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"Comparison of Two Methods of Void Correction Following Warm Vertical Root Canal Obturation"

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[redacted]

George Hwang, Maj, USAF, DC
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24 July 2018

DEPARTMENT OF THE AIR FORCE
AIR EDUCATION AND TRAINING COMMAND

Date: 20 Dec 2016

MEMORANDUM FOR 81MDG IRB CHAIRPERSON, MAJ JOSHUA TYLER

FROM: 81 DS/SGD

SUBJECT: Research Determination Request

1. The attached protocol entitled, **"Comparison of two methods of void correction following warm vertical root canal obturation",** is submitted for your review from Capt George Hwang to make a formal determination as to whether this does or does not constitute human research, and therefore the requirement for further review by the IRB.

2. Previously, it was established after consultation with AFMSA/SGE-C, Research Oversight and Compliance Division, Office of the Surgeon General, that this form of research generally does not constitute use of human subjects per the Common Rule (32 CFR 219), and therefore is not human research and does not require a formal research protocol. Guidance is attached for review.

3. I am asking that you review the attached protocol and the guidance from AFMSA/SGE-C and make a formal determination as to whether this does or does not constitute human research and therefore the requirement for further review by the IRB. We contend that is does not require full IRB approval or protocol oversight.

4. If the determination that the proposed activity is not human research, a study folder will be kept by the IRB Protocol Administrator to maintain documentation of the activity and the ruling for future inspection purposes. The assigned tracking number will be **FKE20170009N.**

[redacted]

JOHN BREWSTER, Lt Col, USAF, DC
Director Graduate Dental Research

Attachments:
1. Protocol #FKE20170009N
2. AFMSA/SGE-C Non-Human Research Guidance Checklist

1st Ind, IRB Chairperson

MEMORANDUM FOR 81 DS/SGD, Lt Col Brewster

I reviewed the submitted proposal, **#FKE20170009N**, and have made the following determination:

__________ This protocol does constitute human research and therefore requires review by the 81 MDG IRB.

__________ This protocol does not constitute human research and therefore does not require review by the 81 MDG IRB. Please notify the 81 MDG IRB of this determination at the next convened meeting.

JOSHUA TYLER, Maj, USAF, MC
Chairperson, 81 MDG Institutional Review Board

____
Date

Comparison of two methods of void correction following warm vertical root canal obturation

George D. Hwang, DDS, Jared W. Cardon, DDS, Steven W. Black, DDS, Timothy C. Kirkpatrick, DDS, Van T. Himel, DDS, and Kent A. Sabey, DDS

Abstract

Introduction: During warm vertical endodontic obturation, voids are occasionally observed between the downpack-backfill junctions, potentially reducing the canal seal. This study compared two methods of correcting obturation voids—re-accomplishment of continuous-wave warm vertical condensation (WVC) procedure versus using a Microseal Condenser (MC) device. **Methods:** Thirty-two maxillary central incisors were obturated with intentional creation of obturation voids. The voids were subsequently eliminated by either repeating traditional downpack and backfill, or using a Microseal Condenser device. The percentage of void reduction was calculated using straight-on and proximal-view digital radiographs. Time required for each technique was recorded. Data was analyzed using Student t-test and Pearson Correlation. Representative teeth from both groups were then sectioned and examined under light microscopy. **Results:** No significant difference in the percentage of void reduction was observed in either the straight-on view (90.5% for WVC; 86.3% for MC) or the proximal view (84.7% for WVC; 81.5% for MC). A very strong correlation (r=0.85) existed for measuring the size of voids between the straight-on and proximal views. A significant difference in procedure times was observed (99 seconds for WVC; 47 seconds for MC). Visual inspection of selected root sections demonstrated satisfactory obturation quality in both WVC and MC groups, however complications such as instrument separation or gouging of canal walls were observed in some sections of the MC group. **Conclusions:** The MC device achieved a similar level of obturation quality, in significantly less time, for correcting obturation voids compared to the WVC technique, however may be associated with more complications.

Introduction

One of the key components of successful root canal therapy is the complete obturation of the root canal space in three dimensions (1). It has been postulated that voids in root canal fillings may compromise the outcome of root canal therapy by allowing 1) residual microbes to grow and populate, and 2) microleakage to occur along the root canal walls (2, 3). Numerous clinical outcome studies have shown that high quality root canal obturations (with absence of voids being a positive evaluating criterion) has a significantly higher success rate, at 81-93%, versus 45-63% for poor quality obturations (4-8). In the meta-analysis published by Gillen et al, it was reported that poor quality RCT has the same odds ratio for failure as compared to effect of poor coronal leakage (9). In clinical practice, formation of voids during obturation is an occasional, undesired complication. Zhong et al. reported 51% of root canals treated teeth in the United States had some type of obturation defect (voids, inhomogeneity, or space between filling and canal walls) (10), and Lee et al. reported the incidence of obturation voids to also be 51% examining 1000 teeth (11). At times, the presence of a void may not be apparent to the clinician until a post-obturation radiograph is acquired. Correcting the void could be a time-consuming procedure depending on many factors to include the clinician's level of skill and the canal morphology. Reportedly, the obturation process can take 7 to 9 minutes *in vitro* (12) when using the warm vertical condensation method; repeating the obturation process to remove voids may consume valuable chair time. Left alone, voids may raise questions as to the overall quality of the obturation and potentially compromise treatment outcome. Studies have investigated obturation void formation (13, 14), however, there is a scarcity of research investigating methods of correcting voids within the root canal space when they occur. The Microseal Condenser, originally designed by Dr. J. McSpadden and known as the McSpadden's compactor, was introduced in 1978 (15). This instrument uses frictional energy via a stainless-steel rotary compactor to melt gutta-percha and compact it apically and laterally. To improve material control and reduce occurrence of instrument fracture in a curved canal, an obturation technique using a Microseal Condenser made of nickel-titanium, and a hybrid method of using laterally condensed master cone and placement of alpha-phase gutta-percha to backfill the canal was developed (16). In theory, such an instrument may be used to correct voids in the obturation by apically displacing existing gutta-percha in the canal. The aim of this study was to evaluate the efficacy (through percentage of void reduction) and efficiency (through time of void correction) of correcting voids using two different methods--re-packing the canal using warm vertical condensation versus using a Microseal Condenser.

Material and Methods:

Sample collection and Specimen Preparation

This study was approved by the Research Ethics Committee of the Louisiana State University School of Dentistry and the Research Ethics Committee of United States Air Force. A total of thirty-two fully formed, extracted human maxillary central incisors were used from the tooth bank at the Department of Endodontics, Louisiana State University School of Dentistry. Soft tissue tags, attached bone, and calculus were removed to eliminate radiographic interferences, and the teeth were stored in a 2% solution of sodium hypochlorite. The teeth were accessed and a size 15 K-file (Dentsply Maillefer, Ballaigues, Switzerland) was inserted into the canal until it was just visible through the apical foramen. Working length was determined by subtracting 1 mm from this length. Patency was reconfirmed by passing a #15 K-file through the apex before and after instrumentation. Canals were prepared in a crown down / step back fashion. Orifice shaping and mid-root preparation was completed with SX, S1, and S2 ProTaper Gold series Ni-Ti files (Dentsply Maillefer, Ballaigues, Switzerland). RC Prep (Premier Dental, Plymouth Meeting, PA, USA) was used as a lubricant until working length was reached. Sequentially, Vortex Blue (Dentsply Maillefer, Ballaigues, Switzerland) files with a constant .04 taper were then introduced until #30 file reached working length. On teeth where the apical foramen exceeded #35 naturally, larger size rotary instruments were used until the apical foramen was shaped. No specimen exceeded #45 in this study. One milliliter of saline was used to irrigate the canals between each change of instruments using a syringe with a 27-gauge needle. After instrumentation, the teeth were stored in a saline solution until obturation was accomplished.

Void Creation

After selecting Gutta-percha cones (Coltene, Ohio, USA) of the appropriate size and taper as the master apical files, canals were obturated using the continuous wave warm vertical condensation technique using the Elements Free obturation device with a 27 gauge tip (Kerr Corp, California, USA) following the manufacturer's instructions (DD). Specifically, the downpack was carried to 4mm from working length. During the backfill step, voids were deliberately created by purposely placing the extruder device's tip 1 mm coronal to the downpacked gutta-percha level. Sealer was not used to avoid sealer masking the presence of voids. After obturation, teeth were mounted in a Reposil (Dentsply Maillefer, Ballaigues, Switzerland) base. Physical markings were then made on the buccal and proximal surfaces of the root by cutting a groove into the root with a 0.1mm thick 14mm diamond disc (Dentsply Maillefer, Ballaigues, Switzerland) at 4mm and 8mm from the WL. These markings served as upper and lower boundaries during the image analysis step below.

Digital Radiograph Imaging

Pre-op radiographs of each tooth were made in the straight-on (buccal-lingual) and proximal (mesial-distal) views using the proposed positional layout (Figure 1). The layout ensured the pre-op and post-op radiographs of each specimen could be obtained at the same reproducible angle and distance from the X-ray cone every time. A 1mm stainless steel spherical bead was embedded in the sensor mount to provide accurate image scale calibration during the analyzing step.

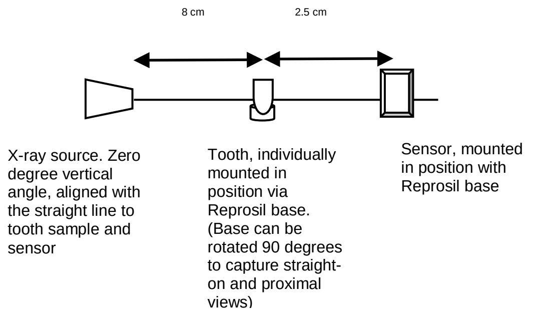

Figure 1—
Experimental position layout for pre-op and post-op radiographs

Void Repair

Teeth in the MC group were instrumented with an unused Microseal Condenser (Kerr, California, USA) to remove voids. Sizes 25/.02, 30/.02, or 35/.02 were used depending on canal diameter. First, void location was determined radiographically, and the rubber stopper on the condenser was set at the corresponding level. Then, the condenser was used at maximum speed using a slow speed air driven handpiece, slowly inserted in the canal to the appropriate length for 2-4 seconds, and slowly withdrawn. Hand pluggers of appropriate sizes were used to compact gutta-percha at the orifice level. The entire step was timed using a stop watch. Post-op radiographs were made of each sample in the straight-on and proximal views.

Teeth in the WVC group were instrumented with the System B / Elements Free Obturation system to remove voids. The appropriate System B plugger was activated and inserted to the depth of the void based on premeasured radiographs. After the GP was heated and removed, hand pluggers were used to flatten the gutta-percha interface. Backfill was performed using the Elements Free obturation device. Hand pluggers of appropriate sizes were used to compact gutta-percha at the orifice level. The entire step was timed using a stop watch. Post-op radiographs were made of each sample in the straight-on and proximal views.

Image Analysis

After the image files for each sample were collected, they were randomized and renamed. Void size analysis was performed by a single examiner, who was blinded as to which group was being analyzed. Using ImageJ software (version 1.50i), the length (in mm) per pixel in each image was calibrated by using the known demensions of the marker bead. The area of the void was determined using the pre-op image and was demarcated by adjusting the optical intensity value. This served two purposes: 1) the outline of the void was more clearly distinguished, and 2) the optical intensity of void space was digitally determined. The voids in the post-op image could then be compared based on the same intensity value. In other words, once the threshold was set, the computer determined fill versus void based on the optical intensity, eliminating subjectivity related to examiner interpretation. Pilot studies indicated that the optical threshold determination could be reproduced with greater than 95% accuracy. To further investigate the extent of possible evaluator bias, a Student t test of the mean threshold values for WVC and MC determined by the evaluator was performed. Using the pre-determined upper and lower boundaries and canal wall, the area of voids was measured in mm^2.

Data Analysis

Using the Excel program (Microsoft Corp, Washington, USA), the percentage of void reduction from the straight-on and proximal views, and the time needed to perform void repair for each group were calculated. The percentage of void reduction was calculated by using the formula: (Pre-operative void size – Post-operative void size) / Pre-operative void size. The void correction time in the WVC and MC groups were analyzed using the two-tailed Student t test. The percentage of void reduction from two viewing angles were analyzed using the Pearson agreement test.

Root Sectioning

Six specimens (three from each group) were sectioned in 1mm intervals in the 4 – 8mm from WL segment using the Accutom-50 section machine (Struers, USA). Specimens were viewed under 10X magnification using the Nikon i50 polarizing light microscope (Nikon, Japan) with the SPOT Insight digital camera and SPOT 5.0 software (Diagnostic Instrument, USA).

Results:

No significant differences ($P > 0.05$) were observed between the two techniques in terms of the percentage of void reduced in either straight-on view (90.5±8.7% for WVC; 86.3±16.5% for MC) or proximal view (84.7±13.5% for WVC; 81.5±17.0% for MC). The average size of pre-operative voids were 0.61mm^2 for WVC and 0.64mm^2 for MC in the straight-on view, and 0.92mm^2 for WVC and 0.96mm^2 for MC in the proximal view. Figure 2 shows the sample pre-operative radiograph images of straight-on and proximal views with intentionally created void spaces. Figure 3 shows identification of voids using computer software. The average size of post-operative voids were 0.05mm^2 for WVC and 0.08mm^2 for MC in the straight-on view, and 0.10mm^2 for WVC and 0.18mm^2 for MC in the proximal view. Overall, the straight-on view and proximal view radiographs showed a very strong correlation ($r = 0.85$) in measuring the size of voids. The mean percentage of void reduction from the straight-on and proximal views in each group is shown in Figure 4. Significant differences ($P < 0.05$) were observed between the two techniques in terms of the time needed to complete the procedure, 99±17.8 seconds for WVC, and 47±13.3 seconds for MC. The mean time needed in each group is shown in Figure 5. Root sections in selected samples showed satisfactory gutta-percha obturation quality in both warm vertical and Microseal Condenser groups (Figure 6a-e). No significant difference in the optical threshold value was observed. The P value was 0.46 for straight-on view and 0.48 for proximal view. It was noted that one incident of file separation occurred in the MC group where a 2mm segment was embedded in the gutta-percha. Also, one incident of the Microseal Condenser gouging into the canal wall during usage was observed.

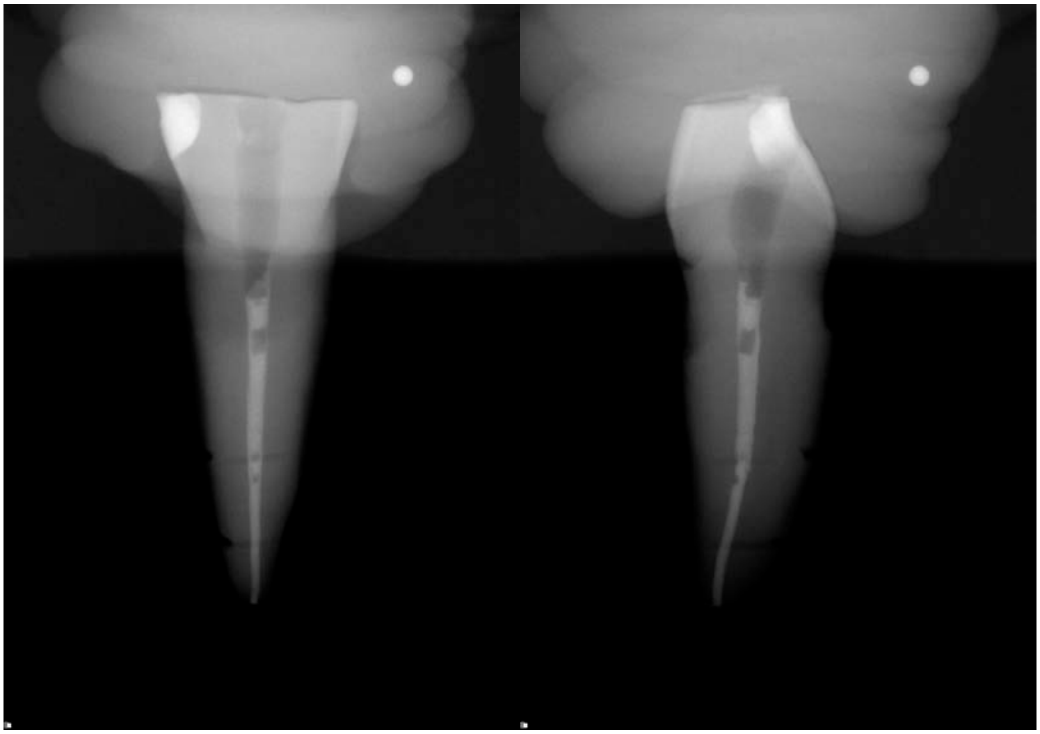

Figure 2 – Sample images showing intentionally created void space in straight-on and proximal views. The zone of interest (8mm and 4mm from WL) is pre-marked by 0.1mm diamond discs and can be seen on radiograph. A 1mm spherical metal bead was embedded for calibration.

Figure 3 – Identifying void space in sample radiograph using ImageJ software. By adjusting optical threshold value, the area of voids (low radiopacity) can be measured in the confined area of interest (4mm – 8mm from WL).

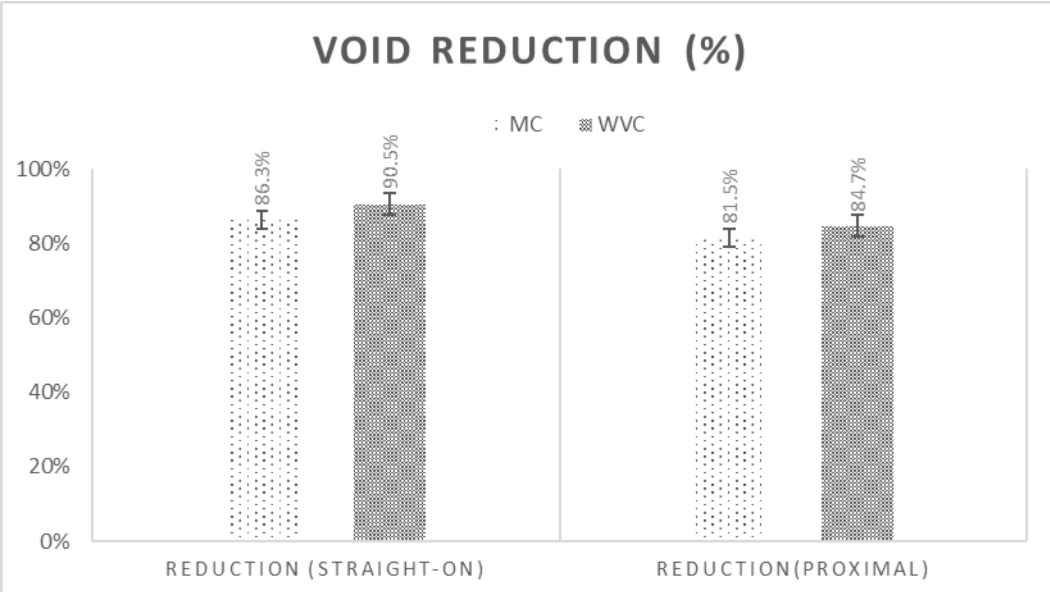

Figure 4. Voids reducetion percentage between MC and WVC groups.

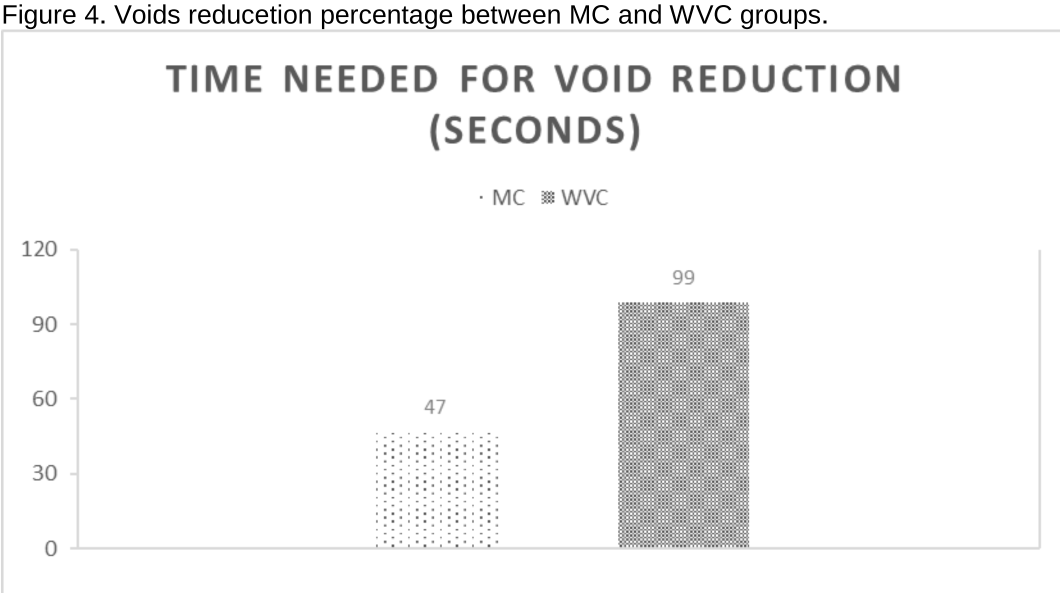

Figure 5. Time spent to perform repair in MC and WVC groups.

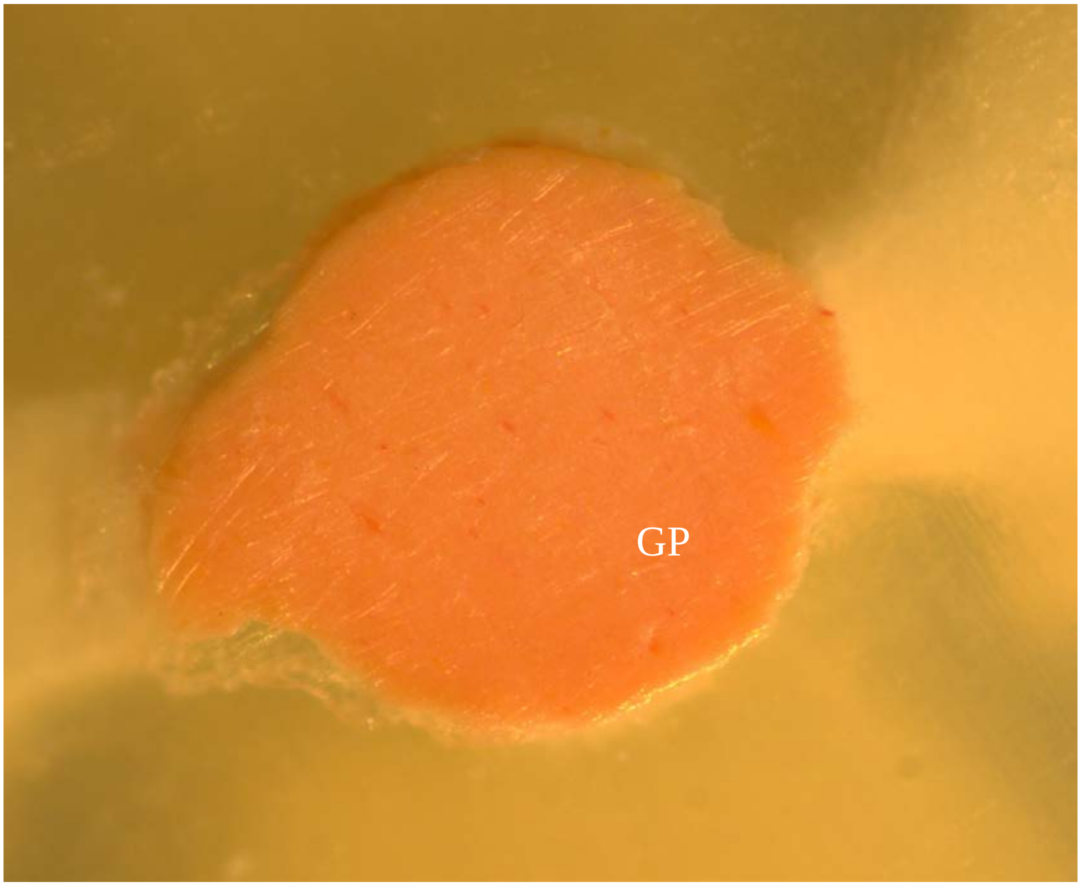

Figure 6a. 10x magnification of root sectioned at location of MC repair. This specimen had a corresponding void reduction of 99.7% for straight-on view and 98.4% for proximal view. The cross-section reflected gutta-percha with good homogeneity and density, and absence of unfilled space.

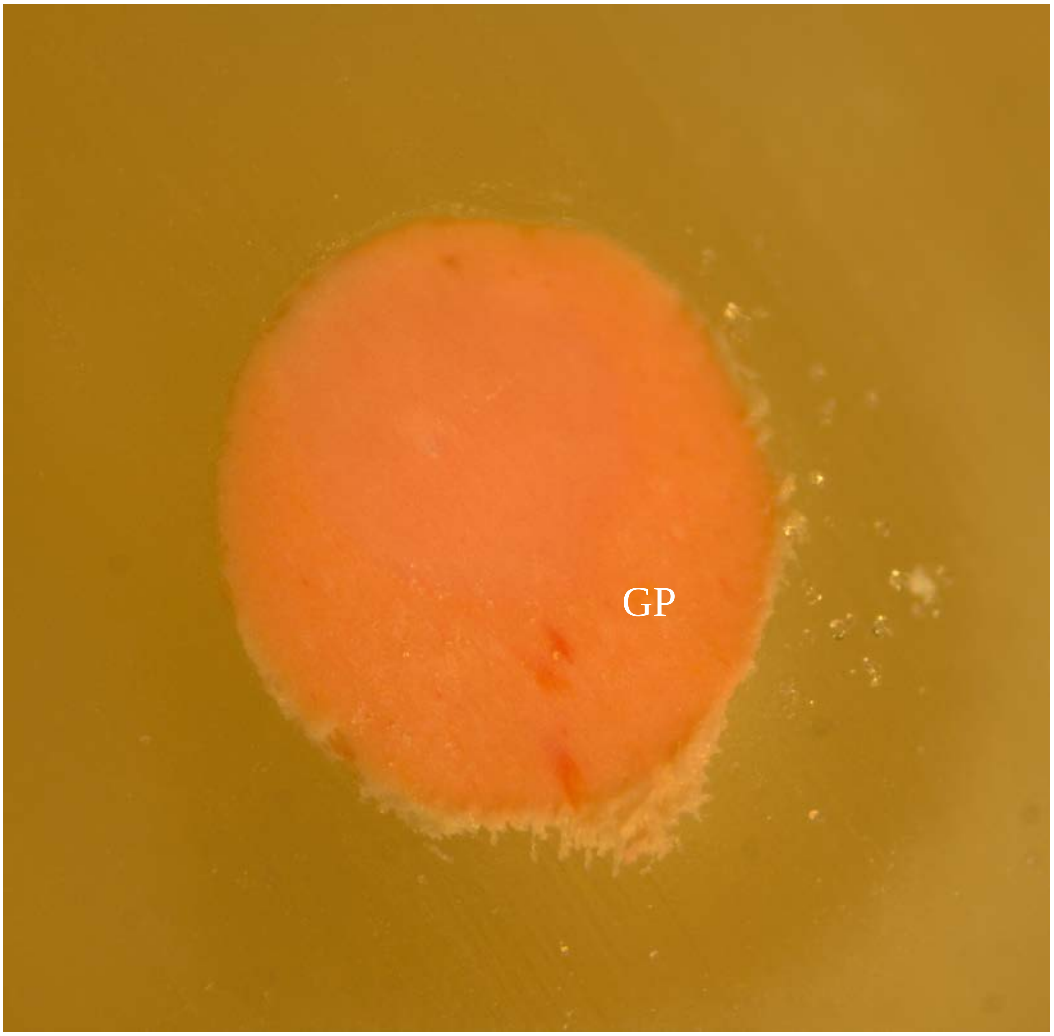

Figure 6b. 10x magnification of root sectioned at location of WVC repair. This specimen had a corresponding void reduction of 97.2% for straight-on view and 91.9% for proximal view. The cross-section reflected gutta-percha with good homogeneity and density, and absence of unfilled space.

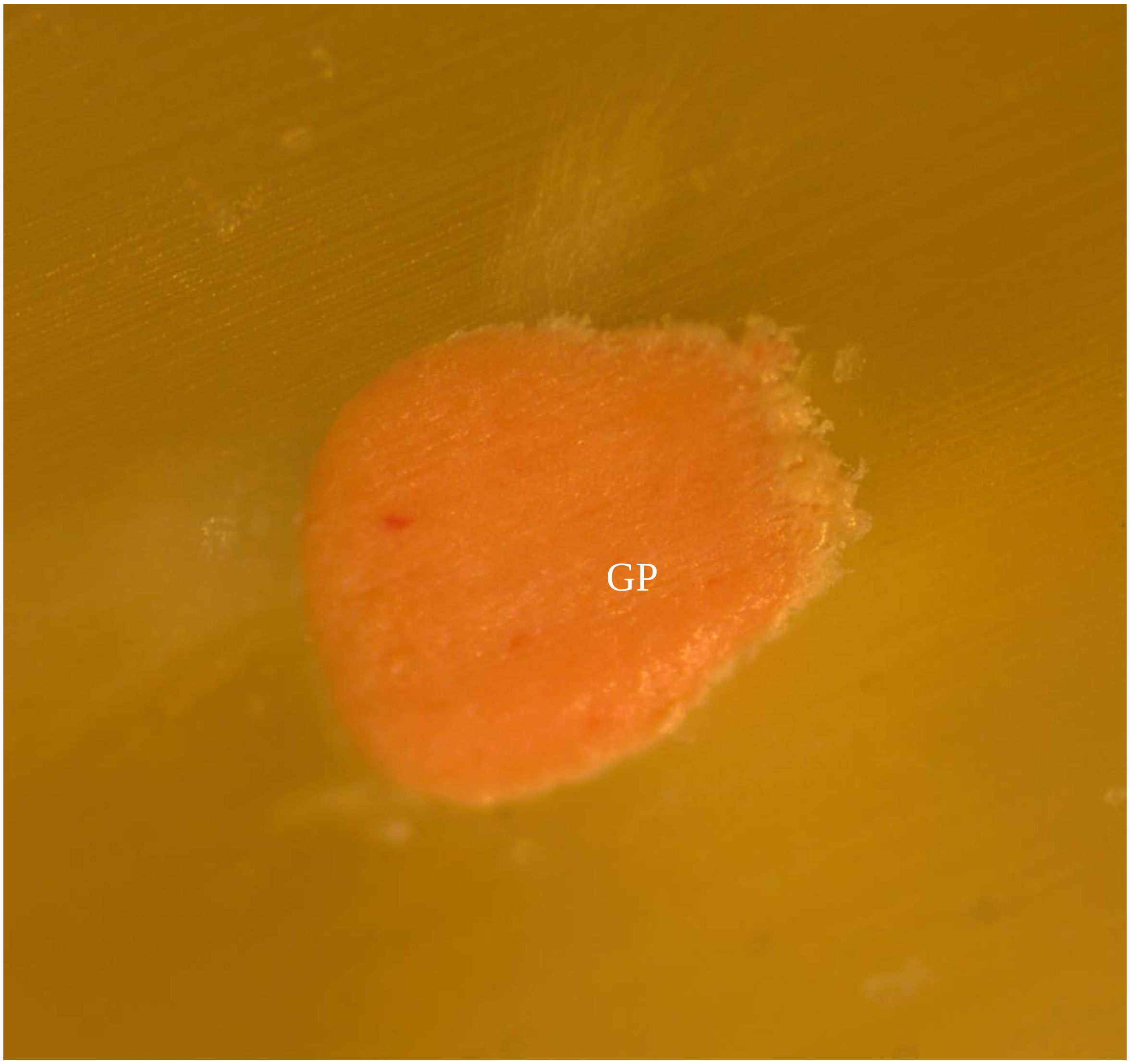

Figure 6c 10x magnification of root sectioned at location of MC repair. This specimen had a corresponding void reduction of 91.8% for straight on view and 84.5% for proximal view. The cross-section reflected gutta-percha with good homogeneity and density, and absence of unfilled space.

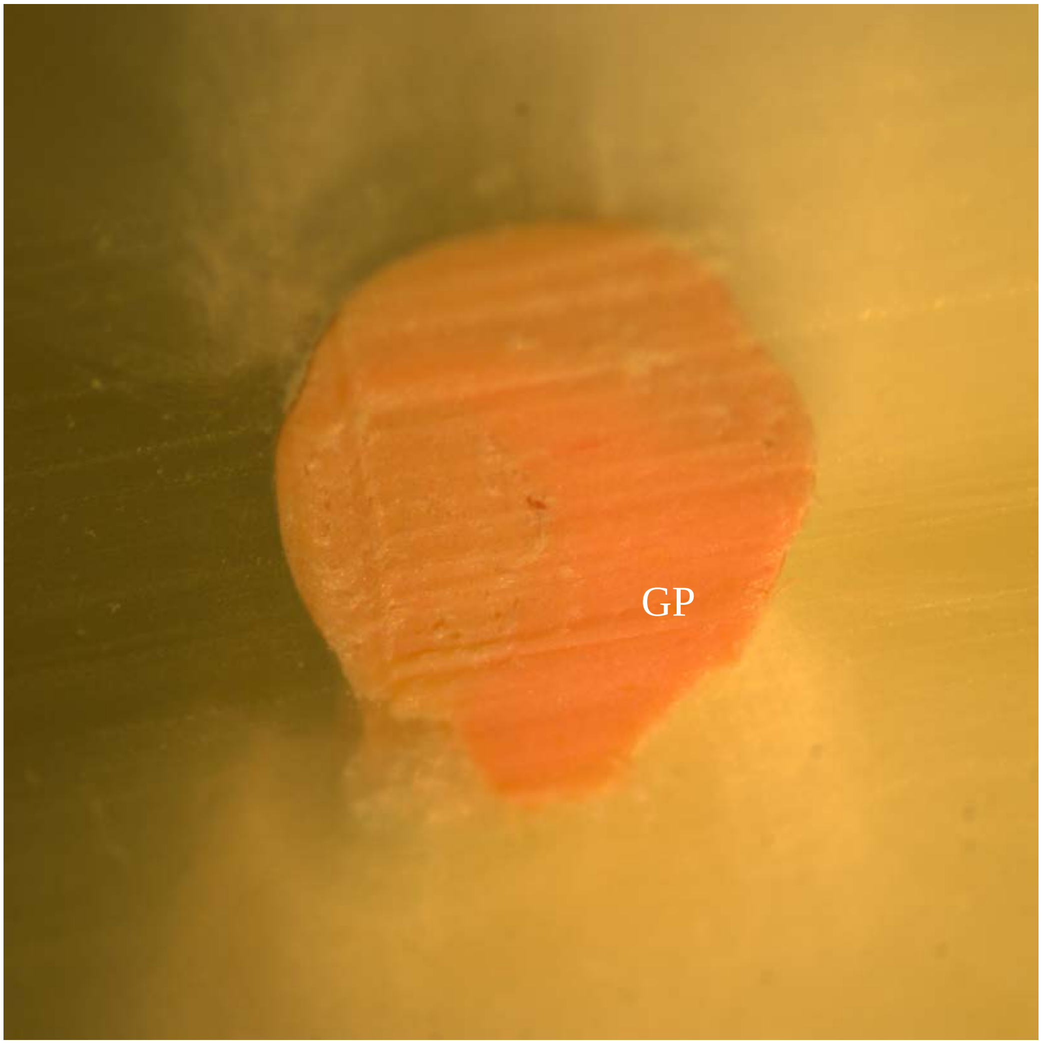

Figure 6d. 10x magnification of root sectioned at location of MC repair. This specimen had a corresponding void reduction of 93.2% for straight on view and 92.6% for proximal view. The cross-section reflected gutta-percha with good homogeneity and density, and absence of unfilled space.

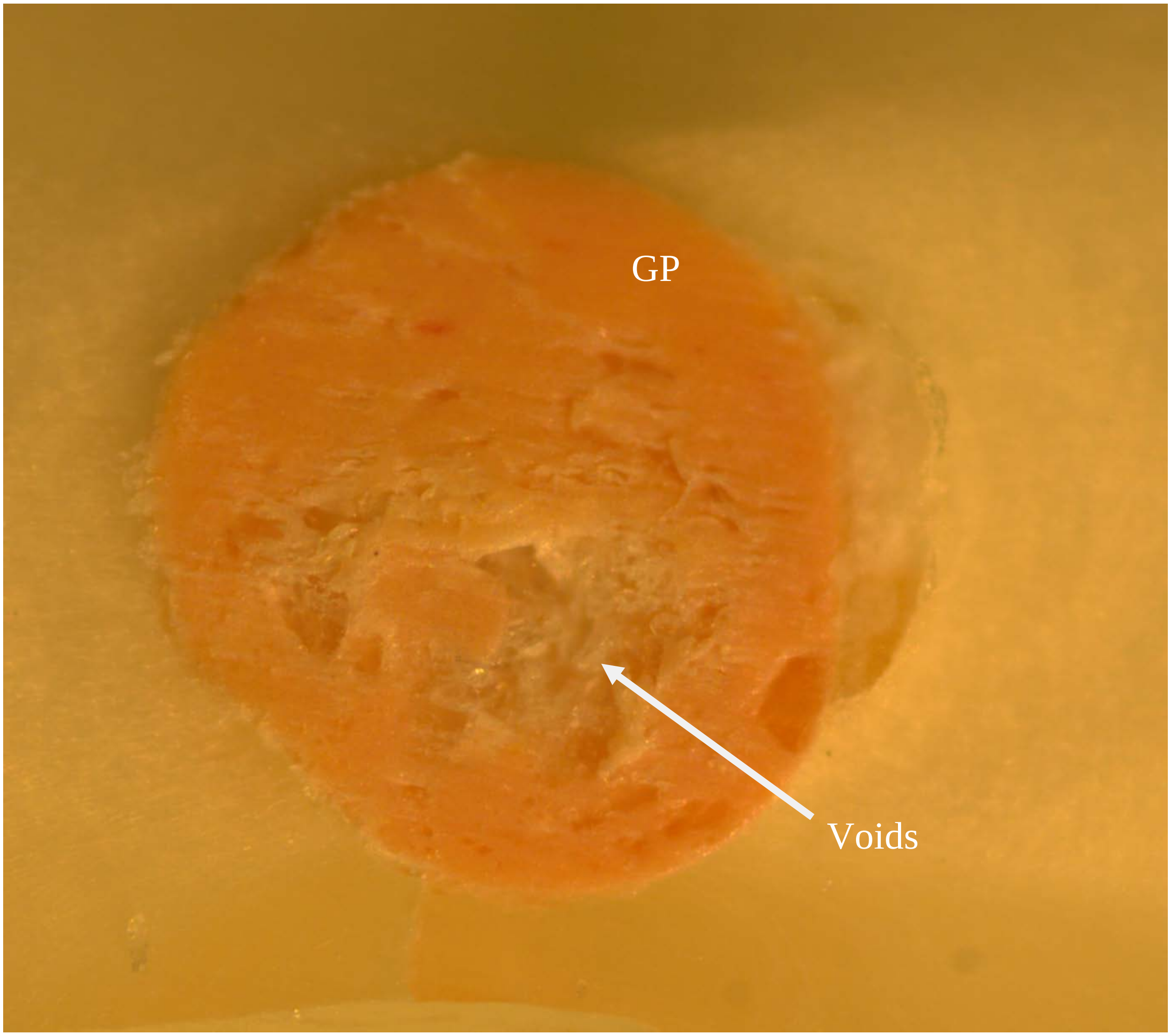

Figure 6e. 10x magnification of root sectioned at location of MC repair. This specimen had a corresponding void reduction of 35.9% for straight on view and 29.3% for proximal view. The cross-section reflected significant non-homogeneity, presence of unfilled space, as well as dentin debris in the gutta-percha.

Discussion:

In this study, we set out to investigate whether the Microseal Condenser could be used as an alternative method to repair voids within a canal. We postulated that because of its motor driven property, and reversed helix design, the MC could plasticize and move masses of gutta-percha apically and laterally to fill obturation void spaces in an efficient manner. Based on our experiences, when using the continuous wave warm vertical condensation method, the interface between the level of downpack and backfill is frequently the location where voids occurs. In this study, we examined the voids present in the 4-8mm zone from WL, the space where the interface is often located (17).

Historically, studies comparing obturation quality often utilized computer software to trace areas of gutta-percha, sealer, and voids in sectioned roots (18). Although micro CT offers a more precise and accurate analysis, digital radiography remains the best method to calculate voids in vivo, thus the majority of outcome studies use this method (9). The main limitation of the digital radiograph lies in its two-dimensional representation of a three-dimensional structure, which can be distorted by factors such as beam angulation, distances between radiation source, specimen, and sensor, and that digital radiographic interpretation is subjected to evaluator's bias (9). Nonetheless, Youngson et al. found the percentage of voids detected by radiographs was not significantly different from a microscopic evaluation of tooth sections (19). In this study, we improved the accuracy of images by fixating the angle and distance of the beam to each sample, and examining them from both straight-on and proximal views. In addition, the experimental design limited the examiner's human bias to a significant degree by using the computer to determine what constituted voids using the same intensity threshold value for each specimen. This is significant because often times a void may not appear totally radiolucent on the radiograph, but instead as a mixture of opacity and lucency that is merely less radiopaque. This poses a challenge for the evaluator to interpret the extent of voids when comparing pre-operative and post-operative images and may introduce a considerable degree of human error (20). To mitigate the challenge in this study, each pre-operative image was assigned a radiopacity value. This value effectively defined the minimum radiopacity needed to be considered as non-void for this given specimen, pre-operatively and post-operatively. The same threshold value was then used in the post-operative image, and therefore, a consistent method to define voids in each specimen was established. This was possible because the X-ray source, pre-operative, and post-operative specimens were exposed at the same position each time. In addition, the evaluator was blinded from which experimental group a specimen belonged to when evaluating images. This measure was proven to be effective as the statistical analysis revealed that the differences of threshold values assigned by the evaluator amongst the MC and WVC group specimens were not statistically significant. While human errors could not be completely eliminated in this study, the authors felt these measures increased the validity of the results.

In this study, the post-operative void size between the MC and WVC groups were comparable. This was supported by sample specimens that were sectioned. The representative 1mm sections of both MC and WVC specimens with high percentages of void reduction showed a satisfactory degree of gutta-percha filling. Our results also showed there is a very strong correlation (r=0.85) between the straight-on and proximal views in accessing voids size, which agreed with Kosibowornchai, who found that there was no significant difference between the mean percentages of voids based on straight-on and proximal radiographic views (21). In our study the Microseal Condenser method was able to reduce void repair time by 53% compared to the warm vertical condensation method (0.78 vs 1.65 minutes). In actual patient treatment, the time disparity may be even more pronounced, as it has been the authors' observation that an array of factors, from heating up devices, to needing to replace gutta-percha cartridges, can make the warm vertical condensation technique time-consuming. Our time results were also comparable to Wong's study which showed an 84% reduction of time between a mechanical compaction method to warm vertical condensation (12), and Shaffer's study that showed the warm vertical condensation method took 4.3 minutes to perform (22). We believe the Microseal Condenser's ability to displace gutta-percha using frictional energy, without needing to remove and replenish material, contributed to the advantage.

Our method of using the Microseal Condenser was similar to the methods described by Maggiore (23) and Malagnino (24) in that the Microseal Condenser was inserted in the canal for a very short amount of time (2-4 seconds) before the rotating instrument was removed from the canal, partially aided by the back-pressure caused by the apical movement of gutta-percha. This was followed by the use of hand pluggers which contributed to better gutta-percha adaption and homogeneity. In our study, the thermoplastisized gutta-percha in the canal from the original backfill would have cooled down before the repair was attempted, since the specimens had to be randomly divided into the MC and WVC groups first. This may be a deviation from regular clinical practice where the majority of clinicians would likely choose to attempt the repair immediately upon discovering presence of voids. One would postulate that the use of Microseal Condenser immediately after voids were noticed may positively affect its performance since the freshly thermoplastisized gutta-percha may have a better flow property.

The effects of sealer on void formation and detection were not investigated in this study. Sealer may play a significant role in masking voids from being detected in radiographs. In addition, with the Microseal Condenser spinning at a high rpm, fresh sealer may be incorporated in the gutta-percha mass and thus affect the homogeneity of the obturation (18). It would be beneficial to study the sealer’s effect on MC obturation in the future.

In this study, only one type of gutta-percha was used. It is conceivable that gutta-percha with different thermal properties may affect the Microseal Condenser’s performance. Maggiore used four different brands of gutta-percha in his Microseal Condenser study and did not find any brand to be a main factor in void formation (23). Other gutta-percha, however, may cause a difference in outcome.

Instrument separation is known to be associated with using Microseal Condenser (23). In this study, one Microseal Condenser separated at the last 2mm from the tip when correcting voids. The authors speculate that too much apical pressure might have caused the separation.

Conclusion:

The Microseal Condenser device achieved a similar level of obturation quality, in significantly less time, for correction of voids compared to the warm vertical condensation technique, however may be associated with more complications.

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