Review

1.1 Endodontics: The Rationale

Prevention and elimination of periapical inflammation is one of the main objectives of endodontic treatment.[1] Microbial infection and invasion of the endodontic system remains the main cause of radicular and peri-radicular pathology.[2] Biomechanical cleaning and shaping in order to facilitate irrigation, disinfection and proper obturation is essential in eliminating apical periodontitis.[1] Protecting and preserving the original canal anatomy and the position and size of the apical foramen also remain important.[3] Long, thin and curved root canals remain a challenge for even the skilled clinician. These difficulties increase the risk for root perforations, apical zipping, strip perforations and apical extrusion of debris.[4]

In order to minimise procedural accidents and preserve dentine while a root canal system is being prepared, root canal preparation systems with a favourable centering ability need to be used. Maintaining the original canal anatomy of a root canal system is critical to the successful shaping of a root canal. Deviation from the canal axis will result in apical transportation[5] leading to large areas of the canal being left unprepared. Preserving original canal anatomy and dentine thickness improves the outcome of endodontic treatment.[6] For this reason it is important to investigate the ability of a file system to preserve the original shape of the root canal with conservative dentine removal.

1.2 Instrumentation and the Use of Nickel-Titanium in Endodontics

Nickel-Titanium (NiTi) files were first introduced into the market for their use in endodontics in 1988.[7] Prior to the use of NiTi endodontic instruments, canal shaping was performed mainly by stainless steel and carbon instruments. Owing to the rigidity of these instruments an increase occurs in procedural errors like zipping, ledge formation, perforation and instrument separation when canals are being prepared exclusively with stainless steel files.[8] Carbon instruments were abandoned because of a lack of corrosion resistance. NiTi with its memory shape effect, superior elasticity and biocompatibility changed the face of endodontic treatment forever.[9]

Compared to stainless-steel endodontic instruments, NiTi instruments can endure higher torsional stress, reduce canal preparation time, and reduce the incidence of procedural accidents.[7] These unique qualities of NiTi also allow for consistent, efficient shaping with the use of fewer preparation instruments.[10]

1.3 Canal Scouting and Initial Enlargement

Initial canal negotiation and glide path enlargement is regarded as the most important stage of root endodontic treatment.[11] Scouting and preflaring are the first phases of endodontic canal instrumentation and, although this stage gives valuable information on the canal anatomy, it is also the stage where the clinician most frequently encounters procedural aberrations like apical blockage, ledge formation and instrument separations.[12]

1.4 Importance of Maintaining Original Canal Anatomy

Identification and accessing of main canals, establishing and maintaining working length, and geometric consideration concerning size selection while a root canal is being prepared remain some of the most challenging and controversial aspects of endodontic treatment.[4]

Procedural errors like instrument fractures, ledge formation, canal zipping, strip perforations, apical perforations, elbow formations and apical blockage are likely outcomes in the instrumentation of thin, curved and long root canals. These errors can possibly lead to endodontic failure as a result of incomplete debridement.[13] Most of these errors can be contributed to the stiffness of stainless steel instruments.[14] The introduction of NiTi rotary instruments revolutionised endodontics with a decreased modulus of elasticity.[15] Although more flexible and stronger than stainless steel instruments, a NiTi rotary instrument still separates as a result of its elastic limits.[7] Fractures might occur even without prior use or deformation.[16,17] Owing to bending stresses and cyclic fatigue, canal curvature is considered to be a major risk factor in instrument separations.[16,18]

Endodontically treated teeth are also more susceptible to fractures compared to vital teeth. The high incidence of fractures can be attributed to the altered physical properties of the dentine, which stem from the use of intra-canal medicaments and irrigants.[19] Another factor that contributes to an increased incidence of tooth fractures is the amount of dentine removed when a tooth is being accessed and canals shaped for endodontic treatment.[6] It is therefore important to look at preserving dentine when a tooth is being shaped and prepared during endodontic treatment.

1.4.1 Ledge Formation

When a curved canal is being prepared with the use of rigid instrumentation, ledge formation is a likely procedural outcome. This platform formation on the inside of the greater curve might also prove difficult to bypass.[13] Ledge formation could be part of the original canal, but could even have deviated from the original canal, creating an artificial/false canal.[20] Shaping in order to facilitate irrigation and disinfection, as well as final obturation, is difficult in these cases. Failure to properly shape and clean the more apical portion of the procedural error might directly influence the outcome of the endodontic treatment.[12]

1.4.2 Transportation

Canal transportation occurs because of the tendency of instruments to return to their original position and therefore deviate from the original canal pathway and remove dentine from the outside of the canal curvature. This occurrence might lead to ledge formation or even perforation. This procedural error is also termed "zipping" or "canal straightening".[13] Owing to the stiffness of stainless steel K-files an increase in lateral forces occurs when canals are being prepared. Straightening of the canals results in deviation from the original canal anatomy.[21] Lam *et al*.[22] found an increase in apical- and mid-curve transportation with an increase in file size, with significantly greater apical transportation with an ISO size 25 hand file.

1.4.3 Ensuring Patency

The American Association of Endodontists defines patency as "a canal preparation technique where the apical portion of the canal is maintained free of debris by recapitulation with a small file through the apical foramen".[23] Patency is an essential aspect of predictable canal negotiation[24] and, by maintaining the canal patent, debris accumulation at the apex is eliminated and results in a reduced risk of canal transportation, ledge formation and even perforation.[25] Loss of apical patency and apical blockage might be a result of incorrect working length. Failure to successfully clean and obturate the apical portion of a canal might increase the risk of endodontic failure.[26]

1.4.4 Perforation

A root perforation is described as a mechanical, iatrogenic or pathological communication of the root canal with the external surface of the tooth.[27] Misalignment of dental burs and endodontic rotary instruments during access cavity preparations and canal negotiation is a likely cause of iatrogenic perforations.[28] According to Kvinnsland *et al.*,[29] endodontic preparation contributes 47% towards iatrogenic causes of root perforations, while 53% of iatrogenic perforations are due to prosthodontic treatment. Maxillary teeth are also reported to have a higher incidence (74.5%) of iatrogenic perforations compared to mandibular teeth (25.5%).

The main causes for pathological root perforation are resorption and root caries.[30] Extraction might be the undesired outcome of a root perforation. In a study relating to the causes of extraction of failed endodontically treated teeth, it was found that 4.2% of the teeth were extracted as a result of iatrogenic root perforations.[31]

Inflexible rotary endodontic instruments with sharp cutting tips can be the cause of iatrogenic root perforations. These perforations are difficult to seal and repair. The remaining part of the original canal apical to the perforations will remain unprepared and might increase the chance of failure if the perforation site cannot be bypassed.[13]

Over preparation and straightening of curved canals can also lead to strip perforations, especially during excessive coronal flaring.[32] The thin walls of the canal towards the furcation area (also termed the "danger zone") should therefore be avoided during coronal flaring and enlargement of root canals.[13]

1.5 Glide Path Preparation

A glide path is defined as a smooth tunnel extending from the canal orifice to the radiographic terminus or exit as determined by the electronical apex locator.[33] Maintaining a smooth reproducible glide path when successive files are used is an important characteristic of a proper glide path preparation.[34] In restricted canals, files can be used in a 30 to 60 degree clockwise (CW) and counter-clockwise (CCW) motion as the file progresses apically. This "watch-winding" motion as described by West[35] removes restrictive dentine and creates an "envelope of motion".

In 2001 Bergmans *et al.*[36] advocated that rotary NiTi instruments not be used for canal preparation without prior hand instrumentation. Creating sufficient space for the first rotary file to passively run in the root canal by means of a glide path significantly reduces the stresses on the rotary instruments and increases its safety.[37]

The use of small hand files to create a glide path has the added benefit that small denticles /canal calcifications are removed while the glide path is being prepared and the canal patency maintained. This use reduces the risk of iatrogenic ledge formation and possible root canal failure.[11,34,35]

An effective glide path preparation has also been shown to reduce torsional stresses and can increase the lifespan of a rotary instrument by up to six times.[1] In a study by Peters *et al.*[38] it was reported that no instrument fractures were found while constricted canals were prepared under high forces, provided that an effective glide path was created before further instrumentation. Patiño *et al.*[39] demonstrated that the incidence of instrument separation was significantly reduced in canals where preparation was preceded by proper glide path preparation. A high incidence of distortion and separation of NiTi files was found in a study where no initial glide path preparation was undertaken.[40] Original curvature of canals is also preserved when an effective glide path is prepared prior to further instrumentation.[41]

1.6 Manual Glide Path Preparation Techniques

Manual glide path preparation can be done using stainless steel K-files by hand or in conjunction with a reciprocating hand piece as described below.

1.6.1 Hand Stainless Steel K-files

Manual glide path preparation with K-files (Figure 1.1) has been recommended by numerous authors.[1,33,35,42] West[33] describes a technique where a stainless steel file is used in a vertical up-and-down motion with a 1 mm amplitude to remove dentine from the canal walls. The amplitude is increased as the file progresses apically.[33]

Figure 1.1: Stainless steel K-files, sizes ISO 10 (purple) and 15 (white)

The following are some of the advantages of using hand stainless steel files compared to NiTi files when creating a glide path:

- The operator has an increase in tactile sensation.[43]
- There is less chance of separation of instruments during preparation.[43]
- When removing a small stainless steel file from a root canal, it retains the anatomy of the canal, leaving the operator with valuable information regarding canal curvature.[1,43-45]
- The cost of hand stainless steel files are lower than other systems.[15]
- No dedicated special hand pieces are required.[15]
- Blocked or calcified canals can be negotiated better using stainless steel K-files due to the increased stiffness of the files.[11,43]

Berutti *et al*.[1] advise that a glide path preparation should be created so that the tip of the first rotary files is one size smaller than the diameter of the glide path created. To reduce the risk of ledge formation, especially where a glide path bigger than an International Organization of Standardization (ISO) size 10 K-file is needed, West[35] advocates the "balance force" motion as described by Roane *et al*.[46] This technique is described as turning the file in a CW direction to engage dentine, followed by a CCW motion while apical pressure is maintained to avoid "unscrewing" the file from the canal. This motion is repeated as the file progresses apically down the canal.

West[35] further recommends a "super loose" size 10 K-file as the minimum glide path requirement. A glide path is confirmed when a size 15 or 20 K-file can be moved 3-5 mm from working length and gently pushed back to length without the need for rotation.[47]

Some disadvantages of glide-path preparation with hand instruments include:

- Increased operator fatigue[15];
- Increased preparation time[48];
- Increased risk of canal aberrations, especially with larger K-files[35,48];
- Increased apical debris extrusion[49]; and
- Increased potential of altering the original anatomy of the canal.[48,50]

1.6.2 Hand Stainless Steel K-files in Reciprocating Hand Piece

With this technique, canal negotiation should first be done by hand with the use of a small size K-file.[15] The K-file is then attached to the reciprocating hand piece to mechanically create a glide path (Figure 1.2).[51] The M4 hand piece (SybronEndo, Glendora, CA) should be used in a vertical up and down motion with an amplitude of between 1 mm and 3 mm for approximately 15 to 30 seconds in each canal.[15] Sequential larger files (ISO sizes 06 - 10) should be taken 0.5 mm beyond the apical foramen to ensure canal patency and reduce the risk of blockage.[15] Van der Vyver[47] advocates that a size 20 K-file should be used 1 mm short of the apical constriction to avoid apical transportation with this relatively stiff K-file.

Figure 1.2: M4 Reciprocating hand piece (SybronEndo)

Advantages of creating a glide path with the M4 reciprocating hand piece include:

- Less operator/hand fatigue[15];
- Less preparation time[15]; and
- Reduced risk of instrument separation when compared to similar NiTi glide path preparation methods.[51]

Disadvantages include:

- The need for a special hand piece[15];
- An increased risk of apical transportation, especially with the larger, less flexible K-files[47,51];
- Reduced dentine preservation compared to manual preparation[52];
- Decrease in tactile sense compared to manual flaring[15]; and
- An increased risk of apical debris extrusion as a result of apical pressure from the hand piece.[51]

Other hand files recommended for manual glide path preparation include the Antaes Stiff "C" Files (Schwed, Kewn Gardens, NY State), C+files (Dentsply Sirona), Pathfinder CS (SybronEndo, Glendora, CA), Stiff K-file (Brasseler, Savannah, GA), Flexofiles (Dentsply Sirona) and Hi-5 files (Miltex, York, PA).

1.7 Rotary Glide Path Preparation Techniques

1.7.1 PathFiles (Dentsply Sirona)

NiTi rotary PathFiles (Dentsply Sirona) were introduced to the market in 2009 to facilitate glide path enlargement. The system consists of three files available in three different lengths (21 mm, 25 mm and 31 mm) (Figure 1.3). PathFiles have a square cross section and a 2% taper, which increases resistance to cyclic fatigue and improves flexibility and cutting efficiency. The tip angle is 50 degrees and non-cutting, reducing the risks of ledge formation. PathFile no.1 (purple) has an ISO 13 tip size, PathFile no. 2 (white) has an ISO 16 tip size and PathFile no. 3 (yellow) has an ISO 19 tip size. The manufacturer recommends a loose size 10 K-file prior to instrumentation with the first PathFile. The gradual increase in tip size ensures progression of the file apically down the canal.

Figure 1.3: PathFiles no.1-3 (Dentsply Sirona)

When one compares flexibility and torsional strength between NiTi rotary glide path files and stainless steel K-files, it is noted that NiTi glide path preparation files display superior flexibility to stainless steel files.[53] NiTi rotary glide path preparation files therefore preserve dentine and the original canal anatomy better than stainless steel K-files, although K-files show a higher torsional resistance.[53]

1.7.2 One G (Micro-Mega)

The One G rotary NiTi glide path file has a non-cutting tip and a 3% taper (Figure 1.4). The file has three cutting edges on three different radii in relation to the canal axis, which enhances the cutting action and allows for debris to be extruded coronally. The screw-in effect of the file is limited by the variable pitch between the cutting edges. The inactive tip also reduces the risk of procedural errors like ledge formation.

Figure 1.4: One G (Micro-Mega)

1.7.3 ProGlider (Dentsply Sirona)

The ProGlider single file system is manufactured using M-Wire technology with increased cyclic fatigue resistance and increased flexibility (Figure 1.5). The file has a progressive taper of 2% to 8% with a square cross section and a diameter of 0.66 mm at D0 and 0.82 mm at D16.

Figure 1.5: ProGlider (Dentsply Sirona)

Van der Vyver *et al.*[54] compared the glide-path preparation times of stainless steel K-files, PathFiles and X-Plorer files (Clinician's Choice Dental Products Inc.) with the ProGlider single file system. The ProGlider demonstrated significant shorter glide path enlargement times compared to the other systems used in the study, with a mean preparation time of 11.3 seconds per simulated canal.

1.8 Reciprocating Glide Path Preparation Techniques

1.8.1 WaveOne Gold Glider (Dentsply Sirona)

The WaveOne Gold Glider was launched in 2017 (Figure 1.6). The file is a reciprocating instrument designed for glide path enlargement prior to shaping canals with a Small or Primary WaveOne Gold instrument.

Figure 1.6: WaveOne Gold Glider (Dentsply Sirona)

The WaveOne Gold Glider is manufactured using NiTi wire that is subjected to a post-manufacturing thermal process, where a new phase-transition point between martensite and austenite is identified to produce a file with super-elastic NiTi metal properties. This process gives the file a gold finish with enhanced flexibility and resistance to cyclic fatigue compared to conventional NiTi and M-Wire alloys.[55] Owing to this process the file might appear to be slightly curved. This is not a manufacturing defect and there is no need to straighten the file before using it. Once the file is introduced into the canal it will follow the natural curves of the prepared glide path.

The WaveOne Gold Glider is a single-use sterile instrument and re-use is not allowed. The file has an ISO size 15 tip size with a variable taper of between 2% (DO) and 6% (D16) and a parallelogram-shaped cross-sectional design. The file has a semi-active tip and an active cutting flute length of 16 mm.

The manufacturers recommend that the WaveOne Gold Glider should not be used in cases of severe or sudden apical curvatures. The manufacturers recommend the mechanical use of the WaveOne Gold Glider in cases with severe root curvature. Flutes should be cleaned and checked frequently and inspected for signs of distortion or wear. The use of copious amounts of irrigant is advocated while the canal is being prepared but files should never be immersed fully in NaOCl solution. The WaveOne Gold Glider should be used in a reciprocating motion with slight apical pressure. An inward pecking motion with slight amplitude strokes is used to advance the file passively towards the apical portion of the canal until full working length is reached. It is important to secure a reproducible micro glide path with a size 10 K-file in combination with a lubricant prior to introducing the WaveOne Gold instrument into the canal.

1.9 Recent Developments in Endodontic File Systems

Recent developments in endodontic instrumentation can be characterised by several factors:

- More flexible alloys allowing better canal negotiation and an increase in fatigue resistance.[56]
- Reciprocation in addition to rotation action of instruments.[56]
- A reduction in the number a files used for canal cleaning and shaping.[56]
- Improved design of file systems in order to clean a greater section of the canal without the need for coronal flaring.[57]

1.10 Reciprocation Versus Rotation Motion for Root Canal Preparation

The majority of NiTi root canal systems are mechanically driven in a continuous rotation motion. Reciprocation (defined as a CW/CCW motion) was introduced in endodontics in 1958.[58] Early reciprocating systems utilised an equal CW/CCW motion of 90 degrees and in more recent systems 30 degrees. None of these systems complete a full rotation.[58] Apical transportation,[59] reduced cutting efficiency, inward pressure, reduced debris removal with increased debris extrusion apically[60] were some of the disadvantages found with these early reciprocation preparation systems.

When conventional NiTi instruments are rotated in root canals, they are subjected to structural fatigue that, if continued, will eventually lead to fracture.[16,61] Torsion and fatigue through flexure are the two main reasons for this failure.[62] Torsional fractures occur when the tip or any other part of the rotating instrument binds to the root canal walls, while the rest of the file continues turning. Fracture due to flexural fatigue (bending stress) occurs when an instrument that has already been weakened by metal fatigue is placed under further stress. The instrument does not bind to the root canal walls but rotates freely until fracture of the instrument occurs at the point of maximum flexure.[63,64] The amount of bending stress imposed on an instrument depends on the anatomy of the root canal and is greater in curved root canals.[16]

The first study experimenting with an alternating movement was that of Yared[65] which used the ProTaper F2 instrument (Dentsply Sirona) in a reciprocating movement. The alternating changes in the direction of rotation would, in theory, reduce the number of cycles of the instrument and, therefore, reduce the cyclic fatigue on the instrument compared with that imposed when instruments are used in a consistent rotating motion.[66,67]

The study showed great promise for the reduction of the number of instruments required in the cleaning and shaping sequence; in minimising possible contamination; and in alleviating operator anxiety of the possibility of instrument failure.[65] Apart from these benefits, preparation time was shown to be less than the same instrument used in full rotation.[66] These findings were confirmed by Bürklein and Schäfer[60] in 2012 when they compared Reciproc (VDW) and WaveOne (Dentsply Sirona) functioning in reciprocating motion to Mtwo (VDW) and ProTaper Universal (Dentsply Sirona) in conventional use.

1.11 Reciprocating NiTi Instruments

Instead of a rotary motion, the files work in a reverse "balanced force" cutting motion[61] and are driven by a pre-programmed motor (X-Smart Plus motor fitted with 6:1 reducing hand piece) (Dentsply Sirona) or the new X-Smart iQ (Dentsply Sirona) endodontic motor and an 8:1 hand piece that is paired with an iPAD mini. The pre-programmed motor is capable of turning the files in a back and forth "reciprocating" motion. The CCW movement of 150 degrees is capable of advancing the instrument apically as the dentine on the root canal wall is engaged and cut. This movement is followed by a 30 degrees CW movement, which ensures that the instrument disengages before excessive torsional stress is transferred onto the metal alloy and before the instrument can bind (taper lock) into the root canal. Three sequential reciprocating cycles will complete one complete CCW rotation and the repeated cutting and release process allows the instrument to advance apically into the root canal.[55]

1.11.1 WaveOne (Dentsply Sirona)

The WaveOne file system was introduced to the dental market in 2011. It was a pre-packaged, pre-sterilised, single-use system that was designed to shape root canal systems to a continuously tapering morphology.[55,68] The WaveOne system consists of three single-use instruments: Small (ISO tip 21, 6% taper) (yellow); Primary (ISO tip 25, 8% taper) (red); and Large (ISO tip 40, 8% taper) (black) (Figure 1.7). The system is manufactured using M-Wire.

This reciprocating file cuts in a CCW action and leaves more centred preparations with a reduced risk of canal transportation, ledge formation and irregular enlargement of the apical foramen.[41]

Figure 1.7: WaveOne system (Dentsply Sirona): yellow (Small) 21/06, red (Primary) 25/08 and black (Large) 40/08

Conventional WaveOne instruments were characterised by different cross-sectional designs over the entire length of the working part of the instruments. In the tip region the cross-section presented radial lands while in the middle part and near the shaft the cross-sectional diameter changed from a modified triangular/convex cross-section with radial lands to a neutral rake angle with a triangular/convex cross-section. [69]

1.11.2 WaveOne Gold (Dentsply Sirona)

The WaveOne Gold system is the latest reciprocating file system with a CCW cutting motion. According to Webber,[58] these single-use shaping files offer the clinician more simplicity, safety, improved cutting efficiency and mechanical properties compared to the previous generation of reciprocating instruments.

The WaveOne Gold system is designed with a unique alternating parallelogram-shaped cross-sectional design with two 85 degree cutting edges (Figure 1.8). This unique design limits the engagement of the file and dentine to only one or two points of contact at any given stage of canal preparation. This limited engagement 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. These files are also designed with a progressively decreasing percentage taper to preserve coronal dentine.

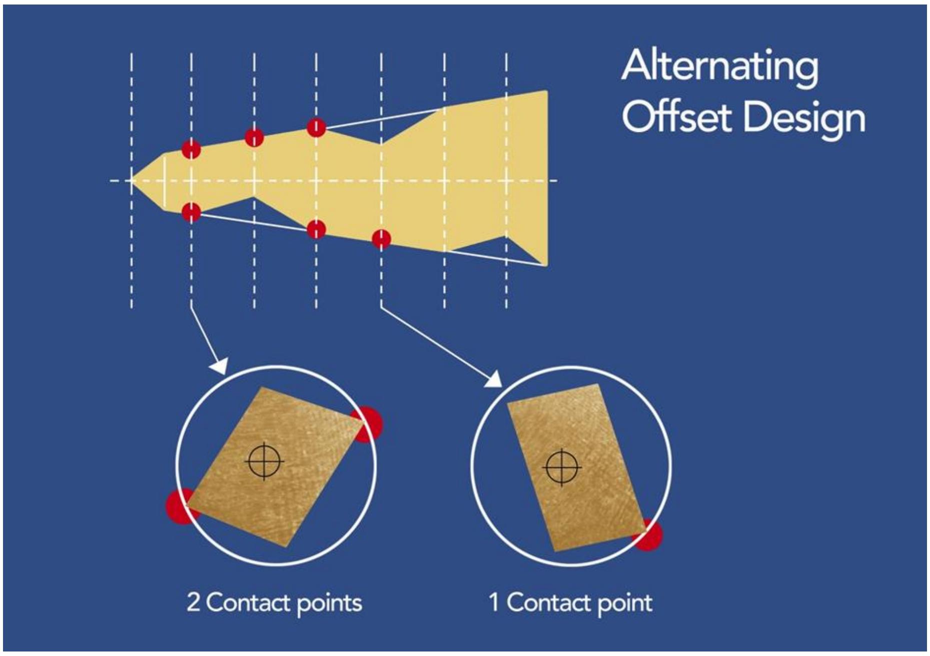

Figure 1.8: Schematic representation illustrating the off-centred parallelogram-shaped cross-section design with two 85 degree cutting

edges. The design limits engagement between the file and dentine to only one or two points of contact at any given cross section.

1.11.2.1 Metallurgy and Design features of WaveOne Gold

The conventional WaveOne system was manufactured from M-Wire technology. M-Wire is prepared by a special thermal process and is claimed to increase flexibility and resistance to cyclic fatigue.[70,71] WaveOne Gold instruments are manufactured using a post-manufacturing thermal process, according to which a new phase-transition point between martensite and austenite is identified to produce a file with super-elastic NiTi metal properties. This process gives the file a gold finish with improved mechanical characteristics. The Primary WaveOne Gold instrument is 50% more resistant to cyclic fatigue, 80% more flexible and 23% more efficient than the conventional Primary WaveOne instrument. [58,72] Owing to the super-elastic properties of the new gold metal, the file may appear slightly curved when it is removed from a curved root canal because the metal demonstrates less memory compared to conventional NiTi or M-Wire (Figure 1.9). The file can either be straightened out or if it is placed back into a root canal it will follow the natural shape of that canal.[58] Another advantage of this reduced memory of the file is that in cases with difficult straight-line access it is possible to slightly precurve the file, to allow easy placement into the canal orifices.

Figure 1.9: WaveOne Gold instrument appears slightly curved due to the reduced memory effect of the improved metal

There are four WaveOne Gold files: Small (20/07), Primary (25/07), Medium (35/05) and Large (45/05). According to the manufacturer, the Primary 25/07 instrument is suitable for shaping most root canals. According to the manufacturer, the Primary WaveOne Gold instrument is 80% more flexible and 50% more resistant to cyclic fatigue compared to its WaveOne gold predecessor. The Gold alloy of the WaveOne Gold system is a super-metal manufactured from a metal produced at the phase-transition point between martensite and austenite and is completed by thermal processing and post-machining procedures.[72] The WaveOne Gold engages at a CCW angle of 150 degrees and a CW disengaging angle of 30 degrees. After three cutting cycles the file rotates one complete circle. This unique movement, according to Ruddle,[72] has three major clinical advantages:

- The CCW engaging angle is less than the elastic limit of the file, which improves the safety of the file when compared to continuous rotating files.
- Unequal CW/CWW angles enable the file to advance more readily to the desired working length without excessive inward pressure.
- Debris extrusion from the canal is also enhanced by the unequal CW/CCW angles.[72]

1.11.2.2 Clinical Guidelines for the Use of WaveOne Gold Instruments

Create Adequate Access

It is always important to prepare an adequate access cavity that will ensure straight-line access into each root canal system after removal of all the pulp chamber contents. Ultrasonic instruments – e.g. Start-X ultrasonic instruments (Dentsply Sirona) – are very useful instruments to remove any pulp calcification and to refine the access cavity walls to improve straight-line access. However, another characteristic of the new WaveOne Gold instruments is that the metal has less memory compared to conventional NiTi or M-Wire instruments. It is therefore possible to slightly prebend the tip of the file to allow easy insertion into a secured canal orifice that fails to have complete straight-line access or in cases where patients present with a limited amount of mouth opening.

Select the Correct WaveOne Gold instrument

The following guidelines can be used for WaveOne Gold file selection:

- WaveOne Gold Primary instrument (25/07) (Figure 1.10)

Any canal where a size 08 and 10 K-file have to be negotiated to working length, followed by preparation of a glide path or where a size 15 K-file fits loosely in the canal to working length. This will usually include the majority of root canal systems with average length with moderate curvatures in midroot and apical regions.

Figure 1.10: WaveOne Gold system: Primary instrument (25/07)

- WaveOne Gold Medium instrument (35/05) (Figure 1.11)

Any canal where a size 20 or 25 K-file fits loosely in the canal, it is not necessary to negotiate and prepare a glide path with smaller instruments. The WaveOne Gold Medium instrument is indicated in larger-diameter, relatively straight root canals. This file can also be used after the Primary instrument if more shape is desired or if it is felt that not enough infected dentine was removed from the canal.

Figure 1.11: WaveOne Gold system: Medium instrument (35/05)

- WaveOne Gold Large instrument (45/05) (Figure 1.12)

Any canal where a size 30 or 35 K-file fits loosely in the canal, it is not necessary to negotiate and prepare a glide path with smaller instruments. The WaveOne Gold Large instrument is indicated in larger-diameter and relatively straight root canals. This file can also be used after the Medium WaveOne Gold instrument if more shape is desired or if it is felt that not enough infected dentine was removed from the canal.

Figure 1.12: WaveOne Gold system: Large instrument (45/05)

- WaveOne Gold Small instrument (20/07) (Figure 1.13)

The Small WaveOne Gold instrument is mainly used when the Primary 25/07 instrument does not passively progress apically or when the operator feels insecure with the Primary instrument, after the canal has been negotiated to patency and a glide path prepared. When this small file reaches working length, the clinician may accept the canal preparation or, alternatively, if more shape is required, further enlarge the canal with the Primary 25/07 instrument. The Small WaveOne Gold instrument is then considered as a "bridge file" between the Small and Primary instrument.[72]

However, in canals with severe apical curvatures, very long root canals or in canals where the glide path preparation was very challenging, the WaveOne Gold Small instrument can be used to start root canal preparation with more safety. When this file reaches working length, the clinician may again accept the canal preparation or, alternatively, if more shape is required, further enlarge the canal with the Primary 25/07 WaveOne Gold instrument.

Figure 1.13: WaveOne Gold system: Small instrument (20/07)

1.12 Micro-computed Tomography

The invention of X-rays in 1895 by Roentgen revolutionised diagnostic medicine and made it possible to examine the body and its structures non-invasively.[73] X-ray computed tomography (CT) developed in the early 1970s further advanced the field of diagnostic imaging, according to which images are taken from multiple angles and reconstructed to produce a three-dimensional (3D) image.[74]

Conventional radiographs have a limited two-dimensional (2D) view that represents only a construction of the object along the path of radiographic exposure. CT scanners produce an image of 1mm³ volume elements (voxels) allowing a three-dimensional qualitative and quantitative assessment.[75]

Micro-computed tomography (micro-CT) system allows for projections rotated through multiple directions in order to produce a 3D reconstructed image of objects. This non-destructive process enables repeated examinations of complex internal and external structures of specimens investigated.[76]

Micro-CT, together with histological sections, plastic model evaluation, serial sectioning and radiographic comparisons, has been used to evaluate NiTi prepared root canals between different systems.[77-80] Cone-beam computed tomography (CBCT) proves effective in evaluating canal instrumentation with the advantage that 'before' and 'after' images can be obtained without cutting the teeth prior to instrumentation.[77-80] CBCT is, however, unable to identify subtle changes in the geometry of a root canal after instrumentation. For this reason micro-CT is preferred for its superior quality of resolution.[81] Extensive information can be obtained from micro-CT evaluation and slices can be recreated in a 2D or 3D plane. Internal and external structures can also be assessed simultaneously or separately.[75,81]

The XTH 225 ST micro-focus X-ray tomography system (Nikon Metrology, Leuven, Belgium) consists of four functional units; a lead-lined cabinet, an external chiller, an external control module, and computers for acquisition and 3D reconstruction of images (Figure 1.14 and Figure 1.15).[82]

Figure 1.14: XTH 225 ST micro-focus X-ray tomography system (Nikon)

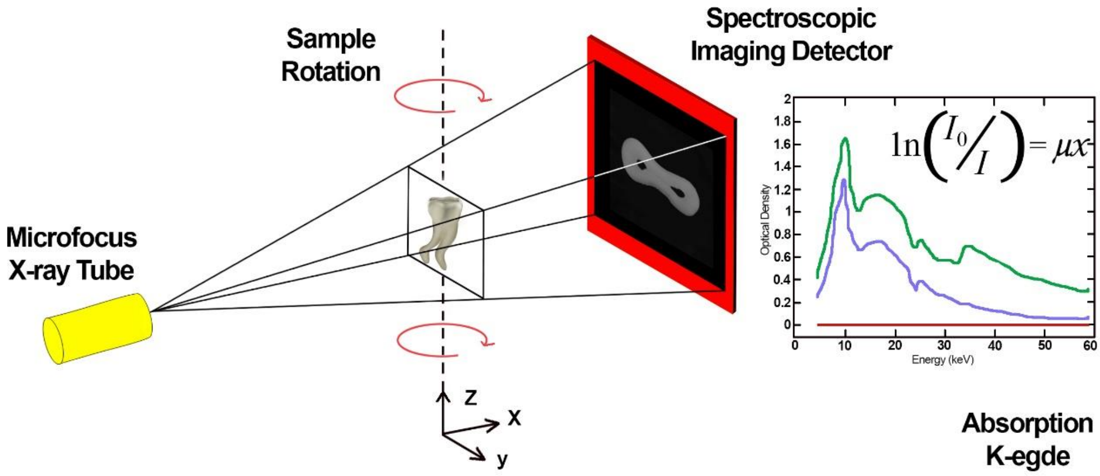

Figure1.15: Tomographic process of the XTH 225 ST micro-focus X-ray tomography system (Nikon)

Chapter 2: Aim and Objectives

2.1 Aim

The aim of this study is to use a new reciprocating root canal preparation instrument (Primary WaveOne Gold instrument) in combination with various glide path preparation techniques to see which combination performs most favourably in preserving canal anatomy in curved first mandibular molar root canal systems. In addition, the preparation times for different glide path preparation techniques as well as final preparation with the Primary WaveOne Gold instrument will also be recorded and compared. No known studies exist on WaveOne Gold (Dentsply Sirona) in combination with various glide path preparation techniques to evaluate canal transportation, centering ability, remaining dentine thickness and preparation time.

2.2 Objectives

- To evaluate **canal transportation** when the Primary WaveOne Gold instrument was used in combination with three different glide path preparation techniques or no glide path preparation.

- To evaluate **centering ability** of the Primary WaveOne Gold instrument when used in combination with three different glide path preparation techniques or no glide path preparation.

- To evaluate the **remaining dentine thickness** after root canal preparation with the Primary WaveOne Gold instrument in combination with three different glide path preparation techniques or no glide path preparation.

- To evaluate the **preparation time** of different glide path preparation techniques.

- To evaluate the **final preparation time** with the Primary WaveOne Gold instrument in combination with three different glide path preparation techniques or no glide path preparation.

2.3 Hypothesis

The Primary WaveOne Gold instrument in combination with the WaveOne Gold Glider glide path instrument will have the most favourable centering ratio with the least amount of dentine removed. This combination of instruments will necessitate fastest preparation time with the least transportation at all the distances measured when these instruments are used to prepare curved first mandibular molar root canals.

2.4 Statistical Null/Zero Hypotheses

Diverse glide path preparation methods prior to final canal preparation with the Primary WaveOne Gold instrument will have no effect on the canal transportation, centering ability, amount of remaining dentine thickness and preparation times in curved root canal systems.

Chapter 3: Materials and Methods

3.1 Material Collection and Selection Criteria

The materials and methods that were used in this study are based on similar materials and methods used in the study by Elnaghy and Elsaka (2014).[83]

Extracted, first mandibular molar teeth were collected after informed consent was obtained (Appendix A) from patients being treated at the Oral and Dental Hospital, School of Dentistry, Faculty of Health Sciences, University of Pretoria. The identity of patients whose teeth were extracted was kept confidential. Teeth were stored in labelled, sealed containers with saline at four degrees Celsius.

3.1.1 Inclusion Criteria

Mandibular first molars collected with two mesial canals and two separate mesial apical foramina were selected. The mesio-buccal canals were used for the study. Root canals had to be visible on pre-preparation radiographs and had to be previously untreated. Only first mandibular molars with a mesial root canal curvature between 25 and 35 degrees were used. (The Schneider method was used to evaluate the canal curvature using a size 08 Kerr K-Flex file) (SybronEndo, California, USA)(Figures 3.1 and 3.2).[84]

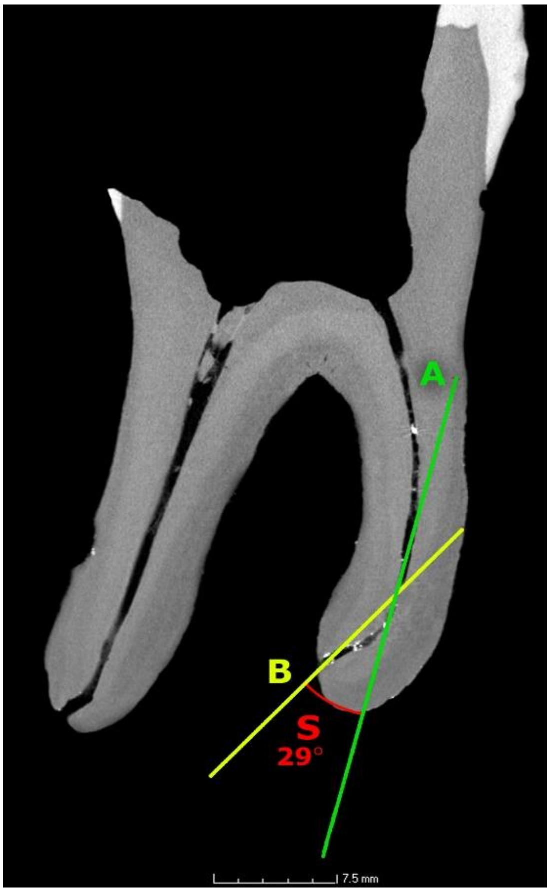

Figure 3.1: **Figure 3.2:**

Figure 3.1: Schneider method for root curvature determination: A (straight line drawn along the coronal third of the canal); B (line drawn from the apical foramen to intersect the point where the first line left the long axis of the canal) S (Schneider angle)

Figure 3.2: X-ray image indicating curvature of mesio-buccal root canal

3.1.2 Exclusion Criteria

- First mandibular molars with mesial roots showing signs of resorption or open apices;
- Molars with sclerosed mesial root canals;

- First mandibular molars with a curvature greater than 35 degrees or less than 25 degrees; and
- Canals that were accessed endodontically prior to extraction.

3.2 Pre-scan Preparation and Instrumentation

Sixty extracted, human first mandibular molar teeth were selected for this ex-vivo study according to the mentioned inclusion and exclusion criteria.

Coronal access (Figure 3.3) was made with the use of a high-speed hand piece and an Endo-Access bur (size 3) (Dentsply Sirona) (Figure 3.4).

Figure 3.3: Coronal access cavity

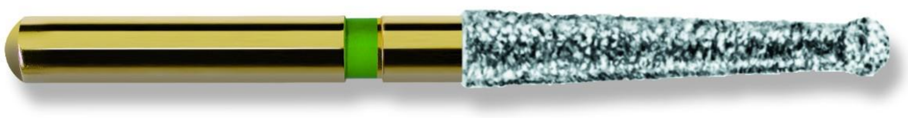

Figure 3.4: Endo-Access Bur (size3) (Dentsply Sirona)

Canal preparation was done on the mesio-buccal root canals. Working length was determined by subtracting 0.5 mm from the length of the canal measured to the major apical terminus under 10x magnification, using a surgical microscope (Zumax Medical Co. Ltd, Suzhou, China). The mesial canals were explored with a size 08 K-file and canals negotiated to patency. Thereafter a pre-operative radiograph was taken to establish if the tooth met the inclusion criteria. Radiographs were taken with the RVG 6000 system (Carestream Health Inc., NY State, USA) to select teeth that met the inclusion criteria.

An initial manually reproducible micro glide path was prepared by moving the 08 K-file in and out of the root canal with amplitudes of 1 mm. Once the K-file moved more freely, the amplitude was increased to 2 mm, then 3 mm, until the K-file moved freely to working length.

Prior to glide path preparation teeth were engraved (Figure 3.5) using an Endo-access Bur (size 1) (Dentsply Sirona), marked with a permanent laundry marker (Artline750) and placed in polystyrene moulds (Figure 3.6) and scanned using the XTH 225 ST micro-focus X-ray computed tomography system at the Micro-focus X-ray Radiography and Tomography Facility (MIXRAD) at the South African Nuclear Energy Corporation (NECSA) (Scan 1).

Figure 3.5 Identification of tooth by means of engraving tooth number on tooth and using permanent laundry marker (Artline750) for enhanced identification

Figure 3.6: Teeth placed in a polystyrene mould for scanning purposes

3.3 Glide Path Preparation

The sixty specimens were then randomly divided using *Research Randomizer* Software (Research Randomizer version 4.0) (Urbaniak, G.C & Plous S) into four experimental instrumentation groups of 15 each.

Group 1: No further glide path preparation (n=15).

Group 2: The initial reproducible glide paths in this group were enlarged with the use of pre-curved size 10, 15 and 20 stainless steel K-files (Figure 3.7). Final reproducible glide paths up to an ISO size 20 were confirmed when the stainless steel size 20 K-file could be placed at working length, pulled backwards for 4 mm and pushed back to full working length using light finger pressure without any interference or obstruction (n=15) in each canal.

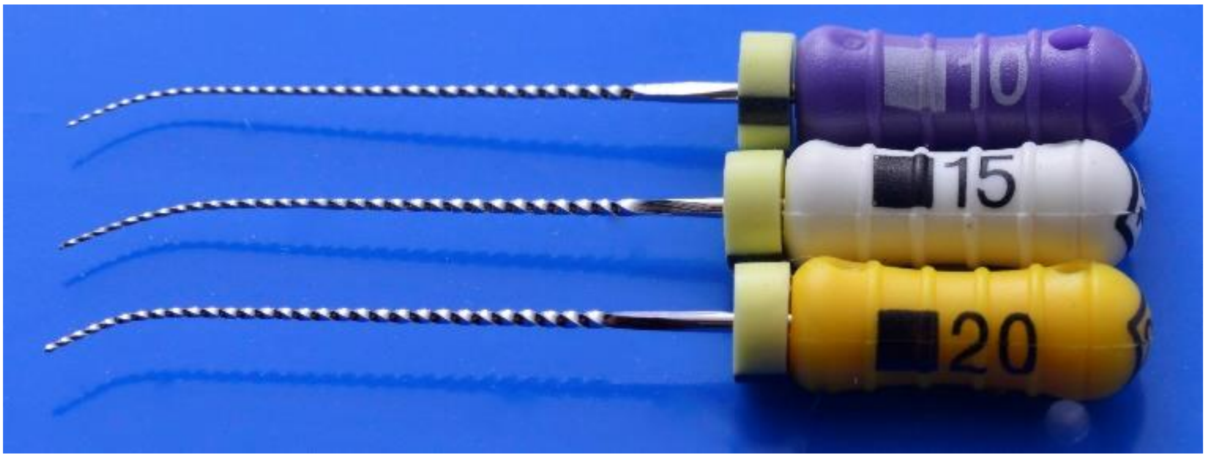

Figure 3.7: Pre-curved stainless steel K-files size 10, 15 and 20 (Dentsply Sirona)

Group 3: For each canal in this group a pre-curved stainless steel size 10 K-file (Figure 3.8) was negotiated to working length with increasing amplitudes of 1-3 mm to ensure an initial manually reproducible glide path. The X-Smart IQ (Dentsply Sirona) (Figure 3.9) operated by the Endo iQ application (IOS, Apple Incorporated, Cupertino, California) on iPad mini (Apple Inc.) with cordless Bluetooth 8:1 speed-reducing hand piece was used with PathFiles no.1-3 (Figure 3.10) according to the manufacturer's instructions to enlarge each canal in this group.

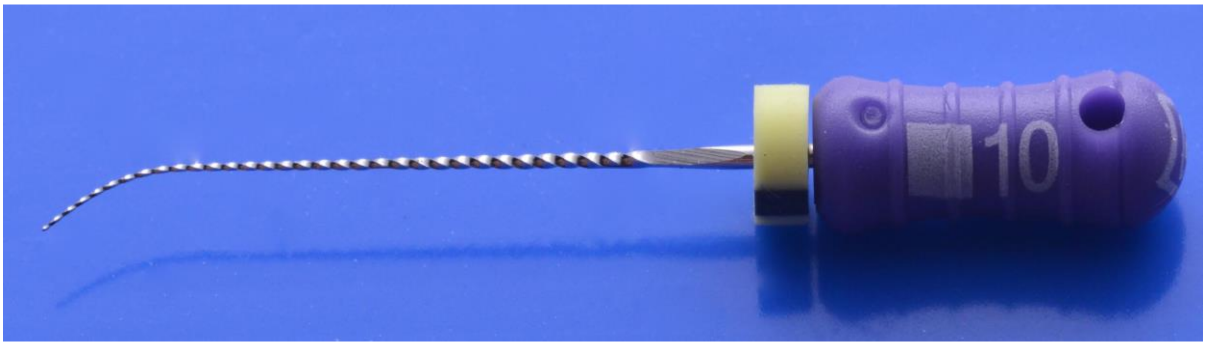

Figure 3.8: Pre-curved size 10 stainless steel K-files (Dentsply Sirona)

Figure 3.9: X-Smart iQ motor (Dentsply Sirona) operated by the Endo iQ application (IOS, Apple Inc.) on iPad mini (Apple Inc.) with cordless Bluetooth 8:1 speed-reducing hand piece

Figure 3.10: PathFiles no.1-3 (Dentsply Sirona)

Group 4: For each canal in this group a pre-curved stainless steel size 10 K-file (Figure 3.8) was negotiated to working length with increasing amplitudes of 1 mm to 3 mm to ensure an initial manually reproducible glide path. The WaveOne Gold Glider (Figure 3.11) (Dentsply Sirona) was used in combination with the X-Smart iQ motor (Dentsply Sirona) in the reciprocating motion setting.

Figure 3.11: WaveOne Gold Glider (Dentsply Sirona)

RC Prep (Premier, Pennsylvania, USA) (Figure 3.12) was used as a lubricating agent during the glide path enlargement and 3.5% sodium hypochlorite (NaOCl) (JIK, Reckitt Benckiser, SA) (Figure 3.13) was used for canal irrigation after the use of each file (n=15). Patency was maintained with an ISO size 08 K-file throughout the procedure.

Figure 3.12: RC-Prep (Premier) used as lubricant during canal preparation

Figure 3.13: Sodium hypochlorite 3.5% (JIK, Reckitt Benckiser) used as root canal irrigant

After glide path preparation all 60 teeth were dried with paper points (ISO size 20) (Dentsply Sirona) (Figure 3.14) and scanned again using a micro-CT scanner (Scan 2).

Figure 3.14: Paper points (ISO size 20) used to dry canals prior to scanning

3.4 Root Canal Preparation

Canals were shaped and prepared using the Primary WaveOne Gold (Dentsply Sirona) (Figure 3.15) reciprocating instrument up to working length, using the X-Smart iQ (Dentsply Sirona)(Figure 3.9) motor according to manufacturers' instructions. Throughout, the instrumentation process RC Prep (Premier) (Figure 3.12) was used as a lubricant and 5 ml per tooth of 3.5% NaOCl (Figure 3.13) was used as an irrigation solution. Each reciprocating file was used to prepare only one canal before it was discarded. Patency was maintained with an ISO size 08 K-file throughout the procedure. A Primary WaveOne Gold Gutta Percha Point (Dentsply Sirona) was placed to working length to determine if preparation was sufficient (Figure 3.16). The selected teeth were dried with matching paper points (WaveOne Gold Primary Paper Points) (Dentsply Sirona) and scanned again with the micro-CT scanner at NECSA (Scan 3).

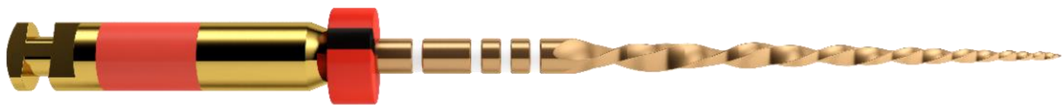

Figure 3.15: Primary WaveOne Gold instrument (Dentsply Sirona)

Figure 3.16: Primary WaveOne Gold Gutta Percha Point (Dentsply Sirona) fitted at working length

CT-scan projections of the pre-operative (Scan 1) glide path preparations (Scan 2) and final preparations (Scan 3) were acquired using the Inspect-X (Nikon, Metrology) software. 2D images were transformed to 3D images with the use of CT-Pro (Nikon, Metrology) reconstruction software. After reconstruction to a 3D image (Figure 3.17), the RAW 3D volume file was imported into VGStudionMax visualisation software (Volume Graphics GmbH, Heidelberg, Germany). The four images were then separated and saved as different files for every tooth. Teeth were aligned according to the Cemento-Enamel Junction (CEJ) in order to superimpose Scans 1, 2 and 3. The engraved number on the teeth was used to identify the specimen.

Figure 3.17: Reconstruction of 2D X-ray images into a 3D image

3.5 Data Collection and Measurements

The method described by Gambill *et al*.[85] was used to measure canal transportation, centering ability and remaining dentine thickness (Figure 3.18).

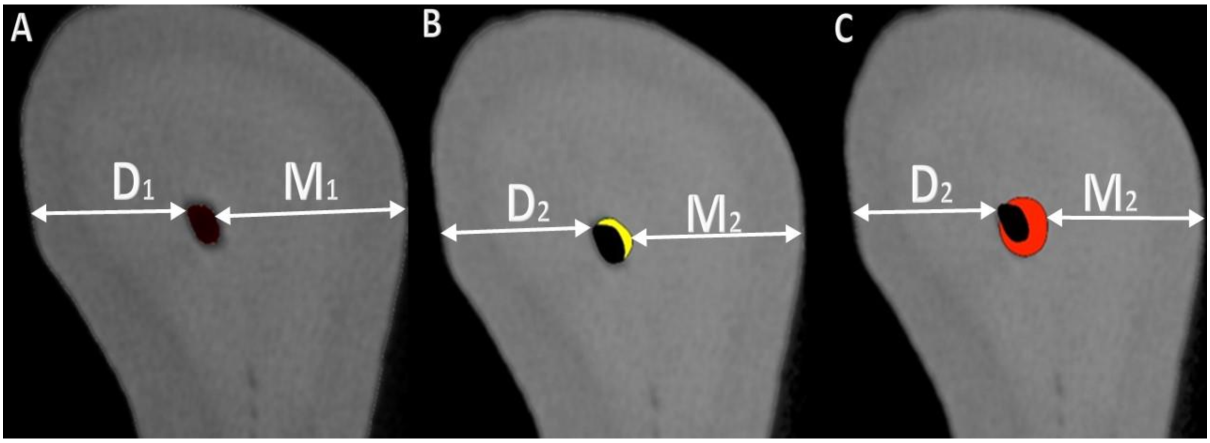

Figure 3.18: (a) Pre-instrumentation; (b) post glide path preparation micro-CT images with yellow markings showing the effect of glide path preparation and points of measurements used for determination of canal transportation and centering ratio; (c) post canal shaping micro-CT images with red markings showing the effect of canal preparation and points of measurements used for determination of canal transportation and centering ratio

The shortest distance from the prepared canal to the mesial or distal wall of the tooth at three different levels from the root apex was measured. Centering ratio and canal transportation were measured at three different lengths from the anatomical apex of the mesio-buccal canals roots.[83] A cross section at levels 3 mm, 5 mm and 7 mm was evaluated using the equations set out immediately below.[83]

Canal transportation = (M1-M2) –(D1-D2)[85]

Canal centering ratio = (M1-M2)/(D1-D2) where (D1-D2 > M1-M2) or (D1-D2)/(M1-M2) where (M1-M1) > (D1-D2)[85]

Where:

M1: Shortest distance from the mesial margin of tooth measured to the mesial margin of uninstrumented canal.

M2: Shortest distance from mesial margin of tooth measured to the mesial margin of the instrumented canal.

D1: Shortest distance from the distal margin of tooth measured to the distal margin of the uninstrumented canal.

D2: Shortest distance from the distal margin of tooth measured to the distal margin of the instrumented canal.

Canal transportation and centering ratios were evaluated after glide path preparation and after final preparation with the Primary WaveOne Gold instrument. The amount of remaining dentine after final preparation with the Primary WaveOne Gold instrument were recorded in order that it could be seen which system preserved the remaining dentine best. The area where the dentine was the thinnest at each of the three levels was measured after instrumentation with the Primary WaveOne Gold instrument.

All micro-CT measurements were done by a skilled third-party operator to avoid bias but was validated by an experienced clinician. Data was recorded in a Microsoft Excel (Microsoft Corp., Redmond, Washington) spreadsheet and verified.

Glide path time and final preparation time were also recorded with an iPhone stopwatch (Apple Inc.). Time to change files was not included in preparation times.

The three levels chosen to evaluate file system performance and canal preservation represent the apical, middle and coronal aspects of the curvature where the root is most susceptible to iatrogenic aberrations.[83] Crowns of teeth were kept intact to reproduce clinical situations where the lack of straight-line access can cause unwanted directional tension or resistance during canal preparation.[77]

3.6 Statistical Analysis

Data analysis was done in conjunction with a biostatistician. Canal transportation, centering ratio values, remaining dentine thickness values and preparation times were compared between the four groups by a one-way analysis of variance (ANOVA) (parametric distributions) and Kruskal-Wallis H test (non-parametric distributions). Statistical significance was set at $p < 0.05$.

All statistical procedures were performed on SAS (SA Institute Inc., Carey, NC, USA), release 9.4 running under Microsoft Windows (Microsoft Corp.).

Chapter 4: Results

4.1 Centering Ability after Glide Path Preparation

The values of the mean canal centering ability were compared at 3 mm, 5 mm and 7 mm from the anatomical root apex. Centering ability was measured for each of the three glide path preparation groups. A value/ratio closest to 1 indicates perfect centering ability.

4.1.1 Centering Ratio Values of Glide Path Instruments at 3 mm from the Root Apex

The data collected showed a parametric distribution; thus, ANOVA was used to compare between groups. Figure 4.1 and Table 4.1 depict the mean centering ratio values for the different groups.

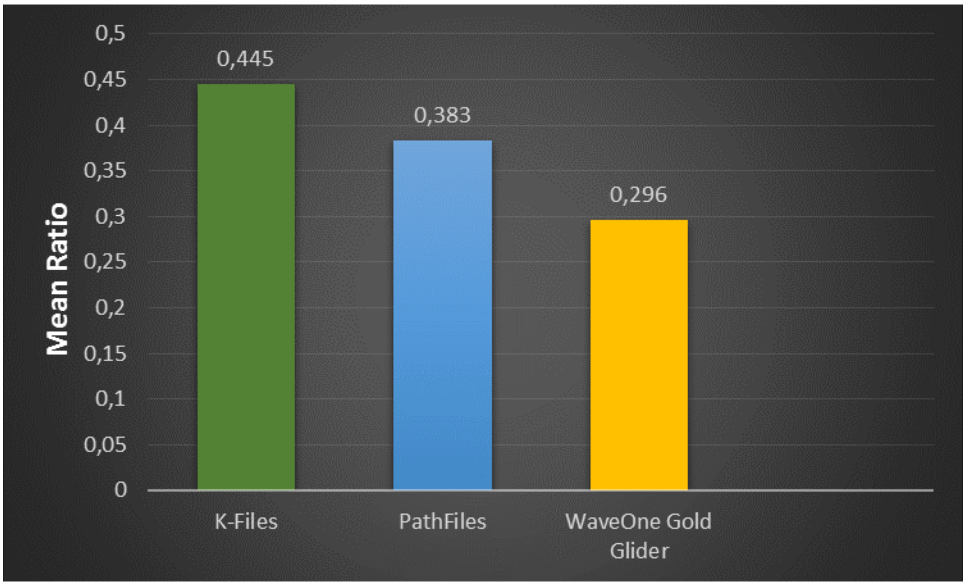

Figure 4.1: Values of mean centering ratio of glide path instruments at 3 mm from the root apex

At 3 mm from the root apex, the best value of the mean centering ratio was observed with K-files (0.45 ± 0.31) followed by PathFiles (0.38 ± 0.35) and then WaveOne Gold Glider (0.30 ± 0.24). There was no statistical significant difference between the mean centering ratio values in any of the glide path preparation groups (p=0.404).

4.1.2 Centering Ratio Values of Glide Path Instruments at 5 mm from the Root Apex

The data collected showed a parametric distribution; thus, ANOVA was used to compare between groups. Figure 4.2 and Table 4.2 depict the values of the mean centering ratio for the different groups.

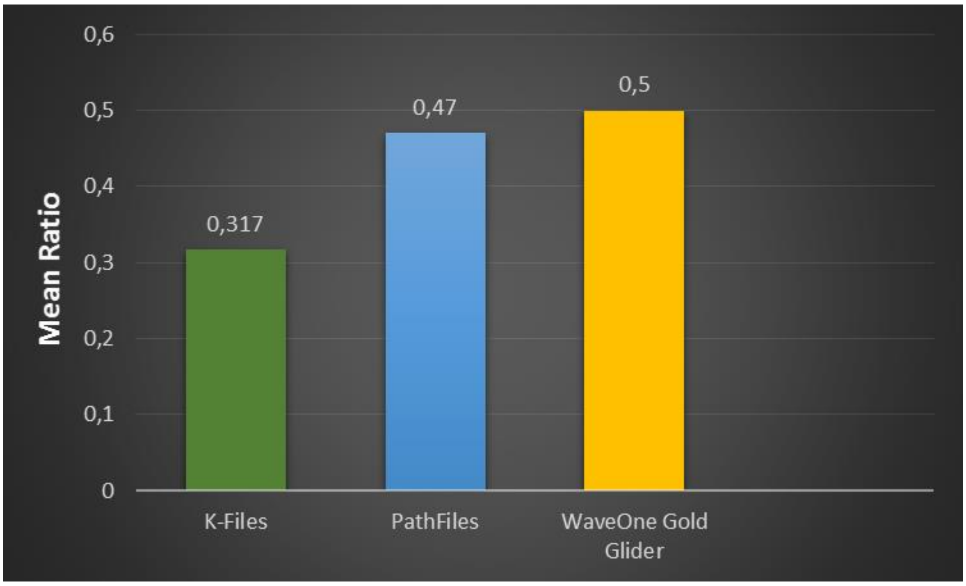

Figure 4.2: Values of mean centering ratio of glide path instruments at 5 mm from the root apex

The best value of the mean centering ratio at 5 mm from the root apex was observed with WaveOne Gold Glider (0.51 ± 0.30) followed by PathFiles (0.47 ± 0.27) and then K-files (0.32 ± 0.20). A statistically significant difference was found in the values stemming from the use of K-files and the WaveOne Gold Glider (p=0.0476). There was no statistically significant difference between the values produced from K-files and PathFiles (p=0.114) or between those produced by PathFiles and the WaveOne Gold Glider (p=0.670).

4.1.3 Centering Ratio Values of Glide Path Instruments at 7 mm from the Root Apex

The data collected showed a parametric distribution; thus, ANOVA was used to compare between groups. Figure 4.3 and Table 4.3 depict the mean centering ratio values for the different groups.

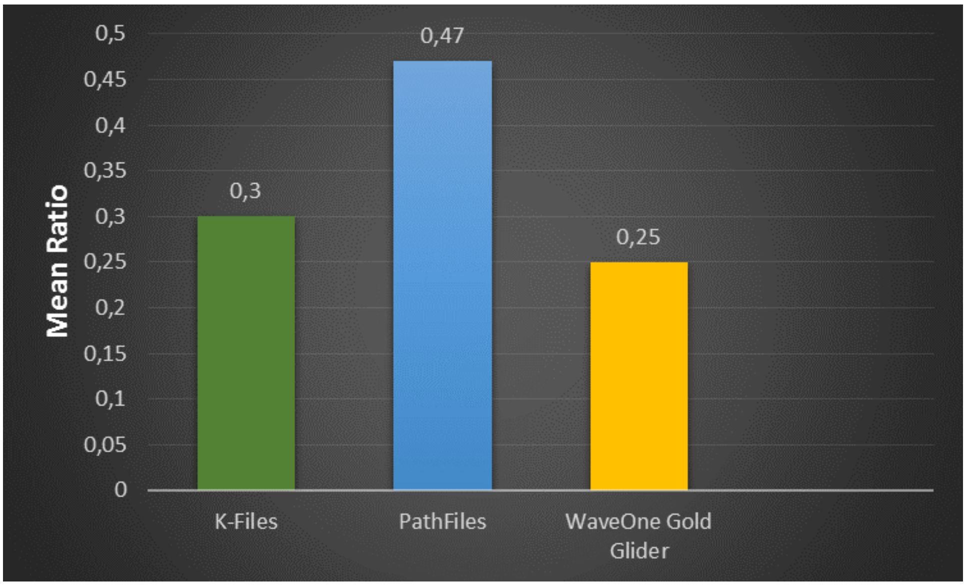

Figure 4.3: Values of mean centering ratio of glide path instruments at 7 mm from the root apex

At 7 mm from the root apex, the best value of the mean centering ratio was observed with PathFiles (0.47 ± 0.37) followed by K-files (0.30 ± 0.24) and then the WaveOne Gold Glider (0.25 ± 0.22). No statistically significant difference was observed between the mean centering ratio values in any of the glide path preparation groups (p=0.11).

4.1.4 Combined Centering Ratio Values of Glide Path Instruments

Figure 4.4 and Tables 4.4 (a and b) depict the combined mean centering ratio values for the different groups. Although PathFiles produced the most centred glide path preparations (0.44 ± 0.32), there was no statistically significant difference between the three glide path groups using both ANOVA and Kruskal-Wallis H tests (p>0.05).

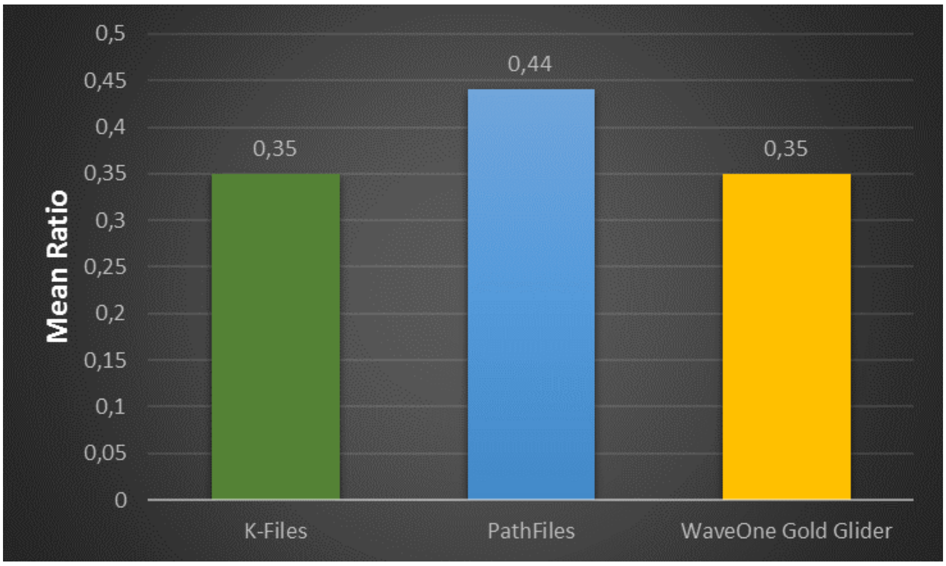

Figure 4.4: Combined mean centering ratio values of glide path instruments

4.2 Canal Transportation after Glide Path Preparation

The mean canal transportation values were compared at 3 mm, 5 mm and 7 mm from the anatomical root apex of the tooth. A transportation value closest to 0 indicates no transportation. The higher the value the greater the transportation.

4.2.1 Transportation Values of Glide Path Instruments at 3 mm from the Root Apex

The data collected showed a parametric distribution; thus, ANOVA was used to compare between groups. Figure 4.5 and Table 4.5 depict the mean transportation values for the different groups.

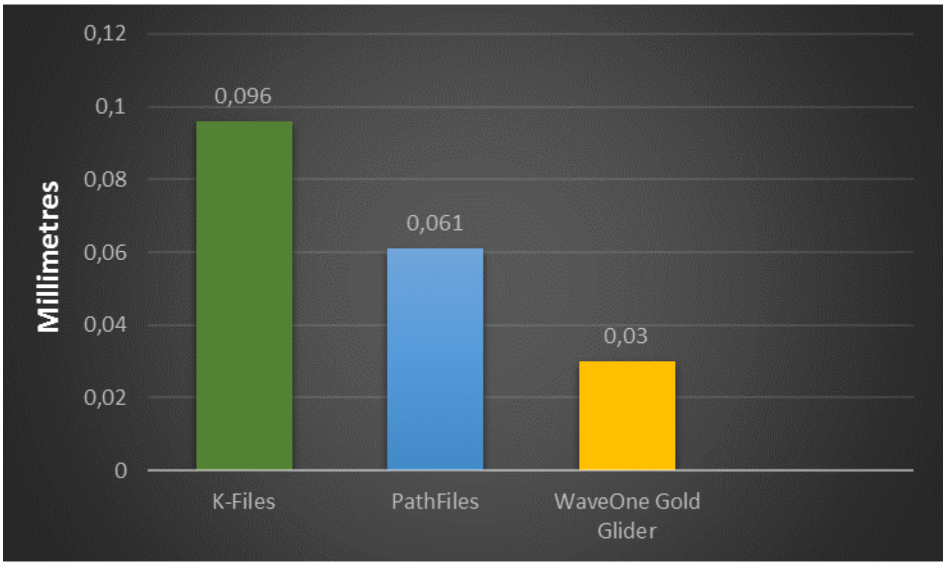

Figure 4.5: Mean transportation values of glide path instruments at 3 mm from the root apex

At 3 mm from the root apex, the lowest transportation value was observed with WaveOne Gold Glider (0.03 ± 0.04 mm) followed by PathFiles (0.06 ± 0.07 mm) and then K-files (0.10 ± 0.07 mm). WaveOne Gold Glider had statistically significant lower transportation values than K-files (p=0.0036). There was no statistically significant difference between the values of the mean transportation ratio between the K-files and PathFiles (p=0.115) nor between the PathFiles and the WaveOne Gold Glider (p=0.147).

4.2.2 Transportation Values of Glide Path Instruments at 5 mm from the Root Apex

The data collected showed a parametric distribution; thus, ANOVA was used to compare between groups. Figure 4.6 and Table 4.6 depict the mean transportation values for the different groups.

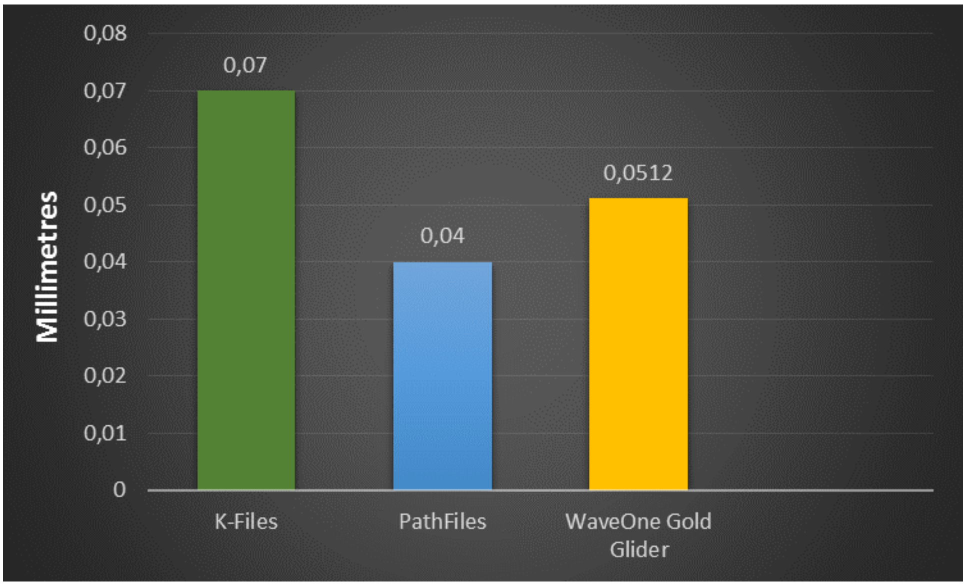

Figure 4.6: Mean transportation values of glide path instruments at 5 mm from the root apex

At 5 mm from the root apex, the lowest transportation value was observed with PathFiles (0.04 ± 0.04 mm) followed by WaveOne Gold Glider (0.05 ± 0.05 mm) and then K-files (0.07 ± 0.07 mm). There was no statistically significant difference in the mean transportation values between any of the glide path preparation groups (p=0.442).

4.2.3 Transportation Values of Glide Path Instruments at 7 mm from the Root Apex

The data collected showed a parametric distribution; thus, ANOVA was used to compare between groups. Figure 4.7 and Table 4.7 depict the mean transportation values for the different groups.

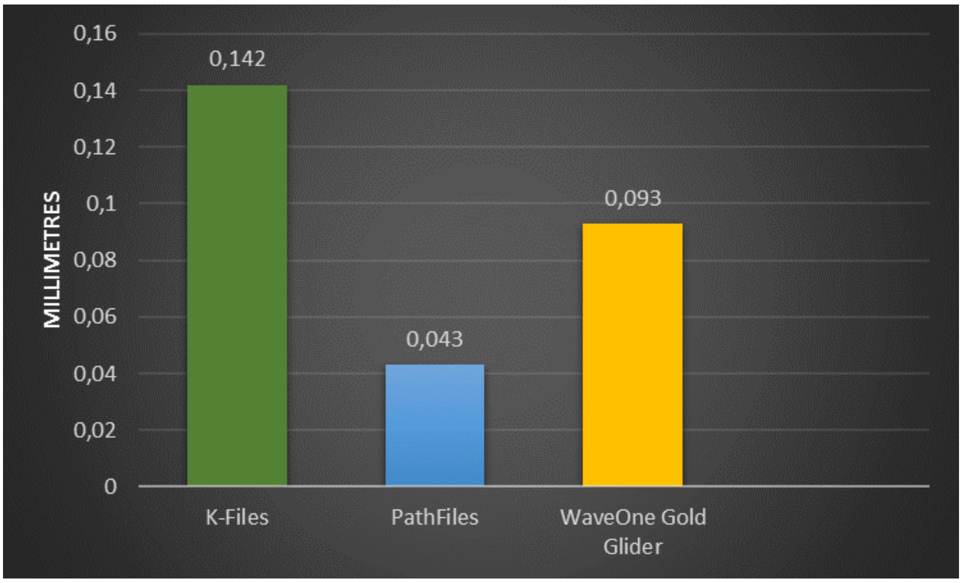

Figure 4.7: Mean transportation values of glide path instruments at 7 mm from the root apex

At 7 mm from the root apex, the lowest mean transportation value was observed with PathFiles (0.04 ± 0.04 mm) then WaveOne Gold Glider (0.09 ± 0.18 mm) then K-files (0.14 ± 0.15 mm). The mean transportation values of the PathFiles were statistically significantly lower than the mean transportation values of the K-files (p=0.0361). No statistically significant difference was observed between the mean transportation values of the WaveOne Gold Glider and the PathFiles (p=0.317) or between the WaveOne Gold Glider and the K-files (p=0.333).

4.2.4 Combined Transportation Values of Glide Path Instruments

Figure 4.8 and Tables 4.8 (a and b) depict the combined mean transportation values for the different groups over 3 mm, 5 mm and 7 mm. No statistically significant difference was found between the mean transportation values of PathFiles (0.05 ± 0.05 mm) and the WaveOne Gold Glider (0.06 ± 0.11 mm) using ANOVA and the Kruskal-Wallis H tests (p>0.05). In contrast, glide path preparation with K-files (0.10 ± 0.11 mm) resulted in statistically significantly more transportation than Pathfiles and the WaveOne Gold Glider (p<0.05).

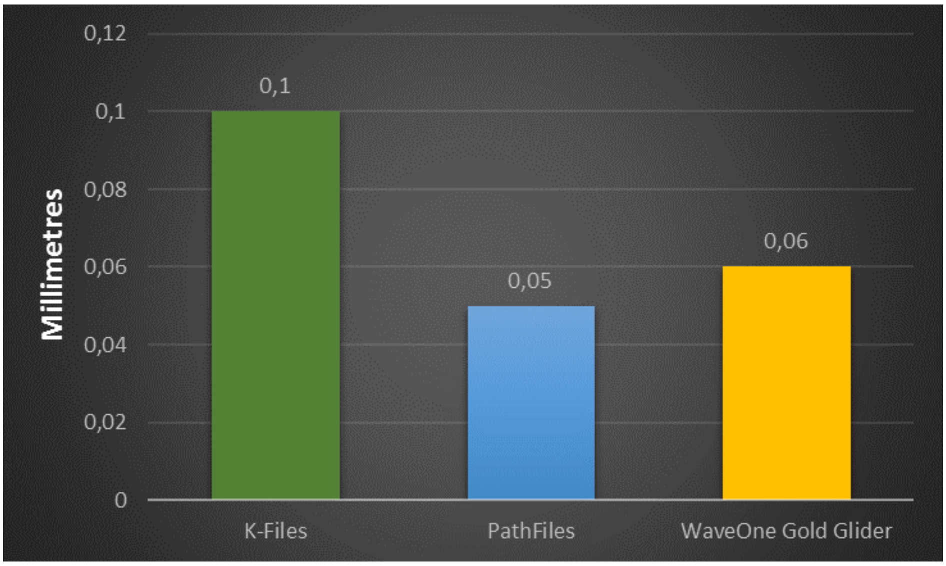

Figure 4.8: Combined mean transportation values of glide path instruments

4.3 Centering Ability of the Primary WaveOne Gold Instrument

The mean canal transportation values were compared at 3 mm, 5 mm and 7 mm from the anatomical root apex of the tooth. The pre-op measurements and measurements after final canal preparation (micro-CT Scan 3) with the Primary WaveOne Gold instrument were used to evaluate centering ability. A value/ratio closest to 1 indicates perfect centering ability.

4.3.1 Centering Ratio Values of the Primary WaveOne Gold Instrument in Combination with Different Glide Path Techniques at 3 mm from the Root Apex

The data collected showed a parametric distribution; thus, ANOVA was used to compare among groups. Figure 4.9 and Table 4.9 depict the mean centering ratio values for the different groups.

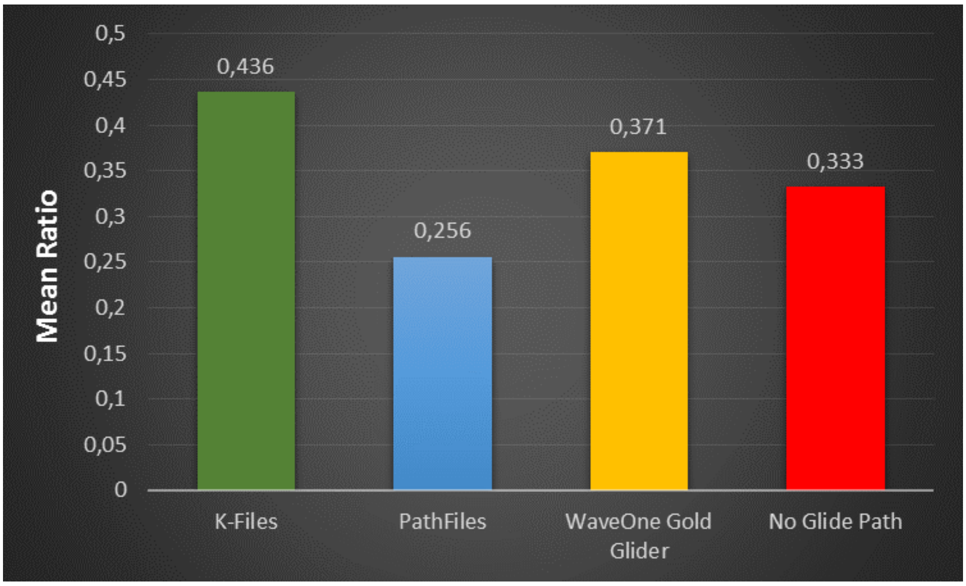

Figure 4.9: Mean centering ratio values of the Primary WaveOne Gold instrument in combination with different glide path instruments at 3 mm from the root apex

At 3 mm from the root apex, the best mean centering ratio value was observed with the Primary WaveOne Gold instrument in combination with K-files (0.44 ± 0.28) followed by the WaveOne Gold Glider (0.37 ± 0.31), then the no glide path group (0.33 ± 0.26), followed by the PathFiles (0.26 ± 0.23). There was no statistically significant difference between the mean centering ratio values between any of the glide path preparation groups (p=0.331).

4.3.2 Centering Ratio Values of the Primary WaveOne Gold Instrument in Combination with Different Glide Path Techniques 5 mm from the Root Apex

The data collected showed a parametric distribution; thus, ANOVA was used to compare between groups. Figure 4.10 and Table 4.10 depict the mean centering ratio values for the different groups.

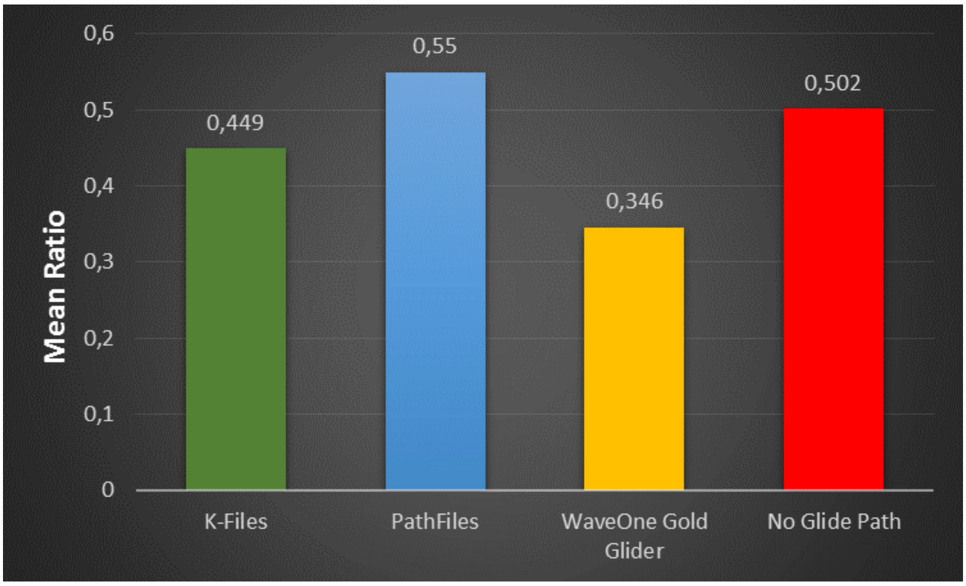

Figure 4.10: Mean centering ratio values of the Primary WaveOne Gold instrument in combination with different glide path instruments at 5 mm from the root apex

At 5 mm from the root apex, the best mean centering ratio value was observed with the Primary WaveOne Gold instrument in combination with PathFiles (0.55 ± 0.28) followed by the no glide path group (0.50 ± 0.30) then the K-files (0.45 ± 0.27) and then the WaveOne Gold Glider (0.35 ± 0.25). PathFiles performed statistically significantly better than the WaveOne Gold Glider group at 5 mm (p=0.0475). There was no statistically significantly difference in the mean centering ratio values between any of the other glide path preparation groups in combination with the Primary WaveOne Gold file (p=0.2219).

4.3.3 Centering Ratio Values of the Primary WaveOne Gold Instrument in Combination with Different Glide Path Techniques 7 mm from the Root Apex

The data collected showed a parametric distribution; thus, ANOVA was used to compare between groups. Figure 4.11 and Table 4.11 depict the mean centering ratio values for the different groups.

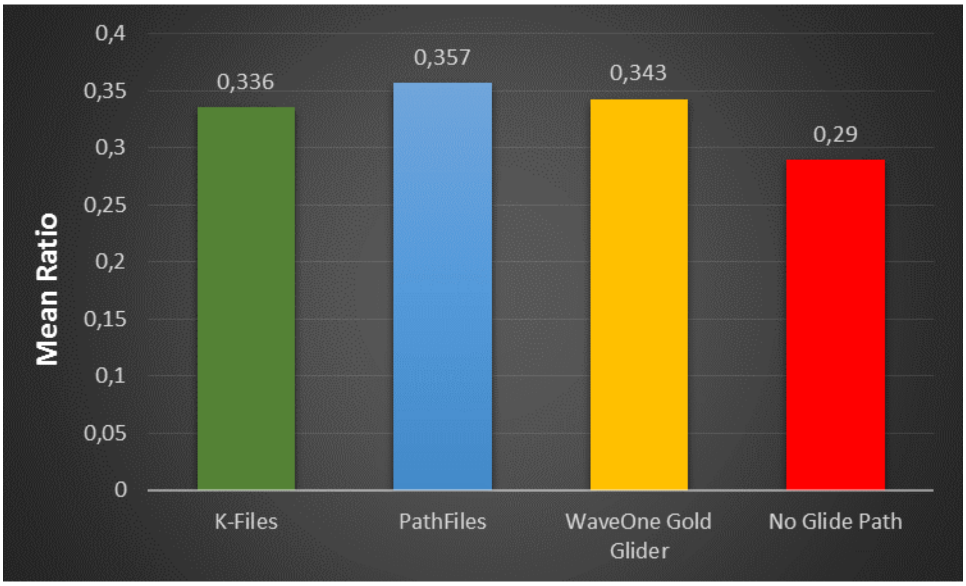

Figure 4.11: Mean centering ratio values of the Primary WaveOne Gold instrument in combination with different glide path techniques at 7 mm from the root apex

At 7 mm from the root apex, the best mean centering ratio value was observed with the Primary WaveOne Gold instrument in combination with PathFiles (0.36 ± 0.28) followed by the WaveOne Gold Glider (0.34 ± 0.25), then the K-files (0.34 ± 0.29), and then the no glide path group (0.29 ± 0.25). There was no statistically significant difference in the mean centering ratio values between any of the glide path preparation groups in combination with the Primary WaveOne Gold instrument (p=0.912).

4.3.4 Combined Centering Ratio Values of the Primary WaveOne Gold Instrument in Combination with Different Glide Path Techniques

Figure 4.12 and Tables 4.12 (a and b) depict the combined mean centering ratio values for the different glide path groups in combination with the Primary WaveOne Gold instrument. Although K-files produced the most centred glide path preparations (0.41 ± 0.28), there was no statistically significant difference between the three glide path groups using both ANOVA and Kruskal-Wallis H tests (p>0.05).

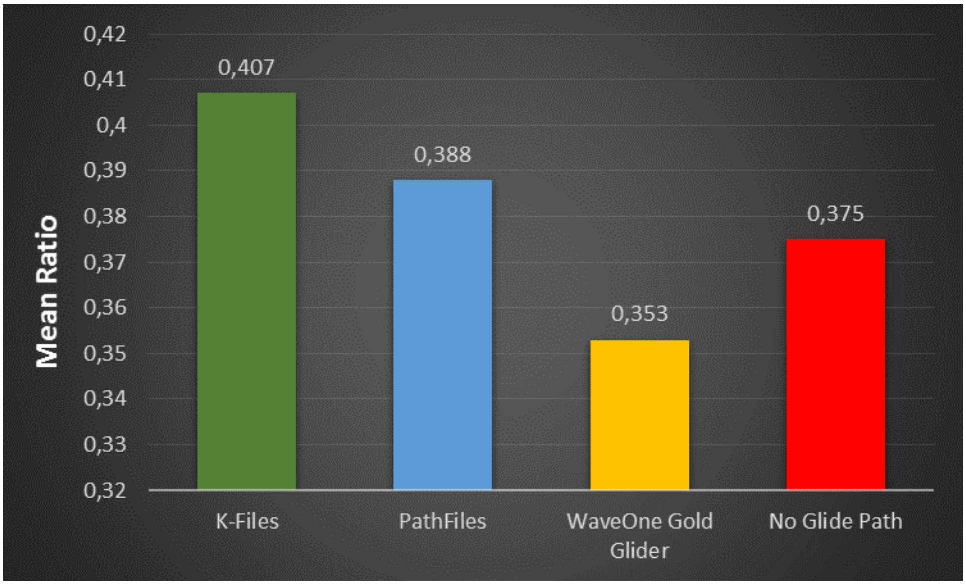

Figure 4.12: Combined mean centering ratio values of glide path techniques in combination with the Primary WaveOne Gold instrument

4.4 Canal Transportation after Canal Preparation with the Primary WaveOne Gold Instrument

The mean canal transportation values were compared at 3 mm, 5 mm and 7 mm from the anatomical root apex of the tooth. A transportation value closest to 0 indicates no transportation. The higher the value the greater the transportation. The pre-op measurements and measurements after final canal preparation (micro-CT Scan 3) with the Primary WaveOne Gold instrument were used to evaluate transportation.

4.4.1 Transportation Values of the Primary WaveOne Gold Instrument in Combination with Different Glide Path Techniques 3 mm from the Root Apex

The data collected showed a parametric distribution; thus, ANOVA was used to compare between groups. Figure 4.13 and Table 4.13 depict the mean centering ratio values for the different groups.

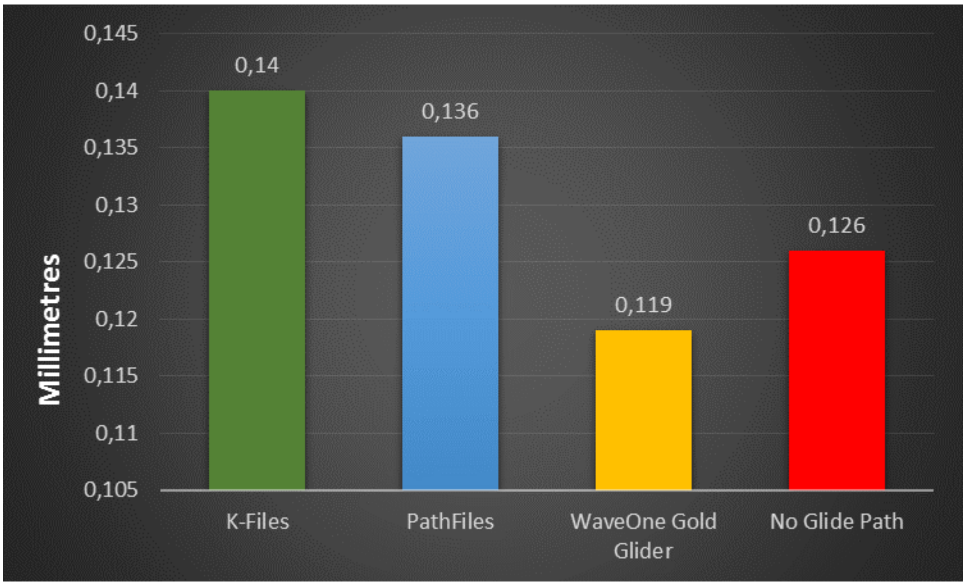

Figure 4.13: Mean transportation values of the Primary WaveOne Gold instrument in combination with different glide path techniques at 3 mm from the root apex

At 3 mm from the root apex, the lowest mean transportation value was observed with the Primary WaveOne Gold instrument in combination with the WaveOne Gold Gllider (0.12 ± 0.07 mm), followed by the no glide path group (0.13 ± 0.08 mm), then the PathFiles (0.14 ± 0.13 mm), and then the K-files (0.14 ± 0.09 mm). There was no statistically significant difference in the mean transportation values between any of the glide path preparation groups (p=0.928).

4.4.2 Transportation Values of the Primary WaveOne Gold Instrument in Combination with Different Glide Path Techniques 5 mm from the Root Apex

The data collected showed a parametric distribution; thus, ANOVA was used to compare between groups. Figure 4.14 and Table 4.14 depicts the mean centering ratio values for the different groups.

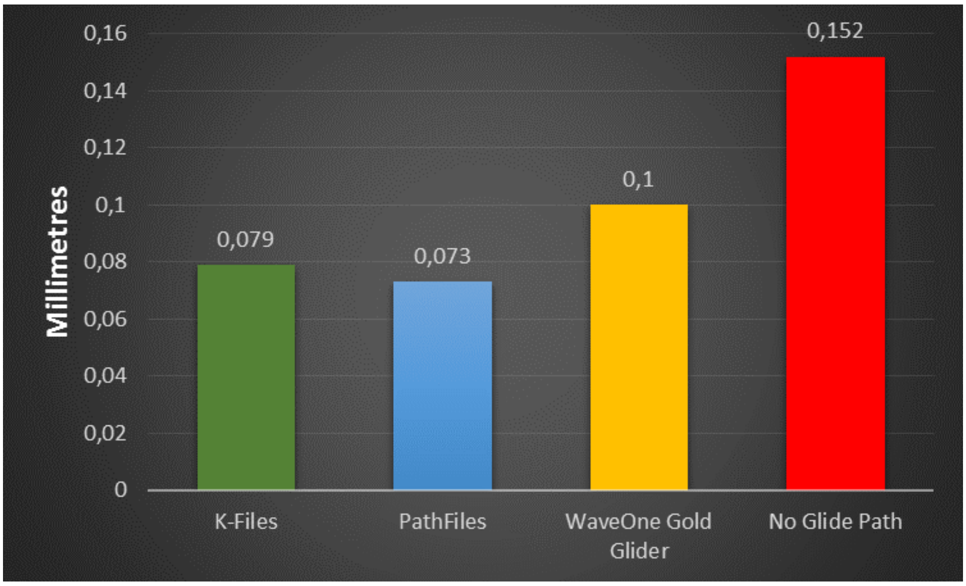

Figure 4.14: Mean transportation values of the Primary WaveOne Gold instrument in combination with different glide path techniques at 5 mm from the root apex

At 5 mm from the root apex, the lowest mean transportation value was observed with the Primary WaveOne Gold instrument in combination with PathFiles (0.73 ± 0.05 mm), followed by K-files (0.08 ± 0.07 mm), then the WaveOne Gold Glider (0.10 ± 0.07 mm), and then the no glide path group (0.15 ± 0.16 mm). PathFiles transported statistically significantly less than the no glide path group (p=0.035). K-files also transported significantly less than the no glide path group (p=0.048). No statistically significant difference was found in the mean transportation values between the remaining glide path groups (p=0.1317).

4.4.3 Transportation Values of the Primary WaveOne Gold Instrument in Combination with Different Glide Path Techniques 7 mm from the Root Apex

The data collected showed a parametric distribution; thus, ANOVA was used to compare between groups. Figure 4.15 and Table 4.15 depict the mean transportation values for the different groups.

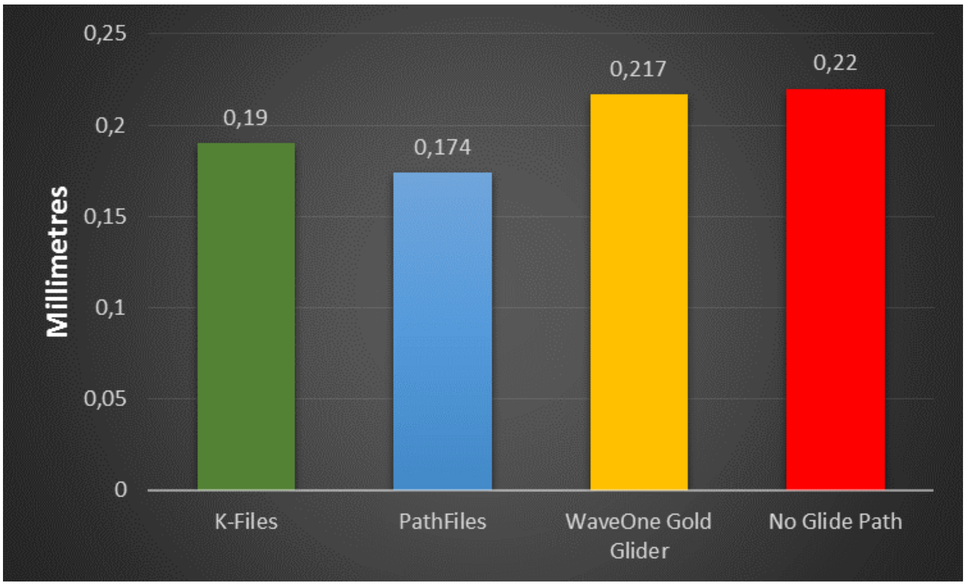

Figure 4.15: Mean transportation values of the Primary WaveOne Gold instrument in combination with different glide path techniques at 7 mm from the root apex

At 7 mm from the root apex, the lowest mean transportation value was observed with the Primary WaveOne Gold instrument in combination with PathFiles (0.17 ± 0.12 mm), followed by K-files (0.19 ± 0.18 mm), then the WaveOne Gold Glider (0.22 ± 0.19 mm), and then the no glide path group (0.22 ± 0.11 mm). There was no statistically significant difference in the mean transportation values between any of the glide path preparation groups (p=0.830).

4.4.4 Combined Transportation Values of the Primary WaveOne Gold Instrument in Combination with Different Glide Path Techniques

Figure 4.16 and Tables 4.16 (a and b) depict the combined mean transportation values for the different glide path groups in combination with the Primary WaveOne Gold instrument.

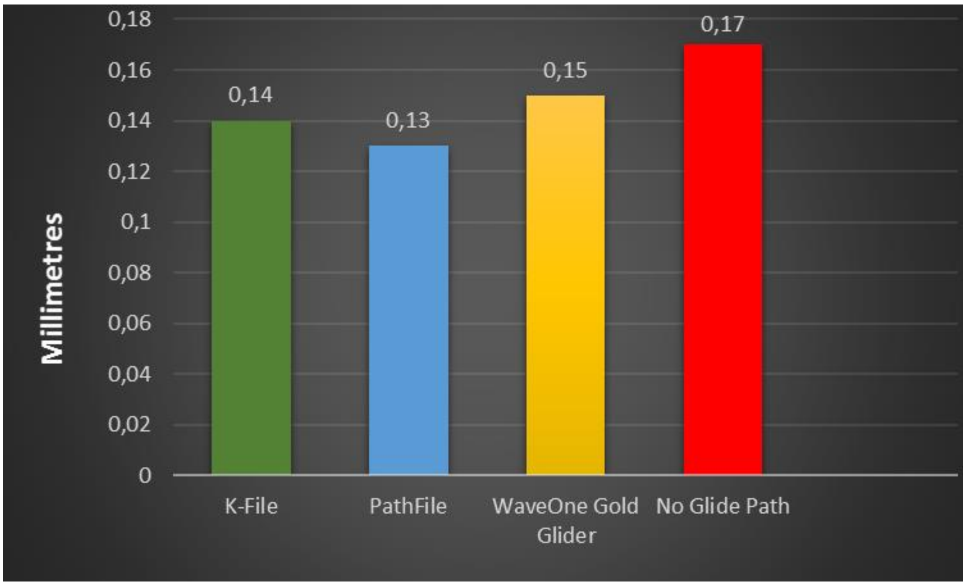

Figure 4.16: Combined mean transportation values of the Primary WaveOne Gold instrument in combination with different glide path techniques

The group for which no glide paths were prepared prior to canal preparation resulted in the highest mean transportation value (0.17 ± 0.13 mm). However, no statistically significant difference appeared in the transportation values between the different glide path groups in combination with the Primary WaveOne Gold instrument using both ANOVA and Kruskal-Wallis H tests ($p>0.05$).

4.5 Remaining Dentine Thickness after Canal Preparation with the Primary WaveOne Gold File at 3 mm, 5 mm and 7 mm from the Root Apex

At 3 mm, 5 mm and 7 mm from the anatomical root apex the amount of remaining dentine thickness after final preparation with the Primary WaveOne Gold instrument in combination with the four different glide path techniques was measured and compared.

The area where the dentine was the thinnest at each of the three levels was measured after instrumentation. The data collected showed a parametric distribution; thus, ANOVA was used to compare between groups.

Figure 4.17 and Table 4.17 (a,b,c) show the amount of remaining dentine (mm) after final preparation with the Primary WaveOne Gold instrument.

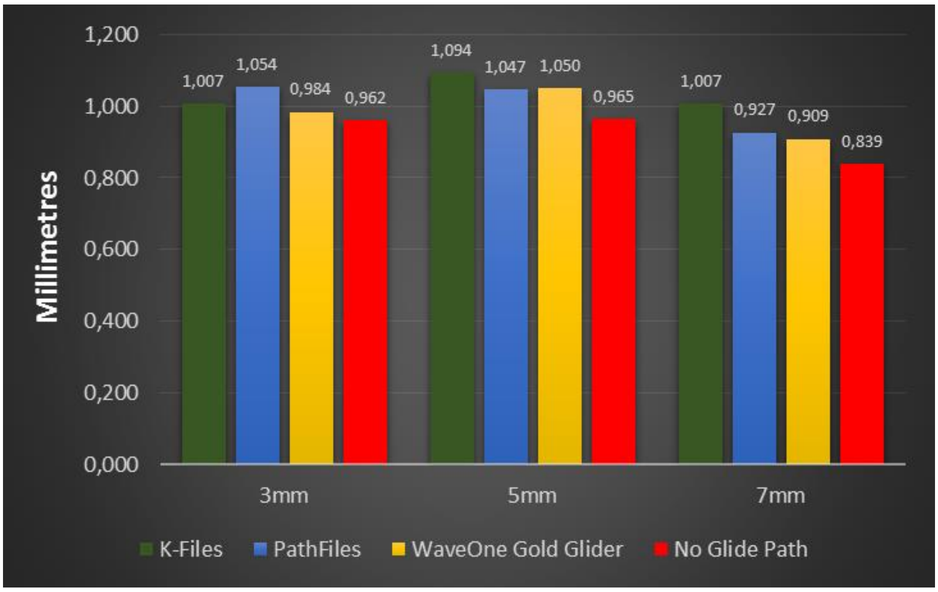

Figure 4.17: Remaining dentine thickness after final preparation with the Primary WaveOne Gold instrument

At 3 mm, 5 mm and 7 mm from the root apex there were no statistically significant differences between the amount of remaining dentine thickness after final preparation with the Primary WaveOne Gold Instrument in combination with the four different glide path techniques (p>0.05).

Figure 4.18 and Table 4.18 show the mean combined remaining dentine thickness after preparation with the Primary WaveOne Gold instrument in combination with four different glide path techniques.

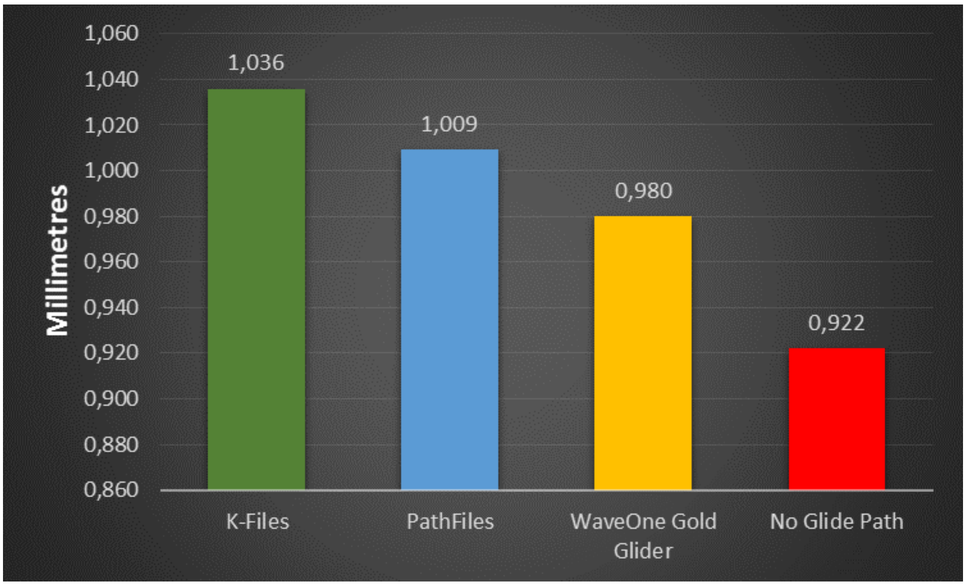

Figure 4.18: Mean combined remaining dentine thickness values after final preparation with the Primary WaveOne Gold instrument in combination with different glide path preparation techniques

No statistically significant difference was found in the mean combined remaining dentine thickness between the four different glide path techniques in combination with the Primary WaveOne Gold instrument (p=0.3220). Although not statistically significant, not having a glide path prior to final instrumentation with the Primary WaveOne Gold instrument resulted in the least dentine preservation at all three levels. The group for which no glide path was prepared also had the lowest minimum (0.78 mm) and maximum (1.26 mm) values of remaining dentine thickness.

4.6 Preparation Times

Glide path preparation times and final canal preparation times with the Primary WaveOne Gold instrument in combination with each glide path preparation group were recorded in this study. The time it took to change between instruments was not included in the total preparation time.

4.6.1 Glide Path Preparation Times

The data collected showed a parametric distribution; thus, ANOVA was used to compare between groups. Mean preparation times and standard deviation values for all three glide path preparation groups are shown in Figure 4.19 and Table 4.19.

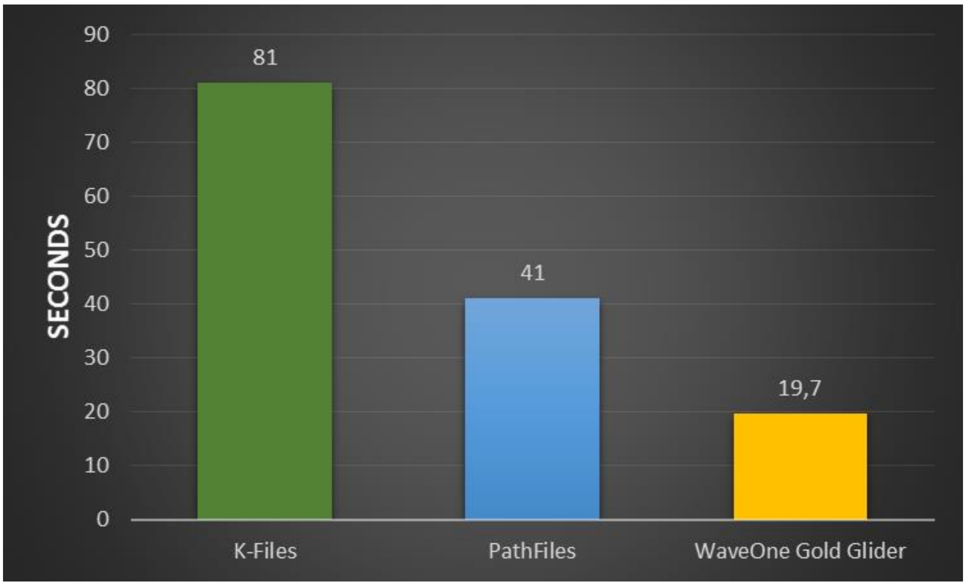

Figure 4.19: Glide path preparation time for the three different groups

Glide path preparation times were statistically significantly different when all three path preparation groups were compared ($p<0.0001$). Glide path preparation was the fastest with the WaveOne Gold Glider (19.73 ± 5.62 s), followed by PathFiles (40.97 ± 6.84 s) and then K-files (81.20 ± 26.32 s).

4.6.2 Final Canal Preparation Times with the Primary WaveOne Gold Instrument in Combination with different Glide Path Techniques

Mean final canal preparation times and standard deviation values for all the glide path groups in combination with the Primary WaveOne Gold instrument are shown in Figure 4.20 and Table 4.20.

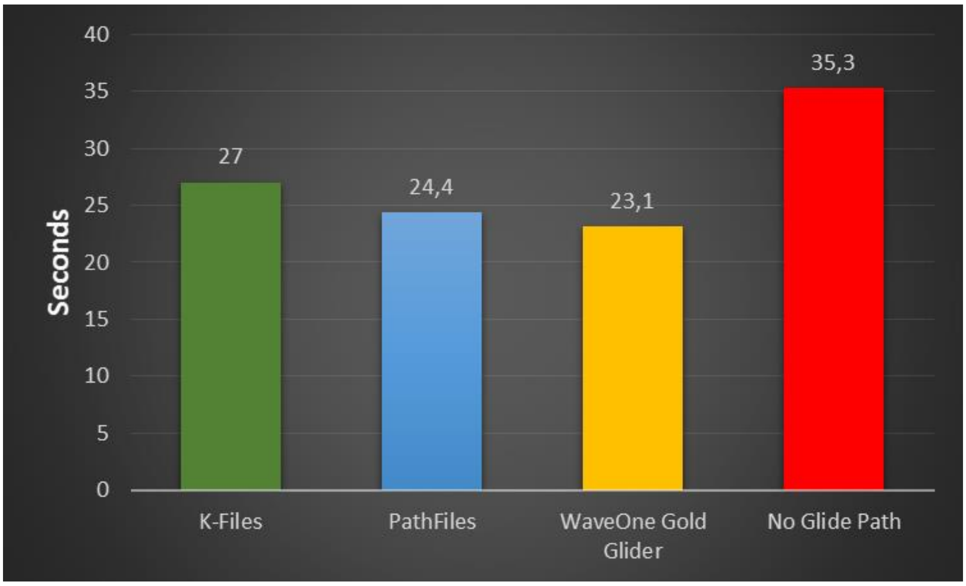

Figure 4.20: Mean final canal preparation time of the Primary WaveOne Gold file in combination with different glide path preparation techniques

Final canal preparation with the Primary WaveOne Gold instrument was the fastest with the WaveOne Gold Glider (23.13 ± 6.03 s), followed by PathFiles (24.40 ± 4.94 s) then K-files (27.00 ± 9.53 s). The preparation were slowest with the no glide path group (35.27 ± 10.16 s). There was no statistically significant difference between the canal preparation times with the Primary WaveOne Gold instrument in combination with the WaveOne Gold Glider, PathFiles or the K-files. However, all of these glide path preparation groups were statistically significantly faster than the no glide path group (p=0.0004).

4.7 Representative Micro-CT Images Displaying Canal Changes before Glide Path, after Glide Path and after Final Canal Preparation with the Primary WaveOne Gold Instrument

The representative sample images below depict the typical axial canal changes after glide path preparation and after final canal preparation with the Primary WaveOne Gold instrument in combination with the four different glide path groups.

In every representative figure the *black* outline represents the original canal shape. (a) Shows the effect of glide path preparation in *yellow*; (b) the effect of root canal preparation with the Primary WaveOne Gold instrument with or without glide path preparation in *red*; and (c) superimposition of the original canal, the effect of glide path preparation followed by root canal preparation.

Pre-instrumented canal

Effect of glide path preparation

Effect of the Primary WaveOne Gold instrument with or without glide path preparation

4.7.1 **K-files** at 3 mm, 5 mm and 7 mm from the Root Apex

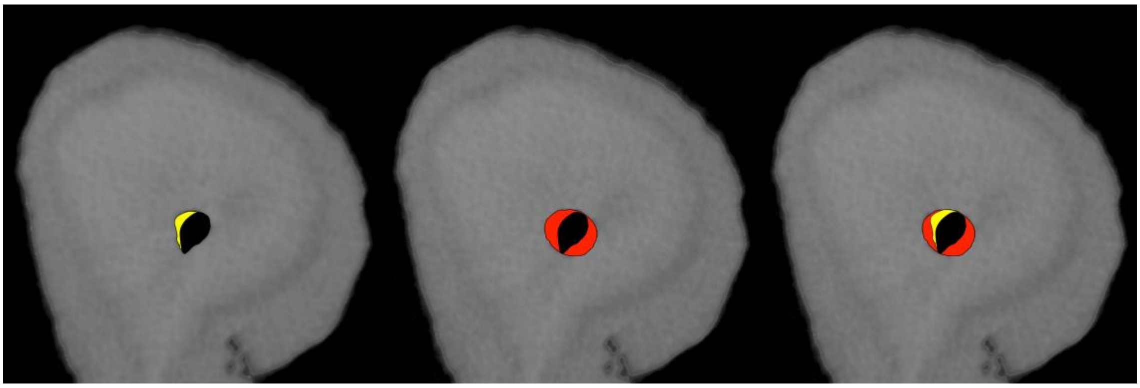

Figure 4.21(a): A representative micro-CT image from the K-file group at the 3 mm level from the root apex

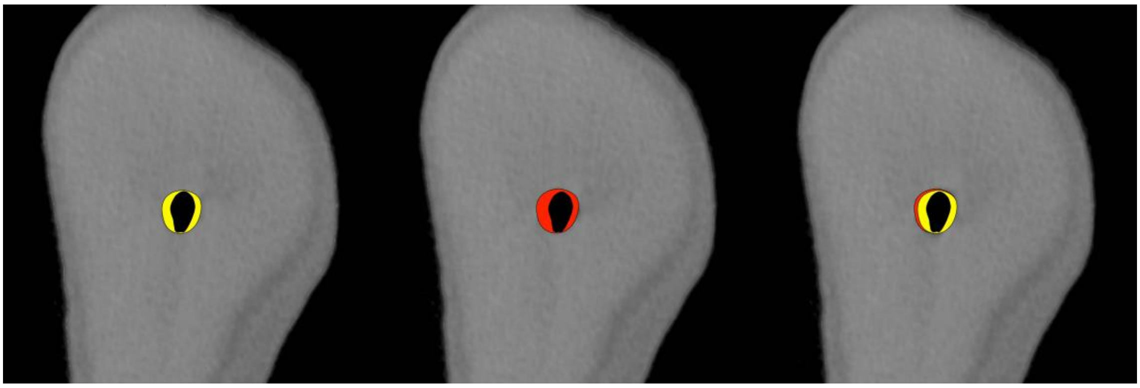

Figure 4.21(b): A representative micro-CT image from the K-file group at the 5 mm level from the root apex

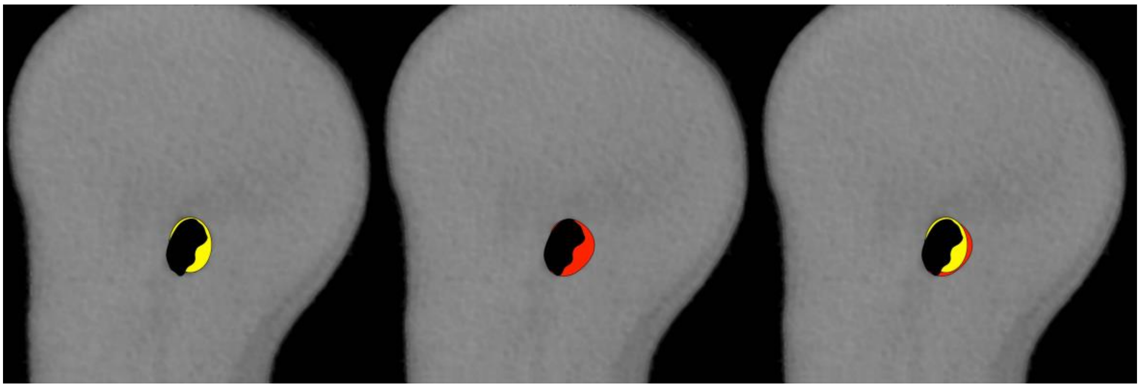

Figure 4.21(c): A representative micro-CT image from the K-file group at the 7 mm level from the root apex

4.7.2 **PathFiles** at 3 mm, 5 mm and 7 mm from the Root Apex

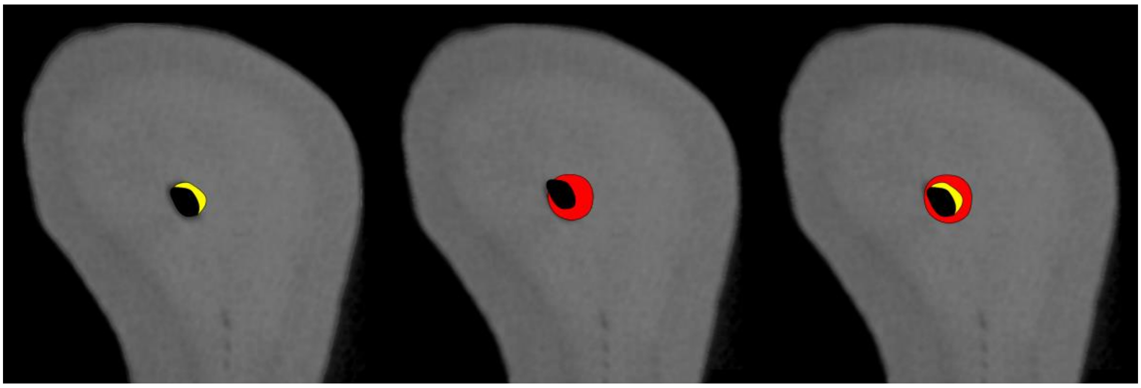

Figure 4.22(a): A representative micro-CT image from the PathFile group at the 3 mm level from the root apex

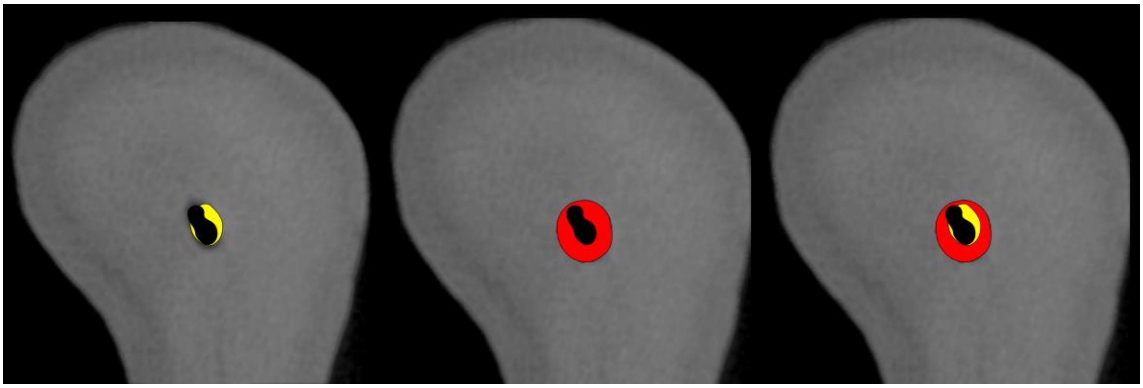

Figure 4.22(b): A representative micro-CT image from the PathFile group at the 5 mm level from the root apex

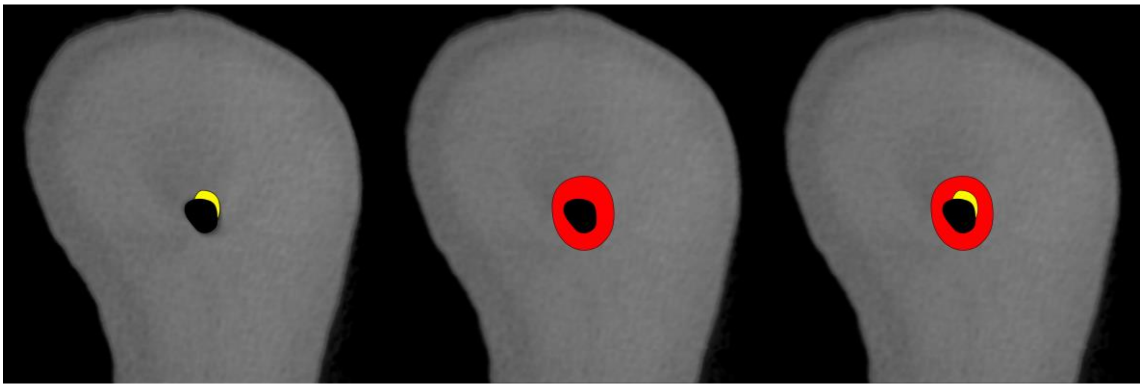

Figure 4.22(c): A representative micro-CT image from the PathFile group at 7 mm level from the root apex

4.7.3 <u>**WaveOne Gold Glider** at 3 mm, 5 mm and 7 mm from the Root Apex</u>

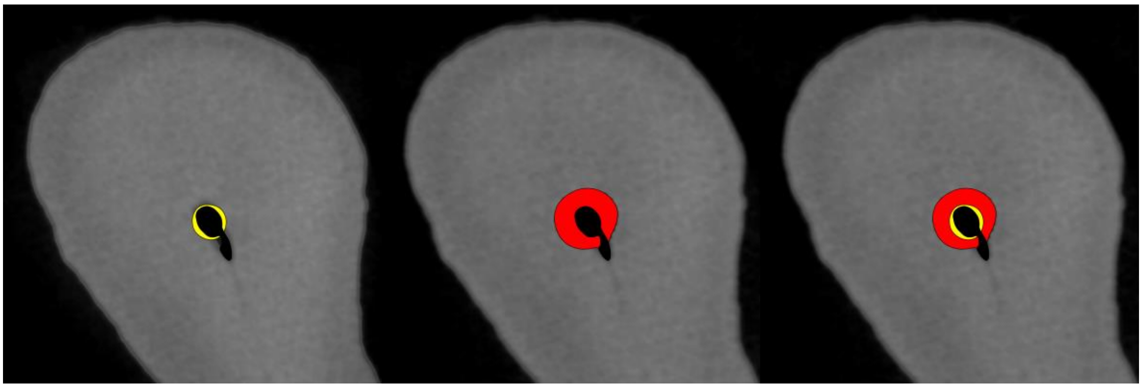

Figure 4.23 (a): A representative micro-CT image from the WaveOne Gold Glider group at the 3 mm level from the root apex

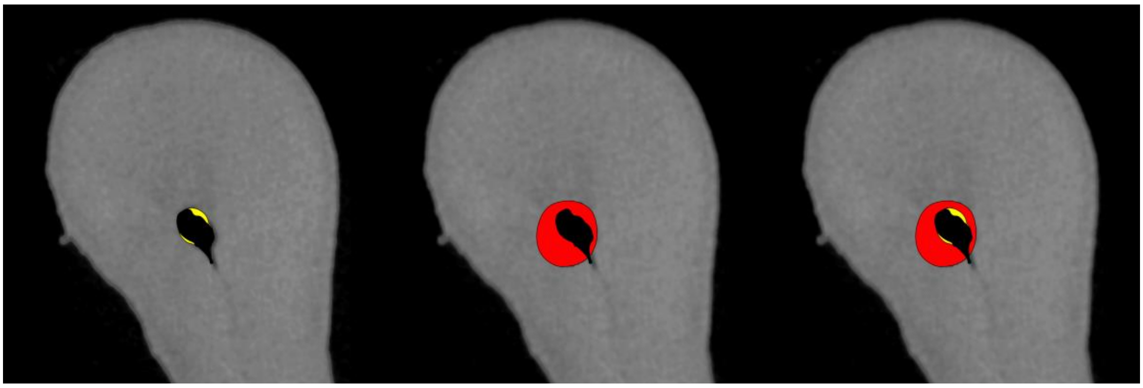

Figure 4.23 (b): A representative micro-CT image from the WaveOne Gold Glider group at the 5 mm level from the root apex

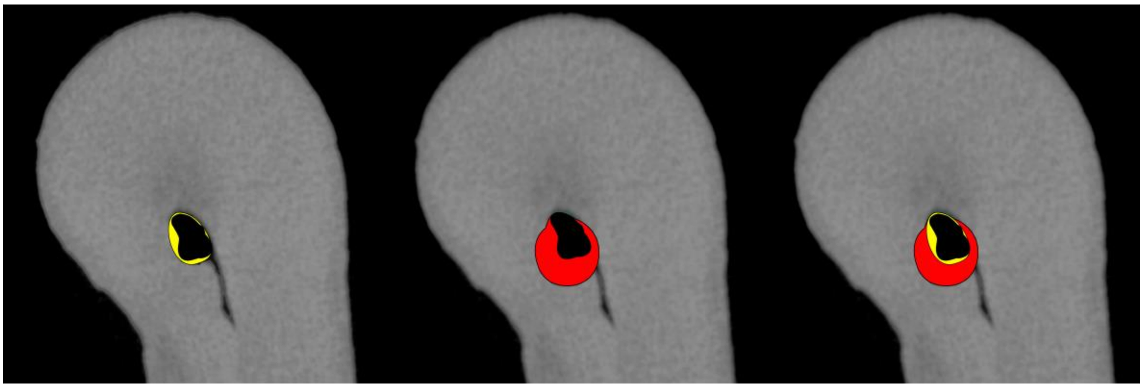

Figure 4.23 (c): A representative micro-CT image from the WaveOne Gold Glider group at the 7 mm level from the root apex

4.7.4 **No Glide Path** Group at 3 mm, 5 mm and 7 mm from the Root Apex

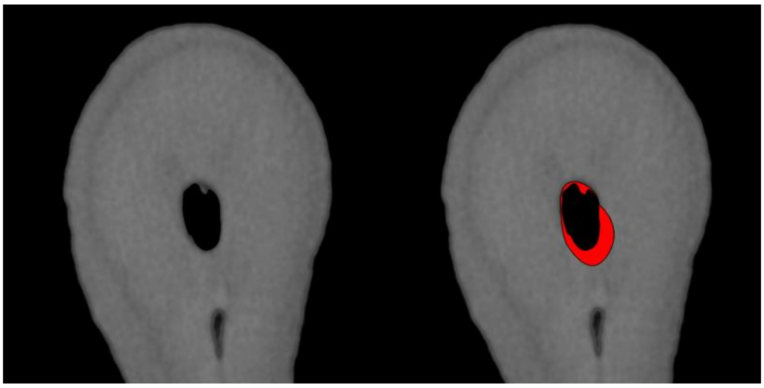

Figure 4.24 (a): A representative micro-CT image from the no glide path group at the 3 mm level from the root apex

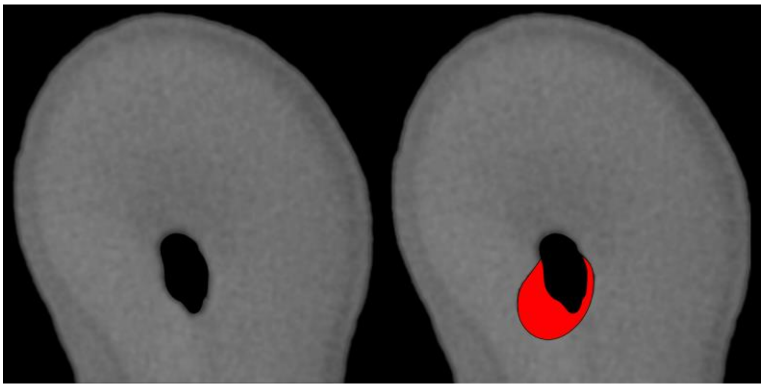

Figure 4.24 (b): A representative micro-CT image from the no glide path group at the 5 mm level from the root apex

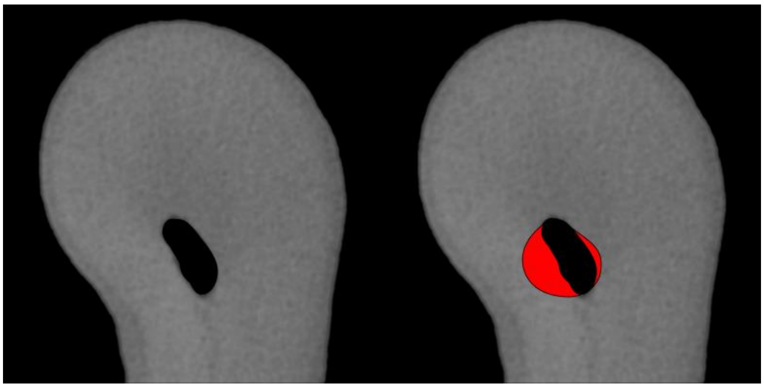

Figure 4.24 (c): A representative micro-CT image from the no glide path group at the 7 mm level from the root apex

4.8 A Set of Representative 3D Micro-CT Images of a Specimen where the Glide Path Preparation was done with PathFiles before Root Canal Preparation with the Primary WaveOne Gold Instrument

Figure 4.25 depict representative 3D micro-CT images of a mandibular first molar tooth. The pre-operative uninstrumented canal volume of the mesio-buccal root canal is shown in *red (a)*; the canal volume after glide path preparation with PathFiles in *yellow* (b); and (c) the canal volume after root canal preparation with the Primary WaveOne Gold instrument in *green.*

A **B** **C**

Figure 4.25: A representative sample of a 3D Image of: (a) pre-instrumented canal; (b) glide path preparation with PathFiles; (c) final canal preparation with the Primary WaveOne Gold instrument

Table 4.1: Descriptive statistics: Mean centering ratio values of glide path instruments at 3 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	0.45[a]	0.31	0.01	0.97
PathFiles	15	0.38[a]	0.35	0.00	0.99
WaveOne Gold Glider	15	0.30[a]	0.24	0.00	0.75

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.2: Descriptive statistics: Mean centering ratio values of glide path instruments at 5 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	0.32[a]	0.20	0.07	0.77
PathFiles	15	0.47[ab]	0.27	0.00	0.89
WaveOne Gold Glider	15	0.51[b]	0.30	0.10	1.00

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.3: Descriptive statistics: Mean centering ratio values of glide path instruments at 7 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	0.30[a]	0.27	0.01	0.91
PathFiles	15	0.47[a]	0.37	0.00	1.00
WaveOne Gold Glider	15	0.25[a]	0.23	0.00	0.71

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.4(a): Descriptive statistics: Combined mean centering ratio values of glide path instruments

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	45	0.35[a]	0.26	0.01	0.97
PathFiles	45	0.44[a]	0.32	0.00	1.00
WaveOne Gold Glider	45	0.35[a]	0.27	0.00	1.00

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.4(b): Descriptive statistics: Combined median centering ratio values of glide path instruments

Preparation method	Number	Median	Standard deviation	Lower quartile	Upper quartile
K-files	45	0.29[a]	0.26	0.17	0.54
PathFiles	45	0.45[a]	0.32	0.16	0.76
WaveOne Gold Glider	45	0.33[a]	0.27	0.15	0.50

Median values with the same superscript letters were not statistically different at $p<0.05$

Table 4.5: Descriptive statistics: Mean transportation values of glide path instruments at 3 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	0.10[a]	0.07	0.00	0.22
PathFiles	15	0.06[ab]	0.07	0.00	0.27
WaveOne Gold Glider	15	0.03[b]	0.04	0.00	0.14

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.6: Descriptive statistics: Mean transportation values of glide path instruments at 5 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	0.07[a]	0.07	0.01	0.23
PathFiles	15	0.04[a]	0.04	0.00	0.16
WaveOne Gold Glider	15	0.05[a]	0.05	0.00	0.19

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.7: Descriptive statistics: Mean transportation values of glide path instruments at 7 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	0.14[a]	0.15	0.01	0.59
PathFiles	15	0.04[b]	0.04	0.00	0.12
WaveOne Gold Glider	15	0.09[ab]	0.18	0.01	0.73

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.8(a): Descriptive statistics: Combined mean transportation values of glide path instruments

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	45	0.10[b]	0.11	0.00	0.59
PathFiles	45	0.048[a]	0.05	0.00	0.27
WaveOne Gold Glider	45	0.059[a]	0.11	0.00	0.73

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.8(b): Descriptive statistics: Combined median transportation values of glide path instruments

Preparation method	Number	Median	Standard deviation	Lower quartile	Upper quartile
K-files	45	0.08[b]	0.11	0.03	0.15
PathFiles	45	0.04[a]	0.05	0.01	0.06
WaveOne Gold Glider	45	0.03[a]	0.11	0.02	0.06

Median values with the same superscript letters were not statistically different at $p<0.05$

Table 4.9: Descriptive statistics: Mean centering ratio values of the Primary WaveOne Gold Instrument in combination with different glide path techniques at 3 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	0.44^{a}	0.28	0.03	0.92
PathFiles	15	0.26^{a}	0.23	0.01	0.76
WaveOne Gold Glider	15	0.37^{a}	0.31	0.00	1.00
No glide path	15	0.33^{a}	0.26	0.00	0.76

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.10: Descriptive statistics: Mean centering ratio values of the Primary WaveOne Gold instrument in combination with different glide path techniques at 5 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	0.45^{ab}	0.27	0.13	0.97
PathFiles	15	0.55^{a}	0.28	0.05	0.96
WaveOne Gold Glider	15	0.35^{b}	0.25	0.00	0.84
No glide path	15	0.50^{ab}	0.30	0.14	1.00

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.11: Descriptive statistics: Mean centering ratio values of the Primary WaveOne Gold instrument in combination with different glide path techniques at 7 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	0.34[a]	0.29	0.00	0.87
PathFiles	15	0.36[a]	0.28	0.10	0.97
WaveOne Gold Glider	15	0.34[a]	0.25	0.07	0.87
No glide path	15	0.29[a]	0.25	0.05	0.83

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.12(a): Descriptive statistics: Combined mean centering ratio values of glide path techniques in combination with the Primary WaveOne Gold instrument

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	45	0.41[a]	0.28	0.00	0.97
PathFiles	45	0.39[a]	0.29	0.01	0.97
WaveOne Gold Glider	45	0.35[a]	0.26	0.00	1.00
No glide path	45	0.38[a]	0.28	0.00	1.00

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.12(b): Descriptive statistics: Combined median centering ratio values of glide path techniques in combination with the Primary WaveOne Gold instrument

Preparation method	Number	Median	Standard deviation	Lower quartile	Upper quartile
K-files	45	0.34[a]	0.28	0.19	0.63
PathFiles	45	0.34[a]	0.29	0.19	0.62
WaveOne Gold Glider	45	0.28[a]	0.26	0.17	0.50
No glide path	45	0.27[a]	0.28	0.14	0.61

Median values with the same superscript letters were not statistically different at $p<0.05$

Table 4.13: Descriptive statistics: Mean transportation values of the Primary WaveOne Gold instrument in combination with different glide path techniques at 3 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	0.14[a]	0.09	0.01	0.27
PathFiles	15	0.14[a]	0.13	0.03	0.56
WaveOne Gold Glider	15	0.12[a]	0.07	0.02	0.25
No glide path	15	0.13[a]	0.08	0.03	0.33

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.14: Descriptive statistics: Mean transportation values of the Primary WaveOne Gold instrument in combination with different glide path techniques at 5 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	0.08[a]	0.07	0.00	0.21
PathFiles	15	0.07[a]	0.05	0.00	0.16
WaveOne Gold Glider	15	0.10[a]	0.07	0.01	0.26
No glide path	15	0.15[a]	0.16	0.01	0.64

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.15: Descriptive statistics: Mean transportation values of the Primary WaveOne Gold instrument in combination with different glide path techniques at 7 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	0.19[a]	0.18	0.00	0.66
PathFiles	15	0.17[a]	0.12	0.01	0.42
WaveOne Gold Glider	15	0.22[a]	0.19	0.06	0.87
No glide path	15	0.22[a]	0.11	0.01	0.42

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.16(a): Descriptive statistics: Combined mean transportation values of the Primary WaveOne Gold instrument in combination with different glide path techniques

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	45	0.14[a]	0.13	0.00	0.66
PathFiles	45	0.13[a]	0.11	0.00	0.56
WaveOne Gold Glider	45	0.15[a]	0.13	0.01	0.87
No glide path	45	0.17[a]	0.13	0.01	0.64

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.16(b): Descriptive statistics: Combined median transportation values of the Primary WaveOne Gold instrument in combination with different glide path techniques

Preparation method	Number	Median	Standard deviation	Lower quartile	Upper quartile
K-files	45	0.10[a]	0.13	0.04	0.20
PathFiles	45	0.10[a]	0.11	0.05	0.18
WaveOne Gold Glider	45	0.13[a]	0.13	0.07	0.18
No glide path	45	0.13[a]	0.13	0.09	0.21

Median values with the same superscript letters were not statistically different at $p<0.05$

Table 4.17(a): Descriptive statistics: Mean remaining dentine thickness after final preparation with the Primary WaveOne Gold instrument in combination with different glide path techniques at 3 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	1.01[a]	0.20	0.70	1.44
PathFiles	15	1.05[a]	0.25	0.66	1.61
WaveOne Gold Glider	15	0.98[a]	0.24	0.64	1.56
No glide path	15	0.96[a]	0.19	0.69	1.41

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.17(b): Descriptive statistics: Mean remaining dentine thickness after final preparation with the Primary WaveOne Gold instrument in combination with different glide path techniques at 5 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	1.09[a]	0.19	0.79	1.41
PathFiles	15	1.05[a]	0.21	0.78	1.42
WaveOne Gold Glider	15	1.05[a]	0.22	0.67	1.42
No glide path	15	0.96[a]	0.17	0.72	1.33

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.17(c): Descriptive statistics: Mean remaining dentine thickness after final preparation with the Primary WaveOne Gold instrument in combination with different glide path techniques at 7 mm from the root apex

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	1.01^{a}	0.22	0.56	1.44
PathFiles	15	0.93^{a}	0.26	0.52	1.38
WaveOne Gold Glider	15	0.91^{a}	0.21	0.59	1.29
No glide path	15	0.84^{a}	0.22	0.62	1.48

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.18: Descriptive statistics: combined remaining dentine thickness after final preparation with the Primary WaveOne Gold instrument in combination with different glide path preparation techniques

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	45	1.04^{a}	0.16	0.78	1.28
PathFiles	45	1.01^{a}	0.22	0.75	1.47
WaveOne Gold Glider	45	0.98^{a}	0.17	0.78	1.27
No glide path	45	0.92^{a}	0.13	0.75	1.26

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.19: Descriptive statistics: Mean glide path preparation times for the three different groups

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	81.20[a]	26.32	27	120
PathFiles	15	40.97[b]	6.84	26.94	51.77
WaveOne Gold Glider	15	19.73[c]	5.62	12	32

Mean values with the same superscript letters were not statistically different at $p<0.05$

Table 4.20: Descriptive statistics: Mean final canal preparation time of the Primary WaveOne Gold instrument in combination with different glide path preparation techniques

Preparation method	Number	Mean	Standard deviation	Minimum value	Maximum value
K-files	15	27[a]	9.53	14	45
PathFiles	15	24.4[a]	4.94	18	35
WaveOne Gold Glider	15	23.13[a]	6.03	13	35
No glide path	15	35.27[b]	10.16	23	65

Mean values with the same superscript letters were not statistically different at $p<0.05$

Chapter 5: Discussion

The aim of this *in vitro* study was to investigate various glide path preparation techniques followed by root canal preparation with the reciprocating Primary WaveOne Gold instrument. Micro-CT was used on curved mesio-buccal root canals of extracted human mandibular molars. Canal transportation, centering ability and effect on remaining dentine thickness were evaluated. Preparation times for glide path preparation and final canal preparation with WaveOne Gold were also recorded.

The current study is the first to investigate various glide path techniques in combination with the Primary WaveOne Gold instrument. The WaveOne Gold Glider has not been investigated previously either for its centering ability and transportation after glide path preparation or for its centering ability and transportation in combination with the Primary WaveOne Gold instrument used for final canal preparation.

Cleaning and shaping of a root canal is considered the most important phase in endodontic therapy.[3,86] Preparing a root canal in a shape that tapers from the apical to the coronal aspect of the canal while preserving dentine is ideal.[87] By preserving dentine and using less invasive preparation techniques, endodontic outcomes are enhanced.[4] All endodontic preparation techniques tend to cause deviation from the original canal anatomy during preparation of curved canals.[5]

Inflexible instruments have the tendency to alter original canal anatomy and to result in a reduction in debridement and less positive treatment outcomes.[88] Alterations like over-straightening may also lead to root perforations and unsuccessful treatment outcomes.[4] Initially, canal preparation was mostly performed using stainless steel hand instruments that resulted in canal deviations, zipping and perforations.[89]

In order to better respect the original canal anatomy and overcome these limitations of endodontic instruments, NiTi systems have been developed to improve safety, flexibility and cutting efficiency.[90,91] Different tapers, sizes and improved alloys exist, but not all instruments behave similarly when used in canals of similar length and curvature.[92]

In order to ensure continued advancement of rotary instruments throughout the entire working length of the canal it is paramount to establish a glide path.[41,50,83] The diameter of the root canal after glide path preparation should ideally be at least the same size as or greater than the first rotary file introduced into the canal.[39] Benefits of glide path preparation include a reduction in torsional stress and an increase in the lifespan of the rotary files.[1] The latest innovations include reciprocating systems, improved metal alloys, as well as single file preparation systems.[69]

Adequate cleaning of the root canal while maintaining and protecting canal curvature should be the main parameters for evaluating a root canal shaping instrument.[93] Evaluation of the changes pre- and post-instrumentation has been proved to be a reliable method for evaluating an instrumentation technique for its preservation of original canal anatomy.[41,94] Various methods have been used to evaluate these parameters including radiographic evaluations, serial sectioning, plastic model analysis. These include: cone-beam computed tomography and more recently micro-CT.[38,77,95] Three-dimensional images acquired from micro-CT are superior to those acquired from the use of other techniques in terms of quality and are ideal for the geometric analysis of root canal anatomy.[77] An added advantage of using micro-CT is that sectioning of specimens is not needed. Specimens can be evaluated, therefore, before and after glide path enlargement, as well as after final canal preparation.

In the first part of the present study the centering ability and transportation of K-files, PathFiles and the recently (2017) launched WaveOne Gold Glider were examined in curved mesio-buccal root canals of extracted human mandibular molars. Curved canals were used, as they present a greater challenge in preserving original canal anatomy during instrumentation.[96] Other similar studies have used plastic training blocks in order to standardise canals.[54,96] The benefits of using natural teeth are shown to be greater than having standardised artificial canals.[96] Levels 3 mm, 5 mm and 7 mm from the anatomical root apex were chosen for evaluating the parameters, as these levels have been shown to be the most vulnerable for iatrogenic alterations.[83] The three levels represent the apical-, middle- and coronal thirds of the canal where iatrogenic aberrations typically occur during preparation of curved canals. The crowns of the teeth were also kept intact to reproduce the clinical scenario where directional tension and resistance could be caused by interference of cervical dentine.[77]

When comparing centering ratios after glide path enlargement there was no statistically significant difference between the three different glide path preparation methods at 3 mm from the root apex ($p=0.404$). At 3 mm from the root apex, the best value of the mean centering ratio was observed with K-files (0.45 ± 0.31 mm). This result might be attributed to operator experience, as the clinician in the present study prepares glide paths mostly by using pre-curved manual stainless steel K-files for glide path preparation in clinical cases.

At 5 mm from the root apex the Primary WaveOne Gold group performed significantly better than the K-file group when centering ability was evaluated (p=0.047). At 7 mm from the root apex no statistically significant difference existed in centering ability between the three different glide path groups (p=0.1123). It has been reported that NiTi rotary glide path instruments produce fewer canal aberrations and preserve canal anatomy best when compared to stainless steel files.[50] Less post-operative pain was also reported when NiTi was used instead of stainless steel files in the preparation of a glide path.[97] The combined glide path results of the present study showed that stainless steel K-files preformed statistically similarly to NiTi glide path preparation instruments.

When transportation was evaluated after glide path preparation the following was found. At level 3 mm from the root apex, K-files transported significantly more compared to WaveOne Gold Glider after glide path preparation (p=0.0036). At 5 mm from the root apex there was no statistically significant difference in transportation between the three glide path preparation groups (p=0.442). At level 7 mm from the root apex the PathFile group transported significantly less than the K-file group after glide path preparation (p=0.0361). The studies by Gergi *et al*.,[98] Paleker and Van der Vyver [53] and Elnaghy and Elsaka[83] showed NiTi files to cause significantly less transportation than manual K-files. According to Fan *et al.*[99] transportation was only found to be clinically significant when greater than 0.3 mm. When evaluating the different glide path systems, most transportation was seen at 7 mm from the root apex in the K-file groups. Although statistically significant, it could be argued that transportation is clinically insignificant as mean transportation was measured as 0.13 mm. When mean combined transportation values were evaluated the K-files group had the highest transportation with a mean transportation of 0.1 mm. It could therefore be argued that in terms of transportation none of the groups performed with any clinically significant implication.

The second part of the present study examined the centering ability and transportation of the Primary WaveOne Gold instrument after glide path preparation with K-files, PathFiles and the WaveOne Gold Glider. In addition, transportation and centering ability of the WaveOne Gold Primary instrument was also evaluated in canals where no prior glide path was prepared.

Centering ratios at both 3 mm and 7 mm from the root apex showed no statistically significant difference between the four glide path techniques in combination with the Primary WaveOne Gold instrument. At level 5 mm, however, there was a statistically significant difference between the PathFile group and the WaveOne Gold Glider group in terms of centering ability. PathFiles showed to be more centred at this level than the WaveOne Gold Glider (p=0.0475). A study by de Carvalho *et al.*[100] showed similar results that indicated no statistically significant difference in centering ability when various glide path preparation groups were compared prior to final canal instrumentation. Neither did Elnaghy and Elsaka[83] find any statistically significant difference between the ProTaper/ProGlider and the ProTaper/PathFile combination groups in evaluating centering ability.

No statistically significant difference in canal transportation was found between the four different glide path preparation techniques at level 3 mm from the root apex (p=0.928). At the 5 mm level a statistically significant difference was found when both the K-file group to the group where no glide path was prepared as well as in comparing the group where no glide path was prepared with the PathFiles preparation group. The preparation group where no glide path was prepared transported statistically significantly more than both the K-file (p=0.048) and PathFile (p=0.0346) groups transported. The importance of glide path preparation to minimise transportation was best demonstrated at level 5 mm form the root apex. At level 7 mm from the root apex there was no statistical significant difference in transportation between the different glide path techniques in combination with the Primary WaveOne Gold instrument (p=0.830).

Similarly a study by de Carvalho *et al.*[100] found no statistically significant difference between the different glide path groups in combination with a single-file reciprocating system. This finding corroborates findings from other similar studies.[101,102] Although not statistically significant, Elnaghy and Elsaka[83] also reported that highest transportation values were seen in the groups where no glide path was prepared before final canal instrumentation.

The third part of the study evaluated the remaining dentine thickness after final canal preparation with the Primary WaveOne Gold instrument. Remaining dentine thickness was evaluated on three levels from the root apex (3 mm, 5mm and 7 mm) to permit an investigation of which combination of glide path technique and the Primary WaveOne Gold instrument preserved dentine the best.

The remaining dentine thickness was compared after final preparation with the Primary WaveOne Gold instrument in combination with the four different glide path preparation techniques. No significant difference was found at the three levels from the root apex between the different preparation groups. Although not statistically significant, the group that performed most poorly on the ability to preserve dentine thickness when mean dentine thickness over all three levels was compared, was the group in which no glide path had been prepared. The findings are similar to those of Elnaghy and Elsaka[83] who concluded that there was no significant difference in the remaining dentine thickness after preparation with ProTaper Next in combination with different glide path techniques. Elnaghy and Elsaka[83] also found that where no glide path had been prepared before final instrumentation with ProTaper Next the amount of dentine preserved was significantly less than in the groups where a glide path had been prepared before final preparation, irrespective of the glide path technique. According to Lim and Stock[103] the minimum dentine thickness post-instrumentation was set at 0.3 mm. This minimum value was determined on the basis of sufficient resistance to obturation forces, as well as forces occurring with normal function. Caputo and Standlee[104] found in 1976 that 1 mm sound dentine was needed around a post for adequate resistance to root fracture. Although statistically not significantly different, most of the canals in the three glide path preparation groups had a remaining dentine thickness of over 1 mm when this dentine thickness was measured post-instrumentation.

The final part of the present study recorded and compared the preparation times for both the glide path preparation phase and the final preparation phase in combination with the Primary WaveOne Gold instrument.

When glide path preparation times were compared, no statistically significant difference was found between all three glide path preparation methods ($p<0.0001$). Glide path preparation in the K-file preparation group took significantly more time than the WaveOne Gold Glider ($p<0.0001$) and the PathFile group ($p<0.0001$). Glide path preparation in the WaveOne Gold Glider group was significantly faster than glide path preparation with the PathFile group ($p<0.008$). Such a finding could be attributed to the fact that it is a single-file glide path preparation system. NiTi PathFiles, however, performed statistically significantly faster than the stainless steel manual K-file glide path preparation group. A study by Kirchhoff *et al*.[105] reported similar results when glide path preparation time for PathFiles was compared with glide path preparation time for the single file ProGlider. In a study by Paleker and Van der Vyver,[106] glide path preparation times of K-Files, G-files and ProGlilder were compared with similar results to this study as well as previous studies. In this study, final shaping times for the Primary WaveOne Gold instrument were statistically similar after glide path preparation, regardless of the glide path preparation technique used. In the group where no prior glide path was created before final shaping with the Primary WaveOne Gold instrument, the final shaping times were statistically significantly greater than the times in those groups where a prior glide path had been prepared. The time it took to change instruments was not taken into consideration.

The increased resistance to cyclic fatigue as well as the enhanced flexibility of the WaveOne Gold Glider with its improved heat treated gold metal alloy, together with the convenience of a single-file system with the added benefit of reduced preparation time, might make the WaveOne Gold Glider/ Primary WaveOne Gold instrument the preferred combination of choice for preparation of curved canals.

A reduction in preparation time and a reduced number of failures related to instrumentation contribute to the growing popularity and clinical acceptability of single-file endodontic systems.[69] It has been shown that single-file systems used either in rotation or reciprocation are almost three times faster and four times more safe than rotary file systems that comprise multiple instruments in creating the same final shape.[66,107] In studies comparing multi-file rotary systems with single-file reciprocating systems preparation time was significantly reduced in the single-file system,[69] leaving more time for chemical disinfection of the root canal system.

Within the limitations of this study, results could have clinical findings of importance. Poorly centred instruments might result in alteration of original canal anatomy and procedural aberrations with undesired clinical outcomes. The importance of glide path preparation prior to final canal instrumentation for reducing procedural errors has been reported. In this study it was also found that all of the glide path preparation techniques prior to final canal instrumentation with the Primary WaveOne Gold instrument resulted in preparations with a favourable centering ability, minimum canal transportation and best preservation of dentine. The groups with no glide path preparation prior to final instrumentation with the Primary WaveOne Gold instrument resulted in fewer centred preparations, most transportation, poorest dentine preservation and slowest preparation times.

Chapter 6: Conclusions

Within the limitations of this study the points listed below can be concluded:

Glide Path Preparation

- PathFiles performed the most favourably when mean centering ability over the apical, midroot and coronal levels was compared. However, there was no statistically significant difference in the mean centering ratios after glide path preparation when K-files, PathFiles and the WaveOne Gold Glider were compared ($p>0.05$).

- At level 5 mm from the root apex the WaveOne Gold Glider performed statistically significantly more favourably than K-files in terms of centering ability with glide path preparation ($p<0.05$).

- The mean combined transportation values over the apical, midroot and coronal levels after glide path preparation were statistically significantly higher in the K-file preparation groups compared to the PathFile and WaveOne Gold Glider groups ($p<0.05$).

Canal Preparation

- No statistically significant difference was found in the mean combined centering ratios of the various glide path groups in combination with the Primary WaveOne Gold instrument over the apical, midroot and coronal levels ($p>0.05$).

- PathFiles in combination with the Primary WaveOne Gold instrument performed statistically significantly better in terms of centering ability when compared to the WaveOne Gold Glider in combination with the Primary WaveOne Gold instrument at 5 mm from the anatomical root apex ($p<0.05$).

- There was no statistically significant difference in mean combined transportation of the different glide path groups in combination with the Primary WaveOne Gold instrument over the apical, midroot and coronal levels ($p>0.05$).

- Although not statistically significant, the highest mean combined transportation over apical, midroot and coronal levels was seen in the group where no glide path was prepared prior to final preparation with the Primary WaveOne Gold instrument.

- At level 5 mm from the root apex, PathFiles and K-files performed statistically significantly more favourably than the group where no glide path was prepared prior to final preparation with the Primary WaveOne Gold instrument in terms of transportation ($p<0.05$).

Remaining Dentine Thickness

- There was no statistically significant difference in the amount of remaining dentine between different glide path groups in combination with final preparation using the WaveOne Gold Primary instrument ($p>0.05$). However, not having a glide path prior to final canal preparation with Primary WaveOne Gold instrument resulted in the most unfavourable dentine preservation.

Preparation Times

- Glide path preparation was fastest using the WaveOne Gold Glider compared to K-files and PathFiles ($p<0.0001$).

- Having no prior glide path preparation before canal preparation with the Primary WaveOne Gold instrument resulted in statistically slower canal preparation times compared to those for glide path preparation with K-files, or PathFiles, or the WaveOne Gold Glider ($p<0.0001$).

The null hypothesis is therefore rejected.

References

1. Berutti E, Negro AR, Lendini M, Pasqualini D. Influence of manual preflaring and torque on the failure rate of ProTaper rotary instruments. *J Endod* 2004;30(4):228-230.

2. Kakehashi S, Stanley H, Fitzgerald R. The effects of surgical exposures of dental pulps in germ-free and conventional laboratory rats. *Oral Surg Oral Med Oral Pathol* 1965;20(3):340-349.

3. Schilder H. Cleaning and shaping the root canal. *Dent Clin North Am* 1974;18:269-296.

4. Peters OA. Current challenges and concepts in the preparation of root canal systems: a review. *J Endod* 2004;30(8):559-567.

5. Abou-Rass M, Frank AL, Glick DH. The anticurvature filing method to prepare the curved root canal. *J Am Dent Assoc* 1980;101(5):792-794.

6. Reeh ES, Messer HH, Douglas WH. Reduction in tooth stiffness as a result of endodontic and restorative procedures. *J Endod* 1989;15(11):512-516.

7. Walia H, Brantley WA, Gerstein H. An initial investigation of the bending and torsional properties of Niti root canal files. *J Endod* 1988;14(7):346-351.

8. Pettiette MT, Metzger Z, Phillips C, Trope M. Endodontic complications of root canal therapy performed by dental students with stainless-steel K-files and nickel-titanium hand files. *J Endod* 1999;25(4):230-234.

9. Buehler WJ, Gilfrich J, Wiley R. Effect of low-temperature phase changes on the mechanical properties of alloys near composition TiNi. *J Applied Physics* 1963;34(5):1475-1477.

10. Glosson CR, Haller RH, Dove SB, Carlos E. A comparison of root canal preparations using Ni-Ti hand, Ni-Ti engine-driven, and K-Flex endodontic instruments. *J Endod* 1995;21(3):146-151.

11. Young G, Parashos P, Messer H. The principles of techniques for cleaning root canals. *Aust Dent J* 2007;52(1):52-S63.

12. Jafarzadeh H, Abbott PV. Ledge formation: review of a great challenge in endodontics. *J Endod* 2007;33(10):1155-1162.

13. Hülsmann M, Peters OA, Dummer PM. Mechanical preparation of root canals: shaping goals, techniques and means. *Endod Topics* 2005;10(1):30-76.

14. Goldberg F, Araujo J. Comparison of three instruments in the preparation of curved root canals. *Dent Traumatol* 1997;13(6):265-268.

15. Cassim I, Van der Vyver PJ. The importance of glide path preparation in endodontics: a consideration of instruments and literature. *SADJ* 2013;68:322-327.

16. Pruett JP, Clement DJ, Carnes DL. Cyclic fatigue testing of nickel-titanium endodontic instruments. *J Endod* 1997;23(2):77-85.

17. Shen Y, Coil JM, Mclean AG, Hemerling DL, Haapasalo M. Defects in nickel-titanium instruments after clinical use. Part 5: single use from endodontic specialty practices. *J Endod* 2009;35(10):1363-1367.

18. Martin B, Zelada G, Varela P, Bahillo JG, Magan F, Ahn S, Rodriques C. Factors influencing the fracture of nickel-titanium rotary instruments. *Int Endod J* 2003;36(4):262-266.

19. Grigoratos D, Knowles J, Ng YL, Gulabivala K. Effect of exposing dentine to sodium hypochlorite and calcium hydroxide on its flexural strength and elastic modulus. *Int Endod J* 2001;34(2):113-119.

20. Lambrianidis T. Ledging and blockage of root canals during canal preparation: causes, recognition, prevention, management, and outcomes. *Endod Topics* 2006;15(1):56-74.

21. Craig R, McIlwain E, Peyton F. Bending and torsion properties of endodontic instruments. *Oral Surg Oral Med Oral Pathol* 1968;25(2):239-254.

22. Lam TV, Lewis DJ, Atkins DR, Macfarlane RH, Clarkson RM, Whitehead MG, Brockhurst PJ, Moule AJ. Changes in root canal morphology in simulated curved canals o ver-instrumented with a variety of stainless steel and nickel titanium files. *Aust Dent J* 1999;44(1):12-19.

23. Endodontists AAo. *Glossary of endodontic terms*: Am Assoc Endod 2003.

24. Buchanan L. Management of the curved root canal. *J Cal Dent Assoc* 1989;17(4):18.

25. West J. Manual versus mechanical endodontic glidepath. *Dent Today* 2011;30(1):136-140.

26. Siqueira J. Microbial causes of endodontic flare-ups. *Int Endod J* 2003;36(7):453-463.

27. Eleazer P, Glickman G, McClanahan S, Webb T, Jusrman B. Glossary of endodontic terms. *Editorial AAE: Chicago* 2012.

28. Siew K, Lee AH, Cheung GS. Treatment outcome of repaired root perforation: a systematic review and meta-analysis. *J Endod* 2015;41(11):1795-1804.

29. Kvinnsland I, Oswald R, Halse A, Grønningsaeter A. A clinical and roentgenological study of 55 cases of root perforation. *Int Endod J* 1989;22(2):75-84.

30. Alhadainy HA. Root perforations: a review of literature. *Oral Surg Oral Med Oral Pathol* 1994;78(3):368-374.

31. Touré B, Faye B, Kane AW, Lo CM, Niang B, Boucher Y. Analysis of reasons for extraction of endodontically treated teeth: a prospective study. *J Endod* 2011;37(11):1512-1515.

32. Kessler JR, Peters DD, Lorton L. Comparison of the relative risk of molar root perforations using various endodontic instrumentation techniques. *J Endod* 1983;9(10):439-447.

33. West J. Endodontic update 2006. *J Esthet Dent* 2006;18(5):280-300.

34. Khatavkar R, Hegde V. Importance of patency in endodontics. *Endodontology* 2010;22:85-91.

35. West J. The endodontic Glidepath:" Secret to rotary safety". *Dent Today* 2010;29(9):86, 88, 90-83.

36. Bergmans L, Van Cleynenbreugel J, Wevers M, Lambrechts P. Mechanical root canal preparation with NiTi rotary instruments: rationale, performance and safety. *Am J Dent* 2001;14(5):324-333.

37. Blum J, Machtou P, Ruddle C, Micallef J. Analysis of mechanical preparations in extracted teeth using ProTaper rotary instruments: value of the safety quotient. *J Endod* 2003;29(9):567-575.

38. Peters O, Peters C, Schonenberger K, Barbakow F. ProTaper rotary root canal preparation: effects of canal anatomy on final shape analysed by micro CT. *Int Endod J* 2003;36(2).

39. Patiño PV, Biedma BM, Liébana CR, Cantatore G, Bahillo JG. The influence of a manual glide path on the separation rate of NiTi rotary instruments. *J Endod* 2005;31(2):114-116.

40. Shen Y, Haapasalo M, Cheung GS-p, Peng B. Defects in nickel-titanium instruments after clinical use. Part 1: Relationship between observed imperfections and factors leading to such defects in a cohort study. *J Endod* 2009;35(1):129-132.

41. Berutti E, Paolino DS, Chiandussi G, et al. Root canal anatomy preservation of WaveOne reciprocating files with or without glide path. *J Endod* 2012;38(1):101-104.

42. Walsch H. The hybrid concept of nickel–titanium rotary instrumentation. *Dent Clinics* 2004;48(1):183-202.

43. Mounce R. Endodontic K-files: invaluable endangered species or ready for the Smithsonian? *Dent Today* 2005;24(7):102, 104-102, 104.

44. Jerome CE, Hanlon RJ. Identifying multiplanar root canal curvatures using stainless-steel instruments. *J Endod* 2003;29(5):356-358.

45. Van der Vyver PJ. Creating a glide path for rotary NiTi instruments: Part Two. *Endod Prac* 2011:46-53.

46. Roane JB, Sabala CL, Duncanson MG. The "balanced force" concept for instrumentation of curved canals. *J Endod* 1985;11(5):203-211.

47. Van der Vyver PJ. Creating a glide path for rotary NiTi instruments: part one. *Int Dent SA* 2010;13(2):6-10.

48. Berutti E, Cantatore G, Castellucci A, Chiandussi G, Pera F, Migliaretti G, Pasqualini D. Use of nickel-titanium rotary PathFile to create the glide path: comparison with manual preflaring in simulated root canals. *J Endod* 2009;35(3):408-412.

49. Madhusudhana K, Mathew VB, Reddy NM. Apical extrusion of debris and irrigants using hand and three rotary instrumentation systems–An in vitro study. *Contemp Clin Dent* 2010;1(4):234.

50. Pasqualini D, Bianchi CC, Paolino DS, Mancini L, Cemenasco A, Cantatore G, Castelucci A, Berutti E. Computed micro-tomographic evaluation of glide path with nickel-titanium rotary PathFile in maxillary first molars curved canals. *J Endod* 2012;38(3):389-393.

51. Kinsey B, Mounce R. Safe and efficient use of the M4 safety handpiece in endodontics. *Roots* 2008;4(2):36-40.

52. Wagner MH, Barletta FB, Reis MdS, Mello LL, Ferreira R, Fernandes ALR. NSK reciprocating handpiece: in vitro comparative analysis of dentinal removal during root canal preparation by different operators. *Braz Dent J* 2006;17(1):10-14.

53. Paleker F, Van der Vyver PJ. Comparison of canal transportation and centering ability of k-files, proglider file, and g-files: A micro-computed tomography study of curved root canals. *J Endod* 2016;42(7):1105-1109.

54. Van der Vyver PJ, Paleker F, Jonker C. Comparison of preparation times of three different rotary glide path instrument systems. *SADJ* 2015;70(4):144-147.

55. Webber J, Machtou P, Pertot W, Kuttler S, Ruddle C, West J. The WaveOne single-file reciprocating system. *Roots* 2011;1(1):28-33.

56. Peters OA, Paqué F. Current developments in rotary root canal instrument technology and clinical use: A review. *Quintessence Int* 2010;41(6).

57. Peters OA, de Azevedo Bahia MG, Pereira ESJ. Contemporary Root Canal Preparation: Innovations in biomechanics. *Dent Clin North Am* 2017;61(1):37-58.

58. Webber J. Shaping canals with confidence: WaveOne Gold single-file reciprocating system. *Roots* 2015;1:34-40.

59. López FU, Fachin EV, Fontanella VRC, Barletta FB, Só MVR, Grecca FS. Apical transportation: a comparative evaluation of three root canal instrumentation techniques with three different apical diameters. *J Endod* 2008;34(12):1545-1548.

60. Bürklein S, Schäfer E. Apically extruded debris with reciprocating single-file and full-sequence rotary instrumentation systems. *J Endod* 2012;38(6):850-852.

61. Sotokawa T. An analysis of clinical breakage of root canal instruments. *J Endod* 1988;14(2):75-82.

62. Serene TP, Adams JD, Saxena A. Nickel-titanium instruments: applications in endodontics. *Ishiyaku EuroAmerica* 1995:112

63. Gabel WP, Hoen M, Steiman HR, Pink FE, Dietz R. Effect of rotational speed on nickel-titanium file distortion. *J Endod* 1999;25(11):752-754.

64. Sattapan B, Palamara JE, Messer HH. Torque during canal instrumentation using rotary nickel-titanium files. *J Endod* 2000;26(3):156-160.

65. Yared G. Canal preparation using only one Ni-Ti rotary instrument: preliminary observations. *Int Endod J* 2008;41(4):339-344.

66. You S-Y, Bae K-S, Baek S-H, Kum K-Y, Shon W-J, Lee W. Lifespan of one nickel-titanium rotary file with reciprocating motion in curved root canals. *J Endod* 2010;36(12):1991-1994.

67. Varela-Patiño P, Ibañez-Párraga A, Rivas-Mundiña B, Cantatore G, Otero XL, Martin-Biedma B. Alternating versus continuous rotation: a comparative study of the effect on instrument life. *J Endod* 2010;36(1):157-159.

68. Van der Vyver PJ. WaveOne Instruments: Clinical application guidelines. *Endod Prac* 2011;(11):45-54.

69. Bürklein S, Hinschitza K, Dammaschke T, Schäfer E. Shaping ability and cleaning effectiveness of two single-file systems in severely curved root canals of extracted teeth: Reciproc and WaveOne versus Mtwo and ProTaper. *Int Endod J* 2012;45(5):449-461.

70. Gambarini G, Grande NM, Plotino G, Somma F, Garala M, de Luca M, Testarelli L. Fatigue resistance of engine-driven rotary nickel-titanium instruments produced by new manufacturing methods. *J Endod* 2008;34(8):1003-1005.

71. Shen Y, Zhou H-m, Zheng Y-f, Peng B, Haapasalo M. Current challenges and concepts of the thermomechanical treatment of nickel-titanium instruments. *J Endod* 2013;39(2):163-172.

72. Ruddle CJ. Single-file shaping technique achieving a gold medal result. *Dent Today* 2016;(1):1-6.

73. Dunn PM. Wilhelm Conrad Röentgen (1845–1923), the discovery of x-rays and perinatal diagnosis. *Archives of Disease in Childhood-Fetal and Neonatal Edition* 2001;84(2):F138-F139.

74. Hounsfield GN. Computerized transverse axial scanning (tomography): Part 1. Description of system. *The Brit J Radiol* 1973;46(552):1016-1022.

75. Rhodes J, Ford T, Lynch J, Liepins P, Curtis R. Micro-computed tomography: a new tool for experimental endodontology. *Int Endod J* 1999;32(3):165-170.

76. Swain MV, Xue J. State of the art of Micro-CT applications in dental research. *Int J Oral Sci* 2009;1(4):177.

77. Hashem AAR, Ghoneim AG, Lutfy RA, Foda MY, Omar GAF. Geometric analysis of root canals prepared by four rotary NiTi shaping systems. *J Endod* 2012;38(7):996-1000.

78. Bernardes RA, Rocha EA, Duarte MAH, Vivan RR, de Moraes IG, Bramante AS, de Azevedo JR. Root canal area increase promoted by the EndoSequence and ProTaper systems: comparison by computed tomography. *J Endod* 2010;36(7):1179-1182.

79. Pasternak-Júnior B, Sousa-Neto M, Silva R. Canal transportation and centring ability of RaCe rotary instruments. *Int Endod J* 2009;42(6):499-506.

80. Marzouk AM, Ghoneim AG. Computed tomographic evaluation of canal shape instrumented by different kinematics rotary nickel-titanium systems. *J Endod* 2013;39(7):906-909.

81. Dowker SE, Davis GR, Elliott JC. X-ray microtomography: nondestructive three-dimensional imaging for in vitro endodontic studies. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 1997;83(4):510-516.

82. Hoffman JW, De Beer F. Characteristics of the micro-focus x-ray tomography facility (MIXRAD) at Necsa in South Africa. Paper presented at: 18th World Conference on Nondestructive Testing 2012.

83. Elnaghy AM, Elsaka SE. Evaluation of root canal transportation, centering ratio, and remaining dentin thickness associated with ProTaper Next instruments with and without glide path. *J Endod* 2014;40(12):2053-2056.

84. Schneider SW. A comparison of canal preparations in straight and curved root canals. *Oral Surg Oral Med Oral Pathol* 1971;32(2):271-275.

85. Gambill JM, Alder M, Carlos E. Comparison of nickel-titanium and stainless steel hand-file instrumentation using computed tomography. *J Endod* 1996;22(7):369-375.

86. Peters OA. Cleaning and shaping of the root canal system. *Pathway of the pulp* 2006:290-357.

87. Thompson S, Dummer P. Shaping ability of HERO 642 rotary nickel–titanium instruments in simulated root canals: Part 1. *Int Endod J* 2000;33(3):248-254.

88. Weine FS, Kelly RF, Lio PJ. The effect of preparation procedures on original canal shape and on apical foramen shape. *J Endod* 1975;1(8):255-262.

89. Fornari V, Silva-Sousa Y, Vanni J, Pécora J, Versiani M, Sousa-Neto M. Histological evaluation of the effectiveness of increased apical enlargement for cleaning the apical third of curved canals. *Int Endod J* 2010;43(11):988-994.

90. Schäfer E, Florek H. Efficiency of rotary nickel–titanium K3 instruments compared with stainless steel hand K-Flexofile. Part 1. Shaping ability in simulated curved canals. *Int Endod J* 2003;36(3):199-207.

91. da Frota MF, Bonetti Filho I, Berbert FLCV, Sponchiado Jr EC, Marques AAF, Garcia LdFR. Cleaning capacity promoted by motor-driven or manual instrumentation using ProTaper Universal system: Histological analysis. *JCD* 2013;16(1):79.

92. Peters O, Schönenberger K, Laib A. Effects of four Ni–Ti preparation techniques on root canal geometry assessed by micro computed tomography. *Int Endod J* 2001;34(3):221-230.

93. Versümer J, Hülsmann M, Schäfers F. A comparative study of root canal preparation using ProFile. 04 and Lightspeed rotary Ni–Ti instruments. *Int Endod J* 2002;35(1):37-46.

94. Merrett SJ, Bryant ST, Dummer PM. Comparison of the shaping ability of RaCe and FlexMaster rotary nickel-titanium systems in simulated canals. *J Endod* 2006;32(10):960-962.

95. Backman CA, Oswald RJ, Pitts DL. A radiographic comparison of two root canal instrumentation techniques. *J Endod* 1992;18(1):19-24.

96. de Oliveira Alves V, da Silveira Bueno CE, Cunha RS, Pinheiro SL, Fontana CE, de Martin AS. Comparison among manual instruments and PathFile and Mtwo rotary instruments to create a glide path in the root canal preparation of curved canals. *J Endod* 2012;38(1):117-120.

97. Pasqualini D, Mollo L, Scotti N, Cantatore G, Castelucci A, Migliaretti G, Berutti E. Postoperative pain after manual and mechanical glide path: a randomized clinical trial. *J Endod* 2012;38(1):32-36.

98. Gergi R, Rjeily JA, Sader J, Naaman A. Comparison of canal transportation and centering ability of twisted files, Pathfile-ProTaper system, and stainless steel hand K-files by using computed tomography. *J Endod* 2010;36(5):904-907.

99. Fan B, Wu MK, Wesselink P. Leakage along warm gutta-percha fillings in the apical canals of curved roots. *Dental Traumatol* 2000;16(1):29-33.

100. de Carvalho GM, Junior ECS, Garrido ADB, Lia RCC, Garcia LFR, Marques AAF. Apical transportation, centering ability, and cleaning effectiveness of reciprocating single-file system associated with different glide path techniques. *J Endod* 2015;41(12):2045-2049.

101. Gergi R, Osta N, Bourbouze G, Zgheib C, Arbab-Chirani R, Naaman A. Effects of three nickel titanium instrument systems on root canal geometry assessed by micro-computed tomography. *Int Endod J* 2015;48(2):162-170.

102. Bürklein S, Poschmann T, Schäfer E. Shaping ability of different nickel-titanium systems in simulated S-shaped canals with and without glide path. *J Endod* 2014;40(8):1231-1234.

103. Lim S, Stock C. The risk of perforation in the curved canal: anticurvature filing compared with the stepback technique. *Int Endod J* 1987;20(1):33-39.

104. Caputo A, Standlee J. Pins and posts-why, when and how. *Dent Clinics North Am* 1976;20(2):299-311.

105. Kirchhoff AL, Chu R, Mello I, Garzon ADP, dos Santos M, Cunha RS. Glide path management with single-and multiple-instrument rotary systems in curved canals: A micro–computed tomographic study. *J Endod* 2015;41(11):1880-1883.

106. Paleker F, van der Vyver PJ. Glide path enlargement of mandibular molar canals by using K-files, the ProGlider file, and G-Files: A comparative study of the preparation times. *J Endod* 2017;43(4):609-612.

107. Gambarini G. Cyclic fatigue resistance of nickel-titanium rotary instruments used in reciprocating or continuous motion. *J Endod* 2010;36(3):563.

Appendix A

PATIENT / PARTICIPANT'S INFORMATION & INFORMED CONSENT DOCUMENT

RESEARCH TITLE: Evaluation of Root Canal Transportation, Centering Ratio and Remaining Dentine Thickness in Curved Canals Prepared with WaveOne Gold in Combination with Different Glide Path Techniques.

SPONSOR: Researcher – Dr Martin Vorster

Principal Investigators: Dr Martin Vorster

Institution: Pretoria Oral and Dental Hospital, University of Pretoria

DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):
Daytime numbers: 012 319 2637
Afterhours: 012 319 2637

DATE AND TIME OF FIRST INFORMED CONSENT DISCUSSION:

dd	mm	yy

:
Time

Dear Patient

INTRODUCTION

You are **invited** to volunteer for a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about all the procedures involved. In the best interests of your health, it is strongly recommended that you discuss with or inform your personal doctor of your possible participation in this study, wherever possible.

WHAT IS THE PURPOSE OF THE RESEARCH?

The purpose of the research is evaluate which root canal file system prepares teeth in the most favorable way when doing root canal treatment. Once your tooth that is deemed not restorable is extracted it will be prepared with different file systems and evaluated for its preparation properties.

WHAT IS THE DURATION OF THIS RESEARCH?

If you decide to take part you will be one of approximately sixty patients. No follow up visits will be necessary.

DESCRIPTION OF PROCEDURES

This study involves three-dimensional scanning of extracted teeth after being prepared with different root canal preparation files. Teeth will be randomized and divided into three different preparation groups. After preparation, teeth will be scanned and evaluated to see which system prepared the teeth in the most favourable way.

HAS THE RESEARCH RECEIVED ETHICAL APPROVAL?

This clinical trial Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, telephone numbers 012 356 3084 / 012 356 3085 and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2008), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT IN THIS RESEARCH?

Your participation in this research is entirely voluntary and you can refuse to participate. Your refusal will not affect your access to other medical care.

MAY ANY OF THESE RESEARCH PROCEDURES RESULT IN DISCOMFORT OR INCONVENIENCE?

There are no risks involved in participating in this study. Teeth will be used for research purposes only after extraction. <u>It is important to note that no teeth will be extracted solely for this study and that teeth extracted would have been extracted regardless of the study.</u>

WHAT ARE THE BENEFITS TO YOU

Although you will not benefit directly from this study, the results of the study will enable us to improve pulp treatment in permanent teeth.

WHAT ARE THE RISKS INVOLVED IN THIS RESEARCH?

Your participation in this study is entirely voluntary. You can refuse to participate by not giving permission to use extracted teeth for this research project.

There are no risks involved in participating in this study.

ARE THERE ANY WARNINGS OR RESTRICTIONS CONCERNING MY PARTICIPATION IN THIS TRIAL?

No. The contact person for this investigation is Dr Martin Vorster 012 319 2440. You are welcome to contact him should you require any additional information.

CONFIDENTIALITY

All information obtained during the course of this trial is strictly confidential. Data that may be reported in scientific journals will not include any information which identifies you as a patient in this research.

COMPENSATION

Participation is voluntary. No compensation or contribution will be given for your participation

INFORMED CONSENT

I hereby confirm that I have been informed by the investigator, Dr Martin Vorster about the nature, conduct, benefits and risks of above mentioned research. I have also received, read and understood the above written information (Patient Information Leaflet and Informed Consent) regarding the research.

I am aware that the results of the research, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a research report.

I may, at any stage, without prejudice, withdraw my consent and participation in the research. I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the research.

Patient's name: ____

(Please print)

Patient's signature: ______________________ Date: _____________

I, Dr Martin Vorster herewith confirm that the above patient has been informed fully about the nature, conduct and risks of the above research.

Investigator's name: ____

(Please print)

Investigator's signature: ______________________ Date: _____________

Witness's name*: ______________________________

Witness's signature: ______________________ Date: ____________

(Please print)

VERBAL PATIENT INFORMED CONSENT (applicable when patients cannot read or write)

I, the undersigned, Dr Martin Vorster, have read and have explained fully to the patient, named ……………….. and/or, his/her relative, the patient information leaflet, which has indicated the nature and purpose of the research in which I have asked the patient to participate. The explanation I have given has mentioned both the possible risks and benefits of the research and the alternative treatments available for his/her illness. The patient indicated that he/she understands that he/she will be free to withdraw from the research at any time for any reason and without jeopardizing his/her subsequent injury attributable to the drug(s) used in the clinical trial, to which he/she agrees.

I hereby certify that the patient has agreed to participate in this research.

Patient's Name: ____
(Please print)

Investigator's Name: ____
(Please print)

Investigator's Signature: ______________________ Date: _____________

Witness's Name: ____

Witness's Signature: ______________________ Date: _____________

Appendix B

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 28 August 2018.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 22/04/2017.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

3/10/2016

Approval Certificate
New Application

Ethics Reference No.: 360/2016

Title: Evaluation of Root Canal Transportation, Centering Ration and Remaining Dentine Thickness in Curved Root Canals Prepared with WaveOne Gold in Combinat

Dear Dr Martin Vorster

The **New Application** as supported by documents specified in your cover letter dated 13/09/2016 for your research received on the 13/09/2016, was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 3/10/2016.

Please note the following about your ethics approval:
- Ethics Approval is valid for 1 year
- Please remember to use your protocol number (**360/2016**) 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, or monitor the conduct of your research.

Ethics approval is subject to the following:
- The ethics approval is conditional on the receipt of **6 monthly written Progress Reports**, and
- 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); MPharMed,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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