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Evaluation of the Quality of Root Canal Obturation Using Resin and Silicon-Based Sealers: A Randomized Clinical Trial

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Aim: to assess and compare the quality of root canal obturation using AH Plus and GuttaFlow 2 in patients with symptomatic irreversible pulpitis.
Materials and methods: This randomized clinical trial included 50 participants with mandibular molars diagnosed with symptomatic irreversible pulpitis. Participants were randomly assigned to two groups: the AH Plus group (RBS) and the GuttaFlow 2 group (SBS). Clinical procedures included local anesthesia, access cavity preparation under a surgical microscope, rubber dam isolation, and root canal preparation using the ProTaper Gold system. For the RBS group, AH Plus sealer was used with cold lateral condensation, while for the SBS group, GuttaFlow 2 was used with a cold free-flow compaction technique. Following endodontic treatment, coronal restoration was performed using flowable composite. Outcome assessment involved evaluating sealer extrusion together with the level of root filling and root-filling voids.
Results: A total of 47 participants successfully completed the study. Regarding gender and age, no significant difference was shown between the groups in the demographic data. Qualitative analysis indicated no significant difference between the two materials in terms of voids, length, and extrusion ($p<0.05$).
Conclusion: Both sealers provided comparable quality of root canal obturation, as evident by similar rates of sealer extrusion together with adequate levels of root filling and root-filling voids. The findings suggest that clinicians can choose either sealer based on preference or specific clinical scenarios without compromising treatment quality.

Keywords: root canal obturation, root canal sealers, Guttaflow 2, AH-plus

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Introduction

The long-term success of endodontic treatments largely hinges on the quality of root canal obturation.[1] The primary objective of obturation is to entirely seal the root canal system, preventing bacterial re-entry and fluid leakage, thus avoiding reinfection and treatment failure. [2] Root canal sealers are essential in this operation since they fill the gaps between the walls of the root canal and the core filling material, usually gutta-percha. This improves the seal and reduces the chance of microleakage.[3]

Different types of sealers are available, each with distinct properties and clinical applications. Resin-based sealers, such as AH Plus, and silicone-based sealers, like GuttaFlow 2, are widely used due to their advantageous characteristics.[4] AH Plus is recognized for its excellent sealing ability, low solubility, and strong adhesion to dentin, making it a gold standard among endodontic sealers as it has a long track of success. [5] It is radiopaque, facilitating easy visualization on radiographs, and has appropriate working and setting times, which enhance its usability in clinical settings.[6]

Conversely, GuttaFlow 2 is a silicone-based sealer that integrates gutta-percha powder with a polydimethylsiloxane matrix.[7] This combination provides unique benefits, such as excellent flow into the root canal system, biocompatibility, and minimal shrinkage upon setting.[8] Its thermoplastic nature allows it to be used with a cold free-flow compaction technique, simplifying the obturation process and reducing voids. [9]

Achieving high-quality obturation requires not only selecting the appropriate sealer but also ensuring precise application. Evaluating parameters such as sealer extrusion together with the level of root-filling and root-filling voids is essential for assessing obturation quality.[10] Sealer extrusion beyond the apex can cause periapical inflammation and postoperative pain.[11] while voids within the root filling can serve as pathways for bacterial leakage and shelter surviving bacteria, compromising the treatment outcome.[12]

Understanding the performance of different sealers is crucial for clinicians to make informed decisions during endodontic procedures. Additionally, a systematic review[13], highlighted the importance of selecting sealers based on their biocompatibility and sealing ability, affirming that both AH Plus and GuttaFlow 2 remain popular due to their proven efficacy. However, further research is needed to provide a comprehensive evaluation of these sealers in clinical practice.

This study aims to assess and compare the quality of root canal obturation using AH Plus and GuttaFlow 2 in patients with symptomatic irreversible pulpitis. By evaluating radiographic parameters such as sealer extrusion together with the level of root-filling and root-filling voids, this research seeks to provide insights into the clinical performance of these widely used sealers and support evidence-based endodontic practice. The null hypothesis was that there would be no difference in obturation quality between the AH plus and Guttaflow 2.

Materials and methods

Ethical considerations

This trial was conducted with the approval of the ethics committee at the Faculty of Dentistry, British university, Cairo, Egypt (FDBUE-REC-22-017) and the protocol was registered at the clinicaltrials.gov (ID: NCT05841290). The procedures were explained in detail to the patients along with any side effects. Patients were not promised any incentive on approval of participation nor warned of any consequences/punishments upon refusal. Patients who did not meet the eligibility criteria for the study enrollment had received an appropriate treatment according to ethical

regulation, in complete adherence to the rules set out by the World Medical Association Declaration of Helsinki (2008).

Trial design and Sample size calculation

The study was designed as a randomized controlled trial with 2 parallel groups, with 1:1 allocation ratio. Sample size calculation was performed using G power (3.1.9.4) software, based on a previous study.[14] using an alpha (α) level of 0.05 and beta (β) level of 0.85. The predicted sample size (n) is a total of 40, number of patients was increased by 20 % to count for dropout.

Eligibility criteria

Patients for this study were chosen from the outpatient clinic of the Endodontic Department at the Faculty of Dentistry, British university, Cairo, Egypt, during the period from May 11th, 2023, to April 4th, 2024. Every patient was provided with information on the treatment's indications, advantages, hazards, and possible problems. All participants provided written informed consents.

Inclusion criteria

Patients aged 18 to 50 years old, with the first mandibular molar diagnosed with symptomatic irreversible pulpitis, were included in the study. These patients exhibited a positive response to Endo-Ice (1,1,1,2 Tetrafluoroethane; Hygenic Corp) and the response to the low voltage output of an electric pulp tester (Diagnostic Unit, Sybron) verified the diagnosis of "symptomatic irreversible pulpitis". A negative reaction to touch and percussion, as well as radiographic evidence of bony alterations with a PAI score of 1, corroborated the periapical diagnosis. Only mandibular first molars with three root canals were included to avoid the effect of the wide morphological variations reported in Egyptian population.[15,16]

Exclusion Criteria

Patients were excluded if they presented with teeth that had immature roots, non-restorable teeth, medically compromised conditions with systemic complications, necrotic teeth, teeth with apical periodontitis or periapical lesions, or teeth requiring multiple visits for treatment. Also, mandibular first molars showing any variation from the three root canals configuration including a fourth canal in the distal root, middle mesial canals[17], radix entomolaris and C-shaped molars.

Randomization and blinding

Participants meeting the eligibility criteria were randomly assigned to one of two groups (25 participants per group) using computer-generated randomization from www.random.org, according to the sealer used for obturation. The first group included patients whose teeth were obturated using AH plus resin-based sealer and was denoted as the RBS group. The second group included patients whose teeth were obturated using Guttaflow 2 silicone-based sealer and was denoted as the SBS group. The opaque envelopes were used to seal the sequentially produced numbers, which were chosen by participants at the time of intervention to determine their group assignment. Both participants and the assessor were blinded to the group allocation, although the clinician was aware of the instruments used and thus could not be blinded.

Clinical Procedures

After collecting demographic information, as well as each patient's medical and dental status and history, teeth were anaesthetized using local anesthesia containing 4% Articaine with epinephrine 1:100,000.[18] Supplemental intraligamentary local anesthesia was administered when needed. Access cavity was performed using a carbide round steel bur and tapered diamond stone or ENDO-Z ((Mani Inc., Tochigi, Japan) until complete deroofing was achieved. The access cavity preparation was performed under surgical microscope (Leica Microsystems, Wetzlar, Germany) its

magnification range (1.5x-40x) to ensure locating all canals. Rubber dam isolation (Coltene, Altstätten, Switzerland) of the tooth was then performed using the proper clamps (Ivoclar Vivadent, Schaan, Liechtenstein).[19]

After the working length has been determined using a #10 K File in conjunction with an electronic apex Locator (Root ZX II - J. Morita, Japan) and verified by radiography, apical patency was ensured by extending the #10 K file beyond the apex by 0.5-1mm.[20] Glide path was then established using #15 K-files (M-Access, Dentsply, Switzerland) before the root canal were prepared in a crown-down manner using ProTaper Gold system (Dentsply Sirona, Ballaigues, Switzerland) at the manufacturer's suggested speed and torque settings using an Endodontic motor (X-Smart Plus, Dentsply-Maillefer).

Throughout the shaping process, the instruments' flutes were cleaned after every three pecking motions to prevent debris buildup, ensuring the files operated efficiently and reached the full working length without any blockages. The procedure continued until the final working length was reached, confirming successful root canal preparation. The final step for apical preparation involved the use of an F2 file, equivalent to a #25 size in mesial canals and F3 file was used in distal canals. 2 mL of 5% sodium hypochlorite (NaOCl) was used for root canal irrigation after each file, each canal was irrigated with a total of 10 mL of a 5% NaOCl solution. A 27-gauge notched-tip irrigation needle with a working length of 2 mm was used in all irrigation procedures. In the final wash, 5 ml 17% EDTA and 5 ml 2.5% NaOCl was used to flush each canal.[21] The total volume of NaOCl solution used during cleaning and shaping was 20 ml/canal.[22] The final flush was 10 ml saline solution. Irrigants were activated using eddy tips that were sonically triggered for 60 seconds with a 6000 Hz sonic device EDDY handpiece (VDW Dental, Munich, Germany) powered by an air scaler 1 mm short of the canal's working length.[23,24]

After the master gutta-percha cone radiograph obturation was done according to the randomization process. For the RBS group: AH Plus sealer was used according to the instructions of the manufacturer. The matching gutta-percha cone (Dentsply Maillefer, Ballaigues, Switzerland) was soaked in AH Plus sealer (Dentsply Sirona, Ballaigues, Switzerland) and placed to the working length in the root canal. Accessory cones were employed until the spreader reached the root canal opening no more than 1-2 mm. A heated excavator was used to remove excess gutta-percha cones. For the SBS: According to the manufacturer's instructions, GuttaFlow 2 was dispensed on mixing paper. The matching gutta-percha cone was soaked in this mixture and inserted into the root canal to cover the root canal walls with GuttaFlow2. The matching gutta-percha cone was then recoated and inserted inside the root canal at the working length with reciprocating movements. A heated excavator was used to remove excess gutta-percha cone. After the canals have been entirely filled with GuttaFlow 2, additional gutta-percha points were added in oval distal canal.

Following the completion of endodontic treatment, coronal restoration was done using both standard composite (3M, Filtek™ Universal Restorative, United states) and flowable composite (3M, Filtek™ Flowable Restorative, United states). Postoperative radiographs were obtained using the paralleling technique.[25]

Outcome assessment

Quality of Root Canal Obturation

Two blinded endodontists with over 10 years of experience, evaluated all the radiographs twice. At the beginning of the study, examiner calibration was achieved by evaluating 15% of the radiographs. The

interclass correlation coefficient (ICC) scores, which ranged from 0.87 to 0.92 with a 95% confidence interval, were calculated. To prevent eye strain, a break was taken after evaluating three consecutive radiographs. The examiners had the flexibility to adjust the viewer settings, such as contrast, density, and sharpness, and could magnify the images to enhance identification and visualization of the measured structures.[26]

Three parameters were examined to assess the quality of obturation: sealer extrusion together with the level of root filling and root-filling voids. Sealer extrusion and root-filling voids were categorized as either present or absent. If there was evidence of root-filling voids or sealer extrusion in at least one root, the tooth would be classified as having these problems. Since cases with a short working length were excluded from the study, the level of the root filling was classified as either "adequate" or "long." Fillings extending beyond the radiographic apex were considered long, while the rest were deemed adequate.[27]

Statistical Analysis

To quantitatively assess whether there is an association between the type of material used (AH Plus or GuttaFlow 2) and the presence of voids, a chi-square test of independence was performed. The null hypothesis (H0) posits that no relationship exists between the variables, whereas the alternative hypothesis (H1) proposes that an association is present.

Results

Demographic data

The study was conducted on 50 patients randomly and equally allocated to each of the studied groups (i.e., 25 cases each). Two cases (8%) and a single case (4%) dropped from the RBS and SBS groups, respectively, and were excluded from the study. This was due to their fatigue, anxiety and intolerance to complete the treatment in a single session. 47 patients completed the study, with 23 in the RBS group and 24 in the SBS group. In the AH plus group, there were a cumulative total of 23 individuals, consisting of 9 men and 14 females. The individuals in this group had an average age of 36.09 years, with a standard deviation of 10.62 years. Within the SBS group, there were a total of 11 men and 13 females. The individuals in this group had an average age of 34.75 years. with a standard deviation of 8.28 years. There was no statistically significant difference between the two groups in terms of gender and age ($p<0.05$).

Analysis

A qualitative analysis was performed to understand the patterns and trends in the data (Table-1, Fig. 1). The presence of voids, the adequacy of the length, and the occurrence of extrusion were examined in both the RBS and SBS groups. The analysis revealed that there were no discernible patterns indicating a significant difference between the two materials concerning voids, length, and extrusion.

Table 1: Intergroup comparisons and descriptive statistics for Obturation quality parameters.

Parameter	AH Plus	GuttaFlow 2	Chi-square Statistic	P-value
Voids	3 present 20 absent	3 present 21 absent	0.016	0.899
Length	1 long 22 adequate	1 long 23 adequate	0.002	0.966
Extrusion	2 present 21 absent	3 present 21 absent	0.051	0.821

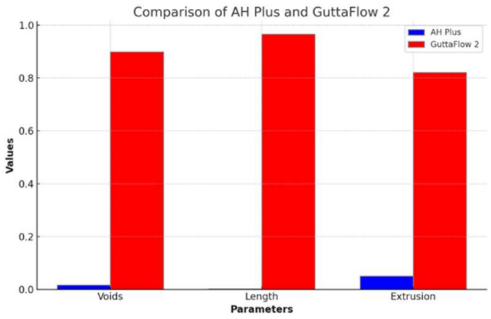

Figure 1: the chart comparing the RBS and SBS materials for the parameters: voids, length, and extrusion, using the chi-square statistic and p-values for each parameter. The blue bars represent the values for RBS group, and the red bars represent the values for SBS group.

Intracanal Voids

The chi-square statistic was approximately 0.016, with a p-value near 0.899, indicating no significant difference in the occurrence of voids between the RBS and SBS groups. Thus, the material type does not appear to be associated with the presence of voids.

Length

The chi-square statistic for the length parameter was calculated as approximately 0.002, with an associated p-value of approximately 0.966. This indicates that there is insufficient evidence to conclude a significant difference in the length distribution between the RBS and SBS groups. Hence, the type of material used does not appear to be associated with the length distribution.

Extrusion

The chi-square statistic for the extrusion parameter was calculated as approximately 0.051, with an associated p-value of approximately 0.821. Thus, we fail to reject the null hypothesis. This indicates that there is insufficient evidence to conclude a significant difference in the presence of extrusion between the RBS and SBS groups. Thus, the type of material used does not appear to be associated with the presence of extrusion.

Discussion

Creating a hermetic seal within the root canal system is crucial for preventing bacterial re-entry and subsequent periapical inflammation or reinfection.[28,29,30] This study aimed to assess the obturation quality of AH Plus, a widely used sealer, and GuttaFlow 2, a newer sealer. focusing on sealer extrusion together with the level of root filling and root-filling voids. These parameters are critical as they directly impact the long-term success and reliability of endodontic treatments.[28,29]

Our study opted to assess the obturation quality in a clinical scenario in which the sealer is surrounded by the dynamic inherent humidity of dentin and is subjected to the fluctuating stresses of functional occlusion and thermal variations, thus taking the testing conditions to another level beyond the limitations of in-vitro testing and artificial teeth.

The criteria for evaluating sealer extrusion together with the level of root filling and root-filling voids, were chosen as parameters of evaluation based on their established significance in endodontic treatment outcomes. Sealer extrusion is closely monitored due to its potential to cause postoperative complications.[2] The presence of root-filling voids can indicate incomplete canal filling, potentially leading to treatment failure.[31,32] Ensuring the level of root filling is at or near the radiographic apex is crucial for achieving a satisfactory apical seal and overall treatment success.[33,34]

The activation of irrigants was performed because it was demonstrated by Urban et al, that it improves the removal of debris and biofilm, creating a cleaner canal environment for obturation.[35] AH Plus, was used for the control group because it is considered the gold standard; a resin-based sealer, known for its excellent sealing ability, low solubility, strong adhesion to dentin, and a documented long-term success in clinical practice.[36]

Sealer extrusion is a well-documented issue with significant clinical implications. Baumgartner et al highlighted the need to control sealer flow to prevent adverse periapical reactions.[37] Similarly, Tunga et al noted that sealer extrusion could cause postoperative pain and discomfort [38]. Sealer extrusion happens when the sealer flows beyond the apex of the root canal, potentially leading to periapical inflammation and postoperative discomfort.[37,38] In this study, both RBS and SBS groups showed a low rate of sealer extrusion, with the RBS group having two cases (8.7%) and the SBS group three cases (12.5%). This low extrusion rate suggests that both sealers have favorable handling and physical properties that limit overextension.

Voids within the root canal filling material are a major concern as they can lead to bacterial leakage and potential treatment failure. Shipper et al emphasized the importance of a void-free filling in maintaining the integrity of the obturation and preventing microbial infiltration.[39] The use of advanced rotary instrumentation systems and improved sealer formulations likely contributed to the favorable outcomes observed in this study. The ProTaper Gold rotary system, used in this trial, has been shown to enhance canal shaping and cleaning, facilitating better obturation.[40] In this study, both RBS and SBS groups exhibited a low incidence of root-filling voids, with each group reporting three cases. The chi-square test of independence indicated no statistically significant difference between the groups ($p = 0.899$), implying that both materials were equally effective in filling the canal voids.

Achieving a consistent level of root filling at or near the radiographic apex is essential for ensuring an adequate apical seal, preventing periapical pathology, and promoting healing.[28,29] In this study, both RBS and SBS groups achieved satisfactory apical sealing, with each group reporting one case of overfilling. The chi-square test of independence demonstrated no significant difference between the groups ($p = 0.966$), indicating that the type of sealer used did not affect the level of root filling. The consistent apical sealing achieved by both sealers suggests that the techniques used cold lateral condensation for RBS group and cold free-flow compaction for SBS group are effective in clinical practice. The thermoplastic nature of GuttaFlow 2, which allows for a cold free-flow compaction technique, simplifies the obturation process and reduces voids, as noted by De-Deus et al.[41]

Both sealers' performance indicates that clinicians can choose either material based on their preference or specific clinical scenarios without compromising treatment quality. Similar clinical outcomes align with findings from studies.[13,42], which reported no significant differences in clinical performance between these sealers. The demonstrated effectiveness of both AH Plus and GuttaFlow 2 in achieving high-quality obturation supports the notion that the choice of sealer can be tailored to individual patient needs and clinician preferences. However, the study's sample size and focus on a single tooth type (first mandibular molar) suggest the need for further research. Larger studies involving various tooth types and conditions could provide more comprehensive insights into the performance of these sealers across different clinical scenarios.

Beyond the technical aspects of obturation, patient-centered outcomes such as postoperative pain, treatment comfort, and incidence of flare-ups are critical considerations.[43,44] Extending the follow-up period would provide valuable insights into the long-term effects of obturation quality, including root canal treatment success rates, potential post-treatment complications, and patient-reported outcomes.

While this study primarily focused on obturation quality, future research should also evaluate these patient-centered outcomes. Studies by Pak et al.[45] and Neelakantan et al.[46] highlighted the importance of minimizing postoperative pain and enhancing patient comfort during and after endodontic treatment.

Conclusion

AH Plus and GuttaFlow 2 sealers exhibit similar root canal obturation quality, in terms of sealer extrusion together with the extent of root filling and root-filling voids.

Declarations

-Funding: None

-Data availability: upon request from the corresponding author.

-Ethics approval and consent to participate: Approval of the ethics committee at the Faculty of Dentistry, British university, Cairo, Egypt (FDBUE-REC-22-017). Eligible participants signed a written informed consent.

Competing interests: None

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