ACCURACY OF DIGITAL SETTINGS OF ENDODONTIC HEAT PLUGGERS

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CERTIFICATE OF APPROVAL

MASTER'S THESIS

This is to certify that the Master's thesis of

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Distribution Statement

ABSTRACT

ACCURACY OF DIGITAL SETTINGS OF ENDODONTIC HEAT PLUGGERS

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Introduction: Confidence in the temperature of the electronic heat plugger is paramount to the provider to ensure proper heating of the gutta percha while minimizing risk for tissue damage. The primary aim of this study was to investigate the accuracy of the digital setting on three electronic obturation units (System-B, Calamus Dual, and Elements™) and secondarily, determine if the manufacturer, position from the tip, or the size and taper influence the heating of the electronic plugger. **Methods**: Three obturation units with corresponding pluggers were tested for accuracy of the display setting of 200 ºC. The temperatures were measured by a 4-Channel RDXL-SD Series portable thermometer (Omega Engineering Inc, Stamford, CT) with thermocouples in a custom 3-D printed jig. Measurements were recorded at four positions: the tip and 3.0 mm, 5.0 mm, and 8.0 mm. Temperature measurements were acquired every second for 4 or 5 seconds with the maximum temperature reached used for data analysis. One variable T-test was used to compare the actual temperatures to display temperature. Analysis of variance (ANOVA) and Tukey HSD for post hoc comparisons were used for secondary comparisons ($p < 0.05$). **Results**: A statistically significant difference between the plugger temperature and the display setting for all pluggers and units was found (p <

0.001). Statistical analysis revealed the Elements and System-B heated significantly higher at 0 and 3 mm compared to 5 and 8 mm ($p < 0.05$). Additionally, Calamus Dual data revealed no difference at the varying distances. Statistical analysis revealed the following relating to plugger size. The ML plugger was shown to have a statistically significant lower temperature than the other pluggers when tested in the System B unit. The XF plugger was shown to have a statistically significant lower temperature than the other pluggers when tested in the Elements unit. All Calamus dual pluggers demonstrated a statistical difference among the three sizes tested (S > M > L) ($p < 0.05$).

Conclusions: Heat pluggers did not reach the digital display settings. Heat pluggers used in the Elements and System-B obturation units heated higher closer to the tip of the plugger. Heating of the Calamus dual pluggers was related to size. Smaller pluggers reached a higher temperature than larger ones.

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LIST OF ABBREVIATIONS

º C	degrees centigrade
XF	extra fine
F	fine
FM	fine medium
M	medium
ML	medium large
S	small
L	large
mm	millimeters
SPSS	Statistical Package for the Social Sciences (IBM Corp)
ANOVA	analysis of variance
HSD	honest significant difference
V	volts

Chapter I: Introduction

Gutta percha is the most prevalent obturation material utilized to seal the canal system (1). It is a form of rubber that exists in two crystalline geometric phases, alpha (α) and beta (β) (2). The α-form of gutta percha is soft, tacky, and can be compacted. The β-form of gutta percha is a solid mass. When the β-form is heated above 56º C, it becomes amorphous and is easily compacted (2). Warm obturation techniques were introduced by Schilder, and later modified by Buchannan (Continuous-wave). Both techniques recommend using a heat carrier to soften the gutta percha, then vertically compacting it with hand pluggers in order to provide a high density, three-dimensional obturation (3, 4). Today, the most common way to heat gutta percha is with the use of an electronic heat plugger. Pluggers are connected to a unit that supply electricity that heats the pluggers. These units have been called gutta percha heating devices, heat carriers, and obturation units in the literature. For the purposes of this manuscript, obturation unit will be used to name the device that heats the attached heat pluggers. Early models, like the Touch n' Heat, were controlled by a single dial which corresponded to a manufacturer's published temperature. However, the Touch n' Heat's clinical temperature did not reach the published temperature level from the manufacturer (5-7). Some electronic obturation units (System-B, Elements, and Calamus) now allow the provider to set the unit to a specific temperature. Three previous *ex vivo* studies have found the System-B Heat source temperatures do not correspond to the actual heat plugger temperature. Venturi et. al (8) and Silver et. al (5) reported the System-B heat plugger temperatures were below the display temperature. The third study reported the System-B heat pluggers to have a wide range of temperatures, above and below the digital display temperatures (9). Without proper heating of the apical gutta percha, incomplete obturation may occur, potentially increasing the likelihood of a poor endodontic outcome (10).

Heated pluggers may also present a physiologic problem. The increase in temperature to the surrounding bone and tissue is potentially harmful. Ericksson and Albrektsson reported the safety threshold for periodontal tissues as an increase of 10º C above physiologic temperature for one minute (11, 12). There are studies that report the System-B unit can potentially cause a greater than 10º C increase in temperature on the external root surface (13, 14). Additionally, other studies have reported electronic heat pluggers to pose minimal risk to the surrounding tissue, however, these studies revealed the electronic heat pluggers did not reach the manufacturers stated temperature or were simply not reported (5, 8, 15-17). Without thorough knowledge of the actual plugger temperature, it is difficult to conclude if electronic heat pluggers pose a threat to surrounding tissue.

Confidence in the actual temperature of the electronic heat plugger is paramount to the provider to ensure proper heating of the gutta percha while minimizing the risk of tissue damage. A thorough investigation of the temperature accuracy of electronic heat carrier units and the potential influence of the plugger size and taper on their heat carrying capacity has not been completed. Thus, the primary aim of this study was to investigate the accuracy of the digital setting on three electronic heat carrier units (System-B, Calamus Dual, and Elements™) and secondarily, determine if the manufacturer, position from the tip, or the size and taper influence the heating of the electronic plugger.

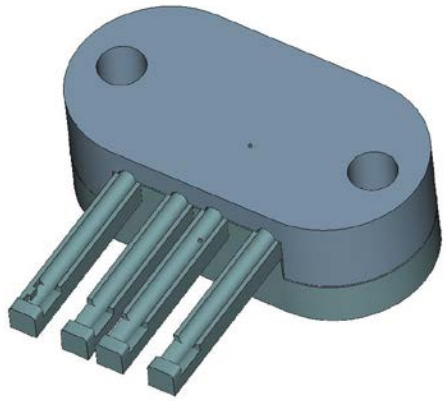
Chapter II: Material and Methods

The following three obturation units were tested for accuracy of the digital display: Elements Obturation Unit (Kerr Endodontics, Orange, CA), Calamus Dual System (Dentsply Sirona, Salzburg, Austria), and System B (Kerr Endodontics, Orange, CA). All systems were purchased for the purpose of this study and unused prior to data collection. Electronic heat pluggers tested with the Elements Obturation Unit and the System B were Buchanan Heat Pluggers (Kerr Endodontics, Orange, CA) sizes XF (.04), F (.06), FM (.08), M (.10), and ML (.12). Electronic heat pluggers tested with Calamus Dual system were the Calamus electrical heat pluggers (Dentsply Sirona, Salzburg, Austria) sizes S (40/.03), M (50/.05), and L (60/.06). All heat pluggers were purchased and unused prior to data collection for the purpose of this study. Three different sets of pluggers were tested three times with each obturation unit for a total of nine measurements per plugger.

The temperature generated by the electronic heat pluggers were recorded at four locations: the 0.0 and 3.0 mm, 5.0 mm, and 8.0 mm away from the tip. K-type thermocouples (Omega Engineering Inc, Stamford, CT) connected to a 4-Channel RDXL-SD Series portable thermometer/data logger (Omega Engineering Inc, Stamford, CT) were used to record the temperatures. Each thermocouple was coated with Omegabond “400” (Omega Engineering Inc, Stamford, CT), an electrically insulating, thermal conductive high temperature cement, to prevent bridging of the thermocouples. The plugger was placed on a custom jig with thermocouples located at corresponding measurements (Fig. 1). The jig was designed by 3-D Medical Application Center at Walter Reed National Medical Center using Solidworks® 2016 (Dassault Systémes, Waltham, MA). It was printed on Form 2 3D printer (Formlabs, Somerville, MA) using high temperature resin. The obturation units were set to the manufacturer's recommended temperature for clinical use 200º C. Temperature readings for the System B and Calamus Dual pluggers were acquired from the start of heat activation through 5 seconds. Due to an internal control, the Elements unit was activated for 4 seconds, at which time the unit automatically discontinued heating, therefore readings were acquired from the start of heat activation through 4 secs. The maximum temperature reached during the given time period was used for data analysis. Pluggers were tested in random order. If a plugger were to be tested in successive tests, a minimum of one minute passed between tests. This was repeated for all three obturation units and corresponding sets of pluggers. All measurements were taken at room temperature (19ºC ± 2ºC).

Data was analyzed using SPSS Version 22 (IBM Corp, Armonk, NY). One variable T-test was used to compare the actual temperatures to display temperature. Three variables were compared to the mean temperatures collected for further analysis. Analysis of variance (ANOVA) and Tukey HSD for post hoc comparisons were used. The significance level was set at $p < 0.05$.

a.



b.

FIGURE 1: Custom 3-D printed Jig (a) schematic drawing of jig (b) Data collection setup with data logger and thermocouples placed in jig

Chapter III: Results

All of the mean average temperatures, regardless of the obturation unit, plugger size, or distance away from the tip, failed to reach the display setting of 200 ºC. Figure 2 presents the mean temperature data and standard deviations for the different plugger sizes and distances from the tip for System B (a), Elements (b), and Calamus Dual (c). One variable T-test revealed a statistical difference between the actual plugger temperature and the display setting ($p < 0.001$). One of the FM pluggers used in the Elements unit exceeded the setting temperature in only one test, reaching a temperature of 221.5º C and 243.2º C at 0 and 3 mm, respectively.

<u>Temperature related to distance on the plugger</u>

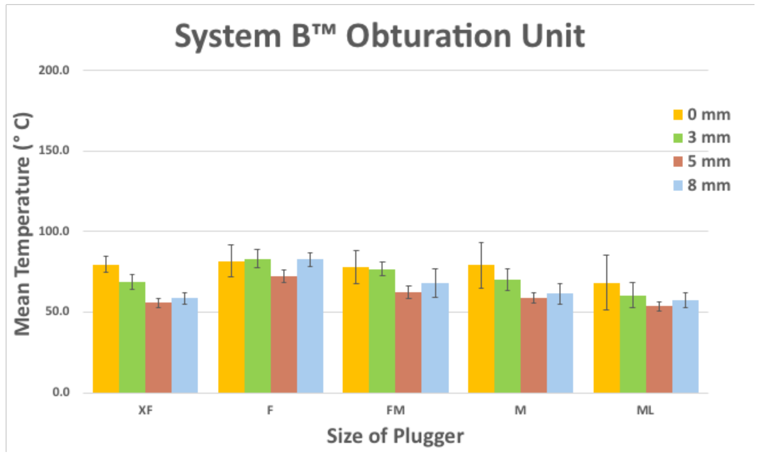
Table 1 presents the mean temperatures at the different distances from the tip for each of the three units tested. One-way ANOVA revealed mean temperature difference at the tested distances for the Elements and System B units. Further analysis with a Tukey HSD post hoc revealed for both systems, 0 and 3 mm were significantly higher than 5 and 8 mm ($p < 0.05$). Calamus Dual ANOVA revealed no statistical difference at the various distances.

<u>Temperature related to size of the plugger</u>

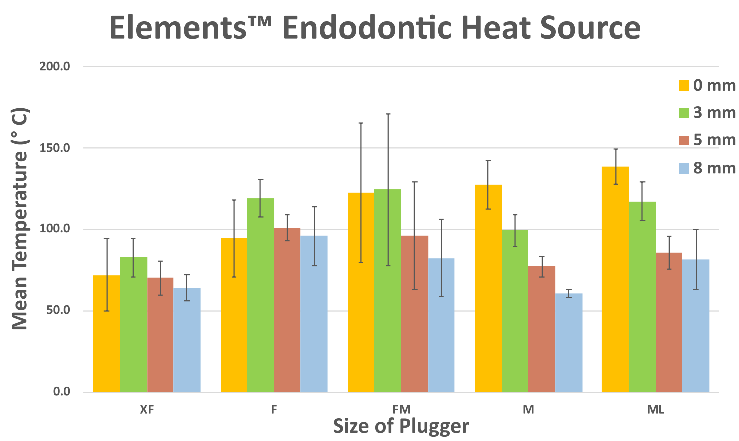
Due to the Tukey HSD analysis resulting in the 0 and 3 mm distance on the System B and Elements pluggers being statistically higher than 5 and 8 mm, the data those two distances were combined and the mean temperature calculated for each plugger size (Table 2). ANOVA revealed mean temperature difference for the different size pluggers and a Tukey HSD post hoc was completed for both. The ML plugger size when used with the System B unit was shown to have a statistically significant lower temperature than the other pluggers. No other significant differences were found among the pluggers when used with System B. The XF plugger mean temperature when used with the Elements unit was shown to have a statistically significant lower temperature than the other pluggers. No other significant differences were found among the pluggers when used with the Elements unit.

Table 3 presents the mean temperatures of the different size pluggers for the Calamus Dual unit. ANOVA revealed mean temperature difference for the different size pluggers and a Tukey HSD post hoc was completed. The mean temperatures of the S, M, and L plugger was shown to all be statistically different from each other. The pluggers heated to a higher temperature the smaller it was (S > M > L).

a.



b.



c.

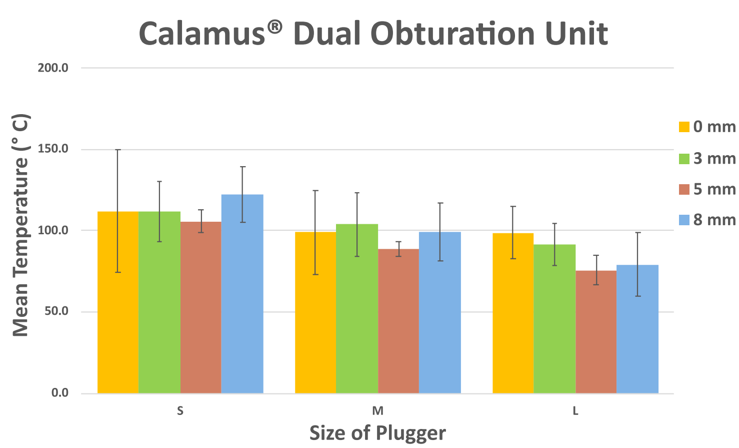


FIGURE 2: The mean temperature and standard deviations at different distances from the tip for each plugger size for System B (a), Elements (b), and Calamus Dual (c)

TABLE 1: Mean Plugger Temperatures at varying distances from the tip

Obturation Unit	Depth	Mean (° C)	Standard Deviation
System B	0*	77.4	12.4
	3*	71.9	9.6
	5	60.5	7.3
	8	65.6	10.9
Elements	0*	111.1	34.4
	3*	108.6	27.1
	5	86.2	19.7
	8	76.9	20.2
Calamus Dual	0	103.3	27.6
	3	102.5	18.5
	5	90.3	14.3
	8	100.5	25.1

***statistical difference, $p < 0.05$**

TABLE 2: Mean Plugger Temperatures at 0 and 3 mm

Obturation Unit	**Size**	**Mean (° C)**	**Standard Deviation**
System B	XF	74.2	7.4
	F	82.5	7.8
	FM	77.5	7.6
	M	74.6	11.9
	ML*	64.4	13.4
Elements	XF*	77.4	18.0
	F	106.9	22.1
	FM	123.5	43.3
	M	113.4	18.8
	ML	128.0	15.8

***statistical difference, $p < 0.05$**

TABLE 3: Mean Plugger Temperatures of different sizes

Obturation Unit	**Size**	**Mean (° C)**	**Standard Deviation**
Calamus Dual	S*	113.1	22.7
	M*	97.9	18.6
	L*	86.4	17.1

***statistical difference, $p < 0.05$**

Chapter IV: Discussion

To ensure accurate simultaneous temperature measurements along a plugger with thermocouples, a custom jig was fabricated and used. Four projections, each with a channel, allowed the thermocouples to be attached and secured (Fig. 1). Temperature measurements were taken at the tip of each plugger and three other locations (3, 5 & 8 mm) away from each plugger tip. Each thermocouple projection flexed to provide resistance against the plugger to ensure solid contact while temperature measurements were taken. The jig had a positive rest on one of the terminal projection to ensure all thermocouples were lined up at the correct distance from the tip, thus providing a reproducible method for temperature measurements. Dimopoulos et al (18) examined temperature change of System B pluggers using a design meant to eliminate heat exchange between the plugger and the environment. Their temperatures recorded for System B were similar to the temperatures recorded within this experimental design. The maximum temperature reached in each experiment was 94º C. The similarity in data helps to support that both experimental designs are accurate and reliable. The heat lost from the plugger to the environment is negligible. This study's results demonstrate the jig utilized provided stable and reproducible contact between the thermocouples and the plugger.

All obturation units were utilized according to manufacturer's recommendations. The System B unit was fully charged prior to use. Both the Elements and Calamus Dual unit recommend a 115 V outlet. The same outlet was used for each unit and verified at 122 V. All units and pluggers tested were new to minimize variability from usage.

Further testing is needed to determine if the amount of use of either of the units or pluggers affect the accuracy of the temperature.

The results of this study reveal the actual temperature of the pluggers do not correspond with the temperature digital display settings of the System B, Elements, and the Calamus Dual. Only one plugger, the FM when used with the Elements unit exceeded the display temperature and it occurred only once during its three tests. Previous studies reported the Buchanan pluggers provided the highest temperatures at the tip (18) and 2 mm (8) from the tip. The results of this study revealed no statistical difference between the tip and 3 mm from the tip. The Calamus pluggers did not demonstrate any difference in temperature produced at the four different positions. This study revealed the System B ML plugger produced significantly lower temperatures than the other four sizes. Dimopoulos et al (18) reported the opposite, the ML plugger produced significantly higher temperatures than the other pluggers. XF plugger in the Elements unit produced a significantly lower than the other four sizes. In terms of size, no statistical differences were noted in heating of the Buchanan pluggers when used with the System B and Elements unit. The Calamus plugger data revealed smaller pluggers heat significantly higher than larger ones.

Damage to the surrounding tissue has been a clinical concern when using heated pluggers. Many studies have investigated the root surface temperature change and compared it to the harmful 10º C rise in temperature as stated by Eriksson and Albrektsson (11). System B has been widely studied and found to not induce harmful external root surface temperatures when used below 250º C, which is higher than the manufacturer's recommended setting (5, 8, 14, 17). Unfortunately, in these studies, the exact temperature of the pluggers were unknown, and therefore, difficult to make any definitive conclusions on the safety of electronic heat pluggers in clinical practice. *In vitro* studies are difficult to design to replicate *in vivo* conditions. Periodontal ligament (PDL) tissue and vasculature influence the thermal conductivity of the external root surface, having an impact on the temperature rise of the bone (18). A finite element analysis revealed PDL blood flow reduced the peak temperature at the alveolar bone when System B was used as the heat source (19). With this new data, studies looking to investigate the safety of heated plugger temperatures *in vivo* need to consider the cooling capacity of the periodontal blood flow.

With the implications of possible surrounding tissue damage, does the setting of obturation unit need to be as high as the manufacturer recommends? Studies over the last 26 years have shown that heat sources do not heat to the unit's settings (5-9, 18). When comparing obturation technique as a factor for healing, a study, that utilized Touch n' Heat or System B for warm vertical obturation, healed 87% compared to 77% for cold lateral obturation (20). Although temperature measurements were not taken during treatment in this study, it can be inferred that clinical outcomes are not affected by lower plugger temperatures. Pluggers at a confirmed temperature, approximately 60º C, are hot enough to induce the phase change in gutta percha (21). Reducing the temperature could potentially eliminate the harmful impact of hotter pluggers.

Chapter V: Conclusions

In summary, the display setting temperature of System B, Elements, and Calamus Dual obturation units is not accurate. For the System B and Elements obturation units that use Buchanan pluggers, temperatures at the tip were the hottest and decreased with distance away from the tip. The Calamus Dual pluggers heat better when a smaller plugger is used. The use of new obturation units and new pluggers does not always accurately represent typical clinical situations. Providers are using the obturation units for extended periods of time and reusing the sterilized pluggers. Therefore, more studies are necessary to determine the accuracy of the digital settings after the units and pluggers have been used under clinical settings. Additionally, further studies are needed to determine if pluggers closer to the gutta percha phase change can be used clinically and if the lower temperature pluggers actually induce damage to surrounding tissue.

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