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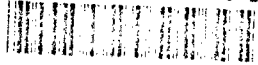


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THE EFFECTS OF NITI HAND AND ROTARY CANAL MASTER "U" AND K-FLEX
INSTRUMENTATION ON ROOT CANAL MORPHOLOGY

by

Robert H. Haller
Doctor of Dental Surgery 1983
University of Maryland School of Dentistry

A research proposal submitted to the faculty of the
Endodontic Department of the UTHSCSA Dental School in partial
fulfillment of the requirements for a

CERTIFICATE IN ENDODONTICS

University of Texas Health Science Center at San Antonio

September 30, 1992

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SECTION ONE: INTRODUCTION

A. SIGNIFICANCE OF THE PROBLEM

Cleaning and shaping of the root canal system is the most important aspect of successful endodontic therapy. The goal of endodontic cleaning procedures is to eliminate all pulp tissue, microorganisms, and irritating debris. Inadequate cleaning allows bacterial toxins and tissue-breakdown products to remain, risking short-term treatment failure as well as persistent periradicular inflammation and infection.

The goal of shaping procedures is to create a continuously tapering conical form to facilitate total obliteration of the canal space with a dense, stable, nonirritating, sealing material. Insufficient shaping will result in less effective condensation of the material and poor sealing of all pathways of the root canal system. The incomplete three-dimensional filling of the root canal space allows microleakage of tissue exudate and reinfection by microorganisms, which creates an unfavorable biologic environment for tissue healing to take place. Therefore, complete cleaning and shaping of the root canal system with three dimensional obturation is essential for successful therapy.

Endodontic files are the conventional instruments of choice for cleaning and shaping. Many studies on the cleaning efficacy of these endodontic instruments indicate that significant amounts of pulp tissue and debris often remain after canal preparation. No conventional

instrument or technique will predictably provide complete debridement of the root canal system.

When preparing the ideal shape for complete canal obturation, conventional instruments tend to straighten the real curvature of the canal. Because of the elastic memory of these instruments, they cut counter to the curve of the canal so the true foramen becomes transported from its original position in the root surface. This canal transportation can lead to apical ledging, blockage, and perforations, which are difficult to seal with conventional filling material. The inability to predictably clean and shape the root canal system undoubtedly increases the likelihood of endodontic failure.

B. STATEMENT OF THE PROBLEM

Conventional endodontic instruments have remained basically unchanged since the introduction of the K-type file in 1915. Different instrumentation techniques have been devised in order to minimize the difficulties encountered during canal preparation with this standard instrument. In 1989, Wildey and Senia developed a unique instrument called the Canal Master, which varied considerably from conventional design. This instrument incorporated a noncutting pilot, a limited cutting segment (2.5 to 4.0 mm), and a smooth round flexible shaft which reportedly allowed it to follow the true curvature of the root canal system, thereby reducing canal transportation, ledging, and perforations.

Early studies showed that this new instrument design tended to produce rounder preparations with less transportation than conventional

endodontic instruments, thus reducing the possibility of iatrogenic effects in curved canals. These studies primarily focused on the shaping abilities of the Canal Master and did not investigate its safety and cleaning efficacy.

The acceptance of this instrument was compromised by clinical reports of instrument separation in the apical third of the canal, which were often impossible to bypass or remove. The apical blockage compromised complete cleaning and shaping of the canal. Incorrect instrument design, variability in the stainless steel material, or inadequate quality control during the manufacturing process could have contributed to this undesirable characteristic.

In response to this problem, the manufacturer modified the instrument and introduced it as the Canal Master "U". This altered the flute design and method of use, which improved the instruments performance in both laboratory and clinical trials. Most recently the Canal Master "U" was manufactured using nickel-titanium wire instead of traditional stainless steel. Early investigations of nickel-titanium (NiTi) files indicated that they possess greater flexibility as well as superior resistance to torsional fracture than stainless steel files. Increased flexibility and torsion resistance potentially provides the new NiTi Canal Master "U" with improved physical characteristics. The release of a completely rotary version of this instrument could significantly reduce operator fatigue and increase the speed of canal preparation. The efficacy of cleaning and shaping as well as the safety of the NiTi Canal Master "U" instrument must be investigated before it

can be considered an ideal replacement for conventional endodontic instruments.

The goal of this study is to critically assess the shaping abilities of a promising improvement in the Canal Master "U" instrument system. Both the NiTi Canal Master "U" hand and rotary instruments will be compared to the commonly used K-Flex file. The roundness of the canal, direction and extent of transportation, amount of dentin removed and the ability of each instruments to remain centered in the canal will be evaluated.

C. NULL HYPOTHESIS:

No significant differences exist between K-Flex files, NiTi Canal Master "U" hand instruments, or NiTi Canal Master "U" rotary instruments in the preparation of curved lower molar mesial root canals. The instrumented canals will be evaluated by comparing the roundness of each canal, the direction and extent of transportation, amount of dentin removed, and the ability of each instrument to remain centered in the canal.

D. ASSUMPTIONS:

1. The experimental model used in this study is a valid representation of clinical root canal cleaning and shaping.
2. Any significant differences in quantitative analysis of canal morphology are due only to the different instrumentation employed.
3. The sample of mandibular molars used will be sufficient to allow for meaningful data interpretation.

4. Individual differences in root canal morphology will not affect the data due to their random distribution.

5. A new technique of image acquisition and data analysis of root sections will improve the accuracy and sensitivity of sample measurements. Computerized longitudinal digital subtraction radiology developed at UTHSC will be applied to the analysis of Bramante (21) sections in this study using the image acquisition module and the image analysis workstation.

5. A clinically relevant addition to the understanding of root canal instrumentation will occur if results indicate that the NiTi Canal Master "U" hand and/or rotary provide better control and speed in cleaning and shaping procedures than a standard method.

B. LIMITATIONS

1. This study only analyzes one apical and one mid-root section of the root canal system before and after instrumentation. Although these two sections will provide information for quantitative analysis of each instruments performance, the application of these results to the entire root canal is interpretive.

2. Any variation in instrumentation technique will change the final root canal shape.

3. The time required to complete assembly of the experimental model and instrument manipulation adds another dimension of variability even with a single operator.

SECTION TWO: REVIEW OF THE LITERATURE

Since cleaning and shaping of the root canal system is the most important aspect of successful endodontic therapy (1), it seems logical to investigate how the development of endodontic instruments led to a recent modification that may improve the effectiveness of root canal preparation. In the review of literature that follows a brief discussion of the historic development of standard root canal instruments, recognition of instrumentation deficiencies, and a recent unique instrument design modification, the Canal Master, is presented.

A. ROOT CANAL INSTRUMENT DEVELOPMENT

In 1728, Pierre Fauchard, the "founder of modern dentistry," wrote *The Surgeon Dentist* (2). It provided accurate descriptions of pulp cavities and root canals. Fauchard also described the practice of opening teeth to relieve abscesses and the extirpation of pulp tissue utilizing a small pin.

Frederick Hirsch, a noted German practitioner of the late 18th century, repeatedly inserted a red-hot probe in the root canal prior to obturation (2). An Englishman, Robert Woofendale, described a method of alleviating pain by cauterizing the pulp with a hot instrument. In addition to hot instruments, many dental practitioners used boiling oil, herbs, opium, and arsenic to desiccate the pulp even as late as the early 20th century.

In 1838, Edward Maynard invented the barbed broach from the untempered steel of watch springs filed down to the fineness of horse

hair and barbed on one side (3). To facilitate pulp removal he made reamers from piano wire and filed them to the desired shape.

Baker is credited with the first published account of pulpal extirpation, canal cleaning, and root canal filling (2). In 1839, he wrote in the *American Journal of Dental Science* that his treatment of an exposed pulp was to completely clean the canal and then fill it with gold foil.

By the late 19th century, broaches, probes, and Gates-glidden reamers were used to remove the pulp. In 1915, the patent for the K-type file was applied for by the Kerr Manufacturing Company (4). The basic design of this endodontic instrument has changed very little over the years. The K-type file is still the most widely used endodontic instrument for cleaning and shaping of the root canal system.

The first half of the 20th century provided few changes in the quality of endodontic instruments. In 1961, commercial manufacturers began to standardize endodontic instruments (5). The first approved specification for root canal instruments was published in 1976 by the ADA Council on Dental Materials and Devices (6). After the introduction of standardized instruments, improvements were largely limited to the replacement of carbon steel with stainless steel, color coding of handles, wider selection of sizes, and sharper more aggressive cutting angles (7).

B. DEFICIENCIES IN INSTRUMENTATION

The primary objective of the instrumentation phase of root canal therapy remained is to remove all pulpal tissue and debris, destroy all

microorganisms, and prepare the canal for the desired filling material (3). The development of a smooth, continuously tapering, conical canal preparation of circular cross-sectional shape has been advocated by most practitioners. Development of this shape, without foramen or canal transportation, facilitates complete three-dimensional obturation of the root canal system (3).

Many recent studies have demonstrated that standard root canal instruments leave pulp tissue and debris as well as surface irregularities within the canal space. Scanning electron microscope studies revealed that significant amounts of pulp tissue and debris remained after canal preparation (8,9). Instrumentation studies illustrated that regardless of the type of enlarging instrument or the technique used, undesirable characteristics including apical transportation, ledging, blockage, and perforations were frequently created during preparation (4). Weine et al. (10) determined that excessive removal of material from the outer portion of the curve near the apex created an hourglass shape rather than the ideal continuously tapered cone preparation (10). If the instruments were overextended, a teardrop appearance developed at the foramen. Clinically, this canal transportation and undesirable apical shape often led to serious complications which compromised the endodontic treatment.

Many instrumentation techniques were devised in an attempt to minimize the difficulties encountered during canal preparation. Alteration of the K-file's flutes and use of a rasping motion was advocated by Weine (10). Abou-Rass et al. (11) introduced anticurvature filing which instrumented into the bulky portions of the root and away

from thinner zones to avoid canal wall stripping or perforation. Foran and Montgomery (12) reported on the crown-down pressureless technique in order to minimize instrumentation complications. In 1984, Roark et al. (13) proposed the "balanced force" concept for instrumentation of curved canals. None of these techniques completely eliminated the deficiencies and iatrogenic effects of conventional endodontic instruments.

C. INSTRUMENT MODIFICATION

Understanding the limitations of existing instruments, Wildey and Senia (4) developed and introduced a uniquely designed endodontic instrument called the Canal Master. The new instrument incorporated three main features (14): (i) It replaced the usual cutting tip with a noncutting pilot that reportedly helped to limit transportation of the canal and guide the instrument down the canal to the foramen. (ii) The cutting segment of the instrument was reduced from the standard 16 mm to between 1.0 and 2.0 mm, which provided minimum cutting surface for maximum control. (iii) To increase the flexibility of the instrument, the diameter of the instrument's smooth, parallel shaft was reduced. The combination of these features was designed to provide an instrument that would follow the original curvature of the root canal system more closely and greatly reduce canal transportation, ledging, blockage, and apical perforation.

A comparison study of the Canal Master instrument and K-type files for the enlargement of curved root canals concluded that the Canal Master transported the canal less frequently and produced rounder preparations than the K-file (15). Lesberg and Montgomery (16)

compared the Canal Master instrument to Flex-R files and K-flex files. Canal Master and Flex-R files both produced rounder preparations than the K-flex files. The Canal Master transported significantly less in the mid-root area, removed less dentin, and remained centered better than the other two techniques. The new instrument did not produce the irregularities in canal shape commonly encountered with conventional instruments.

Even in the absence of iatrogenic instrumentation effects, the breakage of an endodontic instrument can compromise the success of endodontic therapy, particularly if the practitioner cannot bypass or retrieve the instrument from the canal. Reports indicated that the original Canal Master was prone to breakage. Massa et al. (17) found that Canal Master instruments exhibited significantly less torque at yield and at failure in both the clockwise and counterclockwise direction than K-type endodontic files. Zuola et al. (18) revealed that the smaller size Canal Master instruments were more likely to fracture than larger sizes. All separated instruments were wedged in the apical third of the canal. This study also showed that although the majority of instruments examined were shaped as advertised by the manufacturer, the flutes and tips of the Canal Master cutting head were frequently different, particularly in the smallest sizes. Inconsistency in the taper and length of the cutting head also occurred. The study did not determine whether this was a major cause of instrument failure, but it showed the need for better quality control and possibly a different machining process.

The manufacturer (Brassler USA, Inc.) introduced a modification in the instrument, renamed the Canal Master "U". This changed the flute design and the method of use (clockwise rotation instead of a 60 degree watch winding motion). The modification simplified the machining of the stainless steel wire and improved the instrument's performance in laboratory and clinical trials. Pearson et al. (19) tested the Canal Master "U" for torsional failure and revolutions to failure. The study found that all instruments exceeded the ADA specification no. 28 minimum average values for revolutions to failure, but several sizes of Canal Master "U" instruments were below the ADA minimum average values for mean torque failure. Due to the structural design differences of endodontic files versus Canal Master "U", an additional category of ADA specification or alternative testing method was suggested by the study(19).

Recently the Canal Master "U" was manufactured using nickel-titanium instead of traditional stainless steel. Early investigations of nickel-titanium (NiTi) files revealed they were more flexible and superior in resistance to torsional fracture than stainless steel files (20). Increased flexibility and fracture resistance of NiTi instruments provides potential improvement in Canal Master "U" physical characteristics. The manufacturer has also released a completely rotary version of the NiTi instrument for laboratory and clinical testing. The question is whether these design and material changes will make a difference in the performance and safety of the Canal Master. Studies on both the NiTi Canal Maser "U" hand instrument and the completely rotary Canal Master "U" system must be completed. The completely rotary

NiTi instrument is of particular interest as it may reduce operator fatigue and increase the speed of canal preparation.

SECTION THREE: MATERIALS AND METHODS

A. SPECIMEN SELECTION

Human mandibular first and second molars with fully formed apices were stored in 10% formalin after extraction. Thirty-six mesial canals with separate apical foramina will be selected for instrumentation.

B. RESEARCH DESIGN

The 36 sample specimens will be randomly assigned to one of three instrumentation groups (K-Flex file, NiTi Canal Master U hand, or NiTi Canal Master U rotary instrument). Root canal anatomy before and after instrumentation will be determined using the methodology introduced by Bramante (21). An image of the root canal anatomy prior to instrumentation will serve as its own control. The effects of the different instruments (independent variables) upon the root canal anatomy measurements (dependent variables) will be subjected to statistical analysis.

C. METHODS

1. Tooth Preparation

The occlusal surfaces will be flattened on a metal trimmer for an even instrumentation reference point. After removal of the distal roots, access into the pulp will be made with a #557 bur in a high-speed

handpiece under water spray. A #10 file, placed in each canal until just visible at the foramen, will determine the canal length. Buccal and mesial radiographs will be taken and canal curvature determined by the Schnieder (22) method.

A longitudinal groove 0.5 mm in depth will be placed along the mesiobuccal line angle for orientation. A drop of soft boxing wax will be used to seal the two apical foramen, a wet cotton pellet to fill the chamber, and cavit to close the access. Lines will be circumscribed around each root 2.0 mm above the apical foramen and 1.0 mm apical to the point where the canal begins to deviate from a straight line. This mid-root point will be determined by overlaying the buccal view radiograph onto the buccal surface of the mesial root. Each root will be embedded in clear casting resin using a brass jig as a matrix. After setting, the resin blocks will be trimmed, orientation grooves will be placed on opposite sides, and the blocks will be coated with Vaseline. Locking jigs will subsequently be fabricated by embedding one-half of each resin block in die stone. Then the stone will be indexed, Vaseline applied, and the second half of the jigs poured.

Each resin block will be removed from its stone locking jig and sectioned using 0.15 mm diamond wafering blade in a Isomet low-speed saw (Buehler Ltd., Evanston, IL). Cuts will be made perpendicular to the root canal above the two lines previously scribed on the root surfaces. After scribing a cross on diagonal corners of each resin block's coronal surface, the root sections obtained from each sample can be repositioned exactly within the locking jig.

2. Sample Image Acquisition

An integrated imaging system previously utilized for longitudinal radiographic assessment studies at the UTHSCSA Dental School (23) will be applied to the imaging and analysis of experimental samples in the present study. The acquisition module is designed for the registration, digitization, and management of sample images. Image capture is performed by a video camera (Imaging Technologies Inc.) and a transmission light system. All preinstrumentation image data will be stored on an optical disk (and a back-up disk) until postinstrumentation image acquisition is accomplished. Software of the image analysis computer workstation will allow superimposition of preinstrumentation and postinstrumentation images, allowing each canal to serve as its' own control.

3. Canal Instrumentation

After preinstrumentation (control) image acquisition has been obtained, the canals are assigned to one of three groups of 12 canals so that each group has six facial and six lingual canals. Canal curvatures will be evenly distributed among the three groups. Group A canals will be instrumented with K-Flex files (Kerr, Romulus, MI) using a modified step-back filing technique (7), where the files are "set" in the dentin by rotating clockwise one-quarter turn and then forcibly withdrawn. After coronal enlargement of the canal orifice with #2 gates glidden, the canals will be instrumented to a #30 file 0.5 mm short of canal length followed by sequential 1.0 mm step-back flaring to a #45 file. Postinstrumentation images will be recorded and the root sections repositioned in the locking jig. The canals will then be instrumented

to a #45 file 0.5 mm short of canal length followed by step-back to a #60 file. The second postinstrumentation images will be recorded for each sample section.

Group B canals will be instrumented with NiTi Canal Master U hand instruments (Brassler Inc., USA), using the technique described in the UTHSCSA Dental School undergraduate endodontic manual. The coronal portion of the canals will be prepared using the original #50 through #100 stainless steel Canal Master "U" rotary (flaring) instruments to the level of the curve. This will be followed by instrumentation of the apical portion of the canals with the NiTi Canal Master "U" hand instrument. As in the previous group, canals will be enlarged to #30 with a step-back of three sizes and to #45 with step-back followed by postinstrumentation image acquisition in each case.

Group C canals will be instrumented with the new NiTi Canal Master "U" rotary system. The technique described in the UTHSCSA Dental School undergraduate endodontic manual will be again followed as for Group B. A Sensormatic handpiece (Advanced Endodontic Concepts) will be used to drive the rotary instruments. After coronal preparation (flaring), the canals will be enlarged to a #30 with step-back and to a #45 with step-back followed by postinstrumentation image acquisition in each case.

New K-Flex files and Canal Master "U" instruments will be used in each canal. If insufficient proto-type NiTi rotaries are available then each Canal Master "U" instrument will be used in two canals. Canals will be irrigated with 5.0 ml of 2.5% NaOCl after each instrument size. The locking jigs will be coated with rubber base adhesive to prevent

loss of the NaOCl and secured together by a vice during instrumentation. The total time required will be recorded for each canal preparation.

4. Sample Image Analysis

The analysis workstation is an Intel 80486 AT/bus personal computer. The sample images will be retrieved from the optical disk storage (or back-up) and loaded into RAM. The software supports digital subtraction of sample sections to determine the quantitative difference between the preinstrumentation control (reference image) and the postinstrumentation images. The resultant subtracted image or processed image will be displayed in a results window. Quantitative image analysis results will also be displayed and are printed out.

D. STATISTICAL ANALYSIS

Dr. Cheng Yuan will provide statistical assistance for this study. He provided the preliminary determination of sample sizes as well as the anticipated methods of sample analysis.

The length of transportation, area of dentin removed, and centering ratio data for each instrument will be compared. Analysis of variance will be used to determine the statistical significance of the differences. Distribution of the data will also be examined. If the data do not appear to be normally distributed then a Wilcoxon's rank sum test will be used.

The number of round canals for each instrument will be compared. Chi-square test and Fisher's exact probability test will be used for determining statistical significance.

The data of a previous study (16) was reviewed to help determine the sample size for the proposed study. Twelve teeth were used in each of the three instruments in the previous study. One canal was lost to a broken instrument, leaving a total of 35 canals analyzed in the study. A statistical power analysis indicates that the sample size of 12 per instrument was adequate with the exception of the apical section with a #45 file, where the difference between instruments tended to be minimal. On this basis a sample of 12 canals per instrument is proposed for this study. The results of the pilot study will be analyzed to confirm this sample size estimation.

E. TIMETABLE

September 30, 1992	Proposal submitted
October 7, 1992	Submit to Dept. Research Committee (and IRB)
October 15, 1992	Meet with Dept. Research Committee
December 18, 1992	All material assembled, pilot study complete
February 15, 1993	All data collected
March 15, 1993	Statistical analysis, tables, figure complete
March 30, 1993	Initial submission of paper
June 30, 1993	USAF final deadline for completion

F. MATERIALS AND BUDGET

1. Materials	Estimated cost
a. 10% Formalin	available
b. Model trimmer	available
c. High and low speed handpieces	available
d. #557 high speed burs (12)	\$13.20
e. #2 Gates glidden (12)	\$20.00
f. X-ray film: 1 box 150 double packs	\$30.00
g. Cavit (6 tubes)	\$9.30
h. Cotton pellets and Vaseline	available
i. Clear casting resin	\$40.00
j. Die stone and beading wax	available
k. Vice	available
l. Isomet low-speed saw and blade	available
m. Image acquisition and analysis modules	available
n. Computer optical disk (shared item)	\$200.00
o. K-Flex files: #10-#60 (12 packs)	\$103.40
p. Stainless steel Canal Master "U" rotary #60-#100 (12 packs)	\$98.00
q. NiTi Canal Master "U" hand instruments #20-#60 (12 packs)	\$765.00
r. NiTi Canal Master "U" rotary instruments #20-#60 (12 packs)	available
s. Sensormatic handpiece	available
t. Sodium hypochlorite	\$2.00
u. Rubber base adhesive	available
v. Stopwatch	available
w. Statistical analysis	\$200.00
x. Miscellaneous	\$40.00

2. Budget

Projected expenses: \$1420.90
(Instruments already purchased will
reduce costs to available funds)
AFIT funds available: \$1000.00

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