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Jensen, Lauren Elizabeth



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# MECHANICAL PREPARATION OF OVAL-SHAPED ROOT CANALS IN MANDIBULAR PREMOLARS WITH THE TRUSHAPE 3D CONFORMING FILE: A MICRO-COMPUTED TOMOGRAPHY STUDY

by

Lauren Elizabeth Jensen

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of the requirements for the Master of Science
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Thesis Supervisors: Professor Ove A. Peters and Professor Fabricio B. Teixeira

Graduate College
The University of Iowa
Iowa City, Iowa

CERTIFICATE OF APPROVAL

MASTER'S THESIS

This is to certify that the Master's thesis of

Lauren Elizabeth Jensen

has been approved by the Examining Committee for the thesis requirement for the Master of Science degree in Oral Science at the May 2017 graduation.

Thesis Committee:

Ove A. Peters, Thesis Supervisor

Fabricio B. Teixeira, Thesis Supervisor

Anne E. Williamson

William T. Johnson

To my mom, Martha O. Jensen, and my dad, Dr. Niels F. Jensen: mentors, friends, and parents. As mentors, you have humbly demonstrated excellence and have inspired me to achieve at that level. As friends, you have been kindred spirits, unconditional supporters. As parents, you have been remarkable. It has been a privilege to be your daughter. Thank you for being our parents, the heads of our family; for expressing your love for each other and for us—Hannah, Adrienne, and me; and for wanting something for us rather than from us. My love for you is unparalleled. Thank you, Mom and Dad. I love you.

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One may have a blazing hearth in one's soul and yet no one ever came to sit by it.
Passers-by see only a wisp of smoke from the chimney and continue on their way.

Vincent Van Gogh
A Wisp of Smoke

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## ABSTRACT

The TRUShape 3D Conforming File (TRUShape), a novel, S-shaped nickel-titanium (NiTi) rotary file, was developed to facilitate cleaning and shaping of irregular-shaped root canals. The purpose of this study was to evaluate the shaping ability of TRUShape compared to Vortex Blue (VB) when used in non-round, oval-shaped root canals by micro-computed tomography (MCT).

Thirty single-rooted human mandibular premolar teeth with radiographically similar root canal size and curvature were randomly allocated to two groups (N=15), and mechanically prepared with TRUShape or VB. Each tooth was submitted to MCT at 20 μm resolution at three time intervals: before shaping, and after shaping to an intermediate apical size 30 and a final apical size 40. Three-dimensional data sets were superimposed and evaluated for root canal volume, surface area, and treated surface. Matched axial slices in the apical, middle, and coronal root thirds were evaluated for area, roundness, and canal transportation expressed as center of mass shift (CMS). Data were statistically analyzed using parametric and non-parametric tests.

Root canal volumes increased similarly and significantly overall ($p<0.001$; from an initial volume of $7.3\pm3.5$ mm$^3$ to an intermediate volume of $8.7\pm3.1$ mm$^3$ and a final volume of $9.9\pm3.0$ mm$^3$). Treated canal surface was significantly larger in the TRUShape group at both apical sizes 30 and 40 with $72\pm15$% vs. $55\pm23$% and $85\pm12$% vs. $71\pm20$% non-static voxels for TRUShape and VB, respectively ($p<0.05$). Canal transportation was less than 100 μm in all but 8 out of 90 cross sections and was not significantly different between groups.

This MCT study demonstrated the TRUShape 3D Conforming File to be effective in the mechanical preparation, specifically, the surface treatment, of single-rooted premolars with non-round, oval-shaped root canals.

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# PUBLIC ABSTRACT

Endodontic treatment aims to prevent or eliminate apical periodontitis, an inflammatory disease caused by an infected root canal system. Central to endodontic treatment is chemo-mechanical root canal preparation: mechanical enlargement and shaping combined with chemical disinfection of the root canal system. An ever-changing armamentarium is used to perform and evaluate chemo-mechanical root canal preparation, "preparation" for short. The TRUShape 3D Conforming File is a novel instrument, whose unique design, an S-curve in the instrument's long axis, may enhance preparation of non-round root canals. The purpose of this study was to evaluate the preparation ability of TRUShape compared to Vortex Blue (VB), an established endodontic instrument, when used in non-round root canals by three-dimensional (3D) analysis, namely micro-computed tomography (MCT).

Thirty extracted, single-rooted human teeth with similar root canal size and curvature were assigned to two groups (N=15): TRUShape or VB. Root canals were prepared according to manufacturer's instructions. Each specimen was scanned using a desktop MCT unit at three time intervals: pre-, mid-, and post-preparation. Two- and three-dimensional data sets were generated. Root canal volume and prepared or "treated" surface, and each instrument's ability to remain centered in the root canal during preparation were statistically analyzed.

Root canal volumes increased similarly and significantly overall in the TRUShape and VB groups. Treated root canal surface was significantly larger in the TRUShape group. There was minimal difference in files' centering ability.

This MCT study demonstrated the TRUShape 3D Conforming File to be effective in mechanical root canal preparation of single-rooted teeth with oval-shaped root canals.

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# CHAPTER 1

# INTRODUCTION

The principal aim of endodontic treatment is to prevent or eliminate apical periodontitis, mostly occurring secondarily to an inflamed or infected dental pulp. Non-surgical root canal treatment (NSRCT) is a predictable, highly successful procedure with significant potential for a favorable outcome [1]. Central to NSRCT is root canal preparation, which is achieved through a chemo-mechanical approach: mechanical enlargement and shaping of the root canal system using a combination of hand-held and engine-driven or rotary instruments in the presence of antibacterial irrigating solutions [2].

Nickel-titanium (NiTi) rotary instruments facilitate mechanical preparation of root canals [3]. A combination of 56% nickel and 44% titanium, the nitinol alloy transitions from austenite to martensite phases during mechanical loading as well as temperature changes, thus exhibiting shape memory and super-elasticity, two special properties of the NiTi alloy [4]. Since their introduction, NiTi rotary instruments have evolved with respect to thermal treatment and tip, cross-sectional, and taper configurations in an attempt to optimize their mechanical properties and shaping potential [3].

Despite these advancements, some types of root canals such as irregular-shaped root canals remain less amenable to mechanical preparation with conventional NiTi rotary instruments. Non-round, oval-shaped root canals are wider buccolingually than mesiodistally and compose the majority of human root canals. They are present in all single-rooted mandibular teeth, distal roots of mandibular molars, maxillary premolars, and mesiobuccal roots of maxillary molars. Previous studies have shown that mechanical preparation of oval-shaped canals fails to eliminate, even debride fins or recesses on buccal and lingual extensions of oval-shaped canals [5]. For example, Peters *et al*. demonstrated that 35-40% of root canal surfaces in maxillary molars remained untouched following instrumentation with NiTi rotary instruments [6]. It is reasonable to conclude that untouched areas within root canal systems may contribute to persistent apical periodontitis, as these areas may harbor inorganic material, organic necrotic tissue, and bacterial biofilms, which, much like the areas in which they reside, are also untouched, undisturbed [5].

Irregularities in root canal anatomy and morphology, such as those present in non-round, oval-shaped root canals, make total debridement virtually impossible. Debridement has been equated with treated root canal surface as shown by changes in surface voxels on micro-computed tomography (MCT) scans [6, 7]. However, this parameter, treated or prepared surface, implies that only a change in surface has occurred. The amount of root canal or radicular wall preparation may be as small as in the range of the resolution of the model, but much more dentin could also be removed. Moreover, adequate debridement, namely the reduction of irritants, as well as maintenance of the original canal anatomy during mechanical preparation are significant outcome predictors of endodontic treatment and must remain priorities, especially during NSRCT. In an attempt to improve root canal debridement in the presence of anatomic and morphologic irregularities in particular, a novel, heat-treated NiTi rotary instrument exhibiting an S-curve in the longitudinal axis, the TRUShape 3D Conforming File (Dentsply Tulsa Dental Specialties, Tulsa, OK), was developed.

Currently advertised to endodontic specialists only, the TRUShape 3D Conforming File (TRUShape), by virtue of its unique longitudinal geometry, produces an envelope of motion that varies in size depending on the initial root canal configuration [8, 9], possibly enhancing mechanical preparation. According to its manufacturer, TRUShape contacts a greater proportion of canal walls and engages and debrides root canal irregularities, while maintaining original root canal anatomy with less dentin removal and apical transportation than conventional NiTi rotary files [10]. Specifically, TRUShape contacts up to 75% of and removes up to 36% less dentin from root canal walls, while creating a predictable apical preparation with up to 32% less transportation than conventional NiTi rotary files [10, 11].

Currently, there is limited research on TRUShape. Peters *et al.* performed an initial assessment of root canal preparation quality using MCT. Small, curved mesial root canals of mandibular molars were prepared with TRUShape and .06 taper Vortex files (Vortex). MCT scans were obtained after canal preparation to apical sizes 20/.06 and 30/.06. Significantly more radicular wall dentin remained in general and, importantly, toward the furcation in root canals prepared with TRUShape than with Vortex at both apical sizes, confirming manufacturer's claims. However, the use of TRUShape in small, curved mesial root canals of mandibular molars did not yield an increase in treated canal surface [11].

Further, the advantages and disadvantages of TRUShape when used to mechanically prepare non-round, oval-shaped canals have not been established. Therefore, the purpose of the present investigation was to compare the quality of mechanical root canal preparation of non-round, oval-shaped root canals instrumented with TRUShape and another NiTi rotary file system with similar heat treatment, Vortex Blue (Dentsply Tulsa Dental Specialties, Tulsa, OK), using micro-computed tomography.

## Null Hypothesis

There is no statistically significant difference between the amount of root canal surface treatment of non-round, oval-shaped root canals instrumented with the TRUShape 3D Conforming File and Vortex Blue based on micro-computed tomography evaluation.

## CHAPTER 2

## LITERATURE REVIEW

### Apical Periodontitis

Etiology and Pathogenesis

Apical periodontitis is inflammation in the apical and periradicular periodontal tissues that occurs in response to a microbial infection in the dental pulp, which comprises the root canal system. Bacteria gain access to and establish an infection in the dental pulp as a consequence of caries, restorative dentistry, periodontal disease, or trauma. Eventually, the dental pulp succumbs to necrosis, the basis for apical periodontitis. Bacterial toxins and noxious metabolic by-products, as well as disintegrated pulp tissue egress from the infected root canal system into the apical periodontal tissues, periapical tissues for short. A complex, multi-factorial, host-mediated immune response ensues and results in pathologic changes in the periapical tissues—apical periodontitis [12].

Bacteria, either directly or indirectly, are the primary causative agents of infection in the dental pulp and root canal system, and apical periodontitis—a notion that was centuries in the making. In the $17^{th}$ century, Antonie Philips van Leeuwenhoek, a Dutch tradesman who became known as the "Father of Microbiology," observed "soft matter" and "animalcules" living within the root canal system of a decayed tooth [13]. Later, in the $19^{th}$ century, Willoughby Dayton Miller, an American dentist, hypothesized that bacteria, Leeuwenhoek's "animalcules," were the primary etiology of apical periodontitis [13]. Finally, in the $20^{th}$ century, Kakehashi *et al.* and subsequently Möller *et al.* implicated bacteria in the pathogenesis of dental pulp necrosis and apical periodontitis in their investigations on germ-free and conventional laboratory rats and monkeys, respectively [13-15].

In addition to bacteria, and bacterial toxins and noxious metabolic by-products, other exogenous factors such as chemical and mechanical irritants, foreign bodies, and trauma, as well as endogenous factors such as products from the host's complex metabolic and inflammatory processes may contribute to apical periodontitis [16]. Microorganisms other than bacteria, such as fungi, viruses, and archaea, also have been isolated from infected dental pulp and periapical tissues [17].

The type—either acute or chronic, progression, and severity of apical periodontitis ultimately depends on the nature of and host's response to the microbial invasion. The identity and virulence of the invaders, and the host's innate and acquired immune defense mechanisms determine the type, progression, and severity of apical periodontitis. The host's immune defense mechanisms are both beneficial and deleterious. Some offer protection to, while others promote destruction of the dental pulp and periapical tissues [18]. When apical periodontitis is present, there can be and often is radiographic evidence of periapical tissue destruction, such as resorption of bone. Apical periodontitis itself may be either symptomatic or asymptomatic.

Apical periodontitis is neither self-limiting nor self-resolving. Bacterial toxins and noxious metabolic by-products as well as disintegrated pulp tissue continuously seep out of the infected root canal system into the periapical tissues, perpetuating apical periodontitis. Apical periodontitis can be eliminated, and the periapical tissues restored to their original, healthy states if the primary etiology, the microbial infection within the root canal system, is identified and eliminated [18, 19].

## Objectives of Endodontic Treatment

The primary objectives of endodontic treatment are to prevent or treat apical periodontitis, and to promote retention of the natural tooth. Given that a microbial infection in the dental pulp and root canal system is a prerequisite for the initiation of apical periodontitis, removal of the microbial infection—the microorganisms, and their toxins and metabolic by-products, as well as disintegrated pulp tissue—is essential in the prevention or treatment of apical periodontitis. Endodontic treatment provides a means for preventing or treating apical periodontitis, and for maintaining the natural tooth [12, 14, 15, 20, 21]. For these reasons, endodontic treatment is the modality of choice for management of apical periodontitis. Extraction of the infected tooth provides another means for managing apical periodontitis, but it does not promote retention of the natural tooth.

Non-surgical root canal treatment (NSRCT) is only one of the many types of endodontic treatments options. Based on the initial diagnosis, other options, which are outside of the scope of the present investigation, include vital pulp therapy, non-surgical root canal re-treatment, and surgical re-treatment. The goals of NSRCT are to 1) remove irritants from the root canal system; 2) fill or obturate the cleaned and shaped root canal system; and 3) prevent future recontamination of the sealed root canal system [22]. Ideally, these goals should be accomplished without altering or damaging either the offending tooth or surrounding tissues and structures.

Regardless of case complexity, NSRCT is usually predictable and successful [1, 23]. Favorable outcome rates of up to 95% [24] and 85% [1] for NSRCT of teeth with vital, inflamed dental pulps and necrotic, infected dental pulps, respectively, have been reported. Further, an epidemiological study, which evaluated outcomes of almost 1.5 million cases of NSRCT over a period of eight years, reported that survival or tooth retention was 97% [23]. Given the predictability, high success rates, and even higher survival rates of NSRCT, the ultimate goal of natural tooth retention usually is achievable.

However, long-term success and/or survival of teeth following NSRCT are not guaranteed [23, 25]. Treatment failure, which manifests as the persistence or development of apical periodontitis, can occur. Microbial colonization of the root canal system is the primary cause of failure of NSRCT [26]. Factors that may contribute to or increase the likelihood for post-treatment apical periodontitis include pre-, intra- and post-operative factors, and importantly the host's systemic health and immune response [27]. Fouad *et al*., for example, suggested a host with compromised systemic health and/or an altered immune response may have a decreased capacity for healing after NSRCT [27].

Adequate debridement of the root canal system, namely, the reduction of irritants, is paramount to long-term success of NSRCT. Adequate debridement of complex, irregular-shaped root canal systems such as non-round, oval-shaped root canals, which often exhibit fins or recesses, and mesial roots of mandibular molars which often exhibit isthmuses [28], however, may not be achievable with the ever-expanding yet still limited endodontic armamentaria.

One of the most significant factors affecting outcome of NSRCT is related to the coronal seal and definitive restoration [29]. While opinions vary regarding the best or most appropriate type of restoration, respected researchers have advocated for full coronal coverage restorations following NSRCT. Aquilino *et al.*, for example, reported a six-fold greater failure rate for molar teeth that did not receive a crown following NSRCT compared to those that received a crown [25]. Further, an epidemiological study reported that a full coronal coverage restoration was absent in 85% of teeth that underwent NSRCT and subsequent extraction due to restorative treatment failure [23].

## Mechanical Root Canal Preparation

### Objectives of Mechanical Preparation

Central to endodontic treatment is root canal preparation, namely the mechanical enlargement and shaping of the root canal system combined with its chemical disinfection [20]. Known as both "cleaning and shaping" and chemo-mechanical root canal preparation, the aims are to remove inflamed, vital and necrotic tissues and infected root dentin from the root canal system; to mechanically enlarge and shape the root canal system to an acceptable configuration in order to facilitate the delivery of anti-bacterial irrigation to, placement of intra-canal medication in, and obturation of the root canal system; and to preserve the original anatomy of the root canal system, as well as sound radicular dentin [2, 20, 30].

Conventional chemo-mechanical root canal preparation is achieved using a combination of hand-held and engine-driven or rotary instruments in the presence of anti-bacterial irrigation. Chemical disinfection by means of anti-bacterial irrigation [31] and intra-canal medication is essential [26, 32], and its importance cannot be over-emphasized. However, the focus of the present investigation is the mechanical aspect of root canal preparation, "mechanical root canal preparation" or "mechanical preparation" for short. A discussion about chemical disinfection, therefore, is outside of the scope of this review.

In addition to manual and automated techniques for root canal preparation, sonic and ultrasonic techniques, as well as the use of laser systems and a non-instrumental technique that utilizes a vacuum pump have been described [20]. The technique employed for root canal preparation varies between practitioners and, in part, may be case-dependent, modified, for example, according to the internal anatomy of the root canal system. There may be a lack of consensus regarding technique for root canal preparation, but all practitioners seek to achieve the same goal, namely the prevention or elimination of apical periodontitis.

Schilder emphasized the importance of root canal preparation in endodontic treatment with his axiom "what comes out is as important as what goes in." Schilder further described five design and four biologic objectives of root canal preparation. The prepared root canal should be a continuously tapering funnel from the apex to the access cavity (1), have a cross-sectional diameter that is narrower at every point apically (2), and flow with the shape of the original root canal (3), and the apical foramen should remain in its original position (4) and be kept as small as practical (5). Further, to preserve the integrity of or promote the healing of periapical tissues, root canal preparation techniques should be confined to the roots themselves (1), not force necrotic debris beyond the apical foramen (2), remove all tissue from the root canal space (3), and create sufficient space for intra-canal medicaments (4) [33].

Schilder's design and biologic objectives for mechanical preparation continue to be cited. However, controversies regarding mechanical preparation have arisen. Practitioners' knowledge and understanding of the anatomical complexity of root canal systems has evolved and expanded, and, in parallel, so too have the armamentaria for mechanical preparation [20, 34-38]. Practitioners must select instruments, devices, and techniques from the current armamentaria that best facilitate root canal preparation, given the anatomical complexity of every root canal system. They must be cognizant of two facts: there is no single instrument, device, or technique capable of achieving every objective of root canal preparation (1); and the removal of the inflamed or infected dental pulp and microorganisms from the root canal system is the most important factor in the prevention or elimination of apical periodontitis (2).

Evaluation of Mechanical Preparation

Two of the parameters of interest when evaluating the efficacy of a given a root canal preparation technique or instrument are cleanliness and shape [20].

Post-preparation cleanliness has been assessed histologically, as well as by scanning electron microscopy (SEM), using serial horizontal and longitudinal cross sections of root canals, either simulated or from extracted teeth. Investigations on post-preparation cleanliness have reported on debris, smear layer, and microbial reduction. While integral to the prevention or elimination of apical periodontitis, microbial reduction per se can be difficult to quantify, and does not consider either the host response or virulence of the microorganisms themselves. Therefore, the majority of investigations has reported on debris and smear layer. Debris includes dentin chips, tissue remnants, and particles loosely attached to the root canal wall. As soon as an instrument contacts dentin during mechanical preparation, the so-called “smear layer,” a “film of debris,” is formed. It is made up of dentin chips, tissue remnants, bacteria and bacterial components, and fluids that remain on the root canal wall. Horizontal root canal cross sections enable lateral recesses and isthmuses to be visualized, and the amount of debris and remaining hard and soft tissues to be quantified. Longitudinal root canal sections enable both halves of the entire, primary root canal to be visualized. Lateral recesses and isthmuses may be less apparent in longitudinal sections, however, and longitudinal sectioning of a curved root canal may be challenging [20].

Post-preparation shape has also been evaluated. Historically, investigations on post-preparation shape have utilized replica techniques, simulated root canals in resin blocks, and extracted teeth. Their aims have been to evaluate conicity, taper, and flow of the prepared root canal, as well as preservation of the original anatomy of the root canal. Replica techniques afforded the evaluation of taper, flow, and wall smoothness of the prepared root canal, and the quality of the apical preparation. They did not, however, afford the evaluation of an important objective of mechanical preparation, namely maintenance of the original root canal shape, because the pre-operative root canal shape was unknown [20].

Researchers have used simulated root canals in resin blocks to standardize root canal curvature in three dimensions, as well as root canal "tissue" hardness and width. One technique created superimposed pre- and post-operative root canal outlines using subtraction radiography, for example. Advantages of simulated root canals in resin blocks over extracted teeth include reproducibility and standardization of the experimental design. Disadvantages of simulated root canals in resin blocks pertain to "tissue" differences. Compared to dentin, the micro-hardness of resin is lower, and so, too, is the mechanical force required to remove it. Further, resin chips, which make up debris that is produced during mechanical preparation, are a different size and may be more difficult to remove than dentin chips. There is a greater propensity for debris to accumulate and eventually block the apical root canal space in resin blocks. Perhaps resin is not a suitable substitute for dentin [20].

To most accurately reproduce the clinical scenario, researchers have used extracted human teeth. The use of extracted human teeth, however, is not without challenges. For example the wide range of variations of root canal anatomy makes standardization, even reproducibility of experimental designs difficult, if not impossible. Still, techniques have been described to evaluate root canal curvature and changes in root canal cross-sectional shapes using extracted human teeth by, for example, Schneider and Bramante *et al*., respectively. The Bramante technique, as it became known, has been revised, and revisions have facilitated the evaluation of changes in root canal cross-sectional shapes. Previously, for example, deviations between pre- and post-operative root canal outlines were evaluated by superimposing pre- and post-operative photographs. Currently, deviations may be quantified using either the centering ratio method or measurements of pre- and post-operative root canal dentin thickness. Further, circumferential root canal wall dentin removal as well as cleanliness of fins, recesses, and isthmuses can be evaluated [20].

Despite its ongoing popularity, serial sectioning as a means of evaluating mechanical preparation, especially root canal cleanliness, may yield misleading results. Inherent to the sectioning process, for example, is the potential for contamination of the root canal system with dust from the saw blade [20]. A different means of evaluating mechanical preparation emerged with the advent of recent technologies such as high-resolution micro-computed tomography (MCT). The primary advantages of MCT, perhaps, are the abilities to visualize the root canal system three-dimensionally, repetitively, and non-invasively—without physically altering or destroying the sample. Parameters that have been evaluated before and after mechanical preparation using MCT include root canal volume and surface area, amount of dentin removed, root canal thickness or diameter, treated or prepared root canal surface, also known as surface treatment, and the extent of transportation of the root canal to name a few [20, 39].

## Oval-shaped Root Canals

The horizontal dimension of the root canal system varies along the longitudinal or vertical axis, thus making the horizontal dimension more complex than the vertical dimension. The horizontal dimension has been characterized using 2D radiographs [36], and more recently, and perhaps more precisely, using MCT and a mathematical formula for “Roundness” [40].

Horizontal dimensions or cross sections of root canals have been described as round, oval, long oval, flat or ribbon-shaped, and irregular, such as C-shaped [7, 36]. Descriptions are based largely on maximum and minimum "working widths," also known as diameters or dimensions, usually obtained from 2D radiographs [36]. A round cross section, for example, has approximately equal maximum and minimum diameters. An oval or long oval cross section has a maximum diameter that is 1-2 times or 2-4 times greater than its minimum diameter, respectively. When cross sections of root canals are evaluated using the formula for Roundness, they are assigned values from 0 to 1 [40]. A perfect circle has a roundness value of 1. As a circle becomes less round and more non-round or oval-shaped, its roundness value approaches 0 [40].

There is a high prevalence of root canals with oval- and long oval-shaped cross sections. Wu *et al*. reported a 25% prevalence of long oval-shaped root canal cross sections in the apical third of human teeth [7, 41]. They reported an even higher prevalence in distal roots of mandibular molars, mandibular incisors, and maxillary second premolars [7, 41]. Root canals with oval- and long oval-shaped cross sections are complex and challenging to treat, even for the most competent endodontic practitioners and even in spite of the ever-expanding endodontic armamentaria. They often present with buccal and lingual surface extensions, which may be difficult, if not impossible to access and debride by conventional mechanical preparation techniques. Wu *et al.*, for example, reported unchanged recesses in 65% of oval-shaped root canals following preparation with hand instruments [42]. Figure 1 depicts adjacent 2D radiographic projections of a mandibular premolar with an oval-shaped root canal cross section [36]. From the standard, buccolingual projection (Figure 1, left), the root canal cross section appears round. The mesiodistal projection (Figure 1, center) and horizontal section of the root (Figure 1, right) more accurately depict the non-round, oval-shaped configuration. However, neither the mesiodistal nor axial projection is attainable during endodontic treatment using 2D radiography.

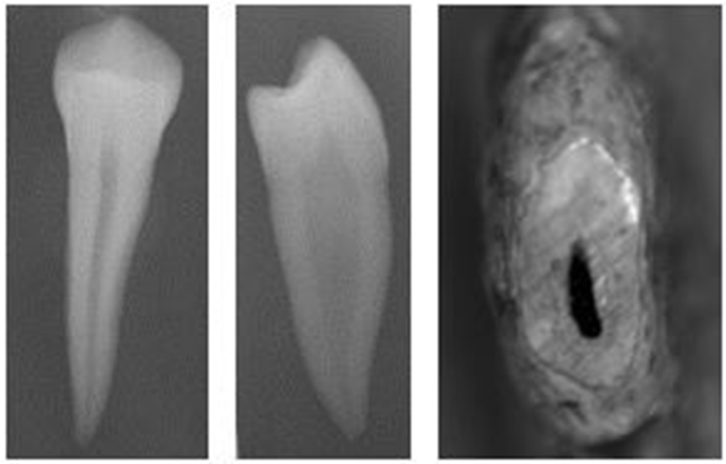

Figure 1. 2D radiographic depictions and a cross section of a human mandibular premolar.

Figure 1 Note: Two-dimensional radiographs of a human mandibular premolar from buccolingual (left) and mesiodistal (middle) projections, and an axial view of the same premolar, depicting the oval-shaped root canal (right). [36]

The present investigation included single-rooted mandibular premolars under the assumption that these teeth, especially in the coronal and middle root thirds, exhibit oval-shaped root canal cross sections. Further, the present investigation utilized both 2D radiographs and MCT scans in order to characterize, initially, and evaluate, subsequently, oval-shaped root canal cross sections.

## Nickel-Titanium Rotary Instruments

### The Evolution of Nickel-Titanium in Endodontics

The armamentaria for mechanical root canal preparation are ever evolving. Currently, the development of new endodontic hand-held and engine-driven or rotary instruments, namely "files," is a market-driven process that is less evidence-based and more empiric-based—in accordance with individual endodontic practitioners' requirements [35, 43]. Historically, files have been fabricated from carbon steel, stainless steel, and most recently, nickel-titanium. The first endodontic instruments were hand-held, small needles made from watch springs and later piano wires [20]. Eventually, stainless steel prevailed over carbon steel, and is the alloy from which the majority of contemporary hand-held endodontic instruments are made. Stainless steel files have considerable fracture resistance, but lack flexibility, a property that facilitates mechanical preparation of non-linear root canal systems, which make up the majority [13].

Two advancements in the field of endodontics, both of which pertain to mechanical root canal preparation, were the development of engine-driven or rotary instruments, and the use of nickel-titanium in instrument fabrication. William H. Rollins, in 1889, introduced an endodontic handpiece that enabled automated mechanical root canal preparation: fine needles were mounted in the handpiece, inserted into the root canal system, and rotated 360° at speed 100 rpm in order to avoid instrument fracture [20]. Since its introduction, the endodontic handpiece has evolved and so, too, have engine-driven instruments. The endodontic handpiece once permitted only continuous rotation of the instrument, which, itself, was fabricated from stainless steel. Currently, endodontic handpieces afford the option of combining different instrument motions, such as reciprocation, a repetitive and alternating clockwise and counterclockwise motion. Further, virtually all engine-driven instruments are fabricated from nickel-titanium, not stainless steel.

Nickel-titanium instruments have improved hand and automated mechanical root canal preparation due to the enhanced flexibility of the metal. The development of nickel-titanium and its initial uses in dentistry are unique. In the early 1960s, William F. Buehler, a research metallurgist at the Naval Ordnance Laboratory, now the Naval Surface Weapons Center, in Silver Springs, Maryland, invented the nickel-titanium alloy, also known as nitinol [44]. "Nitinol" is an acronym derived from the alloy's components and place of invention: "ni" for nickel, "ti" for titanium, and "nol" for Naval Ordnance Laboratory [44]. Composed of 55% nickel and 45% titanium by weight, nickel-titanium transitions between two stable crystalline phases, austenite and martensite, in response to temperature or stress [45]. The "strong and hard" austenitic crystalline form of nickel-titanium transforms into the "soft and ductile" martensitic crystalline form, which is able to endure greater stress [35]. Unique to nickel-titanium, this "transformational elasticity" or "pseudo-elasticity" imparts "shape memory" or a "spring back" quality. Simply, the nickel-titanium alloy "remembers" and returns to its manufactured shape following deformation [13].

In 1972, orthodontists introduced nickel-titanium to clinical dentistry. Just like endodontists, orthodontists initially utilized stainless steel armamentaria, but had begun to seek a material that exhibited lighter forces and a greater working range. With its low modulus of elasticity, approximately one-fourth to one-fifth that of stainless steel, and wide range for elastic deformation, nickel-titanium orthodontic arch wire proved to be a "significant improvement" over conventional, stainless steel orthodontic arch wire [44].

Applications of nickel-titanium in clinical dentistry did not stop with orthodontics. In their ground-breaking investigation, Walia *et al.* manufactured nickel-titanium endodontic hand instruments using a non-traditional manufacturing process [46]. A departure from the traditional manufacturing process in which the instrument's cross-sectional design is created by *twisting* a ground and tapered stainless steel wire blank, was required due to the pseudo-elastic property of nickel-titanium [13]. Walia *et al.*, using nickel-titanium wire blanks they had obtained from nickel-titanium orthodontic arch wire, manufactured endodontic hand instruments by *milling* rather than twisting [46]. Their nickel-titanium hand files were at least twice as flexible as and more resistant to fracture than stainless steel hand files of the same tip size, taper, and cross-sectional design. They suggested nickel-titanium files "may have particular promise for" mechanical root canal preparation, especially of curved root canals [46].

The recognition that nickel-titanium endodontic instruments could be operated in a continuous rotary motion within curved root canals was "game-changing," revolutionary. Drs. John McSpadden and Ben Johnson, the fathers of nickel-titanium rotary files [13], introduced the first nickel-titanium rotary instruments to the field of endodontics in 1992 and 1994, respectively [35]. Over the past quarter of a century, instrument manufacturers attempted to optimize the mechanical properties and shaping potential of nickel-titanium rotary instruments. They have experimented with alloy type, instrument tip, taper, and cross-sectional configurations, and thermal treatment during manufacturing [13, 20]. For example, instrument tips may be either passive and non-cutting or active and cutting, and instrument tapers may be .04, .06, .08, .1, and .12 [13]. They have also experimented with different modes of rotation, namely continuous rotation and reciprocation. To date, more than 50 different nickel-titanium rotary instruments have been described [13].

Types of Nickel-Titanium Rotary Instruments

Nickel-titanium rotary instruments have been categorized based on design into three groups, I, II and III [13]. Group I instruments, considered the first commercially successful nickel-titanium rotary instruments, were designed for passive root canal preparation. Their designs feature a passive, or “non-cutting” tip, lateral surfaces with three round excavations known as U-shapes or radial lands, a constant taper, flat helix and negative rake angles, and a high thread pitch, all of which impart a degree of operating safety. Group I includes ProFile (Dentsply Tulsa Dental Specialties), LightSpeed (SybronEndo), Greater Taper (Dentsply Tulsa Dental Specialties), and K3 (SybronEndro) instruments. A perceived advantage of Group I instruments is their relative safety, while disadvantages may be their limited cutting ability and stiffness, which require that many files be used during root canal preparation [13, 20].

Group II instruments were designed for active root canal preparation. A distinguishing characteristic of Group II instruments is their absence of radial lands. In addition, their designs feature an active, or “cutting tip,” steeper helix and more positive rake angles, and a lower thread pitch. Examples of Group II instruments are ProTaper Universal (Dentsply Tulsa Dental Specialties), EndoSequence (Brasseler), and ProFile Vortex (Dentsply Tulsa Dental Specialties) instruments. Group II instruments are more aggressive and, therefore, fewer files are required during root canal preparation compared to Group I instruments. Given their greater cutting efficiency, however, Group II instruments may be less safe and more prone to procedural mishaps than Group I instruments.  Instruments in both Groups I and II operate in continuous rotation [13, 20].

Group III instruments exhibit novel geometries, unique flute designs, motions other than continuous rotation, such as reciprocation, and/or special operating instructions, any of which exclude them from both Groups I and II.  They have been designed and manufactured, in part, to address perceived problems with or limitations of instruments in Groups I and II.  Problems such as taper lock, threading-in, or instrument fracture are associated with continuous rotation, specifically.  Examples of Group III instruments are WaveOne and Reciproc (both Dentsply Tulsa Dental Specialties), both of which operate in reciprocation in an attempt to minimize problems encountered with continuous rotation [13].

A significant limitation of conventional nickel-titanium rotary instruments as with hand instruments is their inability to gain access to and debride fins and recesses [42].  Previous studies have shown that mechanical root canal preparation fails to eliminate, even contact fins or recesses on buccal and lingual extensions of oval-shaped canals, for example [5, 42].  Peters *et al.* demonstrated that 35-40% of root canal surfaces remained untouched following mechanical root canal preparation with nickel-titanium rotary instruments [6].  Figure 2 depicts the usual effects of mechanical preparation of a long oval-shaped or flat root canal—a "keyhole" or "dumbbell" shape with a significant proportion of the root canal wall appearing unchanged (A-C) [36].

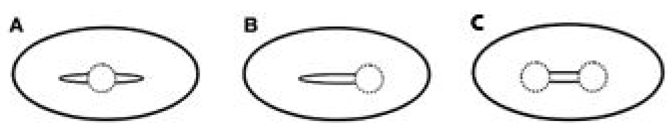


Figure 2.  Effects of mechanical preparation of a long oval-shaped or flat root canal.

Figure 2 Note: Non-round root canals often appear as keyholes (A-B) or dumbbells (C) after mechanical preparation with conventional nickel-titanium rotary instruments.  These instruments fail to contact a significant proportion of root canal surfaces, which remain virtually unchanged. Figure 2 was adapted from a figure by Jou *et al* [36].

Manufacturers have attempted to address this limitation by introducing nickel-titanium instruments whose designs are intended to facilitate greater circumferential root canal wall contact and debridement of fins and recesses. Two examples, both of which would be categorized as Group III instruments, are the Self-adjusting File (SAF; ReDent-Nova, Ra'anana, Israel) and the recently introduced TRUShape 3D Conforming File (Dentsply Tulsa Dental Specialties).

The Self-adjusting File, a hollow, compressible tube-like instrument, supposedly enables greater circumferential root canal wall contact. Metzger *et al.* [47] and Hof *et al.* [48], in a two-part series, described the design and mechanical properties of the SAF. Typically, files consist of a solid core with radial flutes. The SAF consists of a hollow core surrounded by thin, lattice-like nickel-titanium walls. As the SAF rotates, its walls expand and compress, allowing it to adapt to irregularities within the root canal system. Further, the hollow core enables continuous irrigation through the file itself. Peters *et al.* described the dentin removal ability of the SAF in maxillary incisors using micro-computed tomography. As mechanical preparation time increased, the amount of prepared root canal surface area increased to a maximum of 91.4% [2].

While the SAF exhibits the ability to increase the amount of prepared root canal surface area, its disadvantages abound. Specifically, the SAF is prone to irrigation accidents and instrument separation, and its non-traditional root canal preparation presents a challenge from the standpoint of obturation. Given these disadvantages, the SAF is no longer marketed in the United States.

## The TRUShape 3D Conforming File

<u>Introduction to TRUShape</u>

The TRUShape 3D Conforming File (TRUShape) is a novel nickel-titanium rotary file that exhibits a unique sigmoid or S-shape in the longitudinal axis. Introduced in 2015, manufactured by DENTSPLY Tulsa Dental Specialties, and depicted in Figure 3, TRUShape is currently advertised and available exclusively to endodontic specialists [10]. Like the SAF, it was designed to facilitate greater circumferential root canal wall contact, and, specifically, to conform to non-round root canal cross sections. According to the manufacturer, TRUShape contacts a greater proportion of root canal walls, engages and debrides root canal irregularities, and maintains original root canal anatomy with less dentin removal and apical transportation than conventional nickel-titanium rotary instruments. Specifically, TRUShape is claimed to contact up to 75% of root canal walls, to remove up to 36% less dentin from them, and also to create a predictable apical preparation with up to 32% less transportation than conventional nickel-titanium rotary instruments [10, 11].

If these claims were to be substantiated, TRUShape would likely be ideal for cases that involve non-round root canal cross sections and/or irregular anatomy such as fins, recesses, and isthmuses, in which conventional nickel-titanium rotary instruments have been shown to leave significant proportions of root canal walls untouched.

Figure 3. Schematic drawing of the TRUShape 3D Conforming File (size 30/.06*v)*.

Figure 3 Note: TRUShape exhibits an S-shape in the longitudinal axis. When in use, the S-shape creates an envelope of motion.

Characteristics of TRUShape

To yield a file exhibiting an S-shape in the longitudinal axis and a symmetric triangular cross section, first, flutes are ground into blanks using commercially available nickel-titanium. Subsequently, heat treatment is applied while the instrument is placed into a mold that sets the instrument's shape. TRUShape is available in tip sizes 20, 25, 30, and 40, as depicted in Figure 4, and lengths 21, 25, and 31 mm [10]. Each file exhibits a taper of .06 in the apical 2 mm, but, regardless of tip size, the maximum fluted diameter (MFD) is limited to 0.80 mm. The overall taper then is *variable*, specifically .06*v*, and regressive because it decreases between the apical 2 mm and the shank [11]. The sigmoid feature creates an envelope of motion when in use, which supposedly facilitates access to and debridement of ordinarily inaccessible root canal anatomy. The variable-taper feature supposedly facilitates conservation of root dentin, a main contributing factor in overall tooth strength.

Figure 4. Complete set of TRUShape files.

Figure 4 Note: From top to bottom, TRUShape sizes 20, 25, 30, and 40, respectively.

Current Research on TRUShape

TRUShape, with its novel design, is claimed to offer certain advantages over conventional nickel-titanium rotary instruments. Given that TRUShape is still relatively new to the endodontic market, the body of research on TRUShape is growing but limited. Therefore, a review of this body of research would expand one's understanding and appreciation not only of TRUShape but also of the present investigation.

Peters *et al.* performed an initial assessment on the quality of mechanical root canal preparation after the use of TRUShape [11]. Small, curved mesial root canals in mandibular molars were prepared with Vortex and TRUShape, and were assessed at different instrumentation stages using MCT. Investigators were particularly interested in dentin conservation, especially toward the furcation, the "danger zone." Size 20/.06*v* and 30/.06*v* TRUShape were found to remove 36% and 26% less root canal wall dentin, respectively, compared to size 20/.06 and

30/.06 Vortex. While TRUShape did not enhance the amount of treated or prepared surface compared to Vortex, this study assessed the quality of mechanical preparation of small, curved root canals as opposed to the non-round type of root canal that TRUShape was designed to treat—a limitation of this study, perhaps.

Bortoluzzi *et al.* evaluated bacterial reduction after the use of TRUShape [8]. Oval-shaped root canals in extracted maxillary premolars were infected with *Enterococcus faecalis*, prepared with TRUShape and Twisted Files, both in the presence and absence of anti-bacterial irrigation, with and without sonic irrigant agitation, and assessed using scanning electron microscopy (SEM) and light microscopy. Each instrument was used in a buccolingual sweeping motion in order to maximize the instrument's circumferential root canal wall contact. In the absence of anti-bacterial irrigation, TRUShape removed significantly more bacteria from oval-shaped root canals than did Twisted Files. These results suggest that TRUShape has the capacity to conform to, circumferentially contact, and ultimately disturb if not eliminate bacteria from oval-shaped root canals more effectively than conventional nickel-titanium rotary instruments. One limitation of this study may be that bacterial reduction alone was evaluated without any mention of changes in root canal anatomy during preparation.

Rotary instrument fracture can occur during endodontic therapy. While the incidence of rotary instrument fracture is relatively low, 3-5%, it is a challenge for the practitioner [2, 49]. Rotary instrument fracture may occur due to either cyclic or torsional fatigue [50]. Cyclic fatigue results from the repetitive stresses, compressive and tensile, endured by an instrument as it rotates in a curved root canal [51]. Torsional fatigue occurs when a portion of the instrument binds in the root canal while the remainder of the instrument continues to rotate [51]. Given the risk for rotary instrument fracture, the fatigue or fracture resistance of TRUShape has been investigated. De Vasconcelos *et al.* used a methodology that enabled the simulation of different temperatures, 20°C and body temperature (37°C), during cyclic fatigue tests [50]. TRUShape, as well as three other rotary files demonstrated a substantial decrease in fatigue resistance at body temperature, 37°C, compared to 20°C. Shen *et al.* evaluated the fatigue resistance of TRUShape in artificial single and two double curvature canals compared to that of ProFile and Vortex Blue [52]. In single curvature canals, the time to fracture was longer for TRUShape and ProFile. In both double curvature canals, the time to fracture was longer for TRUShape. Not only was there a notable difference in fatigue resistance, but also in the pattern or nature of the fracture particularly in double curvature canals. Contrary to Shen *et al.*, however, Elnaghy *et al.* found that with respect to cyclic fatigue TRUShape did not out-perform any of the other nickel-titanium rotary instruments to which it was compared [51]. Specifically, size 25/.06*v* TRUShape was less resistant to cyclic fatigue compared to size 25/.08 ProTaper Gold and size 25/.06 ProTaper Next.

Another factor related to instrument safety is the creation of dentinal defects during mechanical preparation, as there may be a relationship between mechanical preparation, dentinal defects, and vertical root fracture [53, 54]. Coelho *et al*. evaluated the presence of dentinal defects after mechanical preparation with TRUShape, ProFile, and WaveOne Gold using light-emitting diode (LED) transillumination [53]. Mesial roots of mandibular molars were prepared with sizes 20/.06*v* and 25/.06*v* TRUShape, sizes 20/.06 and 25/.06 ProFile, and size 25/.07 WaveOne. Roots were sectioned at 3, 6, and 9 mm from the apex, and microscopic images were made with the aid of LED transillumination. The images were assessed, and the number of dentinal defects was recorded. There was no significant difference in number of dentinal defects among the three files used and the control group (no mechanical preparation). These findings are in agreement with those by De-Deus *et al.,* who used non-invasive MCT to evaluate for dentinal defects [54]. In general, the proportion of dentinal defects is the same in uninstrumented and instrumented roots alike [53, 54]. From the standpoint of safety as it relates to dentinal defects, there is no evidence that suggests TRUShape poses an increased risk of dentinal defects compared to any other nickel-titanium rotary file system.

Uygun *et al*. evaluated the efficacy of size 25/.06*v* TRUShape in the removal of calcium hydroxide, an anti-bacterial intra-canal medicament, from artificially created grooves on buccal and lingual surfaces of root canals in mandibular premolars using stereomicroscopy [55]. The efficacy of size 25/.06*v* TRUShape was compared to that of the XP-endo Finisher, also a novel nickel-titanium instrument that exhibits a C-shape in the apical half of the file. Both files were compared to passive needle irrigation and ultrasonic irrigation. Needle irrigation performed the poorest compared to the other techniques, all of which were similarly effective in the removal of calcium hydroxide from artificially created surface grooves.

As previously established, endodontic treatment failure can and does occur [23, 29, 56]. An option when apical periodontitis persists or develops following NSRCT is orthograde or non-surgical endodontic re-treatment [56]. Integral to endodontic re-treatment is the removal of existing root canal filling material. Several techniques have been described for the removal of existing root canal filling material, many of which employ the use of nickel-titanium rotary files. Hence, researchers have investigated the efficacy of TRUShape in the removal of root canal filling material.

The efficacy of TRUShape in the removal of root filling material was compared both to that of Vortex Blue using serial sectioning [57], and to that of Reciproc, which operates in reciprocation, using MCT [58]. Compared to Vortex Blue, TRUShape removed a significantly greater amount of root filling material from oval-shaped root canals when the access cavity was "contracted" [57]. Compared to Reciproc, TRUShape performed at a slower rate, namely removed existing root filling material less efficiently, and did not remove a significantly greater percentage of root filling material from oval-shaped root canals [58]. Regardless of the file type used, none of the re-treatment protocols were able to completely eliminate all root filing materials from oval-shaped root canals [57, 58].

The TRUShape 3D Conforming File was developed, in part, to address a significant limitation of nickel-titanium rotary instruments—the inability to debride, even access fins and recesses, which results in a significant proportion of untreated or unprepared root canal surface following mechanical preparation. Specifically, TRUShape was designed to conform to irregular-shaped root canal cross sections, such as those that are non-round, oval-shaped. The quantity of research on TRUShape is limited in general, but especially with respect to its performance during mechanical preparation of oval-shaped root canals.

## Micro-computed Tomography (MCT)

<u>3D Imaging in Dentistry</u>

Integral to endodontic treatment is the practitioner's appreciation and understanding of the uniqueness and complexity of root canal systems. Historically, the anatomy and morphology of root canal systems *ex vivo* and *in vitro* have been investigated three-dimensionally (3D) using vulcanized rubber and wax models, dye, and root canal clearing, as well as two-dimensionally (2D) using conventional film-based and digital grayscale radiographic images [59-61]. Currently, three-dimensional investigations of root canal systems *ex vivo* and *in vitro* often employ non-destructive imaging techniques such as micro-computed tomography [59, 62].

Tomography refers to slice or cross-sectional imaging. Thin slices or cross sections of an anatomy of interest are captured and synthesized or reconstructed either manually or digitally by means of an algorithm. Computed tomography (CT) was introduced in the 1970s and used primarily in medicine, "medical-grade CT," for the evaluation of gross anatomical and neurologic structures. In clinical dentistry, prior to the advent of cone beam computed tomography (CBCT), use of medical-grade CT was limited due to cost, access, radiation dose, lack of high-resolution imaging, and lack of adequate dental-specific software.

At present, CBCT offers many advantages to dentists, especially to endodontists. Compared to medical-grade CT, CBCT is more affordable, exposes the patient to significantly less radiation, and offers relatively high-resolution 3D images. Compared to conventional radiography, CBCT produces lower resolution images, but provides information in three anatomic planes: axial, sagittal, and coronal. The separate or simultaneous evaluation of 3D images provides information not only about the tooth itself, namely its root canal system, but also about the spatial relationship between the tooth and external, adjacent or nearby structures such as alveolar bone, the maxillary sinus, the mandibular canal, or the mental foramen. Hence, CBCT is sometimes the imaging modality of choice in select endodontic cases, as it enables the 3D evaluation and understanding of the tooth and its surrounding structures [19].

CBCT assists practitioners both in diagnosis and case management, as well as enhances their understanding of root canal systems. While CBCT is advantageous in clinical endodontics three factors, at least, may somewhat limit or deter its use in experimental endodontics or endodontology: 1) its lack of high resolution imaging compared to conventional radiography; 2) its design, namely a physically large device designed to accommodate a patient's entire head in vivo; and 3) its radiation dose—too high to be used repetitively on the same patient.

<u>3D Imaging in Endodontic Research</u>

Micro-computed tomography (MCT) has emerged as "an exciting tool for experimental endodontology," as it affords a non-destructive, repeatable evaluation of a small object such as a tooth *ex vivo* or *in vitro*, and provides advantages over other 2D or 3D evaluation modalities [59]. Elliott and Dover described MCT as a non-destructive technique for the 3D evaluation of bone in 1984 [59, 63], and Dowker *et al*. and Nielsen *et al*. used MCT as a means to describe and mathematically investigate root canal systems, respectively [34, 37, 59].

MCT uses micro-focal spot x-ray sources and high-resolution detectors to enable projections rotated through multiple viewing directions [39]. Images of small objects such as a tooth are represented as "spatial distribution maps of linear attenuation coefficients," which are "determined by the energy of the x-ray source and the atomic composition" of the sample's material [39]. For comparison, 2D conventional and digital images "represent the summation of material attenuation along" the path of the x-ray beam [39].

MCT offers excellent image quality. Integral to image quality is spatial resolution, the ability to differentiate two objects in close proximity. Two factors affecting spatial resolution are scan time and voxel size [19, 64]. A voxel is the smallest distinguishable box-shaped or cuboidal part, element, or volume of a three-dimensional image, and is usually isotropic [19, 64]. Specifically, the magnitude of an isotropic voxel does not vary with varying directions of measurement. A fast scan time and large voxel size lower the spatial resolution [64]. Hence, lengthening the scan time and/or decreasing voxel size, with the latter being the most effective, improves the spatial resolution. The MCT voxel ranges from 5 to 50 µm (0.005-0.05 mm) [65], and is approximately one million times smaller than the conventional CT voxel. The virtually unparalleled image quality of MCT has rendered it invaluable for the non-invasive, 3D evaluation of root canal systems [39, 66, 67].

Evaluation of Mechanical Root Canal Preparation by MCT

MCT has become integral to the evaluation of mechanical root canal preparation in endodontic research. MCT imaging affords the non-destructive, 3D replication of the root canal system at different experimental stages, namely, pre-, intra-, and post-preparation, as well as computer-assisted analyses of qualitative and quantitative differences between those images. Data from a MCT scan can be represented as 2D or rendered 3D images. The parameters that have been quantified include changes in root canal cross-sectional area, surface area and volume, alterations in or deviations from the original root canal anatomy, such as root canal transportation, and the surfaces touched and untouched by instruments, a parameter known as “treated” or “prepared” root canal surface. Currently, these parameters are being used to evaluate the quality of mechanical preparation as a means of determining the efficacy of different instruments and techniques [6, 7, 11, 39, 68-70].

# CHAPTER 3

# MATERIALS AND METHODS

## Selection of Samples

Single-rooted, permanent human teeth initially identified as mandibular premolars were selected for potential use from a collection of recently extracted teeth at the University of Iowa, College of Dentistry. The teeth had been extracted for reasons unrelated to the present investigation, and stored in 0.1% thymol solution at 4°C. Premolars with significant caries, heavily restored clinical crowns, or the appearance of previous endodontic treatment were excluded. Selected premolars were further evaluated by visual inspection under a Zeiss OPMI Pico dental operating microscope (Carl Zeiss Meditec, Jena, Germany) at 4.2x magnification prior to and after staining of the external root surface with methylene blue dye. Prior to staining, premolars were discarded if they appeared to lack a mature root apex. The maturity of the root apex was further evaluated by micro-computed tomography (MCT), which will be discussed in the section “Pre-Instrumentation Scanning and Evaluation by Micro-computed Tomography.” After staining, premolars were rinsed, and their external root surface was visually inspected. Premolars were discarded if they exhibited evidence of cracks or fractures. Fifty premolars met these initial inclusion criteria, and were stored in 0.1% thymol solution at 4°C in preparation for radiographic evaluation.

Digital radiographs of each premolar were made from mesiodistal and buccolingual projections using a Dexis Platinum sensor (Dexis LLC, Hatfield, PA) tethered to MiPACS Dental Enterprise Viewer 3.1.1404 imaging software (Medicor Imaging, Charlotte, NC), and a Gendex dental X-ray generator. Both radiographs of each premolar were evaluated to confirm the presence of a single, relatively straight root canal that was oval-shaped in cross section. Specifically, the minimum root canal diameter was determined from the mesiodistal projection radiograph, and the maximum root canal diameter from the buccolingual projection radiograph using the MiPACS on-board measuring tool. The root canal was considered oval-shaped when the ratio of buccolingual to mesiodistal root canal diameters was at least 2:1 at a distance that was 5 mm coronal to the radiographic apex, as shown in Figure 5 [36]. Any premolar that did not meet these additional radiographic inclusion criteria was discarded.

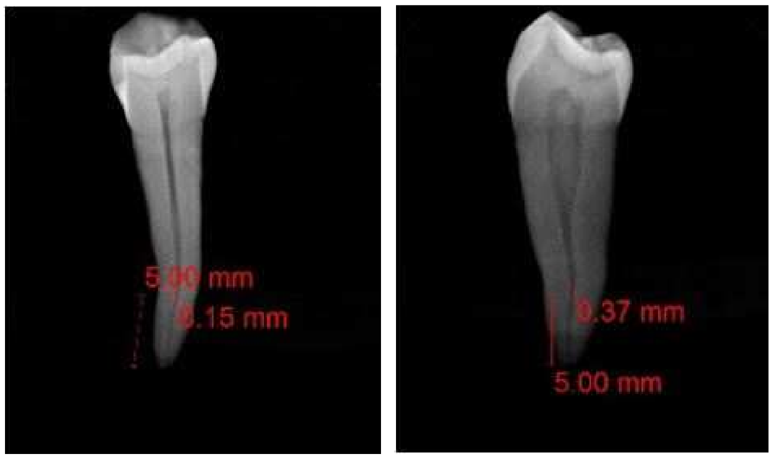


Figure 5. Mandibular premolar with an oval-shaped root canal.

Figure 5 Note: Two-dimensional digital radiographs of a mandibular premolar from buccolingual (left) and mesiodistal (right) projections. The root canal was considered “oval-shaped” because the maximum diameter of the root canal (buccal to lingual using image on right) was at least twice that of the minimum diameter (mesial to distal using image on left) at a distance 5 mm from the radiographic apex.

Thirty-nine of the 50 premolars that were initially selected from the collection of extracted teeth met these additional radiographic inclusion criteria. They were placed in numbered, small, plastic vials, which contained 0.1% thymol solution, and were stored at 4°C.

## Fabrication of Mounting Device

To facilitate precise repositioning of each sample tooth in the desktop MCT unit, a custom-made mounting device was fabricated for each sample tooth. Each tooth was rinsed under running tap water, and dried slightly with gauze. Polyvinylsiloxane (PVS) putty was measured and mixed according to the manufacturer’s instructions. The selected tooth was inverted and submerged into the PVS putty approximately to or slightly short of the level of the

CEJ.  A small, plastic cylinder that measured approximately 1.5 cm x 3 cm was obtained and inverted onto the PVS putty so the outermost aspects of the mold were adapted to the internal walls of the cylinder.  The putty was allowed to set for 5 minutes.  Then, the tooth was removed from its mounting device and returned to its appropriate vial, which contained 0.1% thymol solution.  Each mounting device was numbered to match the sample number, and an individual mounting device was fabricated for each sample.  Figure 6 depicts the custom-made mounting device.

Figure 6.  Custom-made mounting device.

**Pre-Instrumentation Scanning and Evaluation by Micro-computed Tomography**

Each sample was pre-operatively scanned in a desktop MCT unit (SkyScan 1272; Bruker microCT, Kontich, Belguim).  Sample teeth were sequentially selected, dried gently with gauze, and positioned in their respective custom-made mounting devices.  The mounting device was positioned in the MCT unit.  Scanning was performed at settings of 100 kV and 100 μA, with an isotropic voxel size of 20 μm, and by 180° rotation around the vertical axis with a rotational step of 0.4°.  Scanning time per tooth ranged from 1 hour 45 minutes to 2 hours 15 minutes.  Following scanning, each tooth was removed from its mounting device and returned to its appropriate storage vial, which contained 0.1% thymol solution.  Samples were stored at 4°C prior to mechanical preparation.

Initial root canal volumes were determined for each premolar based on their pre-operative MCT scans. Any premolar with an initial root canal volume exceeding 20 $mm^3$, which indicated an immature apical foramen or an abnormally large root canal, was discarded. This step identified and subsequently eliminated 8 premolars with either immature apical foramina not previously identified by either visual inspection or digital radiography, or abnormally large root canals, and yielded a more homogenous study sample.

Thirty-one premolars satisfied all visual, digital radiographic, and MCT inclusion criteria. One of the premolars, however, was excluded from the final analysis due to a procedural error, which will be discussed in greater detail in subsequent sections. Therefore, 31 relatively straight, single-rooted human mandibular premolar teeth with oval-shaped root canals were initially included, but the final analysis was based on a sample size of 30.

## Randomization of Samples

A random number table was generated and used to allocate teeth to each of the two experimental groups, Vortex Blue (Group A, N=15) or TRUShape (Group B, N=16) (both Dentsply Tulsa Dental Specialties, Tulsa, OK).

## Access and Working Length Determination

Conventional endodontic access cavities were prepared in all teeth in sequential order, using high-speed 557 burs (Brasseler USA, Savannah, GA) in a high-speed air-driven handpiece (KaVo North America, Charlotte, NC). Patency of the coronal root canal was confirmed by inserting a size 10 stainless steel K-File (Lexicon; Dentsply Maillefer, Tulsa, OK) into the coronal third of the root canal. Coronal flaring was achieved with a size 2 (#2) Gates Glidden (GG) drill, which was passively advanced to a maximum insertion depth of 2 mm apical to the cementoenamel junction (CEJ). A brushing motion was not used on the outstroke with the #2 GG drill in order to maximize conservation of dentin in the coronal third of the root canal—"pericervical dentin."

Apical patency was confirmed by inserting a size 10 K-file (Dentsply Maillefer) into the root canal until its tip was visible at the apical foramen. A stopper was advanced to a stable reference point (cusp or cavo-surface margin). The file was removed, and the length measured. The working length (WL) was set to 1.0 mm short of measured length. Finally, a reproducible glide path was created using PathFile instruments 13 and 16 (Dentsply Maillefer, Tulsa, OK) at WL. Sodium hypochlorite (3%, NaOCl) was introduced into the pulp chamber and canal space using a 6 mL syringe and a 30-gauge (G) side-vent irrigation needle (Vista Probe; Vista Dental Products, Racine, WI). The solution was mostly removed by needle aspiration. Sterile saline was introduced into the pulp chamber and canal space in an identical fashion using an identical 6 mL syringe and a 30G side-vented irrigation needle, and canals were left moist to prevent desiccation.

Prior to further mechanical preparation with either rotary file, teeth were returned to their containers. The WL of and reference point for each tooth were recorded.

### Root Canal Preparation with Vortex Blue (Group A)

Samples allocated to Group A were sequentially selected, removed from their storage vials, and gently dried with gauze. The root canal was instrumented in hand with Vortex Blue (Dentsply Tulsa Dental Specialties, Tulsa, OK) using a pre-programmed torque-controlled electric motor and manufacturer-recommended presets of 500 rpm and 3 Ncm torque. Instrumentation was performed by serial enlargement at WL beginning with size 20/.04 and followed by sizes 25/.04 and 30/.04 at WL. Each rotary file was introduced and advanced in the root canal by a pecking motion three times, if necessary, and then cleaned in an endodontic sponge. This process was repeated until each file reached WL. An intermediate MCT scan was made, as previously described ("Pre-Instrumentation Scanning and Evaluation by Micro-computed Tomography"), after instrumentation with size 30/.04. The root canal was further instrumented with size 35/.04 and to a final apical size 40/.04.  Following final enlargement, a post-instrumentation MCT scan was made, as previously described.

### Root Canal Preparation with TRUShape (Group B)

Samples allocated to Group B were sequentially selected, removed from their storage vials, and gently dried with gauze.  The root canal was instrumented in hand with TRUShape using a pre-programmed torque-controlled electric motor and manufacturer-recommended presets of 300 rpm and 3 Ncm torque.  Instrumentation was performed by serial enlargement at WL beginning with size 20/.06*v* and followed by sizes 25/.06*v* and 30/.06*v* at WL.  Group B instrumentation techniques were the same as those described for Group A.  An intermediate MCT scan was made, as previously described, after instrumentation with size 30/.06*v*.  The root canal was further instrumented to a final apical size 40/.06*v*.  Following final enlargement, a post-instrumentation MCT scan was made, as previously described.  TRUShape does not have size 35/.06*v*, or another intermediate file between sizes 30/.06*v* and 40/.06*v*.

### Irrigation Protocol

For all samples in Groups A and B, prior to instrumentation with rotary files, 3% sodium hypochlorite (NaOCl) was introduced into the pulp chamber and canal space using a 6 mL syringe and a 30G side-vented irrigation needle (Vista Probe; Vista Dental Products, Racine, WI).  During instrumentation, prior to advancing to the next file in sequence, root canals were passively irrigated with 1 mL 3% NaOCl using a 30G side-vented irrigation needle, which was inserted as deep into the root canals as possible without binding.  Following instrumentation, root canals were passively irrigated with 5 mL 17% EDTA for 1 minute and a final rinse of 5 mL 3% NaOCl for 1 minute in order to remove the smear layer.  Approximately 10 mL 17% EDTA and 12 mL 3% NaOCl were used in total per tooth.

Prior to both intermediate and post-operative MCT scans, the irrigation solution was removed from the root canals by needle aspiration. Sterile saline was placed in the root canals using an identical 6 mL syringe and a 30G side-vented irrigation needle. The root canals were left moist to facilitate scanning and prevent desiccation. Following post-operative MCT scans teeth were returned to their containers.

### The Primary Operator

A single operator performed all root canal preparation procedures under magnification (dental loupes with magnification power 4.5x). The operator was a first year endodontic resident at the University of Iowa, College of Dentistry, when the present investigation was initiated. In preparation for the present investigation, the operator completed a continuing education course in the use of TRUShape, which was and is available online, and can be accessed through the manufacturer's website. Completion of this online training course is mandatory prior to using TRUShape. The operator also reviewed manufacturers' directions and recommended techniques when using TRUShape and Vortex Blue.

To avoid bias, the operator was not permitted to visualize the virtual models of reconstructed teeth prior to or during the course of mechanical preparation. Therefore, the operator was unaware of potentially un-instrumented areas of the root canal and could not attempt to manually direct an instrument into said areas. Prior to and after use, instruments were visually inspected in order to identify signs of fatigue or fracture. Teeth were visually inspected in order to detect cracks or fractures that may interfere with subsequent instrumentation and/or MCT scanning. Total preparation time per tooth was approximately 10 minutes and included only active instrumentation.

**Evaluation of Mechanical Preparation by Micro-computed Tomography**

Approximately 600-800 2-dimensional (2D) cross-sectional images were captured per tooth, per MCT scan. The 2D cross sections were reconstructed to generate 3-dimensional (3D) virtual root canal models using a local gray level threshold and a so-called surface determination dialog in VGStudioMax 2.0 (VolumeGraphics, Heidelberg, Germany). To begin this process, an interim volume of interest was defined that corresponded to all locations where a root canal was evident in cross section. The use of pre-selected initial Volumes of Interest (VOI) allowed refinement of root canal surfaces in order to improve the subsequent 3D registration step. The quality of superimposition was calculated by the fraction of root surface area that was matching better than 1 voxel and was expressed as a percentage. If the value fell below 75%, registration was repeated until a satisfactory result was obtained.

Then, root canal models were colored according to instrumentation stage: green (pre-instrumentation), yellow (mid-instrumentation), and red (post-instrumentation). The resulting color-coded 3D root canal models facilitated the quantitative comparison of the matched root canals pre-, mid-, and post-instrumentation, as shown in Figure 7.

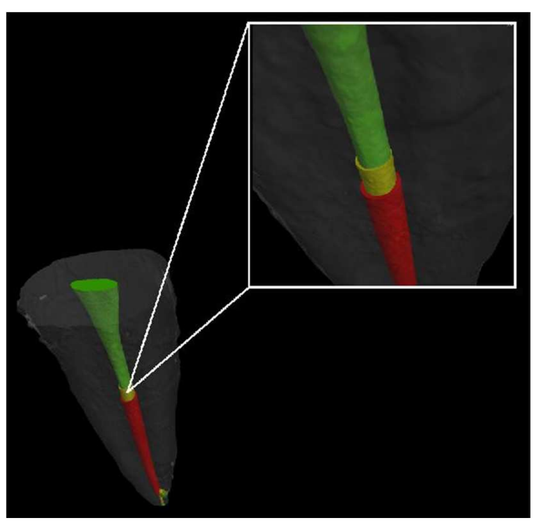

Figure 7. 3D root canal model color-coded according to instrumentation stage.

Additionally, 2D cross sections representing the apical, middle, and coronal root thirds were obtained from the registered, aligned 3D root canal models at the pre-, mid-, and post-instrumentation stages, as shown in Figure 8.

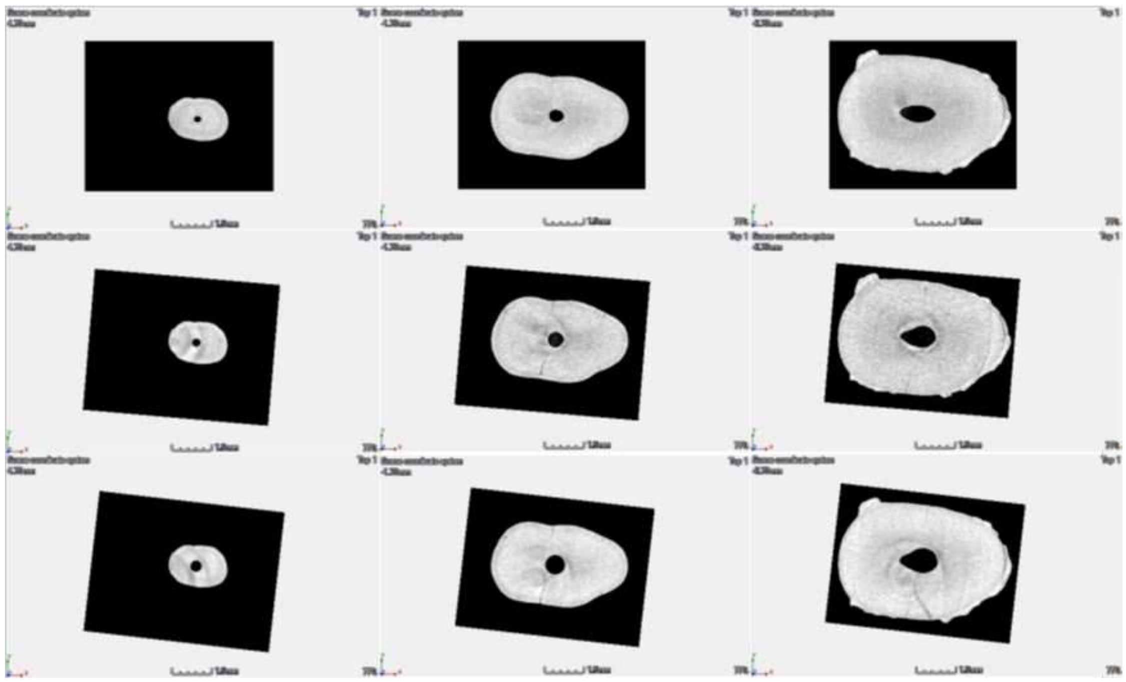

Figure 8. Complete set of 2D cross sections.

Figure 8 Note: Pre- (top row), mid- (middle row), and post-instrumentation (bottom row) cross sections from the apical (left column), middle (middle column), and coronal (right column) root thirds of a sample (Sample 26) from the TRUShape group (B). Subsequently, root canal cross sections were color-coded according to instrumentation stage and superimposed (see Figure 9).

## Qualitative Evaluation

Initially, the virtual root canal models were carefully inspected and scored for obvious errors that may have occurred during instrumentation, such as the presence of a retained instrument fragment, or strip or apical perforation. Virtual root canal models as well as 2D cross sections were also evaluated for the presence of cracks or fractures. Any and all findings were recorded. Presence of a crack did not necessarily require exclusion of the cross section in the final quantitative evaluations.

## Quantitative Evaluation of 2D Root Canal Cross Sections

Two-dimensional cross-sectional images, cross sections for short, of root canals at three different levels, namely at the apical, (“api”) middle (“mid”), and coronal (“cor”) levels, were obtained from aligned 3D root canal models, and were examined to determine cross-sectional area, roundness, and center of mass shift. Root canal levels for each sample were determined by dividing the total number of cross sections by 3. Each MCT scan produced a different number of cross sections because each sample varied slightly in length. Therefore, the process of determining root canal levels was performed once for each sample tooth.

The cross section that represented the apical, middle, and coronal levels of the root were the same pre-, mid-, and post-instrumentation. The cross sections at each of the three levels and at each of the three experimental stages were identified and saved as jpg files as follows: number of sample_level_stage.jpg. For example, “1_api_pre” was the file name of the cross section from sample 1 at the apical level of the root, pre-instrumentation. A complete sample contained 9 jpg files.

Working with one level at a time, the three cross sections, for example, “1_api_pre.jpg,” “1_api_mid.jpg,” and “1_api_post.jpg,” were imported into Adobe Photoshop to create three different layers. The post-instrumentation cross section was set as the “background layer,” and the mid- and pre-instrumentation cross sections, now layers, were superimposed onto the background layer. Four new, blank layers were then created. Working with one cross section at a time, which depicted the root and canal, the canal only was identified and selected using the Magic Wand tool, copied, and pasted onto one of the new, blank layers. The canal was colored according to its experimental stage: green for pre-instrumentation, yellow for mid-instrumentation, and red for post-instrumentation. This process was repeated for each experimental stage. The grid on the background layer was identified, selected, copied, and pasted onto the last of the new, blank layers. Figure 9 depicts a color-coded 3D root canal model (Sample 26 from Group B) and its superimposed cross sections.

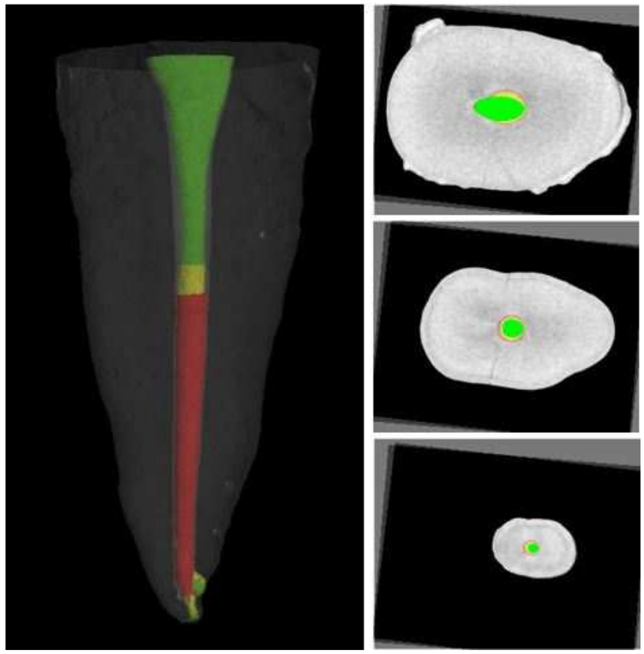

Figure 9. Color-coded 3D root canal model (left) and its superimposed cross sections (right).

Figure 9 Note: Pre-, mid-, and post-instrumentation cross sections from the apical (right, bottom), middle (right, middle), and coronal (right, top) root thirds were color-coded according to instrumentation stage and superimposed.

There were a total of 7 layers for each root level. These 7 layers were saved as a Photoshop file (psd) as follows: Sample #-level.psd. Then, each of the layers containing the color-coded canals and grid were saved as separate jpg files as follows: Sample #-level-stage-canal.jpg or Sample #-level-grid.jpg. This process was repeated for each of the three levels. Ultimately, a complete sample contained a total of 15 files: 12 jpg files and 3 psd files. All images obtained at this step for individual cross sections referenced the same coordinate system. Therefore, root canal transportation could be calculated using the Pythagorean Theorem.

Further, the cross-sectional area in $mm^2$, and a stereological parameter, “Roundness,” of each slice, were determined. “Roundness” was automatically calculated based on the formula $4(\text{Area})/(\pi(\text{Diameter of Major Axis})^2)$ [40]. Accordingly, a perfect circle has a roundness of 1, and the value approaches 0 for an infinitely long oval-shaped root canal.

### Quantitative Evaluation of 3D Root Canal Models

Matched 3D models of the root canals, prior to, during, and after mechanical preparation were examined to evaluate volume, surface area, and surface treatment. A root canal mask was then constructed using the 3D region grower in VGStudioMax 2.0, taking care to fully include each root canal after preparation to apical size 40 with no overlap between the mask and the determined root canal surface. This mask was copied onto the two other root canal volumes, at which stages the root canals were typically fully enclosed as well.

The data dialog in VGStudioMax 2.0 then provided the volumes and surface areas of the VOI at each stage. The next step was to compare root canal models at each instrumentation stage using a nominal-actual comparison dialog, which, in essence, is a ray tracing distance transformation. To evaluate root canal surface treatment or "prepared surface," there must be a change in surface voxels on MCT scans. A surface voxel is that belonging to any given structure when the full or complete voxel also belongs to the given structure [69]. For surfaces to be regarded as "treated" or "prepared," a minimum of one full voxel must be removed from the pre-instrumentation 3D root canal model following superimposition of pre-instrumentation and various post-instrumentation models. A removal of at least 20 μm of dentin was required based on the resolution of the root canal model and theoretical considerations [7]. In order to determine deeper dentin preparation, a second threshold of 100 μm was also used. Data were then expressed as percentage fulfilling each criterion and as color-coded dimension maps.

### Statistical Analysis

Data were reported as mean ± standard deviation (SD), rounded to the nearest 1/100 mm, either $mm^2$ or $mm^3$. Prepared root canal surface area was presented as percentages relative to pre-operative root canal surface areas. Canal transportation was reported in μm distance. Data distribution was checked for normality, and parametric and non-parametric tests were selected accordingly. Variables that changed along the three time points, such as root canal cross-sectional roundness or volume, were contrasted by repeated measures ANOVA, while non-normal distributed data for treated or prepared root canal surface area were compared with non-parametric Mann Whitney tests. Multivariate factorial analyses were performed with ANOVA or Kruskal Wallis tests. Calculations were performed with JMP 12 (SAS Institute, Cary, NC).

# CHAPTER 4

# RESULTS

## Qualitative Analyses

Virtual root canal models from pre-, mid-, and post-instrumentation MCT scans were carefully inspected and scored for obvious errors that may have occurred during instrumentation, such as the presence of a retained instrument fragment, or strip or apical perforation.

No retained instrument fragments were present in any of the MCT scans, consistent with no reported incidents of instrument fracture during mechanical preparation. An apical perforation was identified in one tooth from Group B, as shown in Figure 10. This sample was ultimately excluded from the final analysis, which was based on a total sample size of 30 premolars. None of the other virtual root canal models depicted any obvious errors that may have occurred during instrumentation.

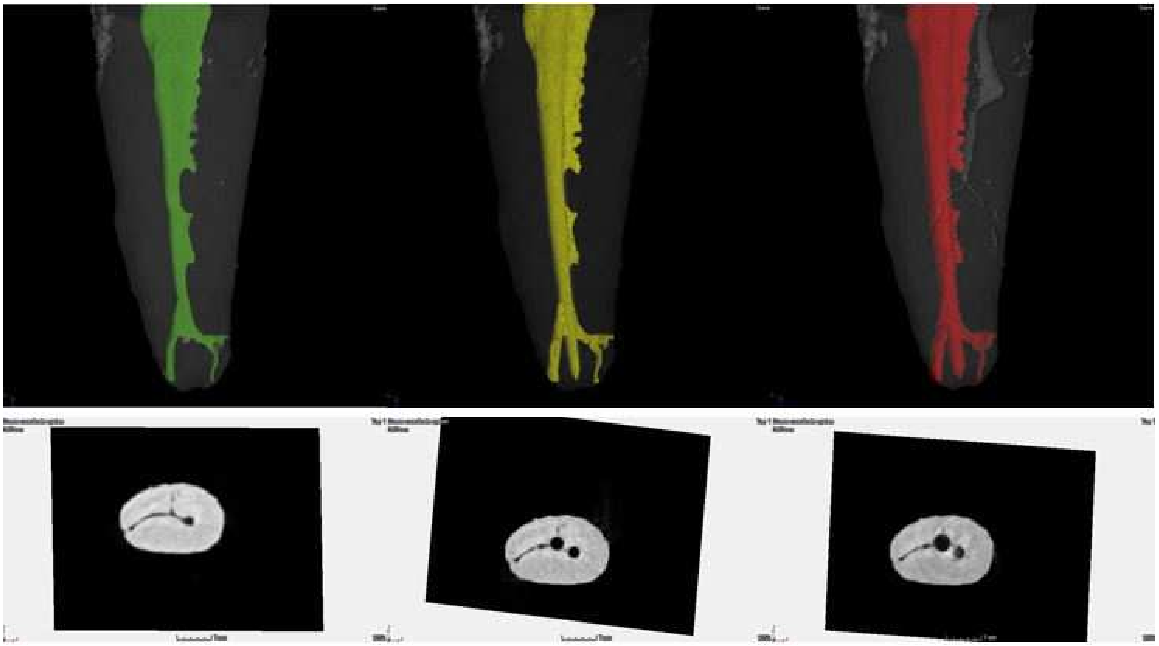

Figure 10. Apical perforation.

Figure 10 Note: The top panel depicts color-coded 3D root canal models, pre- (left), mid- (center), and post-instrumentation (right), of a sample from Group B (TRUShape) in which an apical perforation occurred during instrumentation. The bottom panel depicts 2D cross sections of the apical root third pre- (left), mid- (middle), and post-instrumentation (right). The apical perforation is evident on both mid- and post-instrumentation 2D cross sections and 3D root canal models. The apical perforation likely occurred due to an improper glide path.

Cross-sectional images of the apical, middle, and coronal root thirds, which were obtained from the 3D root canal models, were evaluated for cracks and/or fractures. Cracks were identified in the majority of samples from both experimental groups. Cracks were absent from all but one pre-instrumentation cross section (Sample 5, middle root third). In that sample, which was from Group B (TRUShape), a crack was also present on mid- and post-instrumentation cross sections at the same level (middle root third). In each cross section in which a crack was identified, the crack seemingly initiated from the external root surface. In all but one cross section from Group A (Vortex Blue; Sample 4, coronal root third, post-instrumentation cross section) in which a crack was identified, the crack did not communicate or only minimally communicated with the root canal, and therefore, the crack itself did not interfere with the ability to analyze the root canal cross section. Figure 11 depicts middle root third cross sections from

Sample 5. The crack in Sample 5 worsened, progressed toward the root canal over the course of mechanical preparation, but ultimately only minimally communicated with the root canal. All of the cross sections from Sample 5 were included in the final quantitative analyses.

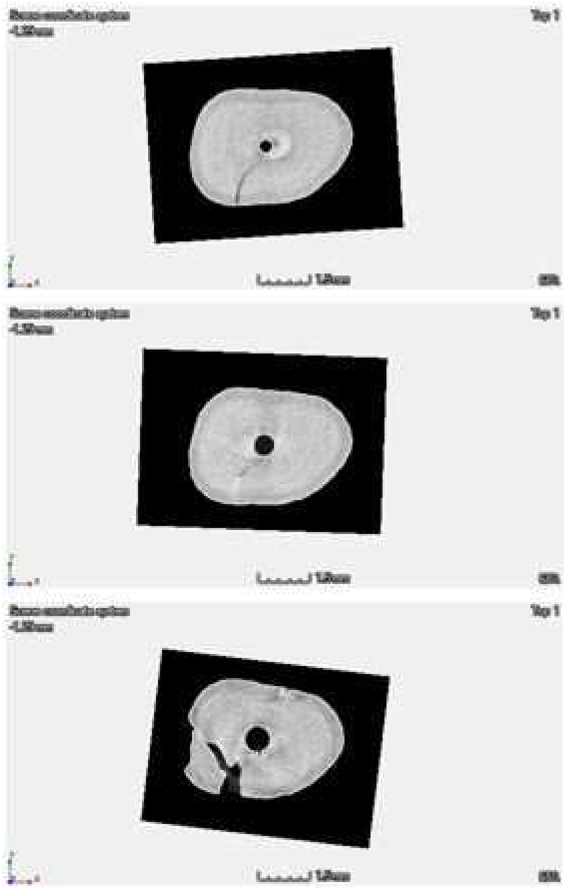

Figure 11. 2D cross sections from middle root third of Sample 5.

Figure 11 Note: Pre- (top), mid- (middle), and post-instrumentation (bottom) 2D cross sections from the middle root third obtained from a 3D root canal model. A crack extending from the external root surface toward the root canal is evident at each instrumentation stage.

### 2D Quantitative Analyses

Overall, cross-sectional root canal areas were largest in the coronal root third. Cross-sectional root canal area increased in the apical, middle, and coronal root third over the course of instrumentation in both experimental groups. This increase was significant at each root third in both experimental groups (repeated measure ANOVA, P<0.01), with no significant difference between experimental groups (P>0.05). The increase in cross-sectional root canal areas was linear in the two documented preparation steps in both experimental groups. Figure 12 summarizes all cross-sectional root canal areas in both experimental groups.

| | **TRUShape (n=15)** | | | **Vortex Blue (n=15)** | | |
|---|---|---|---|---|---|---|
| | **Initial** | **30/.06*v*** | **40/.06*v*** | **Initial** | **30/.04** | **40/.04** |
| **Coronal** | 1.44±1.34 | 1.65±1.28 | 1.79±1.27 | 1.31±.69 | 1.54±.65 | 1.65±.63 |
| **Middle** | .28±.13 | .39±.10 | .53±.10 | .39±.23 | .46±.21 | .53±.22 |
| **Apical** | .07±.03 | .11±.04 | .16±.07 | .08±0.32 | .10±.03 | .15±.03 |

Figure 12. Increasing cross-sectional root canal areas.

Two-dimensional root canal appearance was further quantified using the so-called "Roundness" parameter [40]. Overall, pre-instrumentation roundness was higher in the apical and middle root thirds than in the coronal root third (P<0.001, factorial ANOVA). Roundness in the apical root third increased similarly and significantly (P<0.05) from 0.65±0.19 to a final value of 0.87±0.18 and from 0.70±0.13 to a final value of 0.89±0.11 for root canals instrumented with TRUShape and Vortex Blue, respectively. Roundness in the middle and coronal root thirds also increased similarly and significantly (P<0.05). Comparing both experimental groups, differences in roundness were not significant and are summarized in Figure 13.

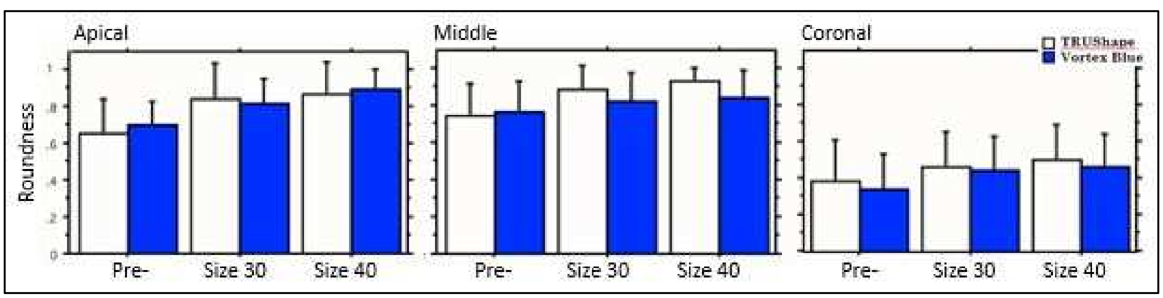


Figure 13. Increasing cross-sectional root canal roundness.

Figure 13 Note: Roundness values pre-, mid- (size 30), and post-instrumentation (size 40) in the apical (left), middle (middle), and coronal (right) root thirds in both experimental groups. Overall, roundness values increased similarly and significantly in each root third and in each experimental group, with no significant differences between experimental groups.

Root canal transportation was expressed as Center of Mass Shift (CMS), namely the displacement of the axis connecting centers of gravity, and distance was reported in µm. Overall, mean root canal transportation from pre- to post-instrumentation ranged from 51.7±30.0 µm to 57.1±44.0 µm to 60.0±35.3 µm at the apical, middle, and coronal root thirds, respectively. Figure 14 summarizes all root canal transportation scores in both experimental groups.

| | **TRUShape (n=15)** | | **Vortex Blue (n=15)** | |
|---|---|---|---|---|
| | **30/.06*v*** | **40/.06*v*** | **30/.04** | **40/.04** |
| **Coronal** | 53.46±23.97 | 48.86±27.28 | 57.93±48.75 | 70.28±39.49 |
| **Middle** | 51.75±41.94 | 70.23±53.80 | 30.68±28.56 | 44.05±34.17 |
| **Apical** | 36.35±21.57 | 52.07±33.53 | 32.24±22.42 | 51.30±26.90 |

Figure 14. Root Canal Transportation (in µm) expressed as Center of Mass Shift (CMS).

**3D Quantitative Analyses**

Overall, root canal volumes increased from 7.3±±3.5 $mm^3$ to 8.7±±3.1 $mm^3$ to 9.9±2.9 $mm^3$ pre-, mid-, and post-instrumentation, respectively ($P<0.001$, repeated measures ANOVA). Figure 15 shows increasing root canal volume in both experimental groups with no significant difference between groups ($P>0.05$).

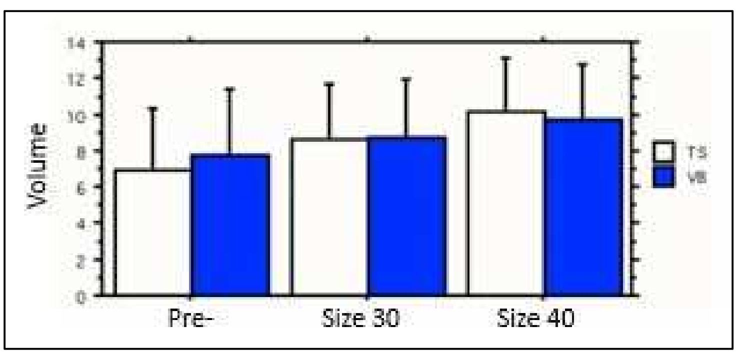


Figure 15. Increasing root canal volumes.

Overall, 3D root canal surface areas increased from 37.0±9.2 $mm^2$ to 40.6±8.2 $mm^2$ to 44.1±9.1 $mm^2$ pre-, mid-, and post-instrumentation, respectively ($P<0.001$, repeated measures ANOVA). Figure 16 shows increasing root canal surface areas in both experimental groups with no significant difference between groups ($P>0.05$).

| | **TRUShape (n=15)** | | | **Vortex Blue (n=15)** | | |
|---|---|---|---|---|---|---|
| | **Initial** | **30/.06*v*** | **40/.06*v*** | **Initial** | **30/.04** | **40/.04** |
| **3D SA** | 36.23±9.04 | 40.56±8.25 | 45.08±8.47 | 37.85±9.61 | 40.75±8.88 | 42.99±9.97 |

Figure 16. Increasing root canal surface areas.

Treated or prepared root canal surface areas increased between apical preparation to sizes 30 and 40 in both experimental groups. Prepared root canal surface area was higher when the threshold for dentin preparation was set at 20 µm compared to 100 µm in both experimental groups. Figure 17 shows percentage of prepared root canal surface area for both experimental groups.

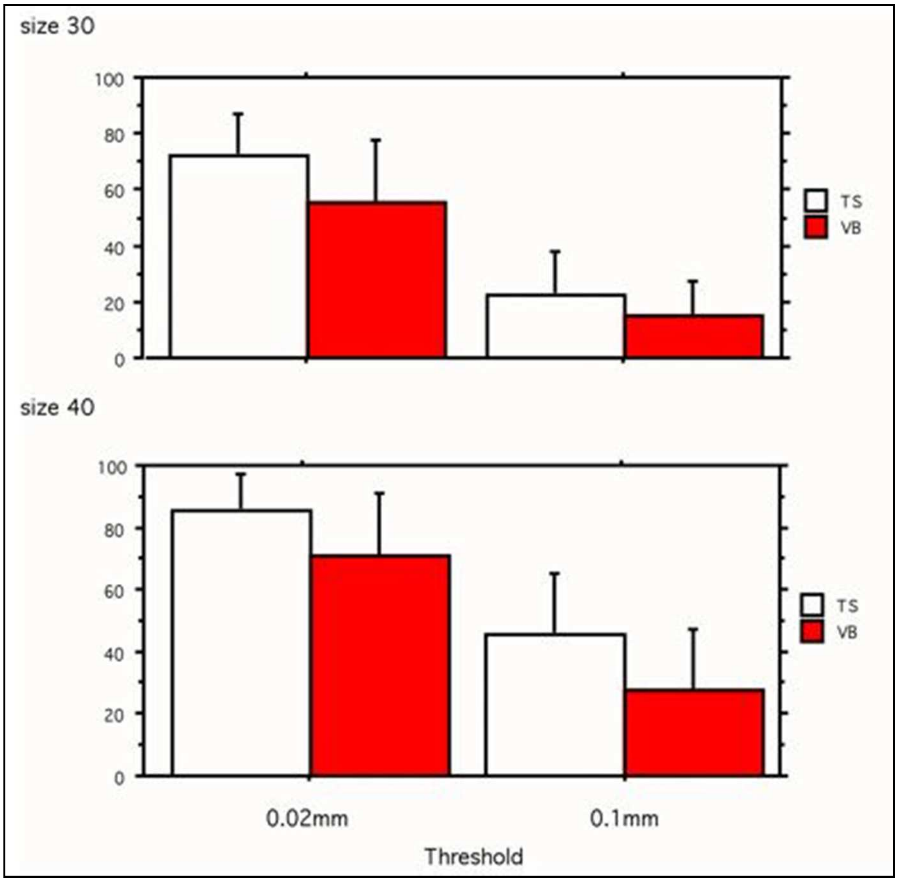


Figure 17. Prepared root canal surface areas at 20 µm (0.02 mm) and 100 µm (0.1 mm).

There was a significant difference in prepared root canal surface area in favor of TRUShape at both apical sizes and at both thresholds 20 µm and 100 µm. Specifically, at 20 µm, prepared root canal surface area increased from 72.1±14.8% to 85.5±11.6% in root canals prepared with sizes 30/.06*v* and 40/.06*v* TRUShape, respectively, compared to 55.3±22.6% to 70.9±20.1% in root canals prepared with sizes 30/.04 and 40/.04 Vortex Blue, respectively. At 100 µm, prepared root canal surface area increased from 22.5±15.3% to 45.5±21.6% in root canals prepared with sizes 30/.06*v* and 40/.06*v* TRUShape, respectively, compared to 14.8±12.6% to 27.4±20.0% in root canals prepared with sizes 30/.04 and 40/.04 Vortex Blue, respectively.

## CHAPTER 5

## DISCUSSION

Endodontic treatment aims to prevent or eliminate apical periodontitis and thereby affords the possibility of retention of a diseased natural tooth [12, 26]. It is well established that the presence of microorganisms in contact with immunocompetent apical and periradicular tissues drives the cascade of immune responses that manifest in apical periodontitis [1, 12, 14-16, 18, 21].

Typically, NSRCT of relatively straight root canals with round cross sections is predictable and successful [1, 23]. However, irregular-shaped root canals such as non-round, oval-shaped root canals pose challenges, especially during mechanical preparation, due to their anatomic and morphologic irregularities—fins, recesses, and isthmuses. Despite the evolution of and advancements in nickel-titanium rotary instruments, they fail to prepare a significant proportion of root canal surfaces. Unprepared root canal surfaces have been equated with debridement. They may harbor bacterial biofilms and other sources of inflammation, and could contribute to persistent or recurrent apical periodontitis. Hence, it is essential to maximize root canal surface treatment during mechanical preparation. A novel, nickel-titanium rotary instrument system, the TRUShape 3D Conforming File, was designed to enhance root canal surface treatment, especially in root canals exhibiting anatomic and morphologic irregularities, such as non-round, oval-shaped root canals.

Currently, there is limited research on TRUShape, especially regarding quality of mechanical preparation of the type of root canal, namely non-round and oval-shaped, for which their use is advocated. Therefore, the purpose of the present *in vitro* investigation was to evaluate the mechanical preparation of non-round, oval-shaped root canals with TRUShape compared to an established nickel-titanium rotary file system with similar heat treatment, Vortex Blue, using MCT. In the present investigation, there was a significant difference in root canal surface treatment following mechanical preparation with TRUShape and Vortex Blue. TRUShape significantly enhanced root canal surface treatment of oval-shaped root canals, which led to rejection of the null hypothesis.

A single operator performed all tooth selection, randomization, and preparation procedures. The operator selected single-rooted human mandibular premolars with oval-shaped root canal cross sections based on 2D digital radiographs. The allocation of premolars to either experimental group was strictly random. Ultimately, the present investigation had a sample size of 15 teeth per group, as one sample was eliminated from final statistical analyses due to a procedural error during mechanical preparation. Specifically, an apical perforation was identified in one sample, and likely resulted from an improper glide path during initial negotiation of the root canal (Figure 10). Though limited, the sample size was similar to those of other MCT investigations [2, 11, 69, 71], and allowed more than adequate statistical power. To avoid bias, the operator was not permitted to visualize the 2D cross-sectional images or 3D root canal models prior to or during the course of mechanical preparation.

To standardize the mechanical preparation protocol for both instruments, a size 2 (#2) Gates Glidden (GG) drill was used to complete coronal flaring in all premolars rather than the manufacturer-recommended TRUShape Orifice Modifier. The #2 GG drill, whose diameter is smaller than that of the TRUShape Orifice Modifier, was used conservatively. Paque *et al.*—who evaluated the mechanical preparation of long oval-shaped root canals with the Self-adjusting File (SAF)—also used the #2 GG drill conservatively in order to preserve root canal wall dentin and minimally alter coronal root canal cross sections [71]. To further standardize the mechanical preparation protocol for both instruments, shaping was completed by serial enlargement at working length in all samples. In the initial investigation on TRUShape by Peters *et al.*, shaping was completed by a crown-down approach, as advised by the manufacturer [10, 11]. While it is unlikely that use of the #2 GG drill or shaping by serial enlargement significantly affected the results of the present investigation, both are noteworthy because both are deviations, one could argue, from the manufacturer's recommended techniques [10]. Further, the presence of cracks, the majority of which were only evident on post-instrumentation MCT scans, suggested desiccation rather than root canal preparation may have been a cause of or contributed to crack formation. Another possible cause could be related to the scanning protocol. While of interest, a detailed evaluation of crack formation was beyond the scope of the present investigation but could be a topic for future investigations on TRUShape.

MCT has become a desirable tool for the evaluation of mechanical preparation of *ex vivo* samples. It affords a 3D evaluation of the effects of mechanical preparation on root canal anatomy without either altering or destroying the root canal. In the present investigation, 2D and 3D data sets were used to evaluate and compare horizontal and vertical dimensions of root canals at three different instrumentation stages. Further, MCT affords calculation of the root canal surface that is treated or prepared during mechanical preparation [71]. As one objective in the mechanical preparation of infected root canals is to remove the inner layer of infected root dentin [42, 72], the ability to non-destructively assess and precisely quantify the amount of treated or prepared root canal surface is invaluable when assessing mechanical preparation and the efficacy of a given shaping instrument. Alternatively, this parameter has been reported as the untreated or unprepared root canal surface [6, 7, 71].

A canal "conforming file," such as the previously described SAF or TRUShape, is designed to promote circumferential root canal surface treatment or removal of the inner layer of dentin in round and non-round root canals alike [71]. Previously, destructive 2D techniques were used to determine the amount of untreated root canal surface. Weiger *et al*., for example, showed that 44-68% of the root canal surface in long oval-shaped root canals remained untreated following mechanical preparation [73]. In a seminal investigation, Peters *et al.* non-destructively evaluated the effects of four different nickel-titanium rotary instrument preparation techniques in maxillary molars using MCT [6]. Following mechanical preparation, all root canals were rounder, had greater diameters, and were straighter. Further, approximately 35-40% of root canal wall surfaces remained unchanged, regardless of the instrument used. Later, Paque *et al.* used

MCT to assess the removal of the inner layer of dentin in long oval-shaped root canals in distal roots of mandibular molars following mechanical preparation with the SAF [71]. They quantified the amount of treated root canal surface at two different thresholds, namely 20 and 34 μm. On average, a minimum removal of 20 μm or 34 μm of dentin was required in order for the root canal surface to register as "treated" or "prepared" at the 20 μm or 34 μm threshold, respectively. When the threshold was limited to 20 μm there was more treated root canal surface than when the threshold was increased to 34 μm. At both thresholds, the amount of treated root canal surface was significantly higher following mechanical preparation with the SAF (76.5±8.9% and 62.6±11.9% at 20 and 34 μm, respectively) compared to ProTaper instruments (56.0±15.3%). In other words, mechanical preparation with the SAF significantly increased the proportion of treated root canal surface compared to ProTaper instruments.

The present investigation also evaluated root canal surface treatment after mechanical preparation to two different apical sizes, and at two different thresholds, namely 20 and 100 μm, the former being the resolution of the 3D root canal model and the latter in order to evaluate deeper dentin penetration. At both apical sizes and thresholds, surface treatment was significantly higher following mechanical preparation with TRUShape compared to Vortex Blue. These results not only reject the null hypothesis but also are in apparent contradiction to those from Peters *et al.,* in which the use of TRUShape in small, curved mesial root canals of mandibular molars did not enhance surface treatment [11]. In contrast to the present investigation, Peters *et al.* compared TRUShape to .06 taper Vortex using a crown-down technique, and made MCT scans after shaping to apical sizes 20 and 30. They evaluated the apical 4 mm of root canals as well as the entire length of root canals up to the level of the CEJ. Mechanical preparation to apical size 20 with both instruments, they found, was insufficient to obtain a high proportion of treated root canal surface. However, mechanical preparation to apical size 30 with both instruments resulted in more than 80% surface treatment [11].

While Peters *et al.* did not observe a significant difference in surface treatment, they observed significant differences in the quantity of dentin removed from the root canal walls. TRUShape removed significantly less dentin toward the furcation, and therefore promoted dentin conservation, in particular pericervical dentin conservation [11]. In the present investigation, overall, root canal volumes and surface areas increased during instrumentation. The changes in volumes and surface areas were similar and significant for each experimental group with no significant differences between experimental groups. Given that TRUShape was designed to be canal conforming and to preserve dentin, this finding was unexpected and may be related, in part, to the use of the Gates Glidden drill. Efforts were made to conserve coronal root canal wall dentin during coronal flaring, but it is possible that the use of the #2 Gates Glidden drill altered the coronal-most region of the root canals in both experimental groups and affected the results. Future research on TRUShape should evaluate changes in volume and surface area in the apical, middle, and coronal root thirds in addition to overall changes over the course of mechanical preparation.

An important difference between the present investigation and that by Peters *et al.* is the former investigated non-round, oval-shaped root canals, and the latter investigated small, curved root canals. Small, curved mesial root canals of mandibular molars are inherently more round and less non-round or oval-shaped. TRUShape was designed to enhance mechanical preparation of root canals that exhibit irregular anatomy in particular, such as non-round, oval-shaped root canals. Observed differences in the quality of mechanical preparation with TRUShape may be related, at least in part, to the initial root canal configurations [68].

A parameter that was not evaluated in previous investigations on TRUShape is "Roundness." The present investigation used the mathematically-derived parameter "Roundness" to evaluate the ability of TRUShape to conform to and maintain the original anatomy of the root canal [40]. Ideally, an oval-shaped root canal would remain oval-shaped following mechanical preparation with a conforming file. TRUShape, then, should not lead to more rounding compared to other non-conforming files, especially of oval-shaped root canals, if the files are, in fact, conforming to and maintaining the original anatomy of the root canal.

Pre-, mid-, and post-instrumentation, the apical and middle root thirds were more round than the coronal root thirds in both experimental groups. Overall, roundness in each root third increased during mechanical preparation, and the increase was significant in the apical root third. In other words, root canals initially described using 2D digital radiography as non-round and oval-shaped became more round and less oval-shaped, especially in the apical root third, during mechanical preparation with both TRUShape and Vortex Blue.

However, an increase in roundness per se, while not necessarily desirable, may not be deleterious. In fact, it may be somewhat beneficial from the perspective of fracture resistance. Root canal treated teeth are not more brittle [74], but they may be more prone to fracture [75, 76]. According to a recently published, longitudinal investigation on survival following endodontic treatment, root fracture is a frequently cited reason for extraction [77]. Factors that may contribute to tooth and/or root fracture in root canal treated teeth include but are not limited to the amount of remaining coronal tooth structure, the access cavity, preparation of the root canal, the resultant thickness of the root canal wall, and the definitive restoration [74, 75]. Further, the influence of these factors may be dependent on tooth type per se, and both external root and internal root canal configurations. For example, the force required to fracture premolars that had undergone mechanical preparation was 30% lower than that for unprepared premolars, whereas a comparable force was required to fracture prepared and unprepared canines alike [75]. Mechanical preparation alters the thickness of the root canal wall as well as its cross-sectional shape, both of which may influence fracture resistance. Mechanical preparation with nickel-titanium rotary files is more likely to incorporate root canal irregularities into the final shape and to produce final shapes that are “rounder and smoother” than is mechanical preparation with hand files, which is more likely to produce final shapes that are “quite irregular” [76]. Given that root canal irregularities reduce fracture resistance, Sathorn *et al.* hypothesized that mechanical preparation with nickel-titanium rotary files would produce root canals with higher fracture resistance or strength [76]. While mechanical preparation with nickel-titanium rotary files did not yield root canals with higher fracture resistance, the pattern of root fracture was found to be less predictable when the root canal shape was round and lacked "highly localized tensile stress" areas, such as those present on buccal and lingual extensions of non-round, oval-shaped root canals, for example [76]. Ultimately, Sathorn *et al.* concluded that a goal during mechanical preparation should be to create a root canal that is round in cross section, is smooth, and lacks irregularities, as these characteristics may reduce root fracture susceptibility [76]. While fracture resistance was not evaluated in the present investigation, the observed increase in roundness in the apical, middle, and coronal root thirds could improve fracture resistance, as more root canal rounding may imply fewer irregularities and fewer localized tensile stress areas [76]. A topic for future investigations on TRUShape could be root fracture resistance following mechanical preparation.

One of the five design objectives of mechanical preparation is to maintain the original root canal anatomy [33]. Procedural errors such as canal transportation, which alter and can even destroy the original root canal anatomy, affect prognosis not only of primary NSRCT but also of non-surgical and surgical re-treatment procedures. Prognosis of non-surgical re-treatment, for example, may be as high as 87% or as low as 47% in the absence or presence of procedural errors, respectively [56]. Practitioners should not necessarily plan for failure but should be aware that procedural errors could affect endodontic treatment prognosis. Understanding instruments' properties, in part, may decrease the risk of procedural errors.

In the present investigation, root canal transportation was evaluated using 2D data sets and expressed as Center of Mass Shift (CMS). It has been suggested that a displacement of up to about 150 μm from the center of gravity can be regarded as acceptable [11, 38]. Peters *et al.* reported overall root canal transportation was greatest in the coronal root third of small, curved root canals at both apical sizes and in both experimental groups [11]. Further, mechanical preparation with TRUShape resulted in significantly lower root canal transportation scores at the apical, middle, and coronal root thirds at apical size 30, and at the middle and coronal root thirds at apical size 20 compared to Vortex. Overall, minimal root canal transportation was observed in the present investigation. However, root canal transportation is less likely to occur in relatively straight root canals compared to small, curved root canals.

It remains unknown whether mechanical preparation with TRUShape will lead to improved clinical success outcomes, namely the prevention or elimination of apical periodontitis. In addition to success, survival is also a reported clinical outcome. Current findings based on large patient cohorts suggested that more teeth were extracted following root canal treatment because of restorative factors than endodontic factors, namely persistent or recurrent apical periodontitis [11, 77]. A challenge, arguably, for current and future root canal preparation techniques is to enhance root canal debridement and simultaneously preserve coronal and radicular dentin in order to maximize the amount of restorable tooth [11].

Within the limitations of the present *in vitro* investigation, the following conclusions may be reached. MCT is an invaluable research tool for a non-destructive evaluation of shaping procedures in endodontics. Both instruments tested, TRUShape and Vortex Blue, are suitable for mechanical preparation of non-round, oval-shaped root canals present in mandibular premolars. TRUShape significantly enhanced root canal surface treatment with minimal root canal transportation. Additional research beyond this initial assessment of the quality of mechanical preparation of non-round, oval-shaped root canals with TRUShape is warranted, as advantages and disadvantages of TRUShape for mechanical preparation of non-round root canals have yet to be definitively established. Further, a correlation between the proportion of root canal surface treatment and the prevention or elimination of apical periodontitis has yet to be established.

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