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**The Effect of Canal Preparation on Fill Length in Straight Root Canals
Obtured With RealSeal 1 and Thermafil Plus**

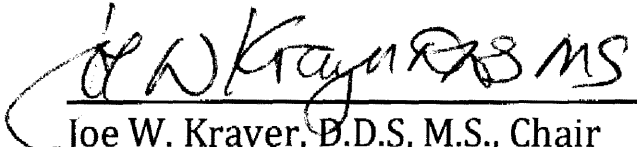
Thomas John Heeren, D.D.S.

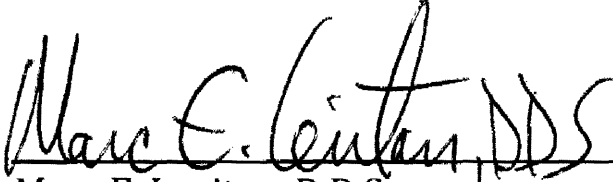
**A thesis submitted to the faculty of the Medical University of South
Carolina in partial fulfillment of the requirement for the degree of
Master of Science in Dentistry in the College of Dental Medicine.**

Department of Oral Rehabilitation
Division of Endodontics

2012

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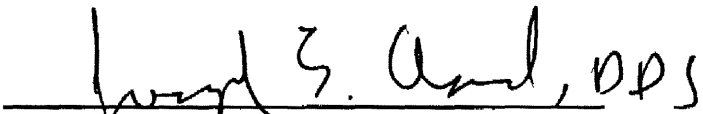

Joseph E. Assad, D.D.S.

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Thomas John Heeren. The Effect of Canal Preparation on Fill Length in Straight Root Canals Obturated With RealSeal 1 and Thermafil Plus. (Under the direction of Dr. Marc Levitan)

Introduction: A common adverse effect using thermoplasticized obturators is overextension. A canal preparation allowing for predictable obturation length would be of clinical value. This study compared straight canals instrumented to a size 40 file using a 0.04 standardized taper preparation (STP) and a varied taper preparation (VTP) by evaluating the extension of two thermoplastic obturation systems: RealSeal 1™ (RS-1) and Thermafil® Plus (TP). **Methods:** Eighty extracted mature human premolars with single straight canals were randomly divided into 4 experimental groups (n=20). Groups 1 and 2 were instrumented to size 40/04 at working length (WL) with STP. Groups 3 and 4 were instrumented to size 40/02 at WL with VTP. Groups 1 and 3 were obturated with RS-1 and groups 2 and 4 were obturated with TP. All groups were obturated per manufacturer's instructions. Extension of material was evaluated and assessed ordinally. Statistically significant differences were determined by logistic regression with significance level set at $P < .05$. **Results:** Significant differences in extrusion existed between groups 2 and 4 when controlling for type of material ($P = .026$), and all groups for extrusion of TP compared to RS-1 when controlling for type of preparation ($P < .001$). **Conclusion:** The results indicate that when filling with RS-1 obturators the canal can be

instrumented to a standardized or varied tapered canal preparation with a low likelihood of excessive extrusion. If the clinician prefers to use TP obturators, this study validates a VTP to decrease the occurrence of overextension.

Introduction

Endodontic therapy treats diseases, injuries of the pulp and associated periradicular conditions, the most common being apical periodontitis. Infection of the pulp tissue by microorganisms caused by caries or other pathways is the primary cause of apical periodontitis (1). After disinfection by chemomechanical instrumentation of the canal, sealing the root canal system from the periodontal bone ensures the health of the attachment apparatus against breakdown of endodontic origin (2). Obturation of the prepared root canal space eliminates avenues of leakage from the oral cavity or periapical tissues and seals within the system any irritants that cannot be fully removed during the cleaning and shaping procedures (3). There are two important aspects in the goal of obturation. First being the complete, homogeneous, three-dimensional (3D) filling of the root canal system. Second, the material filling the canal must ideally extend to a specific working length (WL) and stay confined to the canal space (4). WL is defined as the distance from the coronal reference point to the point at which canal preparation and obturation should terminate (5). The ideal termination of the obturation material is the dentinocemental junction, which is at the apical foramen (6-9). This histological landmark is not possible to accurately locate in the clinical setting and varies in location. The apical foramen consists of the major diameter and the minor

diameter of the constriction, with the constriction identified as the narrowest portion of the canal (10). The constriction provides an ideal location for an apical termination of obturation material providing a natural deterrent to overextension. Traditionally, the apical point of termination is approximately 1 mm from the radiographic apices determined by radiographs.

On average, this measurement is an acceptable location that allows the clinician to create an apical stop within the confines of the canal that may also coincide with the constriction of the minor diameter of the foramen (10, 11, 12). The most popular core material used for obturation is gutta-percha. This material is the trans isomer of polyisoprene and exists in two phases, α and β (13). In the unheated β phase the material is a solid mass that is compactable. When heated above 65°C the β form of gutta-percha melts, changing to the α phase. In its softened state, it can be made to flow when pressure is applied (14). The α form will recrystallize to the β form as it slowly cools. When α -phase gutta-percha is heated and then cooled it undergoes minimal shrinkage, making it dimensionally stable for thermoplasticized techniques.

Techniques that utilize thermoplasticized gutta-percha were developed to compensate for incomplete 3D obturation (2, 15-17). However, if 3D obturation of the canal is established and the obturating material is also extended through the apical foramen, this occurrence will result in decreased healing rates (18). A commonly used product is Thermafil Plus (TP) (Dentsply Tulsa Dental, Tulsa, OK) which utilizes thermoplasticized gutta-percha delivered to the canal via a plastic carrier. Root canals are prepared, coated with sealer, and after the TP obturator has

been heated in a ThermaPrep® Plus oven (Dentsply Tulsa Dental) it is placed to WL. It has been shown that increased extension and ability of the thermoplasticized gutta-percha to flow into lateral canals and irregularities varied directly with the insertion rate of the TP obturators (19). Unfortunately, at rates that ideally reproduced the complex internal anatomy of the canal and produced a 3D fill, extension of the sealer and gutta-percha beyond WL and through the apical foramen is an undesirable common observation (19). When comparing Profile® 0.06 and Profile GT® preparations obturated with TP and Profile GT obturators, the incidence of apical extrusion (overextension) was 30% and 50% respectively (20). Other TP studies have also verified overextension as being a common observation (21, 22). Resilon™ (Pentron Clinical Technologies, Wallingford, CT) is a synthetic polymer-based obturation material designed as an alternative for gutta-percha. SybronEndo purchased Pentron Corporation and renamed Resilon as RealSeal® and developed the product into an obturator, RealSeal 1 (RS-1) (SybronEndo, Glendora, CA). It also utilizes a plastic carrier, is heated in the RealSeal 1 oven, and placed to WL (23, 24). Prior to insertion, manufacturer's instructions for RS-1 and TP recommend that canals be instrumented to a specific tip size and taper for the corresponding obturators. Following completed canal instrumentation each obturation system utilizes a size verifier instrument matching the tip size and taper of the desired obturator. This ensures that obturators will extend to WL by refining the canal to a specific standardized geometry.

In a study comparing Resilon with gutta-percha, it was demonstrated that both have similar flow characteristics when heated (25). Since the flow of these

materials is similar, it could be hypothesized that the incidence of overextension might be similar as well. However, these obturating systems differ in their design. The differences in how the material is shaped over the tapered carriers may be one variable impacting apical extrusion.

As overextension of the thermoplastic obturation systems is both an unpredictable and undesirable outcome, it would be of significant clinical value if a canal geometry other than a standardized preparation were demonstrated to obtain more predictable length control. To date there has been no literature published comparing outcomes of various canal preparations upon apical extension of thermoplastic obturators. The objective of this study is to compare a 0.04 STP to a specific VTP by assessing the apical extension of filling material using two thermoplastic obturation systems.

Materials and Methods

Eighty extracted mature human mandibular premolar teeth with single straight canals and patent apices were selected. All teeth were radiographed from the buccal and mesial directions to aid in assessing the criteria of samples. Canal length was assessed microscopically (5X) by placing a 15 K-file into the canal until it was flush with the root surface at the apical foramen and then measured. WL was established from an occlusal reference by subtracting 1.0 mm from the measured instrument length. WL for selected samples varied from 15.0 - 20.0 mm.

Canal Instrumentation

The teeth were randomly divided into 2 groups (n=40) as follows:

Group A – STP

Group B – VTP

Group A was instrumented to a size 40/04 at WL using the Twisted File® system (SybronEndo). Group B was instrumented using EndoSequence® rotary files (Brasseler, Savannah, GA) to size 40/06 at [WL-3.0 mm], then to size 40/04 at [WL-2.0 mm]. The apical 2 mm of this group was hand instrumented to 40/02 at WL using Triple-Flex SS Files (SybronEndo).

All teeth were instrumented in hand at room temperature by a single calibrated operator using an Aseptico DTC AEU-25 torque controlled motor and a contra angle rotary handpiece with 8:1 reduction (Dentsply Tulsa Dental). The motor was set at 600 rpm and 750 g-cm torque. A total of 10 mL of 3.0% NaOCl (Piggly Wiggly, LLC, Keene, NH) followed by 5 mL sterile water, and then 10 mL of Smear Clear™ (SybronEndo) was used to irrigate the canal during instrumentation. A size 15 K-file was placed into the canal to a length 1.0 mm beyond WL (flush with the root surface) after the use of each rotary instrument to maintain patency. Finally, prepared samples were irrigated with 10 mL of NaOCl, followed by 5 mL sterile water, then 10 mL of Smear Clear. A final rinse with 10 mL of sterile water was completed and the canal was dried with Maxima® size 40 absorbent points #501 (Henry Schein, Melville, NY). A master apical file size of 40 was chosen to ensure consistent geometry at WL among samples. Teeth with canals having a pre-instrumentation size larger than 40/02 were replaced.

Canal Obturation

The teeth from group A were then randomly assigned into 2 equal groups

(n = 20) as follows:

Group 1 – STP obturated with RS-1

Group 2 – STP obturated with TP

The teeth from group B were then randomly assigned into 2 equal groups

(n = 20) as follows:

Group 3 – VTP obturated with RS-1

Group 4 – VTP obturated with TP

The RS-1 verifier fit passively to WL in group 1 and to [WL-2.0 mm] in group 3. The TP verifier fit passively to WL in group 2 and to [WL-2.0 mm] in group 4. Blind assignment was performed by another individual and specifically noted for post obturation assessment.

Forty canals were obturated according to manufacturer's instructions for RS1 (groups 1 and 3); and 40 canals were obturated per manufacturer's instructions for TP (groups 2 and 4). A light coating of RealSeal 1 SE™ root canal sealant (SybronEndo, Glendora, CA) was dispersed throughout the canal for all samples using absorbent points, which is a resin sealer consistent with manufacturer's recommendations. For groups 1 and 3, the RS-1 obturators were heated in a RealSeal 1 oven as specified by the manufacturer. For groups 2 and 4, the TP obturators were heated in a ThermaPrep Plus oven as specified by the manufacturer. Obturators for all samples were introduced into the canals and seated to WL in a single motion with a predetermined insertion rate of 2 seconds

from reference point to WL (7). A single operator was calibrated for consistency of insertion at this rate using a stopwatch by a board-certified endodontist familiar with this technique. Following obturation, excess sealer was rinsed away with 70% isopropyl rubbing alcohol (Henry Schein, Melville, NY) so the obturating material could be directly observed if extrusion existed beyond the apex.

The apices of the roots were evaluated by a single observer by 2 methods. The evaluator was blinded as to which canal preparation was being examined. During radiographic assessment, any sample which was radiographically not 3D obturated would have been excluded from the study. Throughout the study, no samples were excluded from any of the 4 groups. The second evaluation method assessed the apical extent of the obturations with a surgical operating microscope (Seiler IQ DOM, Seiler Precision Microscopes, St. Louis, MO) at 5X, and the extrusion of obturating material was graded ordinally as follows: (1) WL +/- 1.0 mm; and (2) > 1.0 mm beyond WL.

A logistic regression model was used to evaluate differences in apical extrusion between the obturators when controlling for canal preparation, and between the canal preparations when controlling for the obturators. Statistical analysis was conducted using SAS version 9.2 (SAS Institute Inc., Cary, NC) with significance set at (P = .05).

Results

The outcomes from each group are shown in Table 1. Statistically significant differences in extrusion were found in the canal preparation for TP (P = .026) (groups 2 and 4), and between TP and RS-1 obturators (P = .005) (Table 1). Also,

when using an STP, the overextension potential with TP is 21 times the overextension potential with RS-1. If a VTP is obturated with TP the overextension potential is 1.4 times the overextension potential with RS-1.

Table 1. Assessment of RS-1 and TP canal extension with both preparations.

RealSeal 1 Extension	Ordinal	STP Group 1 b ₁ , b ₂	VTP Group 3 c ₁ , c ₂
	1 (WL±1 mm)	18	17
	2 (>1 mm past WL)	2	3
Thermafil Plus Extension	Ordinal	STP Group 2 a, b ₁ , c ₁	VTP Group 4 a, b ₂ , c ₂
	1 (WL±1 mm)	6	16
	2 (>1 mm past WL)	14	4

*Same subscripts indicate statistically significant difference at P = .05 (logistic regression).

(a: P = .026; b₁, b₂, c₁, c₂: P < .001)

Discussion

The ultimate purpose of this study was to evaluate the effect of the geometry of the canal preparation on the extension of obturation material for two thermoplastic systems. An *ex vivo* study design reproducing apical resistance provided by an intact periodontal ligament would have biased the stated purpose. Inhibiting the flow of overextended material would have altered the assessment for the variable tested on the geometric effect of canal variation.

Another consideration was obturating the samples at room temperature instead of normal body temperature. The two systems were tested under similar conditions within 20°F of normal body temperature. The authors deemed this temperature differential to have negligible impact upon assessment of samples. The RS-1 obturators demonstrated similar overextension potential when using either of

the preparation techniques at the defined insertion rate. The TP obturators demonstrated more predictable length control when using the VTP at the defined insertion rate. The canal preparation was not a significant factor in the RS-1 groups and the incidence of overextension was lower overall compared to the TP groups.

The results of this study demonstrated that either the design of the RS-1 obturators and/or the material itself might be contributing factors for the outcomes observed. When design of the obturator systems used in this study is compared, the carriers of the RS-1 were more consistently centered within the tapered volume of obturation material. TP demonstrates more variability in the position of the carrier within the more parallel volume of gutta-percha, and often carriers were exposed through the gutta-percha along the length of the obturator. Lack of centering of the carrier within the TP obturators may have impacted the flow of the material within the canal.

The physical properties of the materials could also play a role in their behavior within the canal (7, 25-27). The gutta-percha of the heated obturator as it approaches the canal orifice is approximately 200°C. Thermoplasticized gutta-percha acts thixotropically allowing it to flow with less viscosity at faster insertion rates (i.e., more force)(19). For group 2, the viscosity was low enough to allow the gutta-percha to flow to WL, but with inadequate time to cool to avoid extrusion. In group 4, the gutta-percha viscosity permitted flow to WL while the VTP may have allowed the material time to cool, resulting in better length control. The thermoplasticized Resilon is approximately 160°C as the RS-1 obturator approached the canal orifices of the samples in groups 1 and 3. To date, there are no studies that

have described the thixotropy of RealSeal. However, since the rheopexy of thermoplasticized gutta-percha and Resilon were found to be similar (25-27), perhaps the lower temperature of the heated Resilon permits a faster cooling back to the original state at room temperature thus avoiding overextension in standard 0.04 preparations.

The results of this *in vitro* study suggest that when filling canals with RS-1 obturators at a specific insertion rate, a low likelihood of extrusion can be attained using either a standardized or varied tapered preparation. If the clinician prefers to use TP obturators, this study validates using a varied taper preparation will decrease the occurrence of overextension. Hence a varied taper canal preparation as demonstrated in this study allows for a more predictable obturation length.

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