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Comparison of Calcium Hydroxide Extrusion with Syringe vs Spiral Filler Delivery: A Pilot Study

Gordon San Lai
University of the Pacific, g_lai@u.pacific.edu

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Gordon Lai, DDS

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Approved by:

Alan H. Gluskin, DDS ________________
Mentor

Christine I. Peters, DMD ________________
Thesis Committee Member

Ove A. Peters, DMD, MS, PhD ________________
Thesis Committee Member

Johnah Galicia, DMD, MS, PhD ________________
Graduate Program Director

Comparison of Calcium Hydroxide Extrusion with Syringe vs Spiral Filler Delivery: A Pilot Study

Lai G, Davis S, Gluskin AH, Peters CI, Peters OA

Abstract

Introduction: The aim of this study was to evaluate the frequency and amount of $Ca(OH)_2$ extrusion in relation to the intracanal delivery technique, apical foramen size, and depth of placement. **Methods:** Standardized training blocks with j-shaped canals were used (n=64); half of the simulated canals were shaped to apical size #35(.06 taper) and the remaining 32 to #45(.06). The frequency and extent of $Ca(OH)_2$ extrusion were measured relative to apical taper, the depth of insertion, and whether syringe or spiral filler was used. Blocks were immersed in pH-sensitive gel and observed for color change. The visible extent of extrusion, indicated by color change, was determined as area and expressed in mm^2. **Results:** Extrusion of $Ca(OH)_2$ occurred in 48/64 of the samples. At 3mm from the canal terminus, the device type had a significant effect on the frequency of extrusion, with syringe placement causing extrusion significantly ($p<0.01$) more frequently, irrespective of device size. Amounts of extrusion were significantly larger at 2mm short of the canal terminus (median 27.44mm^2, IQR 10.02), compared to 3mm distance (median 19.69mm^2, IQR 25.07; $p<0.0001$). Analyzed separately at 2 and 3mm distance, respectively, there was significantly more extrusion with placement using a syringe size #35 compared to spiral filler size #45. **Conclusions:** Considering the limits of the *in vitro* experimental design, a spiral filler at 500rpm, placed 3mm short of the apex found to minimize extrusion of $Ca(OH)_2$ placed in root canals.

KEY WORDS

Calcium hydroxide, extrusion injury, overfill, spiral filler, syringe

Introduction

Calcium hydroxide [$Ca(OH)_2$] has been widely used as an intracanal medicament after its introduction nearly one hundred years ago. Its popularity is mainly due to biological properties of $Ca(OH)_2$ such as antibacterial activity (1), and to an ability to dissolve remaining soft tissues (2, 3). It also serves as a physical barrier inside the pulpal chamber to prevent bacterial recontamination (1).

In order for $Ca(OH)_2$ to achieve its maximum antimicrobial benefit, it is critical for the medicament to be placed sufficiently close to the area to be disinfected (4). In fact, it is considered relevant for an intracanal $Ca(OH)_2$ delivery method to achieve a dense and uniform fill extending to the apical region (5).

In the past, several techniques and specialized instruments for intracanal placement of $Ca(OH)_2$ have been advocated. These can fall into 3 broad categories: (a) injection techniques that utilize a syringe to insert the $Ca(OH)_2$ (b) techniques either with hand files or spiral rotary instruments, such as a Lentulo, at different rotational speeds (c) ultrasonic techniques using specially designed attachments(6). According to previous studies, the effectiveness of these methods varies (7-9). The challenge for a clinician is to predictably deliver $Ca(OH)_2$ into the apical region, while also minimizing the possibility and amount of material extrusion. As illustrated by clinical cases, the effects of a $Ca(OH)_2$ overfill can be traumatizing and indeed life changing for patients; the most deleterious effects are seen when the material is delivered in close proximity with neurovascular structures (10). However, a review of prior studies did not specify specific protocols that are best suited to prevent extrusion of $Ca(OH)_2$ while optimizing placement (10).

A literature search pertaining to this topic found only two experimental studies that focused on investigating the amount of $Ca(OH)_2$ extrusion with different intracanal $Ca(OH)_2$ delivery techniques. One study compared the delivery of $Ca(OH)_2$ with a Lentulo versus Pastinject (6). The results showed that using either method at 3mm short of working length prevented $Ca(OH)_2$ extrusion. It also demonstrated that having Lentulo spiral rotation speed at 500rpm prevented extrusion from occurring. The second study evaluated how Lentulo usage at different rotational speeds (20,000, 10,000, 5,000rpm) compared to hand filing would affect the amount of $Ca(OH)_2$ extrusion (11). There was no significant difference among the groups, however at 5,000rpm the spiral group showed less cases of extrusion from the higher rpm groups.

Given the scarcity of comparative studies evaluating the safety of various $Ca(OH)_2$ delivering techniques, the current pilot study was conducted. The aim of this study was to evaluate the frequency and amount of extrusion of $Ca(OH)_2$ from the apical foramen in relation to the $Ca(OH)_2$ intracanal delivery technique, the apical foramen size, and depth of placement.

More specifically, this study compared two different delivery systems for the placement of a $Ca(OH)_2$ paste. The dependent measure was the amount of extruded paste and independent parameters included the apical size and the location of the delivery device in relation to the working length.

Based on these parameters, the following null hypotheses (H0) were tested: H0 (1): There will be no significant differences in terms of apical extrusion with regards to the delivery method of $Ca(OH)_2$. H0 (2): There will be no significant differences in terms of apical extrusion with regards to the apical size. H0 (3): There will be no significant differences in terms of apical extrusion with regards to depth of $Ca(OH)_2$ placement.

Materials and Methods:

Specimens

A total of 64 ISO 15, 0.02 taper, Endo Training Blocks with j-shaped canals (Dentsply Maillefer, Ballaigues, Switzerland) were used. The blocks were randomly divided into two groups with 32 blocks each based on delivery method: Group 1 (syringe), Group 2 (spiral filler at 500rpm). The groups were subdivided into 4 subgroups (A,B,C,D) with 8 blocks each, based on the apical size as well as depth of placement of calcium hydroxide into the canals:

A: Apical size #35 (.06) with depth of placement 2mm short of canal terminus

B: Apical size #35 (.06) with depth of placement 3mm short of canal terminus

C: Apical size #45 (.06) with depth of placement 2mm short of canal terminus

D: Apical size #45 (.06) with depth of placement 3mm short of canal terminus

Canal Preparation

Group 1:

Canals in all 32 blocks were enlarged up to a size #20 K-file (Dentsply Maillefer) to obtain a glide path. The blocks were then randomly divided into two groups of sixteen each. For 16 of the blocks, Vortex Blue rotary files (Dentsply Sirona, York, PA, USA) were used until the canal terminus was enlarged to #35 (.06). Between each file, the canal was irrigated with distilled water using a 27-gauge needle (Ultradent, South Jordan, UT, USA) and a #10 K-file was advanced until the tip passed 1mm from the canal terminus to maintain patency. Eight of these blocks were randomly assigned to Group A, and the remaining to Group B.

For the remaining blocks, Vortex Blue rotary files were used until the canal terminus was enlarged to #45 (.06). Between each file, the root canal was irrigated with distilled water using a

27-gauge needle and a #10 K-file was advanced until the tip passed 1 mm from the canal terminus to maintain patency. Eight of these blocks were randomly assigned to Group C, and the remaining to Group D.

Group 2:

All 32 blocks were prepared as previously described in Group 1.

Embedding Specimens

After all specimens had canals prepared to their final apical sizes, each block was inserted in a 3D printed platform and secured inside a flat-sided clear plastic container (Fig. 1a). The samples were embedded as previously described (12). Each container was filled to 2mm below the top of the block with 0.3% agarose gel (Sigma-Aldrich, St Louis, MO, USA) containing 0.0013% m-Cresol purple (Sigma-Aldrich). M-Cresol purple dye has a pH sensitive color change from yellow at a pH of 7.4 to purple at a pH of 9 (12). Preliminary experiments had demonstrated that $Ca(OH)_2$ with its pH of 11-12 upon extrusion caused a color change to purple, indicative of extrusion into the gel. All experiments were completed within 3 hours of the gel setting.

Placement of $Ca(OH)_2$

The selected $Ca(OH)_2$ intracanal delivery systems included were: Navident 29 gauge Navitip (Ultradent, South Jordan, UT, USA), and a Lentulo spiral (Dentsply Maillefer) at 500rpm. Before $Ca(OH)_2$ placement in each of the samples, aluminum foil was used to wrap the containers to blind the operator during the delivery process.

Group 1: (Syringe Delivery)

Group 1A (Apical size #35 (.06) 2mm short of canal terminus, n=8)

The $Ca(OH)_2$ paste was delivered into the canal 2mm short of the canal terminus by syringe technique (n=8). A length marker was placed at 13mm of the syringe tip with a silicone stopper. Then, the syringe tip was inserted into the canal until the proper depth was reached and confirmed that the syringe tip was not binding. While withdrawing the syringe, the paste was applied slowly and continuously from the apical to the coronal part until the paste was flush with the canal orifice.

Group 1B (Apical size #35 (.06) 3mm short of canal terminus, n=8)

The $Ca(OH)_2$ paste was delivered into the canal 3mm short of the canal terminus by syringe technique (n=8). A length marker was placed at 12mm of the syringe tip with a silicone stopper. Then, the syringe tip was inserted into the canal until the proper depth was reached and confirmed that the syringe tip was not binding. While withdrawing the syringe, the paste was applied slowly and continuously from the apical to the coronal part until the paste was flush with the canal orifice.

Group 1C (Apical size 45 (.06) 2mm short of canal terminus, n=8)

The $Ca(OH)_2$ paste was carried into the root canal by syringe technique as previously described in Group 1A.

Group 1D (Apical size #45 (.06) 3mm short of canal terminus, n=8)

The $Ca(OH)_2$ paste was carried into the root canal by syringe technique as previously described in Group 1B.

Group 2: (Spiral filler at 500rpm)

Group 2A: (Apical size #35 (.06), 2mm short of canal terminus, n=8)

The $Ca(OH)_2$ paste was delivered into the canal 2mm short of the canal terminus with a Lentulo (n=8). Insertion length was marked at 13mm of a size #30 Lentulo with a silicone stopper. The Lentulo size was selected to be a size smaller than the apical size to ensure the file is able to reach the targeted depth without binding. The working surface of the Lentulo was coated with the paste, inserted in the canal while rotating at 500rpm using an endo handpiece mounted on an endodontic motor (SybronEndo Elements, Kerr, Orange, CA, USA) until the proper depth was achieved. A cotton pellet was used to gently compact the paste at the orifice. This procedure was repeated a total of three times for each block.

Group 2B: (Apical size #35 (.06) 3mm short of canal terminus, n=8)

The $Ca(OH)_2$ paste was delivered into the canal 3mm short of the apical foramen with a Lentulo (n=8). Insertion length was marked at 12mm of a size #30 spiral with a silicone stopper. The Lentulo size was selected to be a size smaller than the apical size to ensure the file is able to reach the targeted depth without binding. The working surface of the Lentulo was coated with the paste, inserted in the canal while rotating at 500rpm using an endo handpiece mounted on an endodontic motor (SybronEndo Elements, Kerr, Orange, CA, USA) until the proper depth was achieved. A cotton pellet was used to gently compact the paste at the orifice. This procedure was repeated a total of three times for each block.

Group 2C: (Apical size #45 (.06) 2mm short of canal terminus, n=8)

The $Ca(OH)_2$ paste was carried into the root canal with a Lentulo as previously described in group 2A except a #40 Lentulo was substituted for the previous #30 size.

Group 2D: (Apical size #45 (.06) 3mm short of canal terminus, n=8)

The $Ca(OH)_2$ paste was carried into the root canal with a Lentulo as previously described in group 2B except a #40 Lentulo was substituted for the previous #30 size.

All clinical procedures were performed by a single experienced operator.

Assessment of Extrusion

The block/gel setup was positioned in front of a light box for transillumination and digitally photographed in mesial/distal (MD) direction by using a SLR camera (Canon, Lake Success, NY, USA) positioned at a fixed distance (27cm). To standardize the time for diffusion of the dye, the gel was photographed exactly 10 minutes after delivery of the $Ca(OH)_2$ (13). The images were analyzed by using ImageJ (version 1.52; National Institutes of Health, Bethesda, MD, USA) to determine the area of the gel color change expressed in mm^2 (Fig. 1b-e).

Statistical Analysis

Data for extruded amounts were not normally distributed and are therefore presented as median with interquartile range (IQR). Chi-square tests were used to compare the frequency of overfills in each groups; Mann Whitney and Kruskal-Wallis tests were used to contrast amounts of overfills. P values of <0.05 were considered significant. Statistical analyses were completed with GraphPad Prism 8.4.3 (GraphPad Software, Inc., San Diego, CA, USA).

Results

Frequency of Extrusion

Overall, extrusion of $Ca(OH)_2$ in amounts measurable in this study occurred in 48/64 of the samples. Table 1 shows the frequencies in each groups; extrusion was more frequently present with insertion to 2mm ($p<0.0001$), independently of the device type and size. At 3mm from the canal terminus, the device type had a significant effect on the frequency of extrusion, with syringe placement causing significantly ($p<0.01$) more frequent extrusion, irrespective of device size. Figure 2 illustrates in the shaded areas the two clusters that appeared to separate, placement with either technique at 2mm and with the syringe at 3mm, compared to Lentulo placement at 3mm distance from the canal terminus. Overfill incidence was 43/48 (89.5%) in the red area compared to 5/16 (31.13%) in the green area.

Amount of Extrusion

Areas of color change observed ranged from 16.67 to 54.91mm^2; Figure 2 shows the distribution of values in each group. Amounts of extrusion were significantly larger at 2mm distance from the canal terminus (median 27.44mm^2, IQR 10.02), compared to 3mm distance (median 19.69mm^2, IQR 25.07; $p<0.0001$). Analysed separately at 2 and 3mm insertion depth, respectively, there was significantly more extrusion for placement with a syringe size #35 compared to Lentulo size #45; all other comparisons did not reveal significant differences in the amounts of extrusion.

Discussion

At present, various commercially available formulations of non-setting $Ca(OH)_2$ pastes are used by practitioners. These formulations typically consist of $Ca(OH)_2$ in aqueous solution mixed with additional components that determine the radiopacity as well as viscosity. Compared to traditional chairside pastes, these commercially available formulations have a creamy consistency which allows easier placement with a syringe and also offers a time saving advantage(14).

The main concern of using a non-setting $Ca(OH)_2$ with syringe delivery is that this method may be associated with a higher risk of apical extrusion. One possibility for this is the needle could be binding inside the canal creating excessive pressure or another possibility could be due to the fact that it is used more frequently by clinicians compared to a spiral filler (10).

In the United States of America, one of the commonly used non-setting $Ca(OH)_2$ pastes is Ultracal XS, hence why it was selected for this pilot study. According to the manufacturer's instructions of use, the recommendation is to deliver the paste preferably with NaviTip (29 gauge), and to stay at least 2mm shy of the apex for safety purposes. Based on these guidelines, a 2=mm distance from the canal terminus was adopted as the minimum distance away and to utilize the recommended NaviTip method of delivery. For comparison, a 3mm distance from the canal terminus was selected as option since a previous study has shown that being 3mm away is preferred, preventing extrusion while still optimizing disinfection (6).

In this study, results showed that at 2mm short of the canal terminus, all of the samples using NaviTip had extrusion regardless of apical size. Practitioners need to be mindful of this and exhibit caution especially when in close proximity to neurovascular anatomy or sinuses.

As an alternative delivery method, Lentulo was used since several studies have shown that this delivery is more effective than the syringe in delivering $Ca(OH)_2$ within the canal (15-17). Studies have varied with regards to the optimal rotational speed. In general the consensus is that the higher the rotational speed, the better density of fill but also greater risk of extrusion (11). A previous study demonstrated that using a Lentulo at 500rpm was sufficient to prevent any extrusion in their samples (6), therefore this rotational speed was selected. The results from the present study are at partial disagreement with the findings of that previous study since there were several Lentulo samples with extrusion although less frequent than the syringe samples. One possible reason to explain this difference could be due to the different types of $Ca(OH)_2$ used. In the previous study, analytical grade $Ca(OH)_2$ was mixed with saline to create a thicker paste which could have helped minimize extrusion as compared to the less viscous Ultracal XS formulation. Furthermore, in the previous study, an apical constriction was created 1mm short of the actual apical foramen. Having an artificial constriction could serve as a deterrent for extrusion. Another possible explanation could be the difference in using plastic blocks used in the present study as compared to extracted teeth in the previous one.

Studies have shown that an increase in the apical foramen size can lead to more extrusion of irrigants and debris (18). This correlates with $Ca(OH)_2$ extrusion injury case reports that indicate most extrusions happen when the apical size is #40 and greater (19-22). Thus, the present study investigated apical sizes in a similar range. Interestingly, the results suggested a tendency for more extrusions occurring with the smaller apical size (size #35 as compared to #45), which should warrant further investigation.

One limitation of the aforementioned extrusion studies (6, 11) was they only evaluated whether or not $Ca(OH)_2$ extrusion was visible but did not try to quantify the amount. This study used imaging software to quantify the amount so that comparisons could be made as well.

Another limitation of the previous studies was that no attempt to simulate periapical tissue conditions was done; this could result in overestimation of the amount of extrusion (23). For this study, an agar gel model previously used in studies to assess NaOCl extrusion was adapted in order to simulate periapical resistance (13). However, caution should be exercised before generalizing these results to the clinical situation, because the density of the gel has not been calibrated with an intact periodontal ligament. Furthermore, the gel allows for continuous diffusion of $Ca(OH)_2$ and expansion of the impacted area as long as the pH remains above 9. To overcome these limitations, photographs were taken exactly 10 minutes after the delivery of $Ca(OH)_2$ to standardize the amount of diffusion (13).

The present study has further limitations including the use of plastic blocks and the use of only one type of $Ca(OH)_2$. For these reasons, the results may not directly applicable to actual clinical situations. However, considering the limits of an *in vitro* experimental design, the best way to apply $Ca(OH)_2$ appears to use a spiral filler at 500rpm, placed 3mm short of the apex. Apical size did not have an effect as much as insertion depth but a larger apical size showed less overall extrusion.

It is also worth noting that even though Ultracal XS material was chosen for this study, the same conclusions may apply to other non-setting $Ca(OH)_2$ pastes with similar consistency.

Since there is minimal research published with regards to the topic of this study, further well-designed follow-up investigations are needed for different parameters that may have an effect on $Ca(OH)_2$ extrusion. Future studies could assess different types of calcium hydroxide products, different syringe types and sizes as well as different spiral filler sizes and rotational speeds. In addition, studies could also investigate if different canal and apex morphologies have an effect on the extrusion of $Ca(OH)_2$. In the present experiment, one operator was used to standardize the amount of periapical pressure and delivery method. It would be interesting to evaluate if different users exerting different amounts of pressure when injecting the paste can have an effect. Nevertheless, it may be concluded from the findings in this pilot study that a spiral filler at 500rpm, placed 3mm short of the apex found to minimize extrusion of $Ca(OH)_2$ placed in root canals.

Table and Figure Legends

TABLE 1: Frequency of extrusion in each sample group.

2mm distance from the canal terminus

Device	**Syringe**		**Spiral Filler**	
Apical size	35	45	35	45
Extrusion present	8	8	6	8
Extrusion absent	0	0	2	0

3mm distance from the canal terminus

Device	**Syringe**		**Spiral Filler**	
Apical size	35	45	35	45
Extrusion present	8	5	4	1
Extrusion absent	0	3	4	7

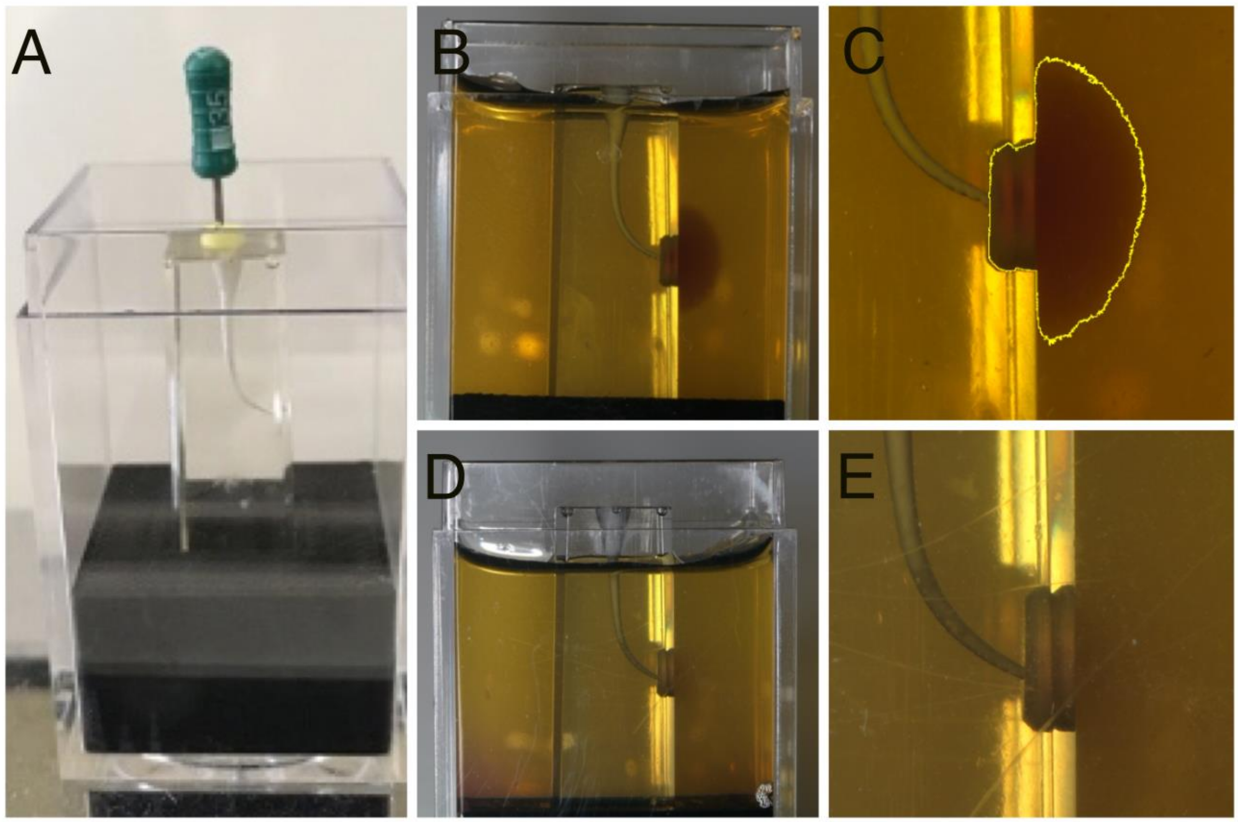

FIGURE 1- (A) View of the 3D printed platform and placement of plastic block in container**.** (B) Representative sample with color change as evidence of extrusion. (C) Sample under 1.5x magnification shows highlighted area in yellow, which represents the area calculated with ImageJ. (D) Representative sample with no extrusion. (E) Sample under 1.5x magnification showing no extrusion.

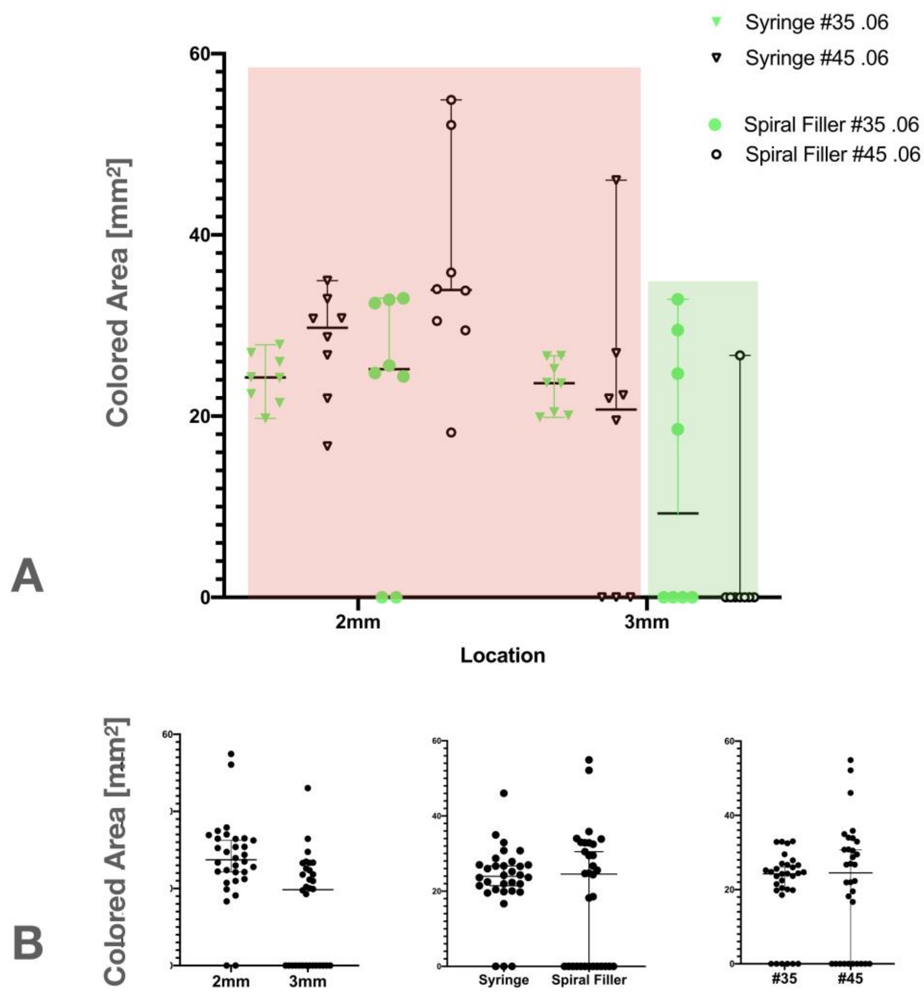

FIGURE 2 Distribution of all extrusion areas, grouped by distance from working length in A. The shaded in color indicate the two clusters associated with more (red) and less (green) overfill. Differently pooled data, grouped by distance, application instrument and preparation size at working length is shown in B.

Note: Data is shown as scattergrams with median and 95% CI.

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