

## Comparative evaluation of Postoperative Pain following Ultrasonic activation and Root Canal Obturation with Bioceramic Sealers versus Epoxy-Resin in Partially Edentulous Patients Rehabilitated with Tooth-Supported Overdentures: A Randomized Controlled Clinical Trial

Hinar Al Moghazy<sup>1</sup>, Mai H. Abdelrahman<sup>2</sup>, Dina Elawady<sup>3,\*</sup>

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### Abstract

**Background:** Endodontic treatment is often precursor to the overdenture fabrication. Ultrasonic activation combined with bioceramic sealers may contribute to reduction in postoperative pain compared to epoxy-resin sealers, warranting further investigation.

**Methods:** This study aimed to evaluate the effect of ultrasonic activation on the incidence of postoperative pain in root canals obturated using two different types of root canal sealers: epoxy-resin based and bioceramic based. Thirty overdenture patients with vital pulps were randomly assigned to each obturation technique. Pain intensity was measured using a Visual Analog Scale (VAS) over a period of seven days postoperatively. Statistical analysis was performed using Mann-Whitney U test for between group comparison.

**Results:** The bioceramic sealer group showed significantly lower pain intensity on the first and second days postoperatively compared to the epoxy-resin sealer group ( $p < 0.05$ ). However, by the third day and beyond, there was no significant difference in pain levels between the two groups.

**Conclusion:** The combination of ultrasonic activation and bioceramic sealers may be more effective in reducing short-term postoperative pain compared to epoxy-resin sealers. The choice of sealer material and irrigation technique can play an important role in minimizing discomfort for patients rehabilitated with tooth supported overdentures. Further research with larger sample sizes is recommended to confirm these results.

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#### \* Corresponding author.

E-mail address: delawady82@gmail.com

<sup>1</sup> Lecturer of Endodontics, Faculty of Dentistry, October University for Modern Sciences and Arts, Giza, Egypt.

<sup>2</sup> Associate professor of Dental biomaterials, Faculty of Dentistry, October University for Modern Sciences and Arts, Egypt.

<sup>3</sup> Associate professor of Prosthodontics, Faculty of Dentistry, October University for Modern Sciences and Arts, Egypt

## 1 Introduction

Endodontic treatment is often a necessary preparatory step prior to the fabrication of overdentures for partially edentulous patients. Overdentures has been shown to offer improved function, esthetics, and patient satisfaction compared to conventional complete dentures<sup>1</sup>. The endodontic treatment of the abutment teeth is a critical component of the overdenture workflow. Careful root canal therapy, including thorough cleaning, shaping, and obturation, helps ensure the long-term health and stability of the abutment teeth supporting the overdenture<sup>2</sup>. The choice of root canal sealer material may impact the postoperative outcomes, including the level of pain experienced by the patient following the endodontic procedure.

Endodontic treatment main goal is to attain thorough debridement and adequate shaping of the root canal system with no or minimal amount of pain, allowing complete healing of the periapical tissues. This is accomplished by absolute disinfection of root canal system

by the use of root canal irrigants which act on the smear layer known to be the reservoir for various microorganisms<sup>3</sup>. Thus, irrigation has a fundamental part in root canal chemo-mechanical preparation by facilitating the elimination of bacteria, debris and necrotic tissue, particularly from areas can't be reached by root canal instruments<sup>4</sup>.

Root canal obturation also plays a vital role in preventing bacterial contamination through leakage by completely sealing the apex from the periapical tissue<sup>3,5,6,8</sup>.

Experiencing pain after therapy is undesirable, yet it often occurs, despite significant advances in endodontics. Endodontic therapy is a complex process comprising a multitude of steps; accordingly, it is hard to define the main cause postoperative pain<sup>3,8</sup>.

The source of post operative pain might be procedural errors, extrusion of materials, intra-canal medicaments, irrigants and/or irrigation techniques, obturating materials<sup>9,10</sup>.

Introduction of different irrigants activation techniques has been implemented, aiming to develop their efficiency. Ultra-sonic activation is one of those techniques; it involves an oscillating tip placed in the root canal which is activated by an ultrasonic device, resulting in mechanical agitation of the irrigant, with no contact between the instrument and the root canal wall. In an attempt to improve the dissociation of the irrigant, resulting in a softening effect on the dentin debris and elimination of the bacteria and smear layer, consequently reducing the incidence of postoperative pain<sup>7</sup>.

Sealer extrusion is a frequently occurring error during obturations, which might have un-desirable effect on the periapical tissues elucidating an inflammatory response, and thus increased postoperative pain<sup>9</sup>. Composition of root canal sealers have direct influence on the degree of inflammation and in return influences the level of postoperative pain<sup>3</sup>.

The advancement of sealers has been from the conventional ZOE based sealers reaching the resin-based sealers like epoxy-resin based sealers which exhibits adhesive properties<sup>9</sup>.

Lately, bioceramic based sealers have been introduced; they offer the advantage of chemical bonding with root dentin through their ability to form hydroxyapatite combined with their biocompatibility thus less postoperative pain than other type of sealers<sup>5,11</sup>.

Therefore, this study aims to evaluate and compare the effect of ultrasonic activation on the incidence of postoperative pain in root canals obturated by two different types of root canal sealers: epoxy-resin based and bioceramic based sealers in partially edentulous patients indicated for overdenture prosthetic rehabilitation.

## 2 Materials and Methods

### 2.1 Ethical Approval:

The Ethics Committee of the MSA University approved the study with number REC-D 4116-4. This RCT has been described according to the CONSORT checklist for RCT writing and publishing guidelines<sup>12</sup>.

### 2.2 Sample size calculation:

For Evaluation of Postoperative Pain after Using Bioceramic Material and Resin sealer Ah Plus as Endodontic Sealers, Chi square test was used for comparison between pain incidence and intensity scores. According to a previous study by Paz et al (2018), the incidence of pain was 50% using single cone+bioceramic, 30% using continuous wave+resin and 20% using lateral condensation +resin. A large effect size of approximately 0.6 is expected<sup>13</sup>. Using an actual power (1- $\beta$  error) 0.8 (80%) and significance level ( $\alpha$  error) 0.05 (5%) for two-sided hypothesis test, the minimum estimated sample size was 36 (18 in each group). Sample size calculation was performed using G power Statistical Power Analyses Version 3.1.9.2. Calculation includes a 20-30% increase for anticipated missing data, resulting in a final sample size of 30 participants. (Fig. 1)

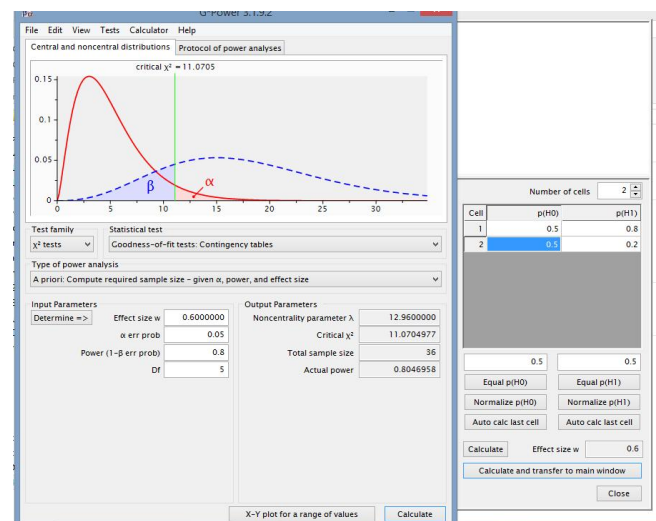


Figure 1. sample size calculation

### 2.3 Patient selection:

Partially edentulous patients were recruited from the MSA University outpatient clinic. All patients were screened and determined to be appropriate candidates for overdenture prosthetic rehabilitation; having remaining bilaterally distributed maxillary or mandibular canines/premolars that were periodontally healthy or had potentially reversible periodontal disease. (Fig.2)



**Figure 2.** Intraoral photo of maxillary arch with remaining bilateral canines (occlusal view).

As part of the treatment planning process, it was determined that the remaining natural teeth to be used as overdenture abutments had vital pulps and single canals. Therefore, an intentional endodontic therapy protocol was planned and implemented prior to final prosthetic rehabilitation. The individual diagnosis was confirmed by obtaining the dental history, peri-radicular radiographs, periodontal evaluation, percussion, and Electric pulp testing. Previous NSAIDs or antibiotic treatment was recorded. Preoperative records (**Fig. 3a-3d**) were gathered to ensure that the patients are candidates for overdenture prosthetic option. Primary maxillary and mandibular impressions were obtained using stock impression trays and an alginate impression material (Cavex ALGINATE CA37, Netherlands).

These preliminary impressions were used to fabricate study casts for each participant. Subsequent to the primary impression making, face bow records and transfer (**Fig. 3a**) were obtained, jaw relation records were registered using wax-wafer technique and the inter-arch space was evaluated by mounting the study casts on a semi-adjustable articulator (**Fig. 3b**) to detect the lack of space in the vertical direction, which can be a major contraindication to overdenture.



**Figure 3a.** Facebow transfer (profile view).

Set-up of teeth was performed (**Fig. 3c**) as well as an occlusal index in which, a silicone matrix was made using high viscosity elastomer to evaluate the prosthetic space horizontally (**Fig. 3d**) to ensure optimal placement of the overdenture prosthesis.



**Figure 3b.** Mounted casts.



**Figure 3c.** Diagnostic setup.



**Figure 3d.** occlusal index (Silicone matrix )

After clinical and radiographic examination, thirty patients (18 men and 12 women), with ages ranging 20 to 50 yr were included in the study. All patients were informed of the aim and design of the investigation and signed an informed consent. Patients were supplied written instructions on how to assess and record the postoperative pain. Patients were randomly assigned using computer generated random numbers to each one of the two obturation techniques: group 1; single cone technique with Resin sealer Ah Plus (dentsplysirona) and

group 2; treatment with single cone technique with bioceramic sealer (Ceraseal, META BIOMED). Allocation concealment was performed by using sealed opaque envelopes. All necessary mouth preparations; surgical preparations like extraction of hopeless teeth and periodontal preparations as scaling or root planning were performed for all patients.

#### 2.4 Endodontic protocol:

All teeth were cleaned, shaped, and obturated during the patients' first visit. Local anesthesia was achieved by local infiltration with 4% articaine with 1:100,000 epinephrine (Laboratories Inibsa, Barcelona, Spain). After anesthesia, an endodontic access cavity was established by using 014 round carbide and Endo Z burs (Dentsplysirona). Crown down technique was employed to prepare canal using rotary files (Mpro files). Stainless steel hand instruments up to a size #10 were used to establish a glide path. Patency was established and verified with #10 files. The working length was determined using an electronic apex locator (Dentaport ZX, Morita, Tokyo, Japan) and periapical radiographs. The final instrumentation size was three sizes larger than the initial file at the working length. Master apical files ranged from #25 to #50, depending on both root anatomy and initial diameter of the root canal. Irrigation was performed using Ultra-sonic activation; it involves an oscillating tip placed in the root canal which is activated by an ultrasonic device, resulting in mechanical agitation of the irrigant, with no contact between the instrument and the root canal wall. Using Acteon® IrriSafe™ Passive Ultrasonic Irrigation Files size K25/21mm with a frequency of 30kHz using Newtron P5 SATELEC US device. Obturation was performed using single cone technique with gutta-percha (Aceone-Endo, Aceonedent. Co. Geonggi-Do, Korea). AH Plus (Dentsplysirona) was mixed according to the manufacturer's instructions for group 1 patients and the master gutta-percha cone was coated with Resin sealer Ah Plus while for group 2 the master gutta-percha cone was coated with bioceramic sealer (Ceraseal, META BIOMED). Following the completion of intentional endodontic therapy (Fig. 4), the abutment teeth were restored using a light-cured, nanofilled composite resin material (3M Filtek Z350, Germany) in combination with a universal bonding agent (3M Scotchbond Universal Plus Adhesive).

The restorative procedure involved shaping the abutment teeth into a domed profile, with a preparation of 2-3 mm coronal to the mucosal tissue. The buccal and lingual surfaces were reduced by 30 degrees and 15 degrees, respectively, to facilitate optimal placement and stability of the overdenture prosthesis.



Figure 4. Endodontic treatment of abutments.

#### 2.5 Overdenture Fabrication:

Final impressions of the maxillary and mandibular arches were made using medium body rubber base impression material (Zhermack SpA). Bite registration was then conducted utilizing occlusal wax rims to record vertical dimension and centric relation. Setting up of teeth was performed (Fig. 5) During the try-in stage, (Fig. 6) the overdenture was assessed for extension, retention, stability, occlusal plane, vertical relation, centric relation, even bearing, speech, and the color and shape of the teeth as well as the adequate clearance of the abutments.



Figure 5. Artificial setup on articulator (left side).



Figure 6. Intra oral photo try in (patient smiling)front.

The final prosthesis was fabricated from heat-cured polymethyl methacrylate material (Lucite International, Netherland). (Fig. 7)



Figure 7. Occlusion (front) overdenture insertion.

2.6 Outcome measure

Postoperative pain intensity, was measured using the Visual Analog Scale (VAS) over a period of seven days. Patients were asked to record their pain intensity daily on the VAS scale, which is a 100-mm line with the endpoints labeled "no pain" and "worst possible pain." The VAS is a widely used tool for the subjective assessment of pain. The mean VAS scores were calculated for each day, providing a summary of the overall pain experience during the first seven days after the endodontic treatment. Statistical analysis was performed using Mann-Whitney U test.

2.7 Statistical Analysis

Data were presented as mean, standard deviation (SD), median and range. Mann – Whitney U test was used for between group comparison. Significance level for statistical tests was set at  $p < 0.05$ . Statistical analysis was performed using SPSS software (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.).

3 Results

A total of thirty patients partially edentulous patients (18 men and 12 women), with ages ranging 20 to 50 yr completed the study.

3.1 Postoperative pain intensity

On the 1<sup>st</sup> and 2<sup>nd</sup> days postoperatively, the bioceramic group showed significantly lower pain intensity than the resin group. On the 3<sup>rd</sup> day forward, there was no significant difference in pain intensity between the two groups. On the 5<sup>th</sup> day forward, pain disappeared completely in both groups. Table 1

Table 1. mean, standard deviation (SD), median, range and the result of Mann – Whitney U test for comparison of main intensity in the two groups.

		Bioceramic group	Resin group	p - value
Day 1	Mean (SD)	2.92 (2.11)	5.25 (2.22)	0.014*
	Median (Range)	2.5 (0 - 6)	6 (0 - 8)	
Day 2	Mean (SD)	1.5 (1.51)	4. (1.81)	0.002*
	Median (Range)	1 (0 - 4)	4 (2 - 8)	
Day 3	Mean (SD)	1. (1.28)	2. (1.65)	0.125
	Median (Range)	0.5 (0 - 4)	2 (0 - 4)	
Day 4	Mean (SD)	0.17 (0.58)	0.42 (0.79)	0.306
	Median (Range)	0 (0 - 2)	0 (0 - 2)	
Day 5	Mean (SD)	0 (0)	1 (0)	1
	Median (Range)	0 (0 - 0)	0 (0 - 0)	
Day 6	Mean (SD)	0 (0)	1 (0)	1
	Median (Range)	0 (0 - 0)	0 (0 - 0)	
Day 7	Mean (SD)	0 (0)	1 (0)	1
	Median (Range)	0 (0 - 0)	0 (0 - 0)	

\*Significant at  $p < 0.05$ .

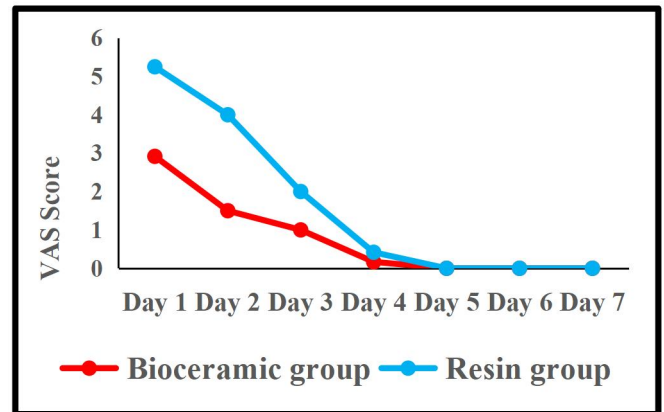


Figure 9. line chart representing the mean pain intensities at different time intervals in the two groups.

4 Discussion

The results of this randomized controlled clinical trial demonstrate that the use of bioceramic-based root canal sealers was associated with significantly lower postoperative pain levels compared to epoxy-resin based sealers. This finding is clinically relevant, as minimizing postoperative pain is an important consideration when performing endodontic treatment on abutment teeth that will support an overdenture prosthesis.

Overdentures offer numerous advantages over conventional complete dentures, including improved function, stability, and patient satisfaction. The support and stability provided by the remaining natural teeth that support the overdenture prosthesis are key factors in the success of this treatment modality. Ensuring the health and

functionality of the abutment teeth is critical, as any complications with these teeth can compromise the entire overdenture system<sup>1</sup>.

The endodontic treatment of abutment teeth is a crucial preparatory step in the overdenture rehabilitation process. By performing root canal therapy and utilizing biocompatible obturation materials, the clinician can help preserve the vitality and integrity of the abutment teeth, thereby supporting the long-term success of the overdenture prosthesis<sup>14</sup>. The findings of this study suggest that the use of bioceramic-based root canal sealers may be preferable in this context, as they were associated with reduced postoperative pain compared to epoxy-resin based sealers.

Post operative pain is a primary concern, although it is undesirable, yet it frequently occurs. It is due to activation of local inflammatory response which might be associated with the release of biochemical mediators, obturation techniques, apical instrumentation, irrigation protocol, microbial stability, number of visits or root canal sealers used<sup>15-19,20,21</sup>.

Root canal sealers as mentioned are one of the factors that might affect the occurrence and the intensity of post operative pain. During the obturation step it either affects the periapical or the periodontal tissues through the apical foramen since sealer extrusion is very common or through the lateral canals, this leads to local inflammatory response that activates the sensory neuron which in term causes discomfort and post operative pain<sup>16,18</sup>. The severity of this pain depends on the physical and chemical properties of sealers as its PH, consistency, setting time and composition<sup>16</sup>.

There are numerous types of root canal sealers; the most widely used are resin-based and bioceramic sealers, as it has been suggested that bioceramic sealers improve the treatment since they are highly biocompatible, nontoxic, bioactive, antimicrobial, chemically stable, with high sealing ability and shows no shrinkage upon setting<sup>15-21</sup>.

On the other hand, Resin-based root canal sealers are preferred as a material of choice due to their ability to penetrate into dentinal tubules and the possibility of creating monoblocks between the gutta percha and the intradicular dentin<sup>15</sup>. Accordingly, two root canal sealers were used in this study (Ceraseal) a bioceramic sealer and (Ah plus) a resin sealer.

In the present study, thirty patients with single rooted teeth were selected in an attempt to minimize the risk of iatrogenic errors due to missed canals or complicated root canal anatomy with multirooted teeth. Age range was between 20-50years old as there are no

reports of evidence documented on influence of age on pain perception.

Eighteen men and twelve women were enrolled. Moreover, only teeth diagnosed with normal pulp of patients being referred for intentional endodontic therapy for prosthetic reasons were selected because the presence of preoperative pain is associated with a more severe postoperative pain<sup>18,22</sup>.

Root canal treatment was performed by a single operator in a single visit with the aim of minimizing the number of procedures, decreasing inter-appointment contamination, eliminate the need to re-familiarize the tooth anatomy by the operator, and reduces chances of immune reactions towards intra-canal medicaments<sup>22,23,24</sup>.

Ultra-sonic irrigation was performed after mechanical preparation of the root canals by crown down technique, this was also done in attempt to decrease the duration and intensity of post-operative pain as it was reported by Shahravan, A., Nekouei, A. in 2021<sup>25</sup> and Middha M, et al in 2017<sup>26</sup> that ultrasonic irrigation may reduce the risk of post-operative pain and microbial counts during the first 24 hours, this might be contributed to its efficiency in microbial control, combined with reduced irrigant extrusion, in addition to enhancing the delivery of irrigant to uninstrumented areas of root canal system and helping removing remaining debris and bacteria by inducing acoustic streaming and cavitation of the irrigant<sup>25,26</sup>.

Single cone obturation technique was used as it was demonstrated that it can achieve a tight apical seal without the need of using accessory cones which also makes it a faster and easier technique<sup>19</sup>.

Pain perception is highly subjective, associated with physiological and psychological factors making it very difficult to be precisely measured with high probability of errors. Accordingly, in this study a 10cmVAS scale ranging from 0 to 10 was used to measure pain intensity after being utilized and described by literature as a simple, sensitive, and effective method for assessing pain by patients<sup>18,22</sup>.

On the first and second days postoperatively, the bioceramic group showed significantly lower pain intensity than the resin group and this might be contributed to the significantly higher pH of bioceramic sealers (12.7-12.9) for longer duration than the resin sealers which gives a high antibacterial effect specially against *Enterococcus faecalis*, while studies had proved that resin sealer has a mild degree of cytotoxicity due to the release of toxic monomers such as epoxy resin, bisphenol and small amount of formaldehyde. Moreover, bioceramic sealer possess a shorter setting time since it is hydrophilic in nature that uses water in dentinal tubules to complete the setting reaction and it shows a better

sealing ability due to formation of chemical bond with dentin walls with no shrinkage detected, in contrary to resin sealer that has a degree of polymerization shrinkage upon setting that might affect the apical seal<sup>15,21,27,28</sup>.

On the third day there was no significant difference in pain intensity between the two groups which might be explained by the release of biochemical mediators such as reactive oxygen species (ROS)<sup>15</sup>.

On the fifth day forward, pain disappeared completely in both groups which indicate submission of inflammation.

These results are in agreement with Farheen Akhtar, Bonny Paul who stated that pain was reduced after 24hours of using a bioceramic sealer in comparison with resin sealer and there was no significant difference between both sealers after 48 hours<sup>15</sup>.

On contrary to other studies done by Kiche Shim and Young-Eun Jang that stated that there was no significant difference in the postoperative pain intensity between bioceramic and resin sealers groups during the seven day postoperative period<sup>19</sup>. Which was also supported by a study done by Indre Graunaite, Neringa Skucaite. That stated that they both perform similarly in terms of the occurrence and intensity of postoperative pain<sup>15</sup>.

Overall, the results of this study highlight the importance of carefully considering the endodontic treatment protocol when preparing partially edentulous patients for overdenture prosthetic rehabilitation. The selection of root canal sealer material can have a significant impact on the patient's postoperative experience, which is a critical factor in the overall success and satisfaction with the overdenture treatment.

Finally, considering that pain is subjective in nature and controlled by multiple factors further clinical researches using larger samples should be done to draw conclusive results.

## 5 Conclusion

The combination of ultrasonic activation and bioceramic sealers may be more effective in reducing short-term postoperative pain compared to epoxy-resin sealers. The choice of sealer material and irrigation technique can play an important role in minimizing discomfort for patients rehabilitated with tooth supported overdentures. Further research with larger sample sizes is recommended to confirm these results.

## Authors' Contributions

Hinar Al Moghazy (Main Reasercher) managed the methodology, Review & Editing, Supervision.

Mai H.Abdelrahman managed the Resources and manuscript writing.

Dina Elawady managed the methodology, Manuscript Writing

## Conflict of interest

The authors declare that they hold no competing interests.

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