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Efficiency and Safety of a Continuous Rotation Instrumentation System and a Reciprocating Motion Instrumentation System: A Randomized Clinical Trial

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Abstract:

Introduction: It has been suggested that single-file reciprocating systems, such as WaveOne, are capable of more rapid root canal instrumentation compared to systems that utilize multi-file continuous rotation. The purpose of this study was to evaluate the efficiency and safety of WaveOne and ProTaper Next instrumentation systems *in vivo* in a randomized clinical trial. The null hypothesis was that no differences would be seen in canal preparation time, working length control, or occurrence of adverse events.

Materials and Methods: A total of 89 teeth requiring primary non-surgical endodontic treatment were included in the study. Root canal therapy was performed per routine clinical procedures. Following glide path creation, teeth were randomized into groups according to instrumentation system to be used: WaveOne or ProTaper Next. Time required for cleaning and shaping was recorded. Discrepancies between the final working length and the initial master cone length and any occurrence of adverse events were also recorded. Differences between groups and tooth types were evaluated with regression models and least squares mean analyses. **Results:** No overall difference was found between instrumentation systems for average time required per tooth or per canal to complete instrumentation. WaveOne required significantly less time to instrument premolar teeth and teeth with a single canal compared to ProTaper Next. No significant differences could be detected between WaveOne and ProTaper Next in regard to working length control. No adverse events occurred in the sample in either treatment group.

Conclusions: WaveOne and ProTaper Next perform with similar efficiency for most tooth types. WaveOne and ProTaper Next can be used safely and predictably to instrument root canals in a clinical setting.

Introduction:

Description of the Disease:

The major concern of the field of endodontics is pathology of the human dental pulp and periradicular tissues. The human dental pulp is a tissue organ composed of several distinct cell types, a vascular supply, nerve fibers, interstitium, and ground substance(1). Surrounding the dental pulp are dentin and enamel, the protective and functional hard tissues of the tooth. The pulp and dentin form a complex that works together to support and protect one another. However, once exposed to the oral environment by trauma or dental caries, this pulp-dentin complex becomes susceptible to injury. The pulpal response that ensues can lead to mass cell death and necrosis.

Microorganisms have a prominent role in the development and progression of endodontic disease. Under aseptic conditions, exposed and traumatized dental pulps are capable of repair by hard tissue formation. In the presence of bacteria, irreversible pulpal inflammation results and eventually leads to pulp necrosis(2). Furthermore, periapical periodontitis lesions have been correlated with root canals containing cultivable bacteria while they are not typically found associated with teeth that are culture negative(3). A non-vital and necrotic pulp alone does not induce apical periodontitis. Apical periodontitis is a disease caused by microbial infection.

Although dentin is porous due to the presence of dentinal tubules, and potentially permeable to bacteria and their byproducts, a normal healthy tooth is rather resistant to microbial challenge. Much of the dentin tubule diameter is occupied by the odontoblastic processes, drastically reducing its actual functional size(1). A constant outflow of fluid resists access of foreign substances(4). Odontoblasts at the pulp-dentin border are capable

of laying down additional dentin when a threat is detected, thickening the barrier between the pulp and the outside world. The permeability of the dentin itself can also be decreased by formation of sclerotic dentin(5), produced by additional peritubular dentin deposition and mineral deposition within the tubules themselves(6). These defense mechanisms are no longer present in a tooth with a necrotic pulp. The remaining chamber and canal spaces constitute an ideal environment for bacterial colonization and growth.

A necrotic root canal is anaerobic, warm, and moist. It contains abundant nutrients and lacks a blood supply capable of circulating host defenses into the area. Unlike epithelial or osseous body surfaces, dentin does not shed or resorb under normal conditions. This allows any bacteria capable of attaching and surviving to form colonies that persist and progress into more advanced communities(7). These communities are made up of interacting and sessile cells up to 300 layers thick which create a matrix of extracellular polymeric substances, collectively called a biofilm(8).

A biofilm confers many advantages to the growth and survival of the microbial community. The many layers of a biofilm possess distinct local environments that provide a broad habitat range conducive to a larger number of potential species. Nutritional interrelationships exist as the byproducts of some species become a source of energy for others such that more complex substrates can be broken down than would be possible by the individual species alone. The matrix itself provides physical protection from host defenses as does the higher variety of enzymes retained within it. In addition, biofilms confer enhanced pathogenicity. Several different functions are required to cause disease and different species can work in concert to sequentially accomplish them(9). Cells within a biofilm can also undergo genetic exchanges and have an increased

resistance to antimicrobial agents. A concentration of antibiotics around 100 to 1000 times higher is required to kill bacteria within a biofilm compared to their planktonic counterparts(10).

Bacterial infection can induce pathologic changes in the tooth supporting structures. Bacteria and their byproducts trigger immune and inflammatory host responses and give rise to apical periodontitis. If the immune system is overcome by the bacterial onslaught, bacteria from the root canal can advance through the periodontal ligament and alveolar bone provoking an acute apical abscess or cellulitis(7). This in turn can spread through fascial planes of the head, neck, and into other body regions such as the mediastinum, cavernous sinus, and around the airway causing serious and potentially life-threatening medical conditions.

Root Canal Therapy as Treatment of Disease:

The goal of orthograde endodontic treatment is to prevent, eliminate, or sufficiently reduce intra-canal infection. As mentioned previously, bacterial biofilms in root canals are located beyond the host's natural defenses and outside intervention is thus required for treatment of an established apical periodontitis(7). Successful outcomes have been correlated with treatment capable of producing a negative bacterial culture from the canal prior to root canal filling(11,12). Remaining bacterial biofilms in the root canal anatomy may lead to treatment failure(13,14). The advantages afforded to a bacterial biofilm make effective killing and removal difficult. Disinfection of the pulp system with root canal therapy is often required to overcome the infection and create an environment conducive to host healing.

Root canal therapy consists of many important steps that set the stage for disinfection or help prevent re-contamination following treatment. Isolation with a rubber dam allows coronal access to the pulp space to be attained while minimizing the potential of reinfection from the oral cavity(15). A proper access cavity preparation will allow the clinician to remove all coronal pulp tissue and locate all root canal orifices(16). Once the root canals have been found they are carefully scouted with a small instrument capable of reaching the apical extent of each root canal. The desired working length is determined and “a smooth radicular tunnel from canal orifice to physiologic terminus”, or glide path, must be confirmed or established(17). The actual disinfection phase can then take place through thorough cleaning and shaping of the root canals. Following cleaning and shaping, a biocompatible material is placed to seal off the root canal from potential recontamination and infection. The process of modern root canal therapy has grown and developed over the past century into its current form, and changes and improvements continue to be made over time.

Cleaning and Shaping:

The disinfection step of root canal therapy consists of two main portions, mechanical instrumentation and chemical irrigation, which are collectively referred to as chemomechanical debridement. Dr. Herbert Schilder outlined the following goals for ideal mechanical instrumentation(18). First, a continuously tapered funnel should be developed such that the cross-sectional diameter is narrower at every point as it progresses from the coronal access cavity to the root apex. Second, the original shape of the canal should be maintained by the preparation in all planes. Third, the apical foramen

should remain in in its original place in the root surface without movement or transportation of the opening. Fourth, the apical opening should be maintained as small as possible. The purpose of this instrumentation shape is to allow coronal clearing of debris from the root canal system, minimize extrusion of debris, and prepare the canals to receive gutta percha or other condensable root canal obturation materials.

While mechanical instrumentation is quite effective at reducing the numbers of bacteria in the canal, it is by itself extremely inefficient and is not sufficient to completely eliminate canal infection(19). The ideal shaping procedures outlined by Schilder have been shown to be clinically unattainable in most cases. Despite every effort, much of the canal wall surfaces remain untouched following mechanical instrumentation(20-22). In addition to merely scraping the walls, an important purpose of canal instrumentation is to create room for the entry of irrigants or medicaments. This can further disinfect the instrumented portions(23) and also clean uninstrumented or otherwise unreachable canal areas such as isthmuses, accessory canals, fins, or irregularities.

Debris remaining after mechanical instrumentation consists of organic and inorganic components. The organic components are necrotic tissue remnants, bacterial cells, and bacterial byproducts, while the inorganic component is mostly the smear layer left behind by the instrumentation process itself. An ideal endodontic irrigant would break down both of these components and have a high anti-microbial effect. No irrigant exists which possesses all of these qualities and thus a combination is often used. Sodium hypochlorite (NaOCl) is the most widely used endodontic irrigant(24). It dissolves organic matter and is very effective at eliminating bacteria(25,26). Ethylenediaminetetraacetic acid, or EDTA, is the most common irrigant used for removal

of the smear layer(27), or inorganic component. Smear layer removal allows further penetration of NaOCl, or other antimicrobial agents into areas that would otherwise be blocked and inaccessible. Although it is recognized that mechanical instrumentation is not fully successful in reaching all desired areas, it is paramount that canal preparation take place as thoroughly as possible. Creation of adequate space for the placement and replenishment of chemical irrigants greatly enhances their penetration into the root canal spaces(28).

Endodontic Working Length:

Wherever possible, orthograde root canal treatment should be confined within the root canal system itself and not extend beyond the apical terminus of the canal. Preparation beyond the apex could result in extruded necrotic debris and bacterial products that are associated with increased post-operative pain(29). Violation of the apical opening may facilitate passage of noxious irrigants into the periapical tissues leading to chemical burns and adverse sequelae(30). Obturation materials may also be expressed into the periapical tissues during root canal filling and can stimulate foreign body or severe inflammatory reactions(31). However, it is also important to clean, shape, and ultimately fill the entire extent of the root canal system. Increased failure outcomes have been correlated with root canal fillings that are beyond the radiographic apex or that terminate relatively short of it(32-34).

The tapering funnel described by Schilder(18) should terminate at the apical constriction, a point not always perfectly coincident with the apex of the tooth or the apical foramen itself. It has been estimated that the apical constriction is roughly 0.5mm

from both the true root apex and the apical foramen and 1mm from the radiographic apex on average(35). Electronic apex locators have been shown to be an accurate means of locating of the apical constriction and determining working length(36-38).

Hand Instrumentation Armamentarium:

Instruments have been used to manipulate the radicular pulp space since the 18th century(39). During this time, Fauchard described using a roughed needle to remove pulp tissue(40). Around a century later, broaches were created to grab tissue by chopping at a round wire to generate sharp projections(41). In the early 20th century, dental practitioners began to grasp the importance of physically instrumenting canal walls in order to remove necrotic debris(42). The Kerr Company fabricated the first instruments with the ability to cut and shape dentin by twisting fine square metal bars to create surfaces that engaged as the file was rotated or moved longitudinally. Similar instruments, known as k-files or k-reamers, are still in use today. The amount of turns per unit of length determines whether a file or reamer is created. The cutting edges of files are more horizontally directed and closer together than those of corresponding reamers(18). Another commonly used manual instrument is the Hedstrom file. These are not twisted, but are milled from round wire making them efficient for translational strokes but poor and weak for rotational movement(43).

In the mid-20th century, a need for uniformity of endodontic instruments was recognized(44). The International Standards Organization (ISO) worked together with the Federation Dentaire Internationale to establish standardized specifications for file taper and tip diameter which are allocated an ISO number(41). File sizes progress

incrementally with the file number corresponding to the diameter at the tip, or D0. A size 10 file has a diameter of 0.10mm at D0 while a size 15 file has a D0 diameter of 0.15mm. The cutting blades advance at an indicated taper over a standardized length of 16mm. A common taper for hand instruments is a 0.02mm increase in diameter per 1mm of length. Thus, at the level denoted D16, any file with a 0.02mm taper would have a cross-sectional diameter than has increased 0.32mm from D0. Several methods were devised to perform root canal cleaning and shaping using hand instruments. Establishing standard instrument sizes has normalized their fabrication, improved quality, and allows more consistent use among operators.

Hand Instrumentation Techniques:

Several methods have been devised to perform root canal cleaning and shaping using hand instruments. An early method of canal instrumentation using hand files was "serial reaming and filing and recapitulation"(18). Bulkier file sizes are increasingly stiff and their placement around curves or to the apex can be restricted. Serial reaming and filing means to use instruments of larger taper and size short of the apex to create space for successively smaller and smaller instruments to be guided apically. Fine files, which have already been negotiated to the apex, are repeatedly re-introduced into the canal between each larger file to unclog debris and maintain working length throughout canal preparation. A flared preparation in the coronal two-thirds of the canal creates a straight access to its apical portion so that a file corresponding to the estimated size of the apical constriction can ultimately be worked to length.

The step-back technique is an addition to serial reaming and filing. In it, larger files instrument the canal further short of the apex as they are taken to successively decreasing lengths in increments of 0.5-1.0mm(45). The double flared technique adds an early flaring phase to avoid the formation of an hourglass shape during preparation and is also claimed to minimize the potential of expelling material through the apical foramen during preparation(46). The concept of "balanced force" was introduced to limit movement of the natural canal anatomy in a curve. The technique consists of clockwise placement rotations of less than 180 degrees followed by counter-clockwise cutting rotations of at least 120 degrees. The placement stroke advances and binds the file in the canal, while the cutting stroke enlarges the canal and frees the file tip. This allows placement to an even greater depth where the process is repeated(47). These methods were innovative and effective, however, they were also tedious, time-consuming, and laborious.

Rotary Instrumentation:

Endodontic instruments were initially manufactured using carbon steel. Their strength and quality vastly increased with the advent of stainless steel. In the late 1980's, nickel-titanium alloy allowed an additional leap forward in the capacity of endodontic instruments(48). Nickel-titanium alloy confers two distinct advantages: superelasticity and high resistance to cyclic fatigue(49). The increased flexibility of the material permits engine-driven continuous rotation with a safety and consistency that had not been deemed possible previously with carbon or stainless steel(50).

The backbone of nickel-titanium rotary instrumentation is the crown-down technique(51), which involves three phases: coronal access, coronal-middle preparation, and apical preparation(52). The crown-down is a modified version of the strategies employed during hand filing described above. After initial scouting to the apex with a small hand file, large rotary files are used to enlarge the canal short of the apex before smaller and smaller files are introduced until full working length can be passively attained. Larger files are then used again until the apical third has been prepared to the desired size(53). Most other techniques that are used with continuous rotation systems are simply variations of the crown-down.

A wide selection of endodontic filing systems is available on the dental materials market today. Most of these are constant tapered files, conforming to ISO standards in both apical size and width, and are compatible with the crown-down instrumentation technique. Several popular examples include Profile, Vortex, GT, EndoSequence, K3, HERO, Twisted File, and Hy-Flex. The ProTaper Universal system is unique because it features a varying taper, meaning that each file has a taper that changes over the course of its long axis. Dr. Cliff Ruddle, Dr. John West, and Dr. Pierre Machtou designed the system in the mid 1990's. It consists of 7 files: 2 shaping files and 5 finishing files. The shaping files, S1 and S2, have small tip diameters of 0.17mm and 0.20mm, respectively, but are relatively wide in the coronal with D14 diameters of 1.2mm and 1.1mm, respectively. The finishing files, termed F1, F2, F3, F4, and F5, have respective tip diameters of 0.2mm, 0.25mm, 0.30mm, 0.40mm, and 0.50mm and apical tapers of 0.07mm, 0.08mm, 0.09mm, 0.06mm, and 0.05mm. Unlike the shaping files, the apical finishing files have a decreasing percentage taper from D4-D14 so that the coronal

portion is not in contact with the canal walls. Protaper Universal is designed to duplicate the Schilder technique and simplify the crown-down process(54). Each Protaper Universal file is worked to full length. The coronal-middle preparation phase is taken care of by the wider diameters of the shaping files used in the beginning and the desired apical size determines the number of finishing files in the sequence that are used. This is in contrast to the technique for straight taper files where larger files are used first, followed by smaller files, and then larger ones again until adequate apical size has been attained.

ProTaper Next is a newer addition to the endodontic market. It is used similarly to ProTaper Universal but has a rectangular, instead of triangular, cross-section which is off-centered. Its axis of rotation is different than its center of mass and limits the amount of surface area in contact between the file and canal wall at any given point in time. This system features 5 files, and is designed to attain full apical preparation with fewer instruments while producing slightly less tapered sizes. The files, X1-X5, have apical sizes of 0.17mm, 0.25mm, 0.30mm, 0.40mm, and 0.50mm and tapers of 0.04mm, 0.06mm, 0.07mm, 0.06mm, and 0.06mm, respectively(55). In comparison to ProTaper Universal, ProTaper Next files have been found to possess significantly enhanced performance with respect to cyclic fatigue resistance(56,57) and in minimizing extruded debris(58,59), microcrack induction(60), and canal transportation(61,62).

Reciprocating Motion:

There are three main areas in which engine driven instrumentation has been modified over the years as more and more file systems are introduced to the market. Most

early advances in rotary instrumentation dealt with changes in cross-sectional design like those in the files described previously. Later, alloys modified through heat treatment and other manufacturing methods were introduced. While improvements in these areas continue to be made, there has been particular interest in recent years surrounding the method of rotation itself. The vast majority of instrument systems, and those already described, employ continuous rotation in a clockwise direction. The instrument simply spins in one direction at a constant speed. However, there have been a few systems released which function via reciprocating motion.

Reciprocating motion is the combined movement of rotation in one direction alternated with rotation in the other direction. The magnitude of rotation in each direction corresponds to the angle of the arc traveled by each point of the file in a circle. The difference between the two angles determines the net amount a file actually travels rotationally per cycle. Alternating the direction of movement reduces torsional stress by minimizing instrument binding as it advances down a narrow canal. While only a few reciprocating systems are available on the market today, there are an infinite number of possible combinations of angles in each direction, thus reciprocating motion can refer to an unlimited amount of different overall and net movements.

WaveOne is a system that utilizes reciprocating motion for canal instrumentation. WaveOne travels a greater magnitude, 170 degrees, in the counter-clockwise direction, than that traveled in the clockwise direction, which is 50 degrees. Its net rotation per cycle is 120 degrees, so one complete rotation is made every 3 cycles(63). The counter clockwise rotation is a cutting and engaging stroke, while the clockwise rotation is releasing and disengaging. Its recommended operating speed is 300 revolutions per

minute(64). This indicates its net speed, while the actual speed would be much faster as backwards rotations of 50 degrees are being made 3 times per cycle, or 900 times per minute. WaveOne is advocated as a single file system, meaning one file can be used from the coronal to the apical portion of the canal for instrumentation without the need of changing files to different sizes as canal preparation progresses. The files come in 3 sizes, called Small, Primary, and Large. WaveOne Small has an ISO tip size of 21 and a continuous 6% taper. WaveOne Primary and WaveOne Large have ISO tip sizes of 25 and 40, respectively. Both the Primary and Large sizes have a variable taper that is 8% in the apical portion and reduces toward the coronal end(65).

Potential Adverse Events Associated with Canal Instrumentation:

Root canal anatomy is often complicated and features canals that can "merge, curve, recurve, dilacerate, or divide"(66). Negotiation of complex root canals can require a great deal of finesse and strategy. Forcing large instruments to the apex can distort the apical anatomy(18). As the canal anatomy is altered in relation to the external root surface of the tooth, canal transportation occurs, which ultimately can lead to perforation, a communication of the root canal with the periodontal ligament and/or alveolar bone. A perforation is a conduit whereby microorganisms gain access to nutrients, spread, and initiate or prolong infection. In most cases perforations are difficult to treat and prognosis is negatively affected(67).

A ledge may be created by continued active force after the passive progress of a file has been impeded. Depending on the severity, subsequent files, including smaller files that may have been capable of reaching the apex previously, may no longer be able

to bypass the ledge and are stopped short of the apical terminus. A separated instrument may similarly block a canal(68). File separation usually happens due to overstressing the file via operator error or, more rarely, because of manufacturing defects in the file itself(69). A ledge or separated instrument can lead to incomplete cleaning, shaping, and filling of the apical region which in turn could result in a lowered prognosis(32,33).

Root canal treatment patients can also experience a post-operative flare-up. Walton and Fouad described a flare-up as pain or swelling within a few hours to a few days after a root canal procedure of sufficient severity that both an unscheduled visit with the dentist and active treatment are required. They reported an incidence of 3.17% out of 946 patients(70). A more recent study conducted in Brazil estimated the flare-up rate to be 1.71%(71). Even though these inter-appointment emergencies are rare, they can be highly problematic for both the patient and the dentist(70). These adverse events may occur following the use of any of the methods and instruments described above. An ideal instrumentation system would minimize their incidence as much as possible.

Clinical Comparisons of Reciprocating and Rotary Systems:

Systems utilizing reciprocation have been increasingly compared in the literature to those using the more traditional rotary motion. While the results of several publications often conflict with one another, many studies have found the performance of each approach to be similar in many areas, including: dentin crack formation(72-75), canal transportation(76,77), bacterial reduction(78-81), remaining intra-canal debris(82), extruded debris(59,83), and shaping ability(84). A key advantage, however, afforded by reciprocating motion is an increase in resistance to cyclic fatigue. This appears to be true

regardless of whether or the not the file system was designed for use with this movement(85-88). The smaller the reciprocating angle of the motion, the further the resistance to cyclic fatigue is increased because the releasing and disengaging portion of the motion is occurring more often(89).

At the same time, this increased protection from instrument separation comes at the expense of working efficiency. As the rotational progression of the file per cycle is incrementally decreased, longer preparation times can be expected(90). This inherent disadvantage of reciprocating motion has been countered by combining it with the use of a single-file technique to completely instrument the canals, which is a fairly novel concept(91). The use of just one engine-driven file from orifice to apex increases the stress placed on the canal walls and on the file itself. The ability to follow the original canal anatomy is also diminished compared to using multiple files in sequence(92,93). Notwithstanding, the improved cyclic fatigue resistance and centering ability inherent with reciprocating movement allows the use of a single engine-driven file to be more feasible(90).

Aims and Objectives:

The combination of reciprocation with single-file endodontics has been claimed not only to provide a safe and reliable alternative, but also to allow faster canal preparation compared to multi-file continuous rotation(94). To this point these assertions have been supported by *in vitro* studies(61,95). At the time of this writing, and to the best of our knowledge, these claims have not yet been evaluated *in vivo* in a prospective randomized clinical trial. The aim of this study was to evaluate the efficiency and safety

of two popular and well-known root canal instrumentation systems, one utilizing single-file reciprocation (WaveOne), and the other utilizing multi-file continuous rotation (ProTaper Next). The specific objectives were:

1) To compare the time required to complete root canal instrumentation with WaveOne and ProTaper Next.
2) To evaluate the incidence of potential adverse events occurring during instrumentation, namely file separation, canal ledges, canal perforations, or patient flare-ups.
3) To evaluate the ability of each system to achieve and maintain full working length.

Materials and Methods:

The study protocol for this prospective, randomized clinical trial was approved by the Institutional Review Board of the University of Connecticut Health Center. All subjects included in the study were patients treated in the Endodontic Clinic at the University of Connecticut Health Center.

Power Analysis and Sample Size

At the time of protocol submission, no similar clinical studies reporting outcomes for instrumentation time *in vivo* for WaveOne and/or Protaper Next could be identified for estimation of anticipated effect size. Power analysis conducted prior to initiating the investigation was thus based on the potential variability of the expected data. It was determined that in order to detect a large size effect as defined by Cohen with 80%

power, or a difference in effect equal to the size of at least 1 standard deviation, 17 teeth would be required per treatment group. A sample of this size was predicted to be easily achievable within the time parameters available. However, it was felt that a medium sized effect, a difference equal or greater than ½ of the standard deviation would still be clinically relevant and important to detect if possible. To detect this difference with 80% power would require 64 subjects per group for a total of 128 subjects. A recruitment goal of 128 patients within the time parameters available was considered realistic, yet ambitious, based on historical patient volume and flow of patients in the endodontic clinic at the University of Connecticut Health Center. In order to include a maximum number of patients in pursuit of this goal, 3 operators were used. To account for potential patient drop out or failure to return for treatment following the initial clinical visit a target was set to recruit 180 patients. In other words, data for a minimum of 34 teeth was required for statistical analysis and a goal was set to include 128 teeth to make the analysis more powerful and meaningful.

Participant Selection:

Consecutive patients referred to the endodontic clinic at the University of Connecticut Health Center for root canal treatment by one of the three study operators from July 31, 2014 – March 19, 2015 were screened for eligibility in the clinical trial by way of routine preoperative radiographic and clinical exams. The three study operators performed all recruitment and treatment of subjects. Eligibility was determined based on set inclusion and exclusion criteria. The criteria for inclusion were as follows:

1) Need for primary root canal treatment of a restorable tooth

2) Subject at least 18 years of age
3) Subject is able to demonstrate proficiency in English and ability to provide informed consent

The following were the criteria for exclusion:

1) Teeth with previously completed root canal treatment
2) Teeth with previously initiated root canal treatment and evidence of previous manipulation extending beyond the pulp chamber and into the canal(s)
3) Teeth with immature or open apices
4) Teeth with severe curvatures or atypical anatomy precluding the use of rotary instrumentation
5) Subjects unable to communicate proficiently in English
6) Inability to provide consent to participate in the study

If it was determined through initial exam that the patient fulfilled the eligibility criteria, the nature of the study and treatment procedures were explained and they were invited to participate. It was stressed to each potential subject that participation was voluntary and that they would receive the same standard of endodontic care regardless of whether or not they decided to participate. Informed written consent was obtained from all subjects included in the study.

Study operators were all endodontic residents in their 3rd year of residency with more than two years of experience using Vortex, EndoSequence, and ProTaper Universal instrumentation systems. All were novices using WaveOne and ProTaper Next at the time of the study design. Prior to beginning the study, operators were trained in the use of both

WaveOne and ProTaper Next, had practiced on plastic simulated canals and extracted teeth, and completed at least 5 clinical cases with each system.

Treatment Group Allotment

Subjects were randomly assigned to either the Protaper Next (PTN) or WaveOne (WO) system treatment groups using pre-randomized cards. An effort was made to keep the numbers as even as possible between the groups so 60 cards were made for each operator, 30 for the WO group and 30 for PTN. The order was determined in advance using a computer randomization program and each card was sealed inside a numbered envelope so that the operators would not know the assigned treatment group for each subject until the appropriate time. If more than one tooth for a given patient was included in the study, each tooth was randomized into one of the treatment groups and treated independently.

Treatment Protocol

The tooth to be treated was isolated with a rubber dam and faulty restorations and caries were removed. The tooth was then disinfected with 30% hydrogen peroxide followed by 5% iodine tincture according to the standard clinic protocol(96). Endodontic access was performed with a high-speed hand piece and the canals were located. A hand file was carefully taken to length according to standard procedures and working length was determined with the use of an apex locator to 1mm short of the apex. Working length was verified radiographically. If necessary, coronal enlargement of the orifices was

performed with Gates Glidden burrs or an SX file to allow passage of the file to the apical portion of the root canal.

Following working length determination and establishment of an appropriate glide path, the operator opened the sealed envelope containing the pre-randomized card indicating whether the tooth would be assigned to the PTN or the WO instrumentation group. A new sterile pack of files was used for each case. Once the random group assignment was known, a timer was started and canal preparation began. The time required for canal preparation was recorded until working length was achieved with the Master Apical File (MAF) in all canals, at which time the timer was stopped. Canal preparation was considered to encompass instrumentation, irrigation, recapitulation, cleaning of file flutes, changing of files, etc. In order to maintain continuity between patients and operators, the help of a dental assistant was not used chair-side during the canal preparation segment of the procedure. Treatment time lost due to variables not associated with the file system itself was excluded from the recorded canal preparation time. These variables may have included:

1) Patient requiring supplemental anesthesia

2) Taking additional radiographs between working length determination and completion of instrumentation to length with the MAF

3) Restroom breaks needed by the patient or operator

4) Interference by a receptionist, a phone call, or other doctors/providers in need of immediate consultation

Each canal was prepared by the indicated system according to the manufacturer's instructions in the "Directions for Use". After every 3 pecking motions with the file, the

file was removed and the flutes were wiped clean with gauze. Each canal was irrigated with 1 ml of 0.5% NaOCl, recapitulated with a size 10 or 15 k-file, and the instrumentation file was reintroduced into the canal for 3 additional pecking motions. This process of instrumentation, flute cleaning, irrigation, and recapitulation was repeated until working length had been reached with the master apical file and canal preparation was considered to be complete. If at any time treatment could not be completed in a single visit, the timer was stopped and the canals were dried with paper points. They were then packed with $Ca(OH)_2$ paste and the occlusal access cavity was temporized with a layer of Cavit followed by an outer layer of Fuji IX. At the subsequent visit(s), the rubber dam was replaced and disinfected in the manner previously mentioned, the provisional restoration was removed, and the canals were irrigated with 0.5% NaOCl prior to restarting the timer and continuing instrumentation from where the procedure was left off at the previous visit. In order to allow treatment between the two systems to be as comparable as possible, only sizes X1, X2, and X4 were used as master apical files when using ProTaper Next. These sizes correspond to the 3 sizes available in the WaveOne system: Small, Primary, and Large, respectively**.** Master apical file size was based on the ISO size of the initial apical file. If the IAF was an extremely tight #10 or smaller then a ProTaper Next X1 or WaveOne Small file was chosen. If the IAF was a well-fitting or loose #10 or #15 file then the MAF was a ProTaper Next X2 or WaveOne Primary file. ProTaper Next X4 or WaveOne Large files were selected as the MAF in canals with an IAF of ISO size 20 or larger.

Following canal instrumentation, a gutta percha cone matched by the manufacturer to the size of the MAF was placed to resistance in each canal and its fit was

evaluated with a periapical radiograph. The master cone was marked at the corresponding occlusal reference point with a pair of cotton pliers. The gutta percha cone was withdrawn and initial master cone length was measured with an endodontic ruler for comparison to the final working length of the MAF. If the initial master cone length was >0.5mm different than the FWL intended by the MAF then the canal was considered to have been instrumented "off" according to length. A notation was also made as to whether this difference was positive, a canal instrumented "long", or negative, a canal instrumented "short". Untimed final irrigation was performed according to standard procedures. Each canal was then dried with paper points and obturation was carried out with AH Plus sealer and gutta percha via the vertical condensation continuous wave technique.

Data were collected for each included tooth on a pre-approved spreadsheet including age, tooth number, system used, number of canals, initial working lengths, final working lengths, initial apical file size, master apical file size, canal instrumentation time, and initial master cone length (see Appendix X). The occurrence of adverse events such as ledges, perforations, file separations, and flare-ups were also recorded. Data were saved and password protected within a software folder to which only the study investigators had access.

Statistical Analysis

The following regression model was used to compare the requirement of canal preparation time per tooth among operators, tooth types, instrument system, and age:

$$time = \beta 0 + \beta 1\ Age + \beta 2 toothtype + \beta 3 system + \beta 4 operator + \beta 5 toothtype * system + \beta 6 operator * toothtype + \beta 7 operator * system.$$

A reduced model was then run to compare the effect of covariates of age, tooth type, system, and operator on time:

$$time = \beta 0 + \beta 1 \quad + \beta 2 tooth\ type + \beta 3 system + \beta 4 operator.$$

The effects of operator and tooth type on time were evaluated using least squares mean analysis. A similar regression model was also performed using average canal instrumentation time per canal as the dependent variable:

$$average\ time\ of\ canals = \beta 0 + \beta 1 \quad + \beta 2 toothtype + \beta 3 system + \beta 4 operator + \beta 5 toothtype * system + \beta 6 operator * toothtype + \beta 7 operator * system.$$

The effect of tooth type and system on average time per canal was determined using least squares mean regression analysis. A reduced logistic regression model was used to compare the proportion of "off" teeth with respect to operators, tooth types, time, and instrumentation system as well as the proportion of "long" or "short" canals:

$$[P/(1-P)] = \beta 0 + \beta 1 Time + \beta 2 Toothtype + \beta 3 System + \beta 4 operator.$$

The proportion of "off" canals among operators, tooth types, instrumentation system, and time was compared using binomial regression:

$$[Pi/(1-Pi)] = 0 + \beta 1 Time\_Canals + \beta 2 Toothtype + \beta 3 System + \beta 4 operator + Time\_Canals * operator\ Time\_Canals * Tooth\_type\ Time\_Canals * system$$ where $Pi = \#\ of\ off\ canals / \#\ of\ canals.$

A regression model was used to evaluate the trend of average time required per case for each operator as the study progressed.

Results:

A total of 79 patients with 89 teeth and 193 total canals were included in the study. Fifty teeth and 111 canals were randomly assigned to the WO treatment group and 39 teeth and 82 canals were randomly assigned to the PTN treatment group. Thirty-seven teeth were treated by operator 1, 18 by operator 2, and 34 by operator 3. More information regarding treatment group characteristics can be seen in Tables 1, 2, and 3.

Significant differences in average instrumentation time per tooth were detected between operators, tooth types, and patient age. Operator 2 required significantly more time per tooth compared to operators 1 and 3, $p = 0.0002$ and $p < 0.0001$, respectively (Table 4). Molars required significantly more time to instrument compared to anterior teeth and premolars, $p < 0.0001$ (Table 5). Age was found to be a significant predictor of time with an additional requirement of 1.98s per tooth estimated per additional year of life ($p = 0.0298$); this was not affected by system used. Analysis controlling for operator, age, tooth type, and system showed no statistically significant difference between WO and PTN in instrumentation time per tooth for the overall data set or for any of the individual tooth types: anteriors, premolars, or molars.

In addition to the above analysis conducted on a per tooth basis, data were also analyzed using average instrumentation time per canal as the key dependent variable. Significant differences in average instrumentation time per canal were again detected between operators with operator 2 significantly slower compared to operators 1 and 3. For each additional year of life an estimated 1.22s more time per canal was required for instrumentation. There was no significant difference in average time required to instrument canals from different tooth types: anteriors, premolars, or molars. Analyses

controlling for operator, age, tooth type, and system show no statistically significant differences in average instrumentation time per canal between WO and PTN among all teeth combined, among molars, or among anteriors. For premolar teeth, however, WO required an average of 127.03s per canal compared to 204.34s for PTN; this difference was statistically significant, p=0.0024 (Table 6).

In addition to division into groups of anteriors, premolars, and molars, teeth were also separately divided into two groups according to number of canals, whether single or multiple. Among teeth with a single canal, a statistically significant difference was found between WO and PTN for average canal instrumentation time, 144.7s versus 216.3s, respectively, p=0.0122 (Table 7). A difference was also detected among premolars with a single canal, p=0.0007 (Table 8), though this difference was significantly influenced by operator (Tables 9 and 10). There was no significant difference between the groups among teeth with multiple canals. There was no significant trend or change in operator's average speed over time as the study went on. In other words, operators did not speed up or slow down from the beginning of the trial to the end.

No adverse events including file separations, flare-ups, perforations, or ledges were detected in the study sample by either group, WO or PTN.

Efficiency in maintaining working length was evaluated by comparing the differences between FWL and initial master cone length (Tables 11 and 12). Initial master cone length data were available for 72 out of the 89 teeth. No significant difference was found between WO and PTN for proportion of teeth or canals with at least one canal instrumented "long", "short", or "off". Molar teeth were significantly more likely to be instrumented "off" compared to premolars [estimated OR: 17.96, (95% CI

2.28-141.40)], although this difference did not remain significant when canals were analyzed independently. Instead, anterior tooth canals were significantly more likely to be instrumented "off" according to length compared to individual molar or premolar canals, p=.0027.

Discussion:

This investigation was a prospective, randomized, *in vivo* comparison of WaveOne and ProTaper Next including all tooth types. Instrumentation time was the primary variable of interest. Double blinding was not possible as proper operation necessitated the providers know which system was being used. While the minimum number of patients, 34, required for analysis was easily achieved, the goal of 128 teeth was not reached as more patients than anticipated did not fulfill the inclusion criteria. Additionally, the number of first year residents in the program increased compared to previous years and, per clinic policy, preference was given to these newer residents when assigning emergency or over-booked patients. This lowered the amount treated by this study's operators. Recruitment of patients ceased when the total number of teeth included was 89 due to time constraints as all three operators involved were nearing the end of their post-graduate residency. A target in excess of the recruitment goal turned out to be unnecessary for the measurement of time; instrumentation was completed on all randomized teeth. Such an excess would have been necessary to ultimately achieve data for the goal of 128 teeth concerning master cone length as patients accounting for 19.2% of teeth did not return to have treatment completed within the study time frame.

Objective 1: Measurement of Time

Results in this study were reported on both a per tooth and a per canal basis. Results on a per tooth basis are important clinically because dental practitioners treat affected teeth as whole, not just the individual canals. However, analysis based on each canal allows for more convenient comparison between groups and between different studies. This has been done in endodontic literature for over half a century(34). Comparison among canals can be more meaningful due to the differences in the number of canals between tooth types or even among teeth of the same tooth type. This is especially true in premolar teeth where most have either one or two canals, representing a potential difference of 100% between one and the other. In this study a statistical difference in canal preparation time was seen only in premolar teeth (Table 4). Further analysis revealed that this difference was due to the sub-type of premolars that have a single canal. No difference was noted among premolars with multiple canals. No difference was detected in anterior teeth, which all had a single canal, due to the small sample size. Only four anterior teeth were treated with ProTaper Next. Analysis by canal also revealed that a molar canal requires a similar amount of time to prepare compared to a premolar or anterior canal. The increased time required to prepare a molar over the other tooth types appears to be due to the presence of more canals rather than an inherent difference in the individual canals themselves. This may not be true of the time required to locate and initially negotiate such canals.

A substantial amount of heterogeneity exists between studies regarding the type of canal instrumented and the method of recording time. Two methods of recording are recognized in the literature and were termed “instrumentation time” and “whole

preparation time" by Zhao et al(61). Instrumentation time refers only to the time in which the file is actively working inside the canal. Whole preparation time includes instrumentation time as well as the time required for changing files, wiping files clean, irrigation, and recapitulation.

Most previously reported values for canal preparation times of WaveOne are considerably lower than those found in this investigation. These are particularly short when only instrumentation time has been considered. Reported times for instrumentation of simulated canals are 25.57s(97) and 49.25s(90). Extracted mandibular molars with three canals required an average instrumentation time of 79s per tooth, which can be calculated to be 26.4s per canal(61). These measurements are not applicable or relevant to clinical root canal treatment as cleaning and shaping consists of more than instrumentation alone. Recorded times are somewhat longer when whole preparation time per canal is reported instead. Two studies using extracted teeth have documented times of 68.6s(61) and 82.3s(95) while the time in a study using a simulated canal was 72.4s(98). In our investigation the whole preparation times required with WaveOne were far greater, 144.7s for teeth with single canals or 155.0s for molar canals, demonstrating the increased difficulty of preparation in an *in vivo* clinical situation.

Whole preparation times per canal with ProTaper Next on extracted teeth have also been reported. These are more similar to the results of this study than the previous accounts concerning WaveOne. Extracted teeth with single canals needed an average of 103s(58) and 188.7s(95) *in vitro*, slightly less than the 216.3s required for single-canal teeth *in vivo* in this study. Extracted molars with 3 canals required 229.4s per canal(61); this is more than the 150.8s per molar canal reported here.

Two previous studies have directly compared the whole preparation times of WaveOne and ProTaper Next. Both found that WaveOne required significantly less time per canal than ProTaper Next. Burklein et al. evaluated only teeth with a single canal and thus is in agreement with the results presented here(95). Zhao et al. used molars with multiple canals(61). This finding is not consistent with our results, as we found no statistical difference *in vivo* for that tooth type.

ProTaper Next instruments have been shown to instrument significantly faster than ProTaper Universal(58,61). ProTaper Next was chosen for this study because the operators had similar experience with that system and WaveOne, limiting the compounding variable of operator experience. Had ProTaper Universal been chosen instead to represent multi-file rotary, a greater difference may have been noted between it and the single-file reciprocating system.

In addition to the differences in study methodology, the large variation in times reported across publications is likely due to differences in operator skill, experience, or preference. Sizable differences were seen with the same system even in identical simulated canals when times were reported for individual operators in other studies(97,99). In this study, the three operators involved did not perform uniformly overall or across tooth types. Operator 2 took significantly more time per tooth and canal compared to operators 1 and 3. Operator 2 also treated a lower number of teeth in the study compared to the other operators. No significant trend in time required from the beginning of the study to the end of the study was seen for any operator so this is not likely to explain the difference. It should be emphasized that reported time averages cannot be extrapolated beyond the specific providers measured.

The present study is unique in that comparisons could not only be made between systems overall, but also between tooth type or between systems within a given tooth type. WaveOne was found to perform significantly faster than ProTaper Next only when compared among premolar teeth and also among teeth with a single canal. A potential explanation for the difference lies within the average size of the canals themselves. With rare exception, the canals in these teeth tend to be larger on average and were prepared to size X4 or Large. The ratio of files used between ProTaper Next and WaveOne is then more pronounced at 4:1. Canals in teeth with multiple canals were usually prepared to size X2 or Primary, except for single distal canals of mandibular molars or palatal canals of maxillary molars. The ratio of files used in multiple canal cases is thus closer to 2:1. This smaller ratio is further diluted by the ability to prepare multiple canals with the same file before changing it in more of a mass production style, rather than the unit production style necessitated by single canals. For multiple canals, one file change is required for 2-4 canals. Whereas for single canals, three file changes were required for one canal.

While this finding is notable, it is equally meaningful to reiterate that this difference was not maintained when more than one canal was prepared per tooth and that no difference was observed between groups when all teeth or all canals in the data set were included in the analysis. Even among those tooth types where a difference was seen, the difference in time was small in relation to the time required for an entire root canal treatment. Wong et al. reported average non-surgical root canal treatment times in two clinics to be 76.2 minutes and 39.9 minutes(100). While this in no way can be generalized to other clinics, it does serve to illustrate that a difference between systems of 72-77 seconds, as found in our study, may not be clinically relevant. These modest

benefits and the variation among individual operators suggest that time should not be the principal factor upon which a decision about file systems should be based. Instead, clinicians should evaluate which system works predictably and safely in their own hands to achieve desired results.

Objective 2: Adverse Events

This study supports the perception that WaveOne and ProTaper Next can be used safely and predictably to instrument root canals during non-surgical endodontic therapy in a clinical setting. No file separations occurred during preparation of 111 canals with WaveOne and 82 canals with ProTaper Next. This finding is consistent with *in vitro* studies where 180(97), 36(61), and 20(95) canals were instrumented with WaveOne without any file separations. An *in vivo* clinical study reported a separation incidence of just 0.42% with WaveOne files after treatment of 711 teeth or 2,215 canals(101). If this percentage were to hold true for this study, then 1 separation would be expected for approximately every 238 teeth, a sample size much larger than the 50 teeth that were ultimately included here. Similarly, no file separations were reported previously with ProTaper Next after in vitro instrumentation of 36 canals(61). Ertas et al. used ProTaper Next files repeatedly until fracture on extracted teeth. They found that the instruments separated after application to a mean of 5.7 teeth and that none of the files fractured during the first use(102). Accordingly, no separations would be expected in our study where all of the files were discarded after a single use.

No patients experienced a flare-up in this study according to the definition by Walton and Fouad(70), that is, no unscheduled visits with active treatment were required

due to post-operative pain and/or swelling. Three out of the seventy-nine patients did, however, call to complain of post-operative pain and were prescribed an analgesic in addition to the ibuprofen already recommended. In all three cases the tooth most recently treated had been from the WaveOne group. While the numbers are extremely small in this study, they are at least consistent with a previous study by Gambarini et al. in which patients instrumented with WaveOne had a significantly higher incidence of post-op pain (30%) compared to patients with teeth instrumented with Twisted Files (0%) or TF Adaptive (6.6%)(103). No ledges or perforations were detected during the treatment of any teeth included in our study, however, no gold standard was used to which clinical and radiographic exams could be compared to for verification of this finding.

Objective 3: Length Control

No statistical differences between ProTaper Next and WaveOne were detected concerning length control, however this is possibly due to lack of power and small sample size. A higher percentage of teeth instrumented "off" with WaveOne approached significance with a p value of 0.066. There was a discrepancy of greater than 0.5mm in 37.5% of teeth and 22.7% of canals prepared with WaveOne compared to 15.6% and 9.4% with ProTaper Next (Table 9). The greatest disparity was in canals instrumented "long", 10.2% with WaveOne versus 3.1% with ProTaper Next (Table 10). Again, no statistical difference could be detected because the number of events was small; only 11 canals total were "long". This trend is in agreement with a study investigating working length alteration of WaveOne reciprocating files on extracted teeth with curved canals. When the canals were instrumented with a reciprocating file to the same length as was

measured with a hand file, 75% of WaveOne instruments projected beyond the experimental apical foramen(104). A loss of canal length can be expected around any prepared curve(47) so providers must exercise prudence and adjust working length strategy according to the system that they are using.

Unrelated to system used, molars were significantly more likely to have a discrepancy between final working length and initial master cone length compared to premolars and anteriors. The estimated odds ratio for molar teeth was 17.955. The 95% confidence interval was extremely large, 2.28-141.403. The low end 2.28 could easily be due to the increased amount of canals in a molar compared to other tooth types. Indeed, the difference for molars disappeared when analysis was conducted per canal. Meanwhile, the difference detected statistically among anteriors compared to premolars and molars for canals "off" could be misleading as the sample size in this tooth type was extremely small.

Conclusions:

No overall difference was found between instrumentation systems for average time per tooth or canal required to complete instrumentation. Instrumentation time of premolar and single-canal teeth was significantly lower with WaveOne compared to ProTaper Next. Increased age significantly increases the time needed for canal instrumentation. Individual operators can demonstrate profound differences in average canal preparation time. No file separations or other adverse events were detected after treatment of 79 patients and 89 teeth. WaveOne and ProTaper Next can be used safely and predictably to instrument root canals in a clinical setting.

Tables:

Table 1. Description of Treatment Group Characteristics

	WaveOne		ProTaper Next	
	n	%	*n*	%
Average Patient Age	41.2	-	41.3	-
Total Teeth	50	56.2	39	43.8
Total Canals	111	57.5	82	42.5

Table 2. Proportion of Tooth Types Assigned to Each System

	WaveOne (*n*=50)		ProTaper Next (*n*=39)	
	n	%	*n*	%
Anterior	8	16.0	4	10.3
Premolar	18	36.0	19	48.7
Molar	24	48.0	16	41.0
Single-Canal	18	36.0	15	38.5
Multiple-Canal	32	64.0	24	61.5

Table 3. Proportion of WO or PTN Cases Performed by Each Operator

	WaveOne (*n*=50)		ProTaper Next (*n*=39)	
	n	%	*n*	%
Operator 1	18	36.0	19	48.7
Operator 2	11	22.0	7	17.9
Operator 3	21	42.0	13	33.3

Table 4. Adjusted Average Overall Instrumentation Time of Each Operator

Operator	Average Time per Tooth (sec)
1	269.92
2	433.60[a,b]
3	219.82

a: Significantly Different than Operator 1, p=0.0002
b: Significantly Different than Operator 3, p=<0.0001
Note: Adjusted for System, Patient Age, and Tooth Type

Table 5. Adjusted Average Instrumentation Time for Each Tooth Type

Tooth type	Average Time per Tooth (sec)
Anterior	193.82
Premolar	239.59
Molar	489.94[a]

a: Significantly Different than other groups, p=<0.0001
Note: Adjusted for Operator, System, and Patient Age

Table 6. Effect of System Used and Tooth Type on Instrumentation Time

Tooth Type	System	Ave Time per Canal (sec)
Anterior	ProTaper	190.23
	WaveOne	183.07
Premolar[a]	ProTaper	204.34
	WaveOne	127.03
Molar	ProTaper	150.76
	WaveOne	155.00

a: PTN and WO Significantly Different among this Group, p=0.0024

Table 7. Effect of System and Single- or Multi-Canal Teeth on Time

Tooth Type	System	Ave Time per Canal (sec)
Single-Canal[a]	ProTaper	216.33
	WaveOne	144.73
Multi-Canal	ProTaper	162.38
	WaveOne	150.06

a: PTN and WO Significantly Different among this Group, p=0.0122

Table 8. Effect of System and Single- or Multi-Canal on Time among Premolars

Type of Premolar	System	Ave Time per Canal (sec)
Single-Canal[a]	ProTaper	255.06
	WaveOne	126.56
Multi-Canal	ProTaper	166.20
	WaveOne	138.20

a: PTN and WO Significantly Different among this Group, p=0.0007

Table 9. Effect of Operator and System on Time among Premolars.

Operator	System	Ave Time per Canal (sec)	Comparison Number
1	WaveOne	91.96	1
	ProTaper	164.46	2
2	WaveOne	155.16	3
	ProTaper	358.87[a]	4
3	WaveOne	150.01	5
	ProTaper	108.56	6

a: Significantly Different Compared to All Other Groups, See Table 10 for p values

Table 10. P-Values for Comparison of Time per Operator and System from Table 9

	1	**2**	**3**	**4***	**5**	**6**
1	-	0.2480	1.0000	<0.0001	1.0000	1.0000
2	0.2480	-	1.0000	0.0002	1.0000	1.0000
3	1.0000	1.0000	-	0.0004	1.0000	1.0000
4*	<0.0001	0.0002	0.0004	-	0.0002	<0.0001
5	1.0000	1.0000	1.0000	0.0002	-	1.0000
6	1.0000	1.0000	1.0000	<0.0001	1.0000	-

* Statistically Significant

Table 11. Working Length Discrepancies per Tooth

	Total Teeth	**Teeth Long**		**Teeth Short**		**Teeth Off**	
		n	%	*n*	%	*n*	%
Overall	72	11	15.28	12	16.67	20	27.78
ProTaper	32	2	6.25	4	12.50	5	15.63
WaveOne	40	9	22.50	8	20.00	15	37.50

Table 12. Working Length Discrepancies per Canal

	Total Canals	**Canals Long**		**Canals Short**		**Canals Off**	
		n	%	*n*	%	*n*	%
Overall	152	11	7.23	15	9.87	26	17.11
ProTaper	64	2	3.13	4	6.25	6	9.38
WaveOne	88	9	10.23	11	12.50	20	22.73

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Appendix

Study Documents

IRB Review
IRB NUMBER: 14-169-3
IRB APPROVAL DATE: 06/16/2014
IRB EXPIRATION DATE: 06/15/2015

Informed Consent Form

Principal Investigator (PI): Dr. Blythe Kaufman

PI Phone Number: (860) 679-2454

Co-Investigator(s): Dr. Justin Farmer

Study Personnel: Dr. Michelle Hack, Dr. Hisham Rifaey

Title of Research Study: A comparison of instrumentation efficiency of Protaper Next and WaveOne: a randomized clinical trial.

Expected Duration of Subject's Participation: 4 years

IRB Number: 14-169-3

External Sponsor/Funding Entity: N/A

Name of Research Participant: _____

What Is The Purpose Of This Research Study?

This research study is being done to compare two instrument systems that are commonly used to help clean a tooth during a root canal. The two systems we will be comparing are WaveOne and Protaper Next. Both systems use rotary files but each of them works in a different way: WaveOne is a single file that moves in a back-and-forth motion while the Protaper Next uses files of different sizes that rotate in the same direction. By looking at both file systems we want to: 1) compare the time required to complete root canal preparation between two different systems; 2) evaluate the ability of each system to achieve and maintain full working length; 3) compare short and long term healing rates between cases treated by each system.

Why Am I Invited To Participate?

You are invited to take part in this study because you have come to the endodontic clinic for primary root canal treatment of a restorable tooth, which means that a root canal can save your tooth so you do not need to have it pulled.

How Many Other People Do You Think Will Participate?

We would like to enroll a total of 180 participants in this study.

Is Participation Voluntary?

Participation in this study is voluntary. The same standard of care and treatment will be provided to you regardless of whether or not you choose to participate in the study. Before making a decision about whether to participate in this research study, please read this consent form carefully and discuss any questions you have with the researcher. You may also want to talk with family members, your primary care physician or a friend before making a decision.

You can choose not to participate. If you choose to participate in the study, you can change your mind later and stop participating at any time. If you decide not to participate or you withdraw from the study after starting participation, your decision will not affect your present or future

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medical care you receive at the University of Connecticut Health Center/John Dempsey Hospital. There will be no penalty or loss of benefits to which you are otherwise entitled.

How Long Will My Participation In This Study Last?
Study participation will not increase nor decrease the normal anticipated time of root canal treatment. Root canal treatment is typically performed in one to three visits of 1 - 2 hours each, over a period of 4 weeks. As with any root canal treatment, rare exceptions may require additional treatment visits for completion. Routine root canal protocol calls for follow-up visits at 6 mos., 1 year, 2 year, 3 year and 4 year intervals. Each visit will take approximately 15 minutes and the tooth will be evaluated radiographically and clinically for any problems. The radiographic results and any clinical symptoms present will be recorded. Whether or not you choose to participate in this research study, your treatment time will remain the same. Reviewing this consent form is the only additional time that will ever be added to your total treatment time.

What Are the Costs To Me For Participating In This Study?
You will not have any additional costs if you choose to participate in this study.

What Will I Be Asked to Do?
Drs. Farmer, Hack and Rifaey will ask each of their patients who comes to Clinic 2 for a primary root canal if he/she would like to participate in this study. If you agree to be in this study, your doctor will review the consent form with you and answer any questions you may have. Once your treatment begins your doctor will document the file system that is used to perform your root canal along with the time it takes to work with that system during the root canal. Your age will be collected because canal sizes tend to decrease as a person gets older and this trend may be important in our analysis.

What Are the Benefits Of Participating In This Study?
You will not benefit directly from the information we gather in this study. Other people who have the same condition may benefit in the future if we find that one system works better than the other. There is also the possibility that no benefit will come from this study.

Will I Be Compensated For Participating In This Study?
You will not be compensated for participation in this study.

What Alternative Procedures or Treatments Are Available To Me?
Standard root canal procedure requires the use of a file system. There are several different systems that are commonly used in dental clinic 2. Even if you choose to not participate in the research study, one of these file systems may still be used on your root canal. All standard Clinic 2 protocols will be followed during your treatment.

What Types of Risk Are Involved If I Choose To Participate?
Risks involved in participating in this study are no greater than normal risks associated with having a root canal procedure.

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If you discuss this with your employer or co-workers your study participation may become known to others. If you do not want anyone to know that you are participating in this study it would be best not to discuss this with anyone.

How Will My Personal Information Be Protected?

We will protect the confidentiality of your data to the best of our ability, but cannot guarantee 100% protection.

The following procedures will be used to protect the confidentiality of your data:

- All information gathered from your participation in this study will be placed in a separate research record that is stored in a different location than your medical record.
- Research records will be labeled with a code and all contents of the research record will be labeled with only that code.
- The code will be derived from your first and last initial followed by a sequential 3 digit number that reflects how many people have enrolled in the study.
- A master key that links names and codes will be maintained in a separate and secure location.
- The study staff (principal investigator, co-investigator, study personnel, etc.) will keep all study records (including any codes to your data) locked in a secure location.
- All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by un-authorized users. Data that will be shared with others will be coded as described above to help protect your identity. Any laptop computers that will be used will be encrypted.
- Age will be collected because canal sizes tend to decrease as a person gets older and this trend may be important in our analysis. Your experimental number and tooth number will appear with your age. Your name will never appear with your age, experimental number nor tooth number.

The Health Center's Institutional Review Board and the Human Subjects Protection Office may inspect records. They may inspect records to ensure that the study is being done correctly.

At the conclusion of this study Dr. Justin Farmer, Co-Investigator and Endodontic Resident, will write his Master's thesis using the findings and results of this study. Dr. Farmer will also write a manuscript and submit it for publication in the Journal of Endodontics, International Endodontic Journal, or the Journal of the American Dental Association. Information will be presented in summary format and you will not be identified in any publications or presentations.

What If I Decide To Stop Participating In The Study?

You are free to stop participating in this study at any time. If you decide to stop participating in the study, your relationship with your doctors or the University of Connecticut Health Center will not be affected. If you decide to withdraw from the study we ask that you let us know by calling Dr. Justin Farmer at (860) 679-2719, or by sending a written notice to Dr. Justin Farmer, Division of Endodontology, University of Connecticut Health Center, 263 Farmington Ave., Farmington, CT, 06032-1715.

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What if I Have Questions?

The Principal Investigator, Dr. Blythe Kaufman, and Co-Investigator, Dr. Justin Farmer, are willing to answer any questions you have about the research. You are encouraged to ask questions before deciding whether to take part. You are also encouraged to ask questions during your study participation. If you have questions, complaints or concerns about the research, you should call the Principal Investigator at (860) 679-2454 or Dr. Justin Farmer at (860) 679-2719.

If you have questions about your rights as a research subject you may contact a coordinator at the Institution Review Board at 860-679-1019, 860-679-4851, or 860-679-4849. You may also call a coordinator at the Institutional Review Board if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies.

Please do not call the IRB number for medical related issues or to schedule or cancel an appointment.

Consent To Participation:

By signing this form you acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form.

By signing this form the individual obtaining consent is confirming that the above information has been explained to the subject (and/or legally authorized representative, parents or guardians) and that a copy of this document, signed and dated by both the person giving consent and the person obtaining consent, along with a copy of the Research Participant Feedback Form, will be provided to the participant.

Role	Printed Name	Signature	Date	Time
Study Participant				
Person authorized to obtain consent				

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AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

Information About the Research Study

Dr. Justin Farmer is conducting a research study called ***A comparison of instrumentation efficiency of Protaper Next and WaveOne: a randomized clinical trial.*** Dr. Blythe Kaufman, a faculty member in the Division of Endodontology, is the Principal Investigator for the study, Dr. Hisham Rifaey and Dr. Michelle Hack are study personnel who will also be treating research participants. The purpose of the study is to evaluate the root canal preparation efficiency of two rotary systems, WaveOne and Protaper Next. Both are commonly used file systems, each using a different instrumentation philosophy. The WaveOne operates in a reciprocal motion (a repetitive up-and-down or back-and-forth linear motion); the Protaper Next is a rotary instrumentation system that uses multiple files of variable tapers. This research study aims to: 1) compare the time required to complete root canal instrumentation between two different instrumentation system; 2) evaluate the ability of each system to achieve and maintain full working length; 3) compare short and long term healing rates between cases treated by each system.

Voluntary Status

Because of a federal law called the Health Insurance Portability & Accountability Act (HIPAA), we must get your permission to use and disclose your identifiable health information for this research study. This form is used to document that permission. Because of HIPAA you must also receive a copy of the Health Center's rules about privacy.

Your decision whether to give permission is voluntary. The only consequence of not granting permission is that you will not be allowed to participate in this research study. Your decision has no impact on your treatment, payment, or enrollment in any health plans, or on your eligibility for benefits

Information That Will be Used / Disclosed

The following information about you may be used and disclosed for the purpose of this research study:

- Your hospital ID number
- Your age

How the Information Will be Used / Disclosed

The information noted above will be used and disclosed for the following purpose(s):

- Your hospital ID number will be used so that we may follow-up at future visits. Each tooth included in the study will be assigned a number (1-180) corresponding to the pre-randomized treatment card. Your name or personal information will never be included in the study file. The experimental number will only be linked to the hospital identification number for routine follow-up examination. At the end of each visit, the treatment data spreadsheet and the

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pre-randomized treatment card will be placed in a locked file cabinet separate from the medical record to which only the investigators have access. The hospital identification number will never be recorded on the spreadsheets or cards. A code will exist on a separate sheet containing the experimental number and hospital identification number which will be kept in a separate locked and secure location.

- Age will be collected because canal sizes tend to decrease as a person gets older and this trend may be important in our analysis. Your experimental number and tooth number will appear with your age. Your name will never appear with your age, experimental number nor tooth number.

People/Offices That Will Have Access to Your Information

The following people/entities may use and disclose your protected health information.

- Dr. Blythe Kaufman, Dr. Justin Farmer, Dr. Hisham Rifaey and Dr. Michelle Hack
- The Health Center's Institutional Review Board and Human Subjects Protection Office and Office of Research Compliance
- Hospital or University of Connecticut Health Center representatives.
- Government representatives, such as the Food & Drug Administration or Office for Human Research Protections; when required by law.

The researchers and staff agree to protect your information by using and disclosing it only as stated in this document and as directed by state and federal law.

Reasons to share your information are to be able to conduct research, and to ensure that the research meets legal, institutional and/or accreditation requirements.

Right to Access Information

You be allowed to review the information collected for this research until the collection of information is complete and/or the study is complete.

Expiration of Permission

Your permission to use and disclose your protected health information expires upon completion of the research study

How to Withdraw Permission

You can withdraw your permission at any time by sending a letter to Dr. Blythe Kaufman at the University of Connecticut Health Center, Division of Endodontology, 263 Farmington Avenue, Farmington, CT, 06030-1715, to inform her. If you withdraw your permission you will no longer be allowed to participate in this study. If you withdraw your permission the PI and her staff will no longer be able to use and disclose your protected health information. There are exceptions to this. For example, the researchers may continue to use and disclose the protected health information that was collected for the research study prior to receiving the request to withdraw your permission.

Questions or Complaints

If you have any questions, concerns or complaints about your privacy rights, you may write to the Director of Patient Relations at the University of Connecticut Health Center, 263 Farmington Avenue, Farmington CT 06030-1112. If you have a complaint, you may

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also write to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, U.S. Dept. of Health and Human Services Government Center, J.F. Kennedy Federal Building, Room 1875, Boston MA 02203. Complaints should be sent within 180 days of when you knew, or should have known, of the problem.

State of Connecticut Requirement

In this study we are not asking for information about AIDS, HIV infection, behavioral health services, psychiatric care, or treatment for alcohol and/or drug abuse. If this type of information pertains to you there is a slight chance that it may be inadvertently disclosed during the course of the study. The State of Connecticut requires that any release of this type of information be specifically authorized. Therefore, by signing this dual-purpose authorization you are also acknowledging that there is a chance that information pertaining to AIDS, HIV infection, behavioral health services, psychiatric care, or treatment for alcohol and/or drug abuse, may be disclosed, even though it is not the focus of attention in this research study.

Permission for Use and Disclosure of Information

You are a voluntary participant in this research study. By signing you acknowledge that you have read this form, had the opportunity to have your questions answered, and that you authorize the use and disclosure of protected health information as described in this form. You will receive a copy of this form after it is signed.

_____

Signature of the research participant Date

_____

Printed name of the research participant

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IRB APPROVAL DATE: 06/16/2014
IRB EXPIRATION DATE: 06/15/2015

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_____You have previously received the University of Connecticut Health Center's Notice of Privacy Practice that explains your rights and the policy of the institution.

_____You have been provided with a hard copy of the University of Connecticut Health Center's Notice of Privacy Practice by the researcher(s) and have been given the opportunity to read it and ask questions prior to signing this form.

Individual Data Spreadsheet

A Comparison of Instrumentation efficiency of Protaper Next and Wave One: a randomized clinical trial.

Dr. Justin Farmer

Experimental # _____	Tooth# _____	# of Canals _____	Instrumentation System		
Age _____			Protaper Next ☐	WaveOne ☐	
Initial Working Length	Canal #1 _____	Canal #2_____	Canal #3_____	Canal #4_____	Canal #5_____
Final Working Length	Canal #1 _____	Canal #2_____	Canal #3_____	Canal #4_____	Canal #5_____
Master Apical File	Canal #1 _____	Canal #2_____	Canal #3_____	Canal #4_____	Canal #5_____
Initial Apical File	Canal #1 _____	Canal #2_____	Canal #3_____	Canal #4_____	Canal #5_____
Canal Prep Time	Visit 1 _____	Visit 2 _____	Visit 3 _____		
Initial Master Cone Length	Canal #1 _____	Canal #2_____	Canal #3_____	Canal #4_____	Canal #5_____
Adjustment Time: _____		Interruption: Cause _____		Time: _____	
Total Canal Prep Time _____			Obturation Time: _____		
Post-op flare-up		Perforation			
Ledge		Separated Instrument			
Master Cone Fit from Apex	Canal #1 _____	Canal #2_____	Canal #3_____	Canal #4_____	Canal #5_____
Obturation Length from Apex	Canal #1 _____	Canal #2_____	Canal #3_____	Canal #4_____	Canal #5_____

Experimental # Code Sheet

Title:A comparison of instrumentation efficiency of Protaper Next and WaveOne: a randomized clinical trial.

Dr. Justin Farmer

Experimental #	Hospital Identification #
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Experimental #	Hospital Identification #
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