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**THE INFLUENCE OF GLIDE PATH PREPARATION ON THE FAILURE  
RATE OF NICKEL-TITANIUM RECIPROCATING INSTRUMENTS**

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## DECLARATION

I Casper Hendrik Jonker, declare that this dissertation entitled, **“The influence of glide path preparation on the failure rate of nickel-titanium reciprocating instruments”**, I herewith submit to the University of Pretoria in partial fulfilment of the requirements for the degree MSc (Odont) is my own original work, and has never been submitted for any academic award to any other institution of higher learning.

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**SIGNATURE**

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**DATE**

*A life spent making mistakes is not  
only more honorable, but more  
useful than a life spent doing  
nothing.*

*George Bernard Shaw*

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## SUMMARY

**Key words:** glide path, WaveOne, Endo-Training-Blocks, PathFiles, hand files, fracture rate, preparation times, Glyde, Anova, Bonferroni

**Introduction:** The aim of this *in vitro* study was to determine the influence of two glide path preparation methods on the fracture rate of the Primary 25/08 WaveOne reciprocating instrument. The number of simulator Endo-Training-Blocks in each group were calculated at the time of instrument fracture and compared to determine the influence of glide path preparation on the failure rate of the Primary 25/08 WaveOne reciprocating instrument. Preparation times for different glide path methods and total time for root canal preparation, with or without glide path, was also calculated. **Materials and Methods:** Simulator Endo-Training-Blocks ( $n = 300$ ) were selected and randomly divided into 3 groups ( $n = 100$ ). The 3 groups were then sub-divided into 5 smaller groups ( $n = 20$ ). Root canal preparation was done with new primary 25/08 WaveOne instruments allocated to each group (5 in total for each group, 1 for each sub-group) following different methods for glide path preparation. Group 1: no glide path (control); Group 2: glide path preparation with stainless-steel hand files (size 10 K-File followed by size 15 K-File and finally size 20 K-File until loose fitting); and Group 3: glide path preparation with rotary PathFiles (size 10 K-File until loose fitting followed by PathFile no.1 (ISO 13 tip), PathFile no.2 (ISO 16 tip) and finally PathFile no. 3 (ISO 19 tip)). The Primary 25/08 WaveOne reciprocating instrument was used with the WaveOne endodontic motor in "WaveOne All" mode with a brushing motion on the outstroke. Simulated root canals were irrigated with sterile water and Glyde was used as lubricating agent. The outcome was measured by recording how many simulators could be prepared with one instrument before instrument breakage occurred. The preparation protocol was repeated 5 times. The time it took to prepare the glide path and the total preparation time was also calculated. The data of the different parts of the project were collected and statistically analysed using the ANOVA / Bonferroni test. **Results:** Glide path preparation with PathFiles was significantly faster ( $13.3 \text{ s} \pm 2.60 \text{ s}$ ) than with hand files ( $25.1 \text{ s} \pm 1.70 \text{ s}$ ) ( $P < 0.001$ ). The highest number of simulators could be prepared after glide path preparation was performed with PathFiles ( $19.2 \pm 0.84$ ) ( $P < 0.001$ ). Pairwise comparisons at the Bonferroni adjusted significance level of 0.017 demonstrated that there were statistical significant differences ( $P < 0.001$ ) when PathFiles ( $19.2 \pm 0.84$ ) and hand files ( $17.6 \pm 1.14$ ) were compared to the no glide



path group ( $7.4 \pm 0.89$ ). There was no statistical significant difference between PathFiles and hand files groups. Total Preparation time was significantly shorter ( $P < 0.001$ ) when an initial glide path was prepared with PathFiles ( $12.7 \pm 0.22$  s). The longest preparation time ( $P < 0.001$ ) was calculated in group 1 where no glide path ( $21.2 \pm 0.20$  s) was present and the Endo-Training-Blocks were left undisturbed.

**Conclusion:** Initial glide path preparation with PathFiles resulted in shorter preparation time (glide path and total preparation) and allowed a higher number of simulators prepared before failure of the WaveOne instrument.

## LIST OF ABBREVIATIONS

ANOVA	-	Analysis Of Variance
DOM	-	Dental Operating Microscope
ISO	-	International Organization for Standardization
mm	-	millimetre/s
Ncm	-	Newton per centimetre
nm	-	nanometre
P	-	Probability
PrP	-	Prion Protein
PrP <sup>C</sup>	-	protease resistant protein, cellular isoform
PrP <sup>Sc</sup>	-	prion protein in Scrapie form
TSE	-	transmissible spongiform encephalopathies
rpm	-	rotations per minute
s	-	second/s
SEM	-	scanning electron microscope
VHN	-	Vickers hardness value
EDTA	-	ethylenediaminetetra-acetic acid

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## **CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW**

The main objective of endodontic treatment is to obtain complete debridement of infected tissues from the root canal complex and to prepare the system to meet biological and mechanical requirements. The second objective is to protect the original design of the root canal system and to preserve the size, shape and position of the apical foramen (Schilder, 1974).

The contour of the endodontically prepared root canal should be that of a smooth funnel, with the smallest diameter at the root apex and the largest at the orifice. The completed funnel allows the complete removal of infected tissues and the subsequent placement of obturation materials (Schilder, 1974; Yee *et al.*, 1984).

Cleaning and shaping of long, thin and curved root canals challenge the clinician's endodontic skills (Haikel *et al.*, 1999; Mandel *et al.*, 1999). These difficulties predispose to instrument fracture, ledging, and blockages resulting from insufficient irrigation, and may result in dentinal mud, root perforations, apical zipping, elbowing, strip perforations and accidental extrusion of debris.

Studies show that procedural accidents are not always due to an error on the part of the clinician and can occur no matter how precise the cleaning and shaping technique or the endodontic device/system (Lim and Stock, 1987; McKendry, 1990; Luiten *et al.*, 1995; Al-Omari, Bryant and Dummer, 1997; Martin and Blaskovic-Subat, 1997).

### **1. Root Canal Instruments**

The endodontic hand instruments of the early 1900's were made from stainless-steel and carbon steel. Carbon steel was abandoned because of its poor corrosion resistance. Stainless-steel hand files were inherently stiff and of limited flexibility. The discovery of nickel-titanium memory alloy in the early 1960's changed endodontics forever. This material has been widely used throughout the health sciences because of its excellent biocompatibility, shape memory effect, and superior elasticity (Buehler, Gilfrich and Wiley, 1963).

Nickel-titanium alloy has unique qualities – mainly increased strength together with the enhanced elasticity. Root canal reamers and files with four-fold and even higher tapers are now available, which makes them completely different from earlier instruments (Walia, Brantley and Gerstein, 1988; Walia *et al.*, 1989; Cantatore, 1998). The introduction of nickel-titanium to endodontics made it possible to produce consistent and efficient canal shaping with fewer instruments (Glosson *et al.*, 1995; Bryant *et al.*, 1998; Cantatore, 1998).

## 1.1 Nickel-Titanium

Civjan, Huget and DeSimon (1975) initiated the use of nickel-titanium in dentistry. The first K-bladed file was created by machining nickel-titanium orthodontic arch wire to produce a fluted instrument (Walia *et al.*, 1988).

Later, Nitinol SE 508 was used for the ProFile endodontic system (Dentsply/Maillefer, Ballaigues, Switzerland). The raw wire undergoes a series of procedures to obtain the desired design and properties. Cold manipulation is carried out to achieve the correct cross-sectional diameter before the wire undergoes thermo-cyclic treatment under strain. The wire blanks are then fashioned to create the rotary endodontic instruments (Thompson, 2000).

The nickel-titanium alloy is super elastic and can return, within considerable limits, to its original shape. Once the material is stretched, however, certain changes can take place within the austenitic structure. A martensitic transformation ensues and, if the instrument is stretched beyond its elastic limit, the structure will rupture and lead to instrument failure (Di Fiore, 2007). Despite this particular risk, the material has been widely used by both general clinicians and specialist endodontists worldwide.

Compared with stainless-steel endodontic instruments, nickel-titanium products endure more torsional stress before failure and are reported to be three times stronger than those made from stainless-steel (Walia *et al.*, 1988). Their introduction in endodontics has led to a reduction in clinical chair time, more accurate cleaning and shaping of root canal systems, and a minimising of procedural risks (Walia *et al.*, 1988; Taschieri *et al.*, 2005; Parashos and Messer, 2006).

Nickel-titanium rotary instruments also provide the potential to clean and shape the root canal system much faster than do stainless-steel hand files (Ferraz *et al.*, 2001). Further, the use of rotary nickel-titanium endodontic instruments has been shown to be associated with a higher success rate than seen in those treatments performed exclusively with stainless-steel hand instruments (Cheung and Liu, 2009).

The super elasticity of nickel-titanium endodontic instruments confers a major advantage in their ability to clean and shape curved root canals. Stainless-steel instruments larger than size 30 are more rigid and robust and are, therefore, prone to procedural accidents in curved canals (Esposito and Cunningham, 1995).

Early studies proved that the use of nickel-titanium endodontic instruments produced more centred and properly tapered preparations of root canals than did stainless-steel instruments (Zmener and Balbachan, 1995). Numerous other studies have confirmed the results (Bou Dagher and Yared, 1995; Lodd Thurani, Parameswaran and Sukumaran, 1996; Bishop and Dummer, 1997). Crown-down preparation techniques were introduced in combination with rotary nickel-titanium instruments of greater taper, which proved to produce root canal preparations with more predictable outcomes and a reduced risk of procedural accidents (Himel *et al.*, 1995; Pettiette *et al.*, 1999; Iqbal *et al.*, 2003; Guelzow *et al.*, 2005).

## 1.2 M-Wire

M-Wire, a new type of nickel-titanium wire, has been developed by a series of proprietary thermo-cyclic processing procedures (Ye and Gao, 2012). This material has showed great promise in reducing the failure risk of endodontic instruments through cyclic fatigue.

The first rotary M-Wire endodontic instruments developed included the GT Series X and the ProFile Vortex systems (Dentsply, Tulsa Dental, Tulsa, Oklahoma, USA) (Johnson *et al.*, 2008; Larsen *et al.*, 2009; Al-Hadlaq, Aljarbou and Althumairy, 2010; Da Cunha Peixoto *et al.*, 2010; Gao *et al.*, 2010). According to the manufacturers, nickel-titanium endodontic instruments created with M-Wire are even more flexible and resistant to failure than those made from traditional nickel-titanium alloy.



Alapati, Brantley and Lijima (2009) conducted a study to determine the metallurgical characterisation of M-Wire and found that the material contains all three crystalline phases (deformed micro-twinned martensite, R-phase, and austenite). M-Wire has a higher Vickers hardness value (VHN) than the super-elastic nickel-titanium material Nitinol and, therefore, a higher micro hardness. A value of 385 VHN was found in M-Wire compared with a value of between 312 and 376 VHN for Nitinol rotary endodontic instruments (Zinelis, Eliades and Eliades, 2010).

A reduction in grain size of metals and alloys leads to increased strength in the new material (Hall, 1951; Petch, 1953). Ye and Gao (2012) speculate that the superior mechanical qualities and increased resistance to torque and mechanical wear and tear of the M-Wire nickel-titanium alloy can be ascribed to its 100 nm martensite grains.

The most recent introduction of M-Wire in endodontics is the WaveOne Endodontic System (Dentsply/Maillefer) where a single instrument is used in a reciprocating movement (150° counter-clockwise movement and 30° clockwise) to prepare a root canal system.

### **1.3 R-Phase**

SybronEndo Corporation (SybronEndo, Orange, California, USA) has adopted a different approach to the manufacturing process of nickel-titanium endodontic instruments and have designed the Twisted File (SybronEndo). The manufacturing technique involves a combination of heat treatment and twisting of a ground blank nickel-titanium wire. A raw nickel-titanium wire is selected in its austenite crystalline structure and, by means of heating and cooling procedures, a completely new crystalline phase of the alloy is created, referred to as the "R-phase. In this phase the nickel-titanium alloy cannot be ground and twisting is the only way it may be processed. Hence the Twisted File is created by twisting the R-phase wire into the desired shape, heating and cooling it to maintain this shape and then converting it back to its austenite crystalline structure. The structure is super elastic once the stress procedure is completed (Gambarini *et al.*, 2008).

The development of these manufacturing techniques and processes was in the endeavour to find a way of enhancing super elasticity and increasing the cyclic fatigue resistance (The Twisted File Brochure, 2008). Larsen *et al.* (2009) demonstrated in their study that the unique design of the Twisted File in conjunction with the use of the R-phase nickel-titanium alloy did indeed contribute to an increase in resistance to cyclic fatigue.

Another advantage of the Twisted File is that the instrument is not created by means of a grinding process, which causes micro-fracture points in the crystalline structure along the complete length of the file. Rather, the new process leads to the formation of the R-phase of the nickel-titanium alloy, which preserves the crystalline structure and increases the resistance to fracture and instrument failure.

Gambarini *et al.* (2008) compared the performance of the size 25, .06 taper Twisted File with that of the K3 (SybronEndo) (size 25, .06 taper) instrument with regard to cyclic fatigue. The authors concluded that together with the new way of creating the superior nickel-titanium material R-phase, the Twisted File concept produced instruments which are far superior regarding fatigue resistance.

#### **1.4 Vortex Blue**

Vortex Blue (Dentsply, Tulsa Dental) is a recent development that will, according to the manufacturer, improve fracture resistance and cutting ability, have superior flexibility relative to previous nickel-titanium rotary systems and will enhance the ability to more precisely shape a centric root canal preparation. The development involves a state-of-the-art proprietary thermo-mechanical process to manipulate the nickel-titanium alloy.

The Vortex Blue instruments have a unique 'blue colour', different from other nickel-titanium instruments. The proprietary manufacturing process results in the formation of an oxide surface layer that has the unique 'blue colour'. The titanium oxide (including anatase and rutile) has a hardness of between 5.5 and 6.5 on the Mohs scale and in the range of 620 to 970 VHN on the Vickers scale (<http://www.mindat.org/min-213.html>., October 8, 2011).

The formation of the titanium-oxide surface has increased failure resistance by providing more hardness to the instrument, which at the same time has more flexibility than the ProFile Vortex instrument (Dentsply, Tulsa Dental). Gao *et al.* (2012) proved that rotary endodontic instruments manufactured with Vortex Blue alloy showed superior elasticity, hardness and resistance to fracture than conventional nickel-titanium instruments.

## 1.5 Controlled M-Wire (CM-Wire)

In October 2011, Typhoon Infinite Flex nickel-titanium rotary endodontic system (Clinician's Choice Dental Products, New Milford, Connecticut, USA) was launched. This endodontic instrument is manufactured using controlled-memory (CM) nickel-titanium wire.

Shen *et al.* (2011) demonstrated that CM-Wire was 300% to 800% more resistant to fatigue failure than conventional nickel-titanium. These authors also noted that the instruments showed many more crack origins than did conventional instruments, but the increased fatigue resistance can be ascribed to CM-Wire's bulk mechanical properties and increased fatigue crack thresholds.

A major advantage of the Typhoon CM file is that its memory has either been removed or controlled by a special thermo-mechanical process. This remarkable product differs from any other nickel-titanium rotary endodontic instrument because the instrument can be pre-curved and bent to adapt to root canal curvature. This feature allows the instrument to follow the root canal anatomy without creating unwanted, disproportionate lateral forces on the canal walls. Pre-curving of the instrument also facilitates working on teeth with limited access (second and third molars) and allows management of root canals with ledges (Sides, 2012).

The Typhoon CM file has increased torsional strength and increased resistance to cyclic fatigue and is more likely to unwind than separate. The design includes a non-cutting tip. The instrument 'follows' the root canal, preserving tooth structure as less is removed during cleaning and shaping (Sides, 2012). Traditional nickel-titanium instruments have perfect memory, which causes straightening of the root canal

curvature (Sides, 2012). The Typhoon CM instrument will not attempt to straighten in-curved root canals and hence should not alter original root canal anatomy.

## 2. Instrument Fracture

There are undeniable advantages in the use of nickel-titanium rotary instruments in endodontics, but the operator does face the risk of instrument fracture, an unfortunate but persistent problem in root canal preparation, especially in curved canals. Fracture of an endodontic instrument inside the root canal remains a serious problem and can alter the prognosis (Haïkel *et al.*, 1999; Mandel *et al.*, 1999), impeding the likelihood of reaching the final goal of the planned treatment (Schilder, 1967; Schilder, 1974).

Unfortunately, conflicting results have been reported on the clinical significance of an endodontic instrument separating within the root canal and on what the long-term result would be were the instrument tip left inside the root canal system. It is sometimes nearly impossible to remove the fractured segment. Evidence shows, however, that in certain cases (teeth with necrotic pulps or teeth with peri-apical lesions) it will be more traumatic and unfortunate if the instrument separates, as the chances of successful healing will be reduced (Spili, Parashos and Messer, 2005).

The tooth undergoing root canal treatment has a poorer prognosis if the endodontic instrument separates in the apical third of the root canal or beyond the root canal curvature, as it will become more difficult to remove. The greater the curvature of the root canal, the more difficult it will become to remove the fractured segment (Hülsmann and Schinkel, 1999; Ward, Parashos and Messer, 2003; Shen, Peng and Cheung, 2004; Suter, Lussi and Sequeira, 2005). If a high risk is involved (possible root perforations or root fractures), the clinician would be well advised to exercise great care when attempting removal of the segment. It may be prudent to accept that these fractured endodontic instruments should be left alone (Souter and Messer, 2005).

With continuous rotation inside the root canal the file encounters torsional and bending stress, which causes intense compression and flexion forces within the file.

This can lead to structural fatigue and fracture (Sotokawa, 1988; Pruett, Clement and Carnes, 1997). Bending stress and cyclic failure seem to be more prominent in curved root canals while torsional stress and torsional failure are more prevalent in straight canals (Yum *et al.*, 2011). The more a rotary nickel-titanium endodontic file is placed under working stress, the greater the pressure on the durability. The risk of failure increases (Zuolo and Walton, 1997; Yared, Bou Dagher and Machtou, 1999; Gambarini, 2001).

## 2.1 Torsional Stress

Torsional stress can be described as the amount of stress generated within the instrument when it engages the root canal wall or when the operator subjects the instrument to increased apical force. This is the main cause of instrument fracture. The instrumentation of root canals of smaller diameter generates more torsional stress during the cleaning and shaping procedure than when dealing with root canals of larger diameter (Sattapan, Palamara and Messer, 2000a). The clinician can control the manipulation of the endodontic instrument and therefore can reduce the intensity of the torsional stress (Sattapan *et al.*, 2000a).

## 2.2 Bending Stress

Bending stress can be described as the force generated within the nickel-titanium alloy by rotating an instrument in a curved root canal. This will result in repeated compression and flexing at the point of maximum curvature - a very destructive form of loading of the instrument, despite the fact that nickel-titanium has superior elasticity and that there is no binding to the canal wall (Pruett *et al.*, 1997).

Larger and more tapered endodontic instruments will encounter much greater bending stress in curved root canals than will an instrument with a smaller diameter and taper (Crandall, Dahl and Lardner, 1972). Larger taper reamers require more material and more detailing in the manufacturing process, unfortunately rendering the instrument liable to earlier failure if it is subjected to flexion stress (Sattapan *et al.*, 2000b; Grande *et al.*, 2006).

Bending stress is a very important factor affecting fatigue within the nickel-titanium file and it may be an unexpected problem if the root canal anatomy is unknown.

### **3. Factors Influencing Instrument Fracture**

#### **3.1 Instrumentation technique**

Research has concluded that the less knowledge and experience the operator has, the higher the incidence of instrument fracture (Yared *et al.*, 2001; Yared *et al.*, 2002). With on-going use of a particular rotary nickel-titanium instrument, the operator's tactile sensation tends to improve and he or she can sense a rise in torsional resistance and the risk of taper lock.

The results of these studies have led to an effort to improve operator proficiency and thereby to reduce the risk of instrument separation. Operators need to be properly trained in the use of nickel-titanium rotary endodontic instruments and to acquire operating experience to avoid procedural mishaps, including fractures of the files (Barbakow and Lutz, 1997; Mandel *et al.*, 1999; Yared *et al.*, 2001).

At present, a number of guidelines are available for operators on the relatively safe use of endodontic instruments (Grossman, 1969). These include: (1) examining instruments before and after use to detect any deformations (the flutes of the instrument should be evenly aligned); (2) not using endodontic instruments in dry root canals; (3) following the manufacturer's instructions carefully; and (4) always avoiding excessive forces, especially apical pressure.

Mareending, Lutz and Barbakow (1998) and Mandel *et al.* (1999) found that the frequency of instrument fracture not only varied between different operators but also at different times with the same operator during the sequence of cleaning and shaping. Recently, a collaborative study conducted by endodontists from four different countries concluded that the most important factor influencing the incidence of endodontic file separation and formation of defects on the instruments was the competence and technique of the operator. Some of the participants in

the study used the endodontic instruments for a limited number of times, while others used them until defects were observed (Parashos, Gordon and Messer, 2004).

### **3.2 Number of uses**

There is a very close relationship between the number of rotary cycles the nickel-titanium file performs and the working stress created within the file (Pruett *et al.*, 1997). The more cycles the endodontic instrument endures, the greater the working stress and the higher the risk of fracture (Zuolo and Walton, 1997; Yared *et al.*, 1999; Gambarini, 2001). Used instruments have a higher risk of failure and fracture than those used for the first time (Alapati *et al.*, 2003; Alapati *et al.*, 2005).

Sotokawa (1990) suggests that the clinician adopt a system for replacing used nickel-titanium instruments when allocated predetermined number of uses has been reached. It is more beneficial to discard used instruments after a certain number of uses than to take the risk of persevering until the instruments show signs of actual deformation (Di Fiore, 2007).

To achieve the most predictable safety it has been suggested that a rotary nickel-titanium endodontic instrument should be used only once (Arens *et al.*, 2003). In that particular study, 786 once-used instruments were examined and only 14% showed visual signs of fatigue and distortion and only seven instruments fractured.

All the modern rotary nickel-titanium endodontic instruments are expensive and at least three to four are usually required in the treatment sequence. A single-use multi-purpose instrument would therefore be very beneficial for the general dentist as well as the endodontist, requiring only the one device in the sequence. However, success would depend on whether all the mechanical and biological endodontic objectives could actually be achieved with a single instrument (Yared, 2008).

### 3.3 Instrument manufacturing

Most clinicians are unaware of the exact composition of the alloy and of the manufacturing methods for each nickel-titanium endodontic instrument. The production process of most involves grinding the material rather than twisting the metal (Serene, Adams and Saxena, 1995). Occasionally a clinician may unknowingly use a faulty instrument (Cheung, Shen and Darvell, 2007; Kim *et al.*, 2009; Kim *et al.*, 2010).

Analysis of the microstructure and surface of brand new nickel-titanium instruments reveals some interesting findings, including: (1) distortions in the lattice structure of the nickel-titanium alloy; (2) inconsistency in the micro hardness; (3) marks left during the machining and milling of the alloy during the production phase; and finally (4) the presence of micro cracks on the surface (Kuhn, Tavernier and Jordan, 2001; Tripi *et al.*, 2001; Martins, Bahia and Buono, 2002).

Occasionally nickel-titanium rotary endodontic files can separate at a point below their elastic limit as a result of factors inside the material, called "slip bands" (Dieter, 1986). These are microscopic mechanisms within the material allowing grains to slide over each other, increasing the chances of fatigue and fracture.

Some studies have confirmed that electro-polishing the instrument after it has been manufactured may increase its resistance to failure and provide superior working properties (Lee *et al.*, 1996; Rapisarda *et al.*, 2000; Rapisarda *et al.*, 2001). Electro-polishing can be described as the process where a very thin layer of the instrument is removed by placing the instrument in a strongly ionic solution through which is passed an electric current. Electro-polishing adds a few very important characteristics to the instrument, including graining the boundaries, creating superior mechanical properties and reducing dimensions. The process also removes pitting and surface irregularities caused by machining the material, which can otherwise act as centres for fracture formation (Pohl, Helßing and Frenzel, 2004).



The ProFile (Dentsply/Maillefer), EndoWave (J Morita Corporation, Osaka, Japan) and RaCe (FKG, La-Chaux De Fonds, Switzerland) rotary nickel-titanium endodontic systems are examples of instruments that undergo the electro-polishing technique.

### **3.4 Tooth anatomy**

A very important factor to consider is the individuality of dental anatomy. Root canal morphology and anatomy are different for every tooth. Variations in root canal anatomy that present hidden challenges to the clinician include: merging canals, curving of canals, and recurving and dilacerating/dividing canals. The original anatomy of the canal before instrumentation is a factor that influences bending stress on the file and has nothing to do with the clinician.

Reports from research show that separation of endodontic instruments occurs more often in molars (Peng *et al.*, 2005; Iqbal, Kohli and Kim, 2006). The mesial roots of the mandibular molars are those most likely to cause instrument separation and, more specifically, the apical third of the root canal compared with the middle or coronal third (Hulsmann and Schinkel, 1999; Ward *et al.*, 2003; Iqbal *et al.*, 2006). A fact that clinicians should keep in mind additionally is that two canals being present with the same angle of curvature does not necessarily mean that they possess throughout the same radii of curvature. This means that some root canals describe curves that are sharper than others and pose more challenges to clean and shape (Gunday, Sazak and Garip, 2005).

### **3.5 Pressure on the instrument**

The more apical force used by the operator, the greater the risk that the nickel-titanium instrument will encounter taper lock, undergo structural failure and fracture (Sattapan *et al.*, 2000a; Sattapan *et al.*, 2000b). Endodontic instruments can be described as 'active' or 'passive', the former having blades for the cutting and removal of tooth structure while passive endodontic instruments have a radial land between the cutting edge and flute.

Active instruments are able to remove more dentine aggressively, faster and more efficiently, while passive instruments produce a scraping or burnishing action and

therefore remove dentine at a much slower rate, reducing the tendency to change and straighten the original canal morphology (Walsch, 2004). The natural tendency for the operator will then be to apply more apical force to proceed deeper and faster and this will eventually lead to torsional fracture (Kobayashi, Yoshioka and Suda, 1997).

### **3.6 Torque-controlled motors**

As mentioned previously, torsional and bending stresses play a crucial role in instrument failure, but there is another factor, namely, torque, that influences the stress placed on the endodontic instrument. In the clinical situation where an endodontic motor is used that generates a high degree of torque, it is very easy to exceed the fracture limit of the endodontic instrument. In combination with torsional and bending stresses, a high degree of torque can increase the risk of instrument failure substantially if great care is not taken.

A possible solution would be to use an endodontic motor with a torque-control function and to determine a maximum permissible torque limit for each instrument. In the event of the instrument tip binding into the root canal, torque-control motors will stop and then start rotating in the opposite direction (Gambarini, 2000; Yared, Bou Dagher and Kulkarni, 2003). This auto-reverse function is an excellent safety measure, especially when the operator uses a low maximum torque endodontic system like the ProFile and SystemGT (Dentsply/Maillefer) rotary nickel-titanium systems.

However, there is one important consideration of which the clinician needs to be aware. A certain amount of force is required to stop the instrument from rotating, to disengage the instrument from its original path, and then to rotate it in the opposite direction. This 'effort' is then stored in the instrument memory. With each cycle having auto-reverse activated, more and more memory is stored leading to a reduction in its lifespan (Castellucci, 2005).

### 3.7 Rotation rate

A study by Gabel *et al.* (1999) and Yared *et al.* (2001) demonstrated that the failure of ProFile rotary endodontic instruments was related to the rotational speed of the instrument. A lower rotational speed produced a lower risk of instrument separation (Gabel *et al.*, 1999; Yared *et al.*, 2001). Consensus has been reached between most manufacturers that rotational speeds ranging from 150 to 350 rpm should be used for the cleaning and shaping procedure.

The higher the rotational speed, the higher the incidence of instrument failure (Martin *et al.*, 2003). Gabel *et al.* (1999) found that when rotational speeds in the region of 333 rpm were used, the risk of instrument failure and separation was four times greater than with rotational speeds in the region of 167 rpm. In this particular study, extracted molar teeth were used as subjects. Significantly, it was also proven that the time it took before endodontic instruments separate dramatically reduced as soon as the rotational speed increased (Li *et al.*, 2002).

### 3.8 Instrument size and radius of curvature

Pruett *et al.* (1997), in ground-breaking work, proved that factors including radius of the root canal curvature, angle of the root canal curvature and diameter of the endodontic instruments were more important as predictors of instrument failure and fracture than the speed at which the nickel-titanium rotary instrument operates. The engine-driven ProFile (Dentsply/Maillefer) rotary endodontic system was used in this study and Endodontic-Training-Blocks (Dentsply/Maillefer) were used to keep all parameters (curve angle, curve radius and instrument sequence) the same.

Published findings show that increased curvature of a root canal and an increase in the diameter of the master endodontic instrument to reach the full working length of the measured root canal, lead to a higher tendency to canal transportation, canal straightening and aberration of the original anatomy (Griffiths, Bryant and Dummer, 2000).

Reports also show that as soon as the angle of curvature of the root canal increases, the incidence of endodontic instrument failure will escalate (Patiño *et al.*, 2005).

Considering all the variables of root canal anatomy, the most influential in endodontic instrument failure is the radius of the root canal curvature (Booth *et al.*, 2003).

### **3.9 Access cavity preparation**

Undeniable advantages stem from adequate access preparation in avoiding complications in the cleaning and shaping sequence. The access preparation should have: (1) no obstructions of the root canal orifices either by dentine or restorative material; and (2) clear, visual direction to enable instruments to approach the apical portion of the root canal or at least the point of initial curvature (Janik, 1984). These initial steps may take some time, but an endodontic instrument that can negotiate a root canal with minimal resistance has a reduced risk of failure and separation. The aim is to decrease the torsional and bending stress on the instrument.

Patients with limited mouth opening are a further risk, as the particular tooth / teeth to be treated cannot be easily reached and the design of the access cavity preparation becomes even more crucial (Yared and Kulkarni, 2002).

### **3.10 Canal orifice enlargement**

The main purpose of canal orifice enlargement / pre-flaring is to aid the negotiation and manipulation of instruments to the apical parts of the root canal. The proper enlargement of the orifices of root canals becomes more valuable when molar or multi-rooted teeth or teeth with severe curvatures are being treated (Leeb, 1983; Morgan and Montgomery, 1984).

The burs used to effectively enlarge the orifices are: (1) number 2 or 4 long-shank, slow-speed round burs or (2) numbers 3 and 4 Gates-Glidden burs (Leeb, 1983; Morgan and Montgomery, 1984). Correct use will achieve the necessary amount of enlargement to allow the rotary nickel-titanium instruments to enter with the least amount of torsional and bending stress coronally. The ideal coronal enlargement needs to be oval shaped and approximately 2 mm to 4 mm deep (Di Fiore, 2007).

### 3.11 Surface condition and inspection of instruments

The manufacturers of rotary nickel-titanium instruments advocate that the instruments be inspected constantly for defects and micro-cracks that can lead to instrument fracture.

On rare occasions the rotary nickel-titanium endodontic instrument can fracture without any prior warning even if a thorough inspection was performed before use (Martin *et al.*, 2003).

Nickel-titanium endodontic instruments have a drawback in comparison with stainless-steel instruments, as in the latter it is easier to detect deformation and metal fatigue, which alert the operator to the potential danger of instrument fracture (Marending *et al.*, 1998). It would seem that inspection of nickel-titanium rotary endodontic instruments by means of visual inspection only is insufficient to detect deformation and potential instrument failure (Martin *et al.*, 2003). More precise methods are indicated.

### 3.12 Effect of sterilization on the instrument

Yared (2008) claims that two main reasons exist for the failure of nickel-titanium rotary instruments: (1) there is always the risk of fracture of the instrument caused by fatigue through repeated use; and (2) the Spongiform Encephalopathy Advisory Committee (2006) found that the risk of cross-contamination exists because it is not possible to completely clean and sterilize the endodontic instruments after use.

The Prion Protein (PrP) can be described as a developmentally regulated glycoprotein found in mammals. When the native prion protein (PrP<sup>C</sup>) is transformed to an alternative conformation (PrP<sup>Sc</sup>), it is believed to play a vital role in the pathogenesis of disorders namely "transmissible spongiform encephalopathies" (TSEs/"prion diseases") (McKinley *et al.*, 1987). A recent study reported that prions were found in human pulp tissue (Schneider *et al.*, 2007).

Tooth structure and organic debris adhere to the surface of nickel-titanium endodontic instruments, even though the instruments are thoroughly

decontaminated and ultrasonically cleaned (Alapati *et al.*, 2003; Alapati *et al.*, 2004; Sonntag and Peters, 2007). This raises the question of what is the effect of such stringent sterilization procedures on endodontic instruments. Endodontic circles accept the fact that thermo-cycling procedures cause metal fatigue to some extent, but researchers are unable to decide which specific type of thermo-cyclic procedure causes the most damage. Some studies have even concluded that thermo-cyclic sterilization does not affect endodontic instruments or that any adverse effects are of no clinical significance (Siviago and Hicks, 1997; Canalda-Sahli, Brau-Aguade and Sentis-Vilalta, 1998; Hilt *et al.*, 2000). The manufacturing of a single-use nickel-titanium endodontic instrument to reduce the risk of instrument failure and cross-contamination would therefore have huge benefits.

### **3.13 Irrigation and lubrication**

Mechanical cleaning and shaping of the root canal system and irrigation cannot be separated from the debridement sequence which is designed to remove infected tissue from the root canal. Scanning Electron Microscopic (SEM) studies conducted by various authors have proven that if irrigation (and some sort of lubrication) is not used during cleaning and shaping, debris will pack in the root canal, especially in the apical portion, and form dentinal "mud" (Baker *et al.*, 1975; McComb and Smith, 1975; Baumgartner and Mader, 1987).

The main purpose of irrigation and lubrication is to ease instrument negotiation in the root canal system – especially in narrow, constricted areas – and to reduce torsional stress on the instrument; in this way lowering the risk of instrument failure (Di Fiore, 2007). One study showed that these adjunctive procedures reduced the torsional stress on the instrument by as much as 400% (McSpadden, 2007). A comparison was made between preparing a root canal system without any form of lubrication or irrigation and preparing the root canal system with a variety of irrigants (water, RC-Prep, sodium hypochlorite and ethylenediaminetetra-acetic acid (EDTA)). The Quantec rotary nickel-titanium system (NT Company, Chattanooga, Tennessee, USA) was the instrument of choice in this particular study. RC-Prep reduced the torsional stress the most on the instrument at depths of 10 mm and 12 mm, followed by water, EDTA and sodium hypochlorite. However, at a depth of 8 mm into the root

canal system, EDTA affected more reduction of torsional stress than any other lubricant or irrigation solution tested. Cleaning and shaping the root canal system without any form of lubrication or irrigation showed the highest levels of torsional stress on the endodontic rotary instrument in this study.

A very recent study demonstrated that when endodontic instruments were immersed in sodium hypochlorite solution of a concentration of 5.25%, the instrument had markedly less resistance to fracture when exposed to cyclic fatigue (Berutti *et al.*, 2006). This finding is most relevant when one considers that sodium hypochlorite is the most common and trusted irrigation solution in endodontics and is used by most clinicians.

### 3.14 Rotary instrument manipulation

The manner in which the rotary nickel-titanium instrument is handled is arguably one of the most important factors contributing to instrument failure. Dederich and Zakariasen (1986) advocate that instruments used in a smooth, cyclic and axial motion (up-and-down motion without allowing the instrument to rotate in one area for a longer period) will reduce the risk of instrument failure. More recent studies have confirmed these recommendations (Haikel *et al.*, 1999; Sattapan *et al.*, 2000a; Li *et al.*, 2002).

### 3.15 Instrument design

Three design factors that influence the failure rate of nickel-titanium instruments stand out. These are (1) instrument size, (2) instrument taper and (3) cutting flute depths (Kuhn *et al.*, 2001; Chaves Craveiro de Melo, Guiomar de Azevedo Bahia, Lopes Buono, 2002; Ullman and Peters, 2005; Xu *et al.*, 2006; Yao, Schwartz and Beeson, 2006).

The **size** of the instrument will determine how many times it should be used within the root canal before it should be replaced (Wolcott *et al.*, 2006). Chaves Craveiro de Melo *et al.* (2002) concluded that larger instruments are more likely to fracture in the cleaning and shaping sequence.

The **taper** of the instrument can also play a role in the frequency of instrument separation. Nickel-titanium instruments with a taper of 0.04 had more resistance to fracture than 0.06 instruments (Yao *et al.*, 2006).

The **cutting flute depths** are the final factor influencing failure rate of nickel-titanium instruments. The combination of deep-cutting flute depths and progressively increasing and variable tapers provides great risk of instrument failure. Different cross-sectional diameters along the complete length of the instrument shaft will pose higher levels of torsional stress when engaged on the root canal walls during the cleaning and shaping procedure. The shallower the cutting flutes and more even the taper and cross-sectional diameter of the instrument, the more evenly the forces (torsional and bending stresses) are distributed along the instrument shaft, which makes the instrument more resistant to instrument failure and separation (Guilford, Lemons and Eleazer, 2005; Shen *et al.*, 2006; Yao *et al.*, 2006).

### 3.16 Rotation vs reciprocation

Different systems that make use of alternating movements have been studied in order to find a way to decrease the risk of instrument fracture (Malentacca and Lalli, 2002; Varela-Patiño *et al.*, 2008; Yared, 2008). The reciprocating motion would, in theory, reduce the number of cycles of the instrument and, therefore, reduce the cyclic fatigue on the instrument compared with rotary instruments used in a consistent rotating motion (Varelo-Patiño *et al.*, 2010; You *et al.*, 2010). Varela-Patiño *et al.* (2008) tested the assumption by using Endodontic-Training-Blocks. Their study confirmed that when operated in a reciprocating motion the nickel-titanium endodontic instruments were less prone to separation.

During repeated rotation, with continuous compression and flexion, micro fractures form within the nickel-titanium file that will lead to instrument fracture (Martin *et al.*, 2003). The alternating rotary movement decreases the binding of the file to the root canal wall, reducing torsional stress in this way and is recommended not only to reduce risk of instrument fracture, but also to decrease the chances of root canal deformation and to improve the centring ability of the instrument (Roane and Sabala, 1984; Roane, Sabala and Duncanson, 1985; Southard, Oswald and Natkin,



1987; Varela-Patiño *et al.*, 2008; Yared, 2008). Very recent studies were able to confirm that using nickel-titanium instruments in a reciprocating motion will increase the lifespan of the instrument by minimising cyclic fatigue and flexural stress as the number of cycles required within the root canal is lower (De-Deus *et al.*, 2010; You *et al.*, 2010).

#### **4. Reproducible Glide Path Preparation Prior to Instrumentation**

A factor that could greatly influence the failure rate of nickel-titanium endodontic files is the initial use of stainless-steel files in the creation of a 'glide path' before the first rotary instrument is introduced into the root canal (Berutti *et al.*, 2004; Varela-Patiño *et al.*, 2005).

A glide path is a smooth passage that extends from the canal orifice in the pulp chamber to its opening at the apex of the root (West, 2006). This should in theory, provide a continuous, uninterrupted pathway for the rotary nickel-titanium instrument to enter and to move freely to the root canal terminus. The main purpose of a glide path is to create a root canal diameter the same size as, or ideally a size bigger than, the first rotary instrument introduced (Berutti *et al.*, 2004; Varela-Patiño *et al.*, 2005; Berutti *et al.*, 2009).

Varela-Patiño *et al.* (2005) found that fewer fractures occurred when a wide and smooth-walled glide path was created and the canal was pre-flared before the introduction of rotary files into the root canal. It was speculated in this study that the creation of a smooth glide path by means of stainless-steel hand files meant that most of the anatomical interferences that can cause obstructions to the rotary nickel-titanium files were eliminated.

Various methods have been advocated to create a glide path. Several authors use stainless-steel K-files (Berutti *et al.*, 2004; Walsch, 2004; Gambarini, 2005; Mounce, 2005; Ruddle, 2005). Mounce (2005) concluded that the use of hand stainless-steel instruments has four advantages: (1) excellent tactile sensation; (2) lower risk of fracture; (3) small K-files being able to mimic the root canal anatomy at the smaller areas of the canal, giving the clinician a better sense of the detailed anatomy of

the root canal; and (4) an enhanced ability to negotiate blockages and calcifications.

The small stainless-steel instrument (K-file) should be used in a clockwise and anti-clockwise rotation (watch-wind) to scout the narrow part of the canal, followed by a vertical in-and-out movement. The vertical movement should start with 1mm amplitudes and, once the resistance decreases, the amplitudes can be increased (West, 2006).

Other authors advocate the use of a reciprocating hand piece (SybronEndo) (30 degrees clockwise and 30 degrees anti-clockwise movements) in combination with K-files. Using a hand piece to create the glide path gives the operator the advantage of reducing hand fatigue and cuts down chair time considerably, especially in multiple narrow root canal preparation (Kinsey and Mounce, 2008; Mounce, 2008; Van der Vyver, 2011a).

The most recent development in glide path preparation is the PathFile system (Dentsply/Maillefer). Berutti *et al.* (2009) found that this technology caused less canal aberration and less modification of the original canal anatomy in simulated root canals. The PathFile sequence consists of three files (with a choice of 21mm, 25mm and 31mm file lengths) – namely a number 13 (purple with ISO tip size 13, 2% taper), number 16 (white with ISO tip size 16, 2% taper) and number 19 (yellow with ISO tip size 19, 2% taper). Initial preparation of a glide path should be done up to a size 10 K-file before the first PathFile instrument is introduced into the canal (Van der Vyver, 2011b).

## **5. Reciprocation Instead of Rotation of Root Canal Instruments**

Clinicians are faced with expenses related to endodontic treatment as well as the risk of cross contamination. The more instruments used, the higher the risk of cross contamination and instrument fracture and subsequently higher costs.

An experimental technique was launched using a single size 08 (ISO) hand file and one F2 ProTaper (Dentsply/Maillefer) nickel-titanium rotary instrument (Yared, 2008).

The size 08 hand file is used to negotiate the root canal to length with continuous use of lubricant and/or 2.5% sodium hypochlorite irrigation. The F2 ProTaper instrument (Dentsply/Maillefer) is then introduced in a clock-wise and counter-clockwise movement into the canal by means of a 16:1 reduction ratio contra-angle hand piece and ATR Vision motor (ATR, Pistoia, Italy). Although only an experimental study, it showed great promise for reducing the number of instruments, risk of instrument fracture and finally reducing the risk of cross contamination (Yared, 2008).

Compared to full rotation, a few studies confirmed that it is faster to prepare root canals with reciprocating motion. A study by Yao *et al.* (2006) confirmed this advantage. If the ProTaper F2 is used in a reciprocating motion, the time needed to prepare the root canal on extracted molars was half of that of the same instrument used in full rotation. They also noted only one file (ProTaper F2) (Dentsply/Maillefer) was needed to reach full working length, reaching the desired length in half the preparation time with the added benefit of reducing operator fatigue. Similar findings were found in other studies (Azarpazhooh and Fillery, 2008; Yared, 2008; Paqué, Zehnder and De-Deus, 2011). As mentioned earlier, the endodontic instrument undergoes fewer cycles of rotation than with traditional rotation, less binding of the instrument to the canal walls and ultimately decreasing the risk of instrument fracture (De-Deus *et al.*, 2010; You *et al.*, 2010).

It must also be mentioned that a study done by Bürklein and Schäfer (2012) found that instruments like WaveOne and Reciproc (VDW, Munich, Germany) were significantly faster in preparing human mandibular central incisors than instruments like Mtwo (VDW) and ProTaper (Dentsply/Maillefer) operating in full rotation. Kum *et al.* (2000) also found similar results in their study using the ProFile system (Dentsply/Maillefer). Unfortunately, it was found that reciprocation produced much more debris than the instruments used in full rotation and ultimately debris extruded through the apical foramina (Bürklein and Schäfer, 2012). Hülsmann, Rödiger and Nordmeyer (2009) found that extruded debris and irrigation solutions cause irritation of periapical tissues resulting in possible interappointment discomfort and possible unscheduled emergencies.

Despite the above drawback, instrument separation remains a source of anxiety to the operator. A few studies concluded that instruments used in reciprocating movement are less prone to fracture than instruments used in full rotation. Gavini *et al.* (2012) confirmed this statement in their study. They used the Reciproc R25 file (VDW) in continuous and reciprocation motion with a custom made apparatus. It took 357.56 s to fracture with the reciprocating group R25 Reciproc file (VDW) compared to 163.28 s for the continuous group. Similar findings were observed by De-Dues *et al.*, (2010).

The WaveOne endodontic system (Dentsply/Maillefer) consists of a choice of 3 single-use files: Small (ISO tip 21, 6% taper), Primary (ISO tip 25, 8% taper) and Large (ISO tip 40, 8% taper) operating in reciprocating action and manufactured with the highly resistant M-Wire nickel-titanium alloy. In some cases the use of only a single WaveOne file has the ability to leave the prepared root canal with adequate size and taper (Berutti *et al.*, 2012a).

An added benefit of the WaveOne file cutting in a reciprocating action is the fact that the reciprocating cutting action leaves more centred preparations with reduced risk of canal transportation, ledge formation and irregular enlargement of the apical foramen (Berutti *et al.*, 2012a). The WaveOne instrument is also able to maintain original canal anatomy better compared to the file sequence implemented by the ProTaper system (Dentsply/Maillefer) consisting of a minimum of four instruments (Berutti *et al.*, 2012b).

It must be mentioned that Dietrich, Kirkpatrick and Yaccino (2012) also found that the WaveOne primary 25/08 file left considerable more debris in the apical third of a prepared canal compared to K3 and the Self-Adjusting-File (SAF) (ReDent Nova, Ra'anana, Israel). The WaveOne cleaning and shaping technique as well as regular irrigation (with activation) should be emphasized and even slightly adapted to obtain a better sterile environment after completion of the root canal preparation. It can be speculated that the above instrument should be used in a brushing motion to allow the apical isthmus of the canal to be optimally cleaned (Dietrich *et al.*, 2012).

Berutti *et al.* (2011) also showed that there was a reduction in working length after instrumentation with the WaveOne instruments due to straightening of root canal curves. This is a draw back and could result in apical perforation and over enlargement of the apical foramina. The authors advocate that working length should be confirmed before the apical portion is prepared with WaveOne instruments. The authors did their study on extracted molar teeth. A study by Kim *et al.* (2012) showed the instrument is more resistant to torsional stresses and much stiffer compared to a similar reciprocating system (Reciproc) (VDW) and it could be speculated that the WaveOne file (Dentsply/Maillefer) is more prone to canal straightening in severe curved root canals.

## **CHAPTER 2: AIM AND OBJECTIVES**

### **2.1 Aim**

The aim of this study was to determine the influence of two different glide path preparation methods on the fracture rate of the Primary 25/08 WaveOne reciprocating instrument. In addition, the preparation times for different glide path preparation methods and total time for canal preparation, with or without glide path preparation, were calculated.

### **2.2 Objectives**

The broad objectives in this study were to:

- 2.2.1 Prepare a glide path on simulated canals with either hand files or rotary PathFiles.
- 2.2.2 Calculate the time it takes to prepare a glide path with two different methods.
- 2.2.3 Prepare simulated canals with the WaveOne Primary 25/08 reciprocating endodontic instrument after the glide paths had been prepared by either hand files or rotary PathFiles. These findings will then be compared to a group of simulated canals where no glide path is present and then prepared with the WaveOne Primary 25/08 reciprocating endodontic instrument.
- 2.2.4 Calculate the number of simulated canals that can be prepared before instrument fracture occurs.
- 2.2.5 Calculate the total time to prepare a simulated canal with the WaveOne Primary 25/08 instrument, with and without different glide paths preparations methods.

### **2.3 Hypothesis**

More simulated canals can be prepared when a glide path is present before preparation with the Primary 25/08 WaveOne instrument compared to the group

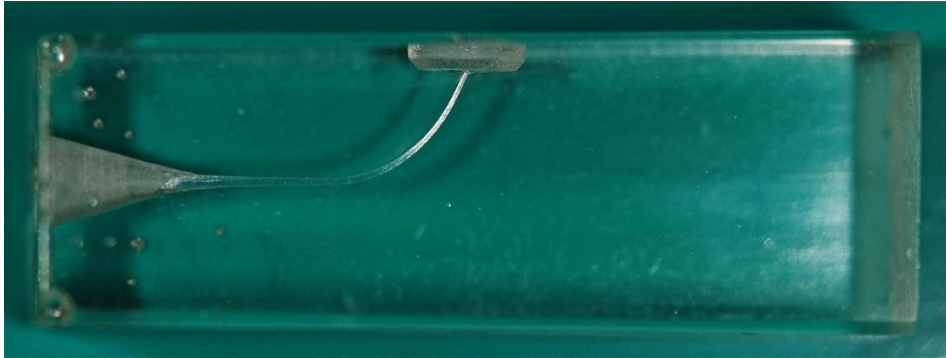
where no initial glide path is prepared. Glide path preparation with PathFiles will be faster compared to glide path preparation with hand files. The presence of a glide path will also reduce total preparation time of the simulated canals.

## **2.4 Statistical Null/Zero Hypotheses**

There will be no differences in glide path preparation time for the hand file and PathFile groups as well as for the number of simulated canals that can be prepared with the Primary 25/08 WaveOne instrument for the different test groups. The total preparation time for the simulated canals will be equal for all the test groups.

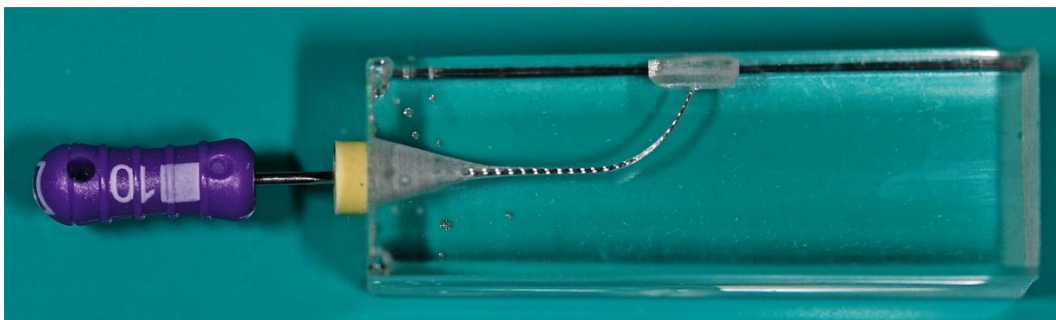
## **CHAPTER 3: MATERIALS AND METHODS**

The principles and techniques outlined by Berutti *et al.* 2004 were used in this study. Three hundred ISO 15, 0.02 taper, Endo-Training-Blocks (Dentsply/Maillefer, Ballaigues, Switzerland) (Figure 3.1) were selected.



**Figure 3.1:** ISO 15, 0.02 taper Endo-Training-Block (Dentsply/Maillefer) with standard apical curvature

A working length of 16.5 mm for each training block was confirmed with a size 10 K-File (Dentsply/Maillefer) (Figure 3.2) under 10X magnification using a Dental Operating Microscope (DOM) (Global, USA).



**Figure 3.2:** A size 10 K-File (Dentsply/Maillefer) with rubber stop placed to working length (16,5mm)



Specimens were randomly assigned to three different groups (n=100) and treated as follows:

### 3.1. GROUP 1: No glide path preparation (control)

In this group (n=100) the Endo-Training-Blocks (Dentsply/Maillefer) were left undisturbed.

### 3.2. GROUP 2: Initial glide path preparation using stainless-steel hand files

In this group (n=100) a stainless-steel hand file (size 10) (Dentsply/Maillefer) was negotiated to working length and moved in and out of the root canal with an amplitude of 1 mm. Once the hand instrument moved more freely, the amplitude was increased to 2 mm, then 3 mm, until the instrument moved freely to working length (Figure 3.3). Glyde (Dentsply/Maillefer) was used as a lubricating agent (Figure 3.4).



**Figure 3.3:** Initial glide path preparation with a size 10 K-file stainless-steel hand instrument (Dentsply/Maillefer) until the instrument could travel freely up to 3 mm in the canal



**Figure 3.4 :** Glyde Root Canal Conditioner (Dentsply/Maillefer)

The next instrument (size 15 K-file) (Dentsply/Maillefer) was then introduced into the artificial canal and used with the same motion as the previous instrument. Finally, the same procedure was followed with a size 20 K-file (Dentsply/Maillefer) (Figure 3.5).

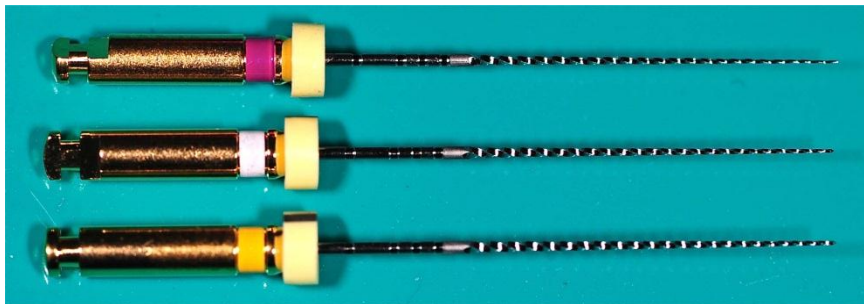


**Figure 3.5:** Glide path preparation with stainless-steel K-files (Dentsply/Maillefer).  
First, a size 10 K-file is used followed by a size 15 K-file and 20 K-file

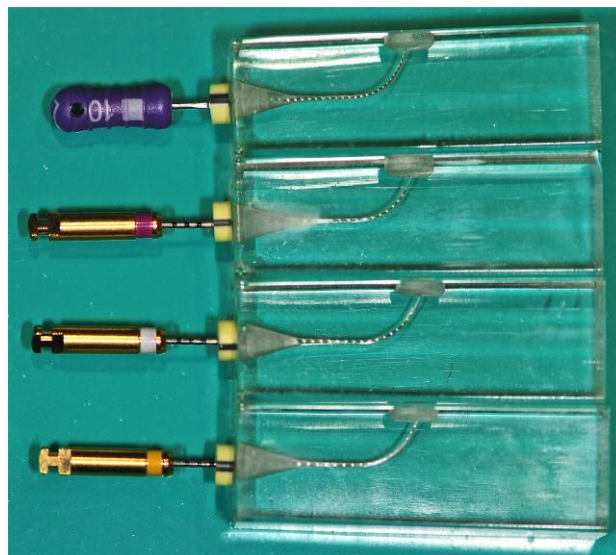
A reproducible glide path to an ISO size 20 was confirmed when the size 20 K-file could be placed at working length, pulled backwards for 1mm and pushed back into the canal with light apical pressure. This process was repeated by increasing the distance to 2, 3 and 4 mm from working length. When the file could travel 4 mm towards working length without any interference or obstruction, a reproducible glide path was confirmed.

### 3.3. GROUP 3: Glide path preparation using stainless-steel hand files followed by rotary PathFiles (Figure 3.6)

In this group (n=100) a stainless-steel hand file (size 10 K-file) (Dentsply/Maillefer) was negotiated to working length and an initial reproducible glide path was prepared up to ISO size 10. The glide path was then enlarged by using rotary PathFiles (Dentsply/Maillefer) (Figure 3.7). PathFile no.1 (ISO 13 tip), PathFile no.2 (ISO 16 tip) and PathFile no. 3 (ISO 19 tip) were used in a sequential manner to enlarge the initial glide path that was prepared by hand.



**Figure 3.6:** PathFiles (Dentsply/Maillefer) no.1 (purple ring), PathFile no.2 (white ring) and PathFile no.3 (yellow ring)



**Figure 3.7:** A stainless-steel hand file (10 K-file) (Dentsply/Maillefer) was negotiated to working length and an initial reproducible glide path was prepared up to ISO size 10. The glide path was then enlarged by using PathFiles

The PathFiles were used in the WaveOne endodontic motor (Dentsply/Maillefer) (Figure 3.8) on the PathFile setting, operating at 300 rpm and a torque of 4 Ncm.



**Figure 3.8:** The WaveOne Endodontic Motor (Dentsply/Maillefer) set to 300 rpm and a torque of 4 Ncm

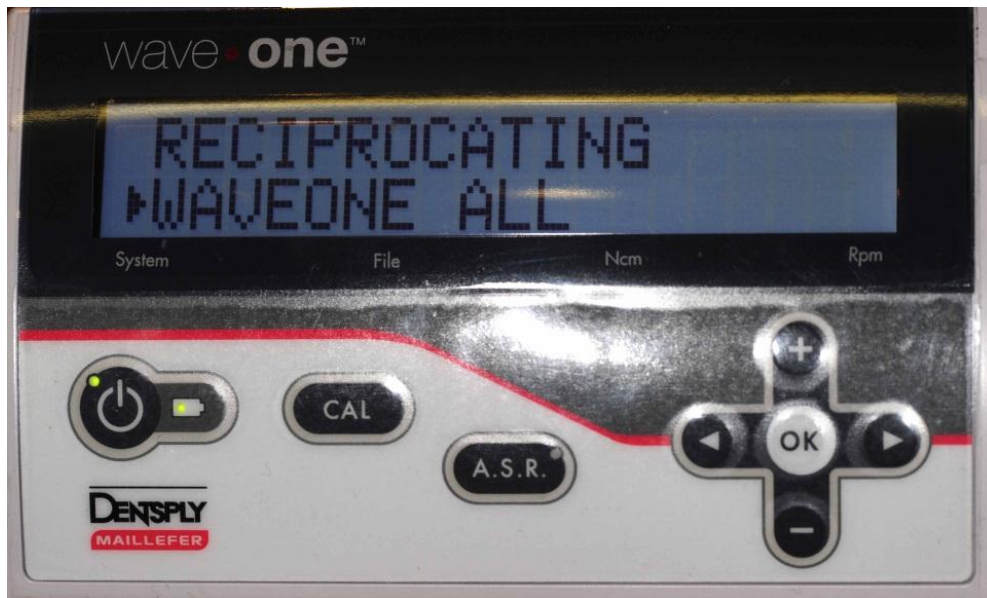
The total time it took to produce and to enlarge the glide paths in groups 2 and 3 was recorded by means of an electronic stop watch (Citizen Watch Company, New Jersey, USA). The time it took to change instruments was not recorded.

The specimens in each group were then randomly assigned into 5 subgroups (n=20). A new Primary 25/08 WaveOne file (Dentsply/Maillefer) was allocated to each subgroup (Figure 3.9).



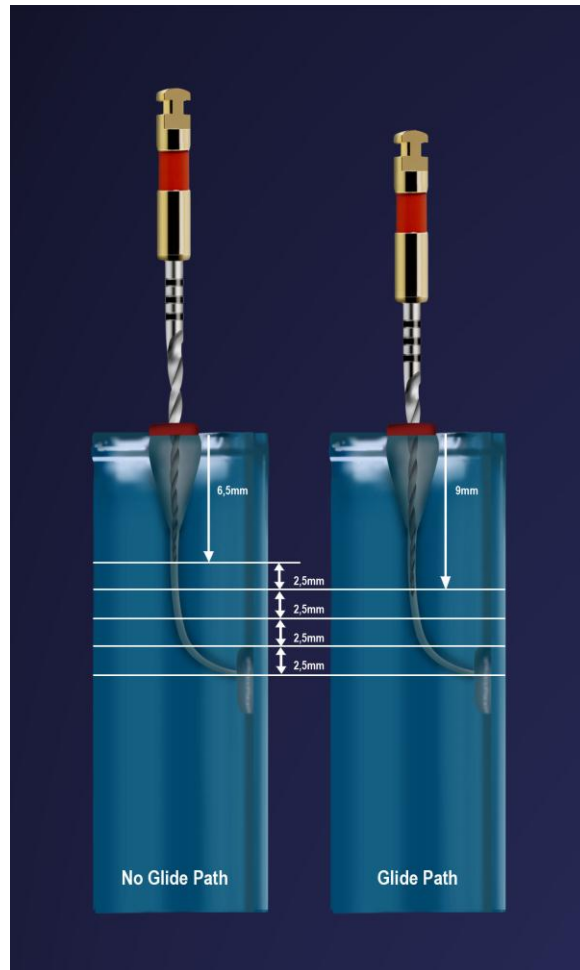
**Figure 3.9:** A size 025/08 WaveOne single-use, reciprocating nickel-titanium instrument (Dentsply/Maillefer)

Root canal preparation was done with the Primary 25/08 WaveOne instruments using the WaveOne Endodontic Motor (Dentsply/Maillefer) in the “Reciprocating WaveOne All” mode (150° counter clockwise and 30° clockwise) (Figure 3.10), using Glyde (Dentsply/Maillefer) (Figure 3.4) as a lubricant.



**Figure 3.10:** The WaveOne endodontic motor (Dentsply/Maillefer) set to operate the WaveOne “ALL” mode

It was found that without any glide path preparation the Primary 25/08 WaveOne instrument was able to penetrate to an average depth of 6.5 mm into the canal, and for the groups where glide path preparation was done an average of 9 mm into the canal before any preparation (leaving 10 mm and 7.5 mm of unprepared canal space, respectively). The canal preparation was done in 2.5 mm increments before the instruments was removed (Figure 3.11).



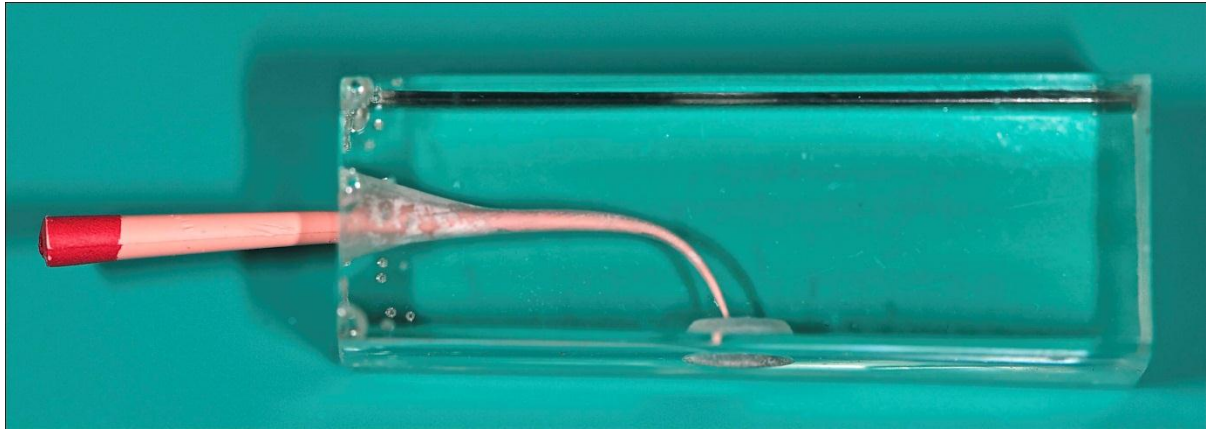
**Figure 3.11:** Preparation increments for the no glide path and glide path groups

Cutting debris was cleaned from the instrument flutes using EndoFoam (Australian Dental Manufacturing, Kenmore Hills, Australia) (Figure 3.12), the canal irrigated with water, recapitulated with a size 08 K-file (Dentsply/Maillefer) and the canal re-irrigated to remove cutting debris from the canal.



**Figure 3.12:** EndoFoam (Australian Dental Manufacturers)

Final root canal preparation was checked by ensuring that a Primary WaveOne Gutta-Percha cone (25/08) could be fitted to full working length (Figure 3.13) and this was confirmed under 10X magnification, using the DOM (Global).



**Figure 3.13:** Primary WaveOne Gutta-Percha cone (25/08) (Dentsply/Maillefer) fitted to working length on completed preparation

The outcome was measured by recording how many simulated canals could be shaped with one Primary 25/08 WaveOne reciprocating instrument for each glide path preparation group and the no glide path group before instrument breakage occurred. The average time it took to prepare each of the artificial canals for the different groups was also recorded with an electronic stop watch (Citizen Watch Company).

In addition, canal preparation time for each segment was recorded by starting at the point of entry into the canal and stopping the clock at the point of instrument retrieval. Total preparation time for each block was calculated by adding the preparation times for different cutting cycles. The time it took to clean debris from the instrument flutes, irrigate, recapitulate and to re-irrigate the canal was not recorded.

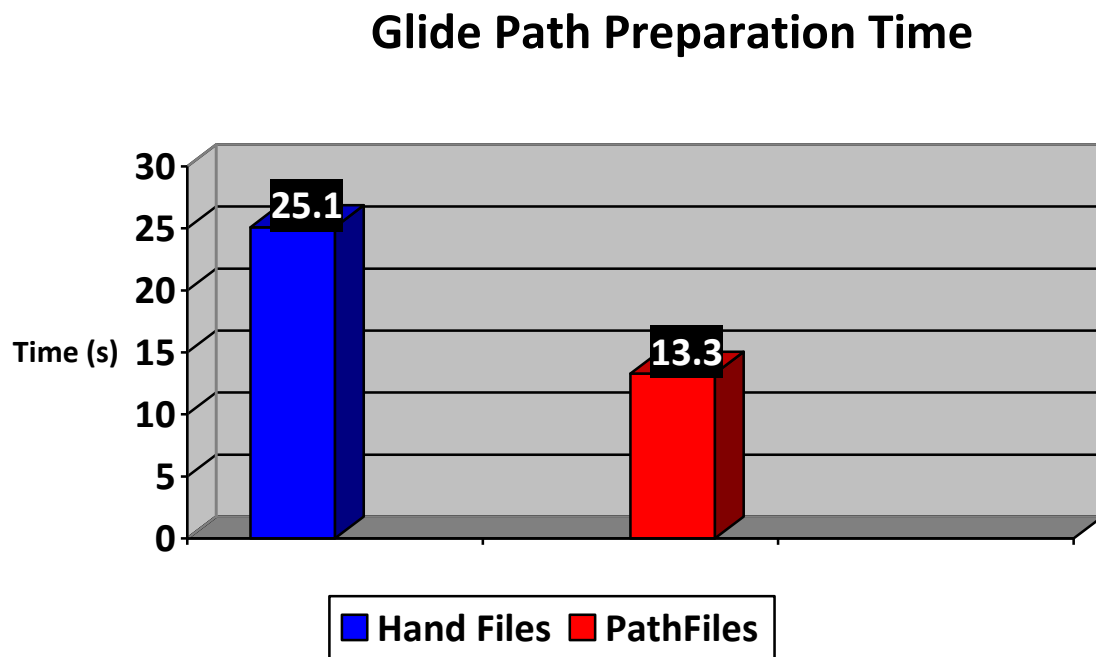
The data for the different parts of the project were collected and statistically analysed using the ANOVA and Bonferoni tests.

## **CHAPTER 4: RESULTS**

### **4.1 Glide Path Preparation Time**

The mean total time for glide path preparation with hand files and PathFiles is presented in Figure 4.1. The means, standard deviations, coefficients of variation and 95% confidence intervals, and significant differences are presented in Table 4.1.

Glide path preparation with PathFiles (13.3 s  $\pm$  2.60) was significantly faster compared to using hand files (25.1 s  $\pm$  1.70) using a one-way analysis of variance (ANOVA) ( $P < 0.001$ ).



**Figure 4.1:** Mean glide path preparation time using hand files and PathFiles



## 4.2. Glide Path Preparation Techniques

The mean fracture rate of the Primary 25/08 WaveOne for the different glide path preparation techniques is presented in Figure 4.2. The means, standard deviations, coefficients of variation and 95% confidence intervals, and significant differences are presented in Table 4.2.

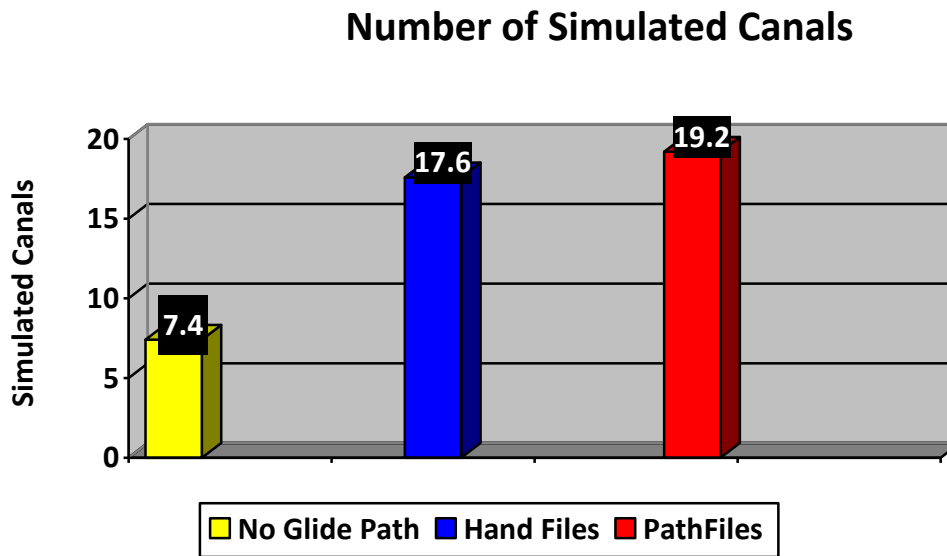
In the group where no glide path preparation (control) was done prior to canal preparation, an average of 7.4 ( $\pm 0.89$ ) simulated canals were prepared before the Primary 25/08 WaveOne instruments fractured.

When the manual hand files were used to prepare the glide path prior to canal preparation, a mean of 17.6 ( $\pm 1.14$ ) simulated canals were prepared before the WaveOne instruments fractured.

In the group where the glide path was prepared manually with a size 10 K-File and mechanically enlarged with rotary PathFiles a mean of 19.2 ( $\pm 0.84$ ) simulated canals were prepared before the WaveOne instruments fractured.

The three groups were compared with respect to the mean number of simulated canals prepared by each Primary 25/08 WaveOne instrument, using a one-way analysis of variance (ANOVA) followed by pairwise comparisons at the Bonferroni adjusted significance level of 0.017.

Pairwise comparisons at the Bonferroni adjusted significance level of 0.017 demonstrated that there was statistical significant differences ( $P < 0.001$ ) when PathFiles ( $19.2 \pm 0.84$ ) and hand files ( $17.6 \pm 1.14$ ) were compared to the no glide path ( $7.4 \pm 0.89$ ) group. There was no statistical significant differences between PathFiles ( $19.2 \pm 0.84$ ) and hand files ( $17.6 \pm 1.14$ ) groups.



**Figure 4.2:** Mean values of the number of simulated canals prepared for the different test groups

### 4.3 Preparation Time with WaveOne

The results of the total preparation time with WaveOne instruments for the three different groups are presented in Figure 4.3. The means, standard deviations, coefficients of variance and 95% confidence intervals, and significant differences are presented in Table 4.3.

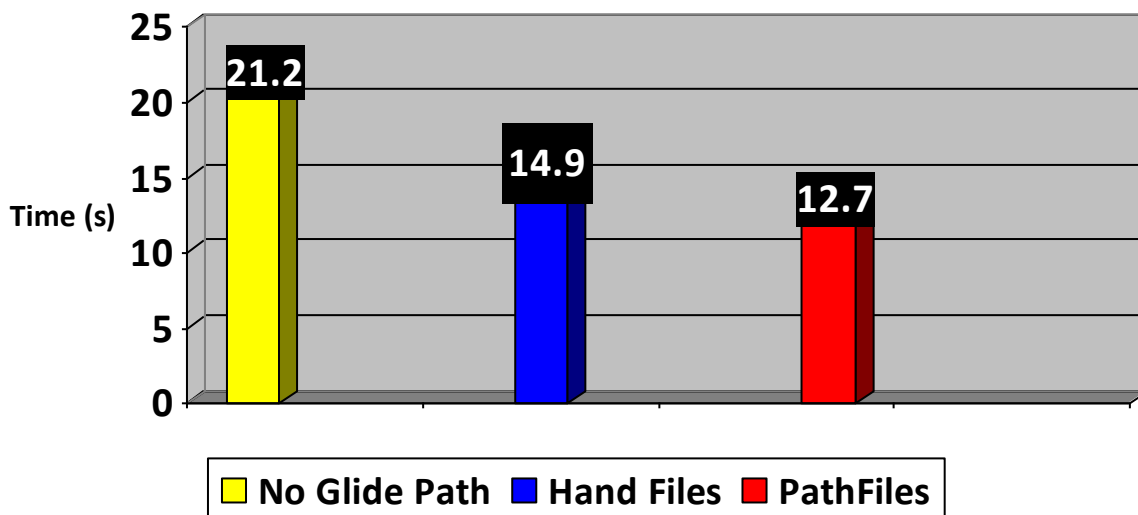
When the Primary 25/08 WaveOne instrument was used to prepare the simulated canals without any glide path preparation, the mean preparation time was 21.2 ( $\pm$  0.20) seconds. The preparation of the simulated canals without glide path was followed by the group where the glide paths were prepared with hand files (14.9  $\pm$  0.47 s) and the shortest preparation time was achieved by the group where the glide paths were prepared with the PathFiles (12.7  $\pm$  0.22 s).

The three groups were compared with respect to the mean preparation time for a simulated canal with an Primary 25/08 WaveOne instrument using an one-way analysis of variance (ANOVA) and were found to differ significantly ( $P < 0.001$ ). In

particular, following pairwise comparisons at the Bonferroni adjusted significance level of 0.017:

- Preparation time for the group where no glide path preparation was done took significantly longer compared to the group where a glide path was prepared with hand files ( $P < 0.001$ ; 21.2 vs 14.9)
- Preparation time for the group where no glide path preparation was done took significantly longer compared to the group where a glide path was prepared with PathFiles ( $P < 0.001$ ; 21.2 vs 12.7)
- Preparation time was significantly shorter where the glide path preparation was done by means of PathFiles compared to the group where a glide path was prepared with hand files ( $P < 0.001$ ; 12.7 vs 14.9)

### Total Preparation Time



**Figure 4.3:** Mean values of the total preparation time with Primary 25/08 WaveOne instruments for the three different groups

**Table 4.1:** Descriptive statistics for the glide path preparation time of hand files and PathFiles

Brand	Mean(s)	Standard Deviation	Coefficient of Variation (%)	95% Confidence Interval
Hand files	25.1 <sup>a</sup>	2.60	5.2	(23.4; 26.8)
PathFiles	13.3 <sup>b</sup>	1.70	6.4	(12.0; 14,1)

Values with the same letters were not statistically different at  $P < 0.001$

**Table 4.2:** Descriptive statistics for the number of simulated canals prepared before the WaveOne instrument fractured in the different test groups

Group	Mean	Standard Deviation	Coefficient of Variation (%)	95% Confidence Interval
No Glide Path	7.4 <sup>b</sup>	0.89	12.0	(6.3; 8.5)
Hand files	17.6 <sup>a</sup>	1.14	6.5	(16.2; 19.0)
PathFiles	19.2 <sup>a</sup>	0.84	4.3	(18.2; 20.2)

Values with the same letters were not statistically different at  $P < 0.001$

**Table 4.3:** Descriptive statistics for the total preparation time for the different test groups

Group	Mean(s)	Standard Deviation	Coefficient of Variation (%)	95% Confidence Interval
No Glide Path	21.2 <sup>c</sup>	0.20	1.0	(21.0; 21.5)
Hand files	14.9 <sup>b</sup>	0.47	3.1	(14.4; 15.6)
PathFiles	12.7 <sup>a</sup>	0.22	1.7	(12.6; 13.1)

Values with the same letters were not statistically different at  $P < 0.001$

## **CHAPTER 5: DISCUSSION**

It is a well-known fact that instrument fracture causes anxiety in both operator and patient and could result in treatment failure. Numerous studies have been published on attempts to create ways to eliminate instrument failure during root canal preparation (Parashos *et al.*, 2004; Da Silva, Kobayashi and Suda, 2005; Shen *et al.*, 2006). The creation of a glide path has been advocated as the gold standard in the prevention of instrument separation (Berutti *et al.*, 2004; Varela-Patiño *et al.*, 2005).

Some manufacturers claim that nickel-titanium instruments can be used to prepare root canals without a glide path. Webber *et al.* (2011) suggest that fewer canal aberrations occur when the WaveOne file is introduced after prior glide path preparation. The main purpose of the glide path is to reduce torsional and flexural stress on the instrument. The introduction of an instrument with a high taper into an unprepared root canal with a low taper will cause a rapid increase in torsional stress. Nickel-titanium files are more likely to fracture at lower cyclic fatigue once they are exposed to torsional stress. Previously used nickel-titanium files are at higher risk because of their reduced resistance to torsional stresses (Bahia, Melo and Buono, 2006; Barbosa, Gomes and Pimenta de Araújo, 2007).

Clinicians face an increasing demand to be more cost effective, see more patients and reduce the risk of cross-contamination. Rushing through procedures and not respecting the limitations of the instrument increase the risk of torsional failure. The areas of the root canal where the small instruments are used are at greatest risk. Sattapan *et al.* (2000a) used Quantec Series 2000 instruments (Tycom Corporation, Irvine, California, USA) in their study and concluded that smaller instruments with lower tapers generate more torque and torsional forces, especially in small root canal configurations. The apical portion of the instrument has a smaller diameter and offers the least amount of resistance to torsional forces. The larger instruments engage more coronally on the instrument shaft where the instrument is thicker and has more resistance to torsional failure.

A very recent study by Pedullà *et al.* (2013) showed that the latest modern instruments like WaveOne and Reciproc operating in a reciprocating motion, have significantly higher resistance to cyclic fatigue compared to instruments like Mtwo and the Twisted File used in full rotation. This study also proved that instruments manufactured with M-wire (Reciproc and WaveOne) have higher resistance to fatigue than traditional nickel-titanium instruments (Mtwo) and instruments manufactured with R-phase nickel-titanium alloy (Twisted File).

This is the first study to calculate the number of simulated canals that could be prepared with the WaveOne Primary 25/08 file (Dentsply/Maillefer), with or without glide path preparation, before instrument fracture. Endo-Training-Blocks are often used to evaluate the performance of endodontic instruments and to standardize experimental conditions (Yoshimine, Ono and Akamine, 2005; Ding-Ming *et al.*, 2007; Berutti *et al.*, 2009).

There are certain drawbacks in using acrylic-training-blocks. In the first instance, the simulated canals tend to generate heat during preparation. This causes softening of the resin material it was manufactured with and this softening might hamper the progression of the file. The cleaning and shaping procedure therefore becomes more strenuous (Kum *et al.*, 2000). However, it was reported in a study that a rise of only 0.6 °C was observed during the oscillating of the file inside the simulated root canal. This very slight rise in temperature for a short amount of time is unlikely to cause melting of the acrylic (Ahmad, 1989). Much care should be taken in analysing the results when simulated canals are being used because of the difference between resin and dentine (Yoshimine *et al.*, 2005; Ozgur Uyanic *et al.*, 2006). The clear resin simulated canals are also softer and can be more compressed than dentine in natural teeth (root dentine). Kim and Webber (1985) showed that almost half the force was used to prepare a simulated root canal than to prepare a root canal in a natural tooth. It can be speculated that torsional stress and pressure applied on the instrument are not a true reflection of a clinical situation and results can be misleading.

In addition, the acrylic simulated canals do not represent the true anatomical variants present in natural teeth (Berutti *et al.*, 2012a). Natural teeth have unique

anatomical characteristics that cause challenges to any endodontic instrument introduced into the root canal. The simulated canals are widely used to point out differences between certain instruments under controlled conditions without anatomical variants. The difficulty arises when comparing 2 or 3 instruments to find natural teeth that are exactly the same anatomically in order to standardize the study conditions. Therefore, acrylic-training-blocks are a suitable replacement (Weine, Kelly and Lio, 1975).

The use of acrylic simulated canals provides certain advantages. They allow for comparison of instruments under controlled, standardised conditions by eliminating variables like root canal anatomy (Kim and Webber, 1985). It is important to mention that a study carried out by Ahmad (1989) proved that the cleaning and shaping action of ultrasonic files was similar in simulated and natural root canals. The manner and areas where material and debris were removed proved to be very similar. Elbow formation was also proven in this study to be very similar in acrylic simulators and natural root canals and, in light of the above facts, it was assumed that instruments cut in a very similar fashion in simulators and natural teeth. Plastic simulated canals also allow for direct examination, which can provide valuable information regarding the finer detail of preparing root canals and the mechanics of certain instruments being tested (Kim and Webber, 1985).

The results of this study showed that when no initial glide path was created, only 7,4 simulated canals could be prepared before the instrument fractured. When a glide path was prepared by means of hand files or with rotary PathFiles a mean of 17.6 and 19.2 simulated canals could be prepared, respectively. Statistically significant differences existed between mean values for the number of simulated canals that could be prepared with hand files and/or PathFiles compared to the group where no glide path was prepared.

This result can be compared to the findings of Berutti *et al.* (2004) where 10 simulated canals could be prepared before failure without glide path creation with the use of the ProTaper S1 file. After glide path preparation to a size 20 K-file it was possible to prepare 59 simulators before the ProTaper S1 instrument fractured.

It must be noted that the ProTaper S1 file removes debris only in the coronal part of the root canal, utilizing the thicker portion of the instrument that is more resistant to torsional stress. In the Berutti *et al.* (2004) study it was observed that in the groups where the ProTaper F2 finishing instrument (25/08) were used, a much lower number of simulated canals were prepared before instrument failure. The F2 ProTaper instrument is the same ISO size and taper as the WaveOne Primary 25/08 file and also cuts dentine mainly in the apical third of the instrument. The WaveOne Primary 25/08 file, on the other hand, has an 8% taper for the first 4 mm from the tip, 6.5% for the next mm, 6% for the next mm and 5.5% taper for coronal 7 mm to 16 mm of the instrument. The WaveOne primary 25/08 file (Dentsply/Maillefer) removes debris along the length of the instrument, but the main area of work load is the apical portion with the greater taper and, therefore, a significantly reduced number of simulators could be prepared when no glide path preparation was done.

According to the results of the present study, it can be concluded that the preparation of a glide path was vital in the number of simulated canals that could be prepared. The technique that was used to prepare the glide path (hand files vs. PathFiles) did not significantly influence the number of simulated canals prepared before the WaveOne Primary 25/08 instrument fractured. Similar observations have been made in other studies where different types of instruments have been used (Berutti *et al.*, 2004; Varela-Patiño *et al.*, 2005; Yared, 2008; Varela-Patiño, 2010).

The results of this study also demonstrated that the preparation time to prepare a glide path with PathFiles (13.3 s) was statistically shorter than preparation time with hand files (25.1 s). A previous study analysed the time taken to perform pre-flaring with hand files or PathFiles by an expert group and an inexperienced group of operators. The time was significantly shorter in the groups using PathFiles (expert = 7.79 s; inexperienced = 7.74 s) versus the hand files groups (expert = 28.08 s; inexperienced = 38.58 s) (Berutti, Cantatore and Castellucci, 2010).

An earlier study proved that the preparation of a glide path with hand files showed more irregularities and over-enlargement of the canal curvature compared to the use of PathFiles (Berutti *et al.*, 2009). It also showed that PathFiles could be easily utilized by inexperienced clinicians. Inexperienced clinicians obtained far superior



results in creating a glide path with far fewer canal alterations than expert clinicians using hand files to create the same glide path. Another study evaluated the importance of creating a glide path with the WaveOne Primary 25/08 reciprocating file (Dhingra, Srivastava and Chugh, 2012). The conclusion was that the creation of a glide path before introducing the WaveOne Primary 25/08 file significantly reduces canal modifications.

In light of the above, there are numerous advantages in using PathFiles to create a glide path before using the WaveOne system. Chair time and operator fatigue is reduced. A hand piece and electric motor are used to create the glide path instead of manual filing by hand motions. There are also fewer canal irregularities and aberrations present after glide path preparation with PathFiles (Berutti *et al.*, 2010; Pasqualini *et al.*, 2012).

The one disadvantage of using PathFiles before the WaveOne instruments is the cost involved. Specific endodontic motors are required to operate these instruments and the PathFiles are more expensive than hand files. However, if PathFiles are used in the correct manner as advocated by the manufacturer, a great number of root canals can be prepared due to the flexibility of the instrument and ability to negotiate complex root canal anatomy.

In the group where no glide path was prepared, the mean total canal preparation time was much longer than for the other two groups. There was also a significant difference in preparation times between the groups where hand files or PathFiles was used to prepare a glide path. No comparative data on the influence of preparation times with or without glide path preparation for the WaveOne system could be found in the literature. A study conducted by Uroz-Torres *et al.* (2009) found that no statistically significant difference existed in working time with the Mtwo rotary system, with and without manual glide path preparation. The results of the present study, however, demonstrate that there was a significant difference in preparation time when a glide path was prepared prior to canal preparation.

Within the limits of this study it can be concluded that glide path preparation increased the longevity of the Primary 25/08 WaveOne instrument and enabled

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more canals to be prepared before instrument fracture. However, although the results of this study indicated that a high number of simulated canals can be prepared with the Primary 25/08 WaveOne instrument after initial glide path preparation, it must be taken into account that the length of canal preparation on the simulated canals was only 7.5 mm. It could be expected that this number of prepared canals will reduce drastically in clinical situations where the length of canal preparation will be often longer.

It was also significantly faster to prepare a glide path with PathFiles than with hand files. The total preparation time is reduced when hand files or PathFiles are used for glide path preparation prior to root canal preparation with the Primary 25/08 WaveOne instrument.

The use of a single file in a reciprocating motion has the potential to reduce costs as a result of fewer files being used in the preparation sequence, reduced chair time, reduced cross-contamination and, most importantly, reduced risk of instrument fracture, operator stress, anxiety and fatigue (Yared, 2008).

Considering the above, the WaveOne endodontic system could be hugely beneficial to clinicians. As discussed in previous chapters, the system consists of a choice of 3 single-use files: Small (ISO tip 21), Primary (ISO tip 25) and Large (ISO tip 40), rotating in reciprocating action and manufactured with the highly resistant M-Wire nickel-titanium alloy. In some cases the use of only a single WaveOne file has the ability to leave the prepared root canal with adequate size and taper (Berutti *et al.*, 2012a).

An added benefit of the WaveOne file cutting in a reciprocating action is the fact that the reciprocating cutting action leaves more centred preparations with reduced risk of canal transportation, ledge formation and irregular enlargement of the apical foramen (Jafarzadeh and Abbott, 2007; Franco *et al.*, 2011). Berutti *et al.* (2012b) showed that the WaveOne file was able to maintain the original canal anatomy better than the file sequence implemented by the ProTaper system consisting of a minimum of 4 files.

## **CHAPTER 6: CONCLUSIONS**

1. A significantly higher number of simulated canals could be prepared with the Primary 25/08 WaveOne instrument when glide path preparation was done with hand files and PathFiles ( $P < 0.001$ ).
2. A significantly lower number of simulated canals could be prepared with the Primary 25/08 WaveOne instrument when no glide path preparation was done ( $P < 0.001$ ).
3. Glide path preparation with PathFiles was significantly faster compared with using hand files ( $P < 0.001$ ).
4. The total mean time to prepare a simulated canals with the Primary 08/25 WaveOne instrument was significantly shorter when an initial glide path was prepared with PathFiles or hand files compared to the group where no glide was prepared ( $P < 0.001$ ).

The null hypothesis is therefore rejected.

Caution should be exercised when extrapolating *in vitro* findings to the clinical situation. The techniques described in this study should be evaluated in extracted teeth or *in vivo* studies.

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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 20 Oct 2016.

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Faculty of Health Sciences Research Ethics Committee  
Fakulteit Gesondheidswetenskappe Navorsingsetiekkomitee

**DATE: 24/11/2011**

<b>NUMBER</b>	<b>212/2011 ~ DENT</b>
<b>TITLE OF THE PROTOCOL</b>	<b>INFLUENCE OF GLIDE PATH PREPARATION ON THE FAILURE RATE OF NICKEL TITANIUM RECIPROCATING INSTRUMENTS</b>
<b>PRINCIPAL INVESTIGATOR</b>	Dr. C.H. Jonker <b>Dept:</b> Division of Endodontics, Department of Odontology, Faculty of Health Sciences; University of Pretoria. <b>Cell:</b> 079 512 7889 <b>E-Mail:</b> <a href="mailto:jonker.ch@gmail.com">jonker.ch@gmail.com</a> , <a href="mailto:casper.jonker@up.ac.za">casper.jonker@up.ac.za</a>
<b>SUB INVESTIGATOR</b>	Not Applicable
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<b>STUDY DEGREE</b>	<b>MSc.(Odontology)</b>
<b>SPONSOR COMPANY</b>	Not applicable
<b>MEETING DATE</b>	23/11/2011

The Protocol was approved on 23/11/2011 by a properly constituted meeting of the Ethics Committee subject to the following conditions:

1. The approval is valid for 2 years period [till the end of December 2013], and
2. The approval is conditional on the receipt of 6 monthly written Progress Reports, and
3. The approval is conditional on the research being conducted as stipulated by the details of the documents submitted to and approved by the Committee. In the event that a 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.

*Members of the Research Ethics Committee:*

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**Prof R Delport**

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