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# TWO-MONTH ASSESSMENT OF SOLUBILITY OF FOUR DIFFERENT ROOT CANAL SEALERS: A COMPARATIVE IN VITRO STUDY

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#### **ABSTRACT**

Aim: To evaluate and compare the solubility of four root canal sealers (Dia-Root BIO, Endofill, Sealapex, and AH Plus) at three intervals (24 hours, 30 days, and 60 days) and to assess whether each sealer's solubility changes over time.

Materials and Methods: Solubility was assessed by measuring weight loss following immersion in distilled water at the specified intervals, based on standardized testing protocols. Data were statistically analyzed using SPSS software. One-way ANOVA followed by Tukey's post hoc test was used to assess differences between sealers at each time interval, while repeated-measures ANOVA evaluated solubility changes within each sealer across time points. A significance level of  $p \le 0.05$  was set for all tests.

Results: Statistically significant differences in solubility were observed among the sealers at each time interval (p < 0.05), except between AH Plus and Dia-Root BIO, which showed no significant difference. Both exhibited lower solubility values, while Endofill and Sealapex showed higher values, with Sealapex consistently exceeding Endofill at each time point. Although numerical increases in solubility were observed over time within each sealer, these changes were not statistically significant (p > 0.05).

Conclusion: Among the tested sealers, AH Plus and Dia-Root BIO consistently exhibited lower solubility values at all time intervals, suggesting potential for long-term sealing effectiveness. In contrast, although Sealapex and Endofill showed relatively stable behavior over time, their solubility values remained comparatively higher at each time interval. Selecting sealers with low solubility remains essential to enhance the longevity and success of endodontic treatment.

KEYWORDS: Endodontic materials; Root canal sealers; Solubility; Material stability

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#### INTRODUCTION

Root canal sealers are essential in endodontic treatment, as they play a pivotal role in establishing and maintaining an effective seal within the root canal system <sup>(1)</sup>. Successful treatment outcomes rely not only on mechanical preparation and obturation but also on the characteristics of the sealer itself. Sealers serve multiple functions, including facilitating the positioning of the gutta-percha cone, bonding it to the canal walls, and filling voids to achieve a fluid-tight seal <sup>(2)</sup>.

The performance of these sealers is largely influenced by their physicochemical properties, with low solubility being particularly important. An ideal sealer should maintain its integrity and resist dissolution when exposed to tissue fluids, ensuring a durable seal. Solubility is directly linked to a sealer's longevity; high solubility can create voids or gaps, compromising the seal and allowing bacterial re-entry <sup>(3)</sup>.

Various root canal sealers are available with unique compositions that affect their overall properties. The present study focuses on four distinct sealers: Dia-Root BIO, Endofill, Sealapex, and AH Plus. Dia-Root BIO, a calcium silicatebased sealer, is noted for its bioactivity and compatibility with periapical tissues, as bioceramic sealers are often favored for their sealing ability and potential to support healing (4). Endofill (PD), a eugenol-based sealer, contains corticosteroid components that may help reduce inflammation and alleviate postoperative discomfort. This aligns with the known role of corticosteroids in modulating inflammatory responses (5). Sealapex, formulated with calcium hydroxide, is recognized for promoting hard tissue formation and exhibiting biocompatibility (6). Finally, AH Plus, an epoxy resin-based sealer, is valued for its low solubility and strong adhesion, contributing to its durability and recognition in clinical endodontic practice (7).

Given the clinical importance of solubility,

evaluating and comparing the dissolution behavior of different sealers is essential for understanding their long-term efficacy. This study assesses the solubility of these four root canal sealers by measuring their weight loss after immersion in water at 24 hours, 30 days, and 60 days, evaluating both differences between sealers at each time point and changes within each sealer over time. Solubility testing was conducted in accordance with the International Organization for Standardization (ISO) 6876:2012 and the American Dental Association (ADA) specification No. 57 (8,9). The null hypotheses were: (1) there are no significant differences in solubility among the four tested sealers at each time interval, and (2) there are no significant differences in solubility within each sealer across the different time intervals. By investigating the solubility of these four sealers, the present study aims to shed light on an important aspect of their long-term performance, which is one of the key determinants of clinical success. Accordingly, it seeks to answer the question: How does the solubility of different root canal sealers vary between materials and over time?

#### MATERIALS AND METHODS

# **Ethical Regulations**

This study was conducted in compliance with ethical standards governing in vitro research protocols. Ethical approval was obtained from the Research Ethics Committee at the Faculty of Dentistry, MSA University (Ref No. 183). No human or animal subjects were involved in this research.

#### Reference to Standards

To ensure reliability and consistency in evaluating the solubility of the root canal sealers included in this study, testing procedures were conducted with reference to the International Organization for Standardization (ISO) 6876:2012 guidelines and the American Dental Association (ADA) specification

No. 57 (8,9). These protocols are widely recognized in dental material research for standardizing methods and enhancing the reproducibility of results across studies. The ISO 6876 standard outlines requirements for properties such as solubility, dimensional stability, and setting time of sealers, ensuring that materials are assessed under controlled conditions. The ADA specifications further reinforce these guidelines by providing additional criteria specifically for endodontic sealers, including standardized immersion protocols and detailed requirements for testing parameters. By considering these established standards, this study aimed to produce data that are not only accurate but also comparable to findings in other research, supporting an evidence-based understanding of sealer performance over time.

## **Root Canal Sealers and Composition**

Four root canal sealers were selected, each belonging to a distinct class. This selection allowed for a comparative analysis across a diverse range of formulations, representing calcium silicate-based,

eugenol-based, calcium hydroxide-based, and epoxy resin-based sealers. Detailed information on the composition and classification of each sealer is provided in **Table 1**.

# **Sample Size Calculation**

To ensure sufficient power to detect significant differences, a sample size calculation was conducted based on a prior study evaluating the solubility of root canal sealers by Azadi et al. (2012) (10). A minimum detectable effect size of 0.5 was selected, with the significance level  $(\alpha)$  set at 0.05 and statistical power at 80% (0.8). Based on these parameters, the required sample size was calculated to be 10 specimens per sealer at each time point. The sample size was calculated using G\*Power statistical power analysis software, version 3.1.9.7 (11). This calculation approach also follows the standard sample size determination methods for ANOVA-based studies, as described by Cohen (1988) (12). This ensures adequate sensitivity to detect differences in solubility among materials across different time points.

TABLE (1). Composition and classification of the tested root canal sealers

Sealer	Manufacturer (Country)	Class	Delivery System	Composition	
Dia-Root BIO	DiaDent (South Korea)	Calcium silicate-based	Premixed Syringe	Calcium silicates, Calcium phosphate, Calcium hydroxide, Calcium sulfate, Zirconium oxide	
Endofill	Produits Dentaires (Switzerland)	Eugenol-based	Powder- Liquid System	Powder: Thymol Iodide 22.5%, Polyoxymethylene 2.2%, Hydrocortisone Acetate 1.0%, Dexamethasone Acetate 0.01%, Excipient ad 100% Liquid: Eugenol	
Sealapex	Kerr (USA)	Calcium hydroxide- based	Two-Paste System	Base Paste: Calcium Hydroxide, Zinc Oxide, Barium Sulfate, Fatty Acids and Oils Catalyst Paste: Resin Components, Titanium Dioxide, Accelerators, Fillers	
AH Plus	Dentsply Sirona (Germany)	Epoxy resin- based	Two-Paste System	Base Paste: Bisphenol-A Epoxy Resin, Bisphenol-F Epoxy Resin, Calcium Tungstate, Zirconium Oxide, Silica, Iron Oxide Pigments Catalyst Paste: Dibenzylamine, Calcium Tungstate, Zirconium Oxide, Silica	

## **Sample Classification and Preparation**

The sealers were categorized into four groups based on their type: Dia-Root BIO, Endofill, Sealapex, and AH Plus. For each sealer, 10 specimens were prepared for each time point (24 hours, 30 days, and 60 days), resulting in a total of 120 specimens. Stainless steel ring molds with an internal diameter of  $20 \pm 1$  mm and a height of  $1.5 \pm 0.1$  mm were used for specimen fabrication <sup>(8)</sup>.

To ensure surface cleanliness, the molds were thoroughly cleaned in an ultrasonic bath with acetone for 15 minutes. The molds were then weighed three times using an analytical balance with an accuracy of  $\pm$  0.1 mg, and the mean weight was recorded. This step established the baseline weight of the empty molds.

Each root canal sealer was prepared according to its manufacturer's instructions to ensure consistency within each group of specimens. The mixed materials were placed into the molds, which were then allowed to set at 37°C in 100% relative humidity for 24 hours. Once set, the filled molds were weighed three times, and the mean weight was recorded to represent the combined weight. The initial weight  $(W_1)$  of the sealer was calculated by subtracting the mean weight of the empty mold from that of the filled mold.

## **Testing Procedure**

The specimens were then placed in labeled and sealed bottles containing 7.5 mL of distilled water to ensure uniform immersion conditions. The bottles were stored in a controlled environment at  $37^{\circ}$ C, simulating intraoral conditions, for designated immersion times of 24 hours, 30 days, and 60 days. After each immersion period, the specimens were removed from the bottles and dried. Each mold containing its respective sealer was weighed three times, and the mean weight was recorded. The final weight of the sealer ( $W_2$ ) was calculated by subtracting the mean weight of the corresponding empty mold from this mean value.

## **Solubility Calculation**

Solubility was quantified as the percentage of weight loss relative to the initial dry weight, using the following formula:

Solubility (%) = 
$$[(W_1 - W_2) / W_1] \times 100$$

Where

- $W_1$  = Initial weight of the sealer (after setting and drying, before immersion).
- $W_2$  = Final weight of the sealer (after immersion and drying).

# **Statistical Analysis**

The solubility data were analyzed using SPSS software (version 26.0; IBM Corp., Armonk, NY, USA). To evaluate differences in solubility between the four sealers at each time interval (24 hours, 30 days, and 60 days), a one-way analysis of variance (ANOVA) was conducted. Tukey's post hoc test was applied to identify specific pairwise differences between sealers at the same time point. To assess changes in solubility within each sealer across the three time intervals, a repeated-measures ANOVA was performed.

Before conducting these analyses, the assumptions of normality and homogeneity of variances were tested using the Shapiro–Wilk and Levene's tests, respectively. A significance level of  $p \le 0.05$  was considered statistically significant.

# **RESULTS**

Three complementary statistical figures were used to enhance the interpretation of the solubility data. Each figure presents a distinct analytical perspective: the bar chart (**Figure 1**) offers a comparative overview of mean solubility values across all sealers and time points; the box plot (**Figure 2**) illustrates the distribution, variability, and central tendencies in the data; and the line chart (**Figure 3**) visualizes solubility progression over time for each material.

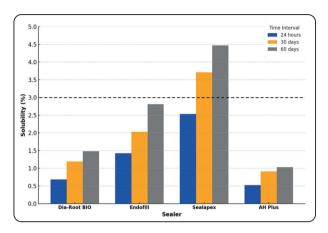


Fig. (1) Bar chart illustrating the solubility of the four root canal sealers at three time intervals (24 hours, 30 days, and 60 days).

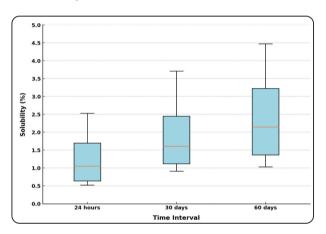


Fig. (2) Boxplot illustrating the overall solubility distribution of all tested root canal sealers at 24 hours, 30 days, and 60 days

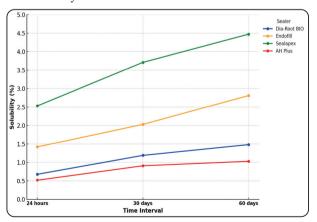


Fig. (3) Solubility trends of root canal sealers over time. The graph illustrates the solubility percentages measured at 24 hours, 30 days, and 60 days. Each line represents the solubility progression of each sealer over the evaluated time intervals.

The solubility test results at 24 hours, 30 days, and 60 days are presented in **Table 2**. The null hypotheses were partially rejected, as significant differences were found among the sealers at each time interval (p < 0.05), but not within the same sealer across different time points. Post hoc analysis revealed that the Dia-Root BIO group and the AH Plus group had significantly lower solubility percentages than the Endofill group and the Sealapex group (p < 0.05) at all time points, with no significant difference between Dia-Root BIO and AH Plus (p >0.05). Sealapex and Endofill exhibited the highest solubility percentages, with a significant difference between them (p < 0.05). Although Sealapex met the ISO 6876:2012 standard, which limits solubility to no more than 3% weight loss after 24 hours of immersion in distilled water, it exceeded this threshold at both 30-day and 60-day intervals, as shown in Figure 1.

TABLE (2). Solubility percentages (mean ± standard deviation) of root canal sealers at 24 hours, 30 days, and 60 days

Sealer	Solubility after 24 hours (%)	Solubility after 30 days (%)	Solubility after 60 days (%)
Dia-Root BIO	$0.68 \pm 0.12^{aA}$	$1.19 \pm 0.21^{aA}$	$1.48 \pm 0.29^{aA}$
Endofill	$1.42 \pm 0.22^{\rm bA}$	$2.03 \pm 0.33^{\rm bA}$	$2.81 \pm 0.39^{bA}$
Sealapex	$2.53 \pm 0.31^{cA}$	$3.71 \pm 0.42^{cA}$	$4.47 \pm 0.52^{cA}$
AH Plus	$0.52 \pm 0.12^{aA}$	$0.91 \pm 0.21^{aA}$	$1.03 \pm 0.23^{aA}$

Different lowercase superscript letters within the same column indicate statistically significant differences between sealers at the same time point (p < 0.05). Identical uppercase superscript letters within the same row indicate no significant difference (p > 0.05).

The boxplot shown in **Figure 2** illustrates the solubility distribution of the tested sealers (Dia-Root BIO, Endofill, Sealapex, and AH Plus) after immersion in distilled water for 24 hours, 30 days, and 60 days. The median solubility value is

represented by the central line within each box, with the top and bottom edges marking the 75th and 25th percentiles, respectively. Whiskers extend to the minimum and maximum values within 1.5 times the interquartile range (IQR).

Figure 3 illustrates the solubility trends of the sealers across three observation periods: 24 hours, 30 days, and 60 days. Sealapex exhibited the highest solubility percentages throughout the study, increasing from 2.53% at 24 hours to 4.47% at 60 days. Endofill displayed the second-highest values, rising from 1.42% to 2.81% over the same time intervals. Conversely, Dia-Root BIO and AH Plus demonstrated much lower solubility, with the former increasing modestly from 0.68% to 1.48% and the latter showing the lowest values, ranging from 0.52% to 1.03%. Although all sealers showed numerical increases in solubility over time, repeated-measures analysis revealed no statistically significant differences within each sealer across time intervals (p > 0.05).

#### DISCUSSION

Understanding the solubility behavior of root canal sealers is crucial for predicting their longterm clinical performance. Solubility directly affects a sealer's ability to maintain an effective seal, which is essential in preventing bacterial ingress and ensuring the success of root canal therapy (13). To comprehensively evaluate both the short-term and long-term stability of the sealers, this study employed time intervals of 24 hours, 30 days, and 60 days. These intervals were selected to assess both the early and progressive changes in solubility under standardized immersion conditions. While sealers are intended to remain confined within the root canal system, exposure to moisture can still occur in clinical situations such as coronal microleakage, apical extrusion, or incomplete sealing. Therefore, assessing solubility over time provides valuable insight into how different sealers might perform under such compromised conditions, which could jeopardize the long-term integrity of the seal. This

approach enabled the present study to capture the dynamic behavior of each sealer in response to fluid contact, offering a more comprehensive understanding of its potential durability and clinical reliability.

The sample size applied in this study is consistent with recommendations aimed at improving methodological rigor. This aligns with findings from a prior systematic review, which highlighted insufficient sample sizes as one of the limitations in many previous in vitro solubility studies (14).

Based on the results, the null hypotheses were partially rejected. Although no statistically significant differences were found within the same sealer across different time intervals, significant differences were observed between the sealers at each time point, except between Dia-Root BIO and AH Plus. This suggests that, under the conditions of this study, material composition may have a greater influence on solubility behavior than immersion duration.

Interestingly, the absence of statistically significant changes within each sealer across the different time intervals suggests that the solubility behavior of each material remained relatively stable over the 60-day observation period. This may imply that once a sealer's solubility profile is established early on, it may not substantially change under the tested conditions. However, despite this relative temporal stability, the absolute solubility levels differed considerably among the sealers. This finding supports the clinical importance of selecting sealers with intrinsically low solubility to enhance long-term sealing effectiveness.

The low solubility of AH Plus aligns with its well-documented physical properties, which contribute to its stability and ability to preserve the root canal seal over extended periods. This epoxy resin-based sealer has been extensively studied and is recognized for its low solubility (15, 16). This could be attributed to its epoxy resin formulation, which provides dimensional stability compared to other sealer types (17).

Similarly, Dia-Root BIO, a calcium silicatebased sealer, showed low solubility, consistent with the performance expected from effective root canal sealers. While traditional literature has reported solubility concerns with bioceramic sealers (18, 19), Dia-Root BIO demonstrated favorable stability, which is crucial for maintaining long-term material integrity. Additionally, Dia-Root BIO may contribute to positive biological outcomes by forming hydroxyapatite upon contact with tissue fluids, which promotes healing and strengthens the biological seal. This behavior reflects the inherent bioactivity of bioceramic materials, which is characterized by calcium ion release and hard tissue formation. This could facilitate the development of a mineralized barrier within the canal and enhance resistance to microbial infiltration (20–22).

Endofill had a higher solubility than AH Plus and Dia-Root BIO at each time interval. While no statistically significant increase in solubility was detected over time within the Endofill group, its comparatively higher solubility may still present a concern for long-term sealing effectiveness. This may lead to some compromise in sealing integrity, in contrast to sealers with lower solubility rates.

Sealapex exhibited the highest solubility values among all tested materials at all time points. Despite demonstrating relative stability over time, its overall solubility was markedly higher than that of other sealers. This elevated solubility may compromise the seal, particularly in scenarios with prolonged moisture exposure. This finding is consistent with previous studies reporting the high solubility of Sealapex (23, 24). Overall, the results of this study support the view that solubility is a key factor in the performance of root canal sealers.

# **CONCLUSION**

Within the limitations of this study, all tested sealers demonstrated relatively stable solubility behavior over time; however, their absolute solubility values differed considerably. AH Plus and Dia-Root BIO exhibited consistently lower solubility at all time intervals, a property favorable

for prolonged sealing performance. In contrast, Sealapex and Endofill showed comparatively higher solubility values at each interval. These findings underscore the importance of selecting root canal sealers with low intrinsic solubility to preserve seal integrity and support favorable treatment outcomes. Future research should focus on optimizing sealer formulations to reduce solubility without compromising essential properties such as biocompatibility and antimicrobial efficacy.

# **Clinical Implications:**

The findings suggest that sealers with low solubility may be better suited for the long-term success of root canal therapy, as they are more likely to maintain a durable seal and resist degradation. This could reduce the risk of void formation and bacterial microleakage, thereby supporting treatment success. These insights can help guide clinicians in selecting root canal sealers based on their requirements for longevity.

#### **Conflict of Interest:**

The authors declare that there is no conflict of interest related to this study.

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