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POSTOPERATIVE PAIN EVALUATION AFTER SINGLE VISIT NONSURGICAL RETREATMENT USING A BIO CERAMIC SEALER

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ABSTRACT

Introduction/Objectives the aim of this study was to compare the difference in the postoperative pain when resin cements are used in comparison to bio ceramic cements in the obturation of root canals.

Methods One hundred patients with permanent molar teeth requiring endodontic non-surgical retreatment were treated in this study. Preoperative assessment of the degree of the patient's pain was done using the visual analog scale. Fifty teeth were obturated with gutta percha using the epoxy resin-based sealer as the control group, and in the other fifty bio ceramic based cement was used. All teeth were prepared by the protaper next rotary files under copious irrigation with 30ml of 2.6 % sodium hypochlorite throughout the procedure. Obturation was done using the cold lateral compaction technique in the resin group and single cone technique in the bioceramic group. Postoperative pain assessment was done for each patient after six hours, twenty-four hours, four days and one week.

Results There was no statistically significant difference between pain scores regarding the postoperative pain between single cone bioceramic based obturation retreatments in comparison to the lateral compaction epoxy resin based obturation retreatments after 6, 24, 48 hours as well as one week. It was also found that There was no statistically significant difference between them in relation to age values and gender in the two groups.

Conclusion with in the limitation of this study Single cone obturation with bioceramics can be used safely in single visit retreatment cases, when postoperative pain is being considered.

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INTRODUCTION

Root canal treatment (RCT) aims to disinfect the canals, fill them and save the teeth from being extracted. By the introduction of contemporary procedures techniques. and unprecedented materials, RCT can be completed safely in a single visit instead of multiple visits. Postoperative pain after endodontic retreatment is considered unpleasant sensation for the patients and affects patient-clinicians relationship (1). During root canal retreatment procedures, even when endodontic instruments do not overextend the apical foramen, products such as dentin chips, disinfection solutions, remaining pulp tissue, microorganisms and root filling remnants tend to extrude into the periradicular tissues (2,3). A great impact has been found between the apical extrusion of debris and periradicular inflammation, postoperative discomfort, which affects the process of periapical healing. It is worth to know that, the rate of flare-ups in retreatment cases is reported to be significantly higher than in initial root canal treatment cases, emphasizing the importance of the use of a technique that promotes healing of tissues and a bioactive role in the tissue process that takes place after intervention (4,5). Single cone obturation using bioceramic sealer has shown favorable treatment outcomes in the past several years. Recent clinical trials found no statistically significant difference in postoperative discomfort and pain when evaluating the effect of bioceramic sealer in comparison to resin sealer in primary root canal treatment cases in single visit. The postoperative pain was generally mild and did not last past three days (6-8). It was found that growing concern about the need of multiple appointments in root canal treatment because no significant differences in antimicrobial efficacies was found in the literature to support the use of multiple appointments over single appointments (9). The breakthrough of rotary nickel-titanium files and innovations in the equipment's and materials of irrigation dynamics have simplified the cleaning and shaping procedures of the root canal treatment,

which makes a single-session treatment a more practical and acceptable treatment regimen than multiple sessions (10,11). The aim of the present study was to compare the incidence of postoperative pain for single-visit primary nonsurgical endodontic retreatments in asymptomatic teeth between two different root canal sealers, Bio ceramic and resin sealers. The hypothesis for this study was the intensity of postoperative pain is lower in single cone bioceramic based obturation retreatments in comparison to the lateral compaction epoxy resin based obturation retreatments.

MATERIALS AND METHODS

This randomized clinical controlled study, with a parallel design 2-arm was registered on www.clinicaltrials.gov (ClinicalTrials.gov ID: NCT05399303). The study protocol was approved by FDASU-REC (Faculty of Dentistry, Ain Shams University-Research Ethical Committee) institutional review board, and the study was performed in agreement with all the applicable laws and regulations, including the Declaration of Helsinki.

A blinded researcher performed the randomization, and another researcher performed the treatment. A third researcher blinded to the groups analyzed the data. Power calculation was performed using G*Power 3.1 software (Heinrich Heine University, Dusseldorf, Germany). The sample calculation showed that the sample size for each group should be a minimum of 35 cases.

One hundred patients, with teeth indicated for root canal retreatment, were recruited from 2 private dental clinics limited to endodontics based in Cairo, Egypt between November 2021 and July 2022. Patients were selected according to the inclusion and exclusion criteria.

Inclusion criteria

 Mandibular molars with fully formed roots that need retreatment.

- Asymptomatic teeth
- Age range 20 50 years.
- Teeth having a baseline periapical lesion (PAI score ≥2) in the affected root.

Exclusion criteria

- Patients with separated files that need to be retrieved or bypassed.
- Pregnant females.
- Patients suffering from a systemic disease.
- Teeth with lesions greater than 5mm.
- Teeth with vertical fractures.
- Teeth with perforations.
- Patients with generalized chronic periodontitis or
- Teeth that need any periodontal surgery before the treatment
- Teeth that had a fiber post and teeth with canal curvature more than 30 degrees.

All participants in the current study signed a written consent form after an explanation of the aim of the study, the procedures, benefits to the community, and every potential risk. The treatment options that were discussed with the patients included nonsurgical root canal retreatment or extraction . Two endodontists participated as investigators. The investigators ensured that the patients names and data were kept secured and confidential. The clinical examination involved periodontal probing depths measurement, mobility testing, the presence or absence of swelling, percussion, palpation and bite tests using a tooth slooth. Periapical radiographs were taken preoperatively.

The cases were randomly divided into two groups; group (A): Root canal retreatment cases obturated in single visit by resin sealer using the lateral compaction technique and group (B): Root

canal retreatment cases obturated in single visit by Bioceramic sealer using the single cone technique. Randomization was done using http://www.random.org.

Group (A): For each case, profound anesthesia was administrated by an inferior alveolar nerve block injection using Lidocaine 2% with epinephrine1:100,000 (Lidocaine HCl, Novocol Pharmaceutical, Ontario, Canada), dental rubber dam isolation was applied. Under a dental operating microscope (OPMI PICO; Carl Zeiss, Gottingen, Germany), the mandibular molar tooth was accessed using a size two round diamond bur under copious water irrigation and wall finishing was done using a tapered diamond bur. The patent missed root canals were detected. Protaper retreatment kit (Dentsply, Maillefer, switzerland) was used to remove the old root canal filling starting with D1 rotary file and ending with the D3. The ProTaper D1 file (30/09) was used to remove the gutta percha from the cornal canal one third, followed by D2 (25/08) to remove gutta percha from the middle half of the canal, and finally D3 (20/07) at the apical one third. When the obturation material is short of the apical canal terminus, small sized manual hand files were used to negotiate the remainder of the root canal. Working length was re-established electronically by the apex locator Root ZX II (J. Morita Mfg. Corp, Kyoto, Japan) and confirmed radiographically using hand manual stainless steel k-files size #10 and #15 (Dentsply, Maillefer, Switzerland). The initial file for each canal was determined and a patent reproducible glide path was created to size #20/.02 by the manual files, and then enlarged using Protaper gold (Dentsply, Maillefer, Switzerland) according to the manufacturer instructions at a rotational speed of 300 rpm and 200 g/cm torque. Each roatary file was used with a brushing motion until reaching the working length using the rotary file F2 (25/08). The canals were finished at the end manually, where the final apical file size was determined in each canal according to the initial file size. An irrigation protocol consisting of 30 ml 0f 2.6% sodium hypochlorite NaOCl (Clorox; Egyptian Company for household bleach, Egypt) delivered using a 30 Gauge safety Steri Irrigation Tip (DiaDent Group International, Burnaby, BC, Canada) in conjunction with ultrasonic activation was done for canal disinfection. Ethylamine diamine tetra acetic acid (EDTA) 17% (PrevestDenPro, Jammu, India) was used to remove the smear layer before the obturation commenced. Obturation was done using the cold lateral compaction technique utilizing an epoxy resin sealer AH plus (Dentsply Sirona NC, USA) and the well-fitting cone corresponding to the final file used for shaping was used. The access was restored, and a final postoperative radiograph was taken. Postoperative pain assessment was done for each patient after six hours, twenty-four hours, four days and one week.

Group (B): The same retreatment, cleaning and shaping procedures were applied to all root canals as group A. Obturation was done using the single cone obturation technique utilizing the Endosequence Bioceramic sealer (Brassler ,USA) where the master cone size was selected according to the final shaping file size. Postoperative pain assessment was done for each patient after six hours, twenty-four hours, four days and one week.

Patients recorded their pain on a 0–10 rating on the visual analog scale (VAS) which is a numerical rating scale (NRS) with 0 indicating no pain and 10 indicating severe pain. Patients were required to report their degree of pain level at the following time points: 6, 24, 48 hours and 1 week after canal obturation.

Statistical Analysis

Pain (VAS) scores showed non-normal (non-parametric) distribution. Data were presented as median, range, mean and standard deviation (SD) values. Mann-Whitney U test was used to compare between the two groups. Friedman's test was used to study the changes within each group. Dunn's

test was used for pair-wise comparisons when Friedman's test is significant. The significance level was set at $P \le 0.05$. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

Results

Pain (VAS) score

a. Comparison between sealer types:

There was no statistically significant difference between pain scores in the two groups after 6, 24, 48 hours as well as one week. Table (1) figure (1)

b. Changes by time within each group:

As regards for the single cone Bioceramic sealer group; there was a statistically significant change in median pain scores by time (P-value <0.001, Effect size = 0.337). Pair-wise comparisons between time periods revealed that there was no statistically significant change in median pain scores after six hours, from six to 24 hours as well as from 24 to 48 hours followed by a statistically significant decrease in median pain scores after one week.

While for the cold lateral compaction group with resin sealer; there was a statistically significant change in median pain scores by time (*P*-value <0.001, Effect size = 0.441). Pair-wise comparisons between time periods revealed that there was a statistically significant increase in median pain scores after six hours followed by a statistically significant decrease in pain scores from 24 to 48 hours. There was a statistically significant decrease in median pain scores from 48 hours to one week. Table (1) figure (1)

Demographic data:

There was no statistically significant difference between mean age values in the two groups. There was also no statistically significant difference between gender distributions in the two groups. Table (2)

Table (1): Descriptive statistics and results of Mann-Whitney U test for comparison between pain (VAS)
scores in the two groups and Friedman's test for the changes within each group:

Time	Single cone Bioceramic Sealer (n = 50)		Cold lateral with resin sealer $(n = 50)$		<i>P</i> -value	Effect size (d)
	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)	_	
6 hours	0 (0-8)	1.22 (1.76) ^A	2 (0-6)	1.94 (2.08) ^B	0.085	0.331
24 Hours	1 (0-8)	1.63 (1.88) ^A	2 (0-9)	2.59 (2.78) ^A	0.150	0.279
48 Hours	1 (0-7)	1.06 (1.39) ^A	2 (0-5)	1.69 (1.75) ^B	0.082	0.334
1 week	0 (0-3)	0.27 (0.6) B	0 (0-2)	0.29 (0.54) ^C	0.653	0.066
P-value	<0.001*		<0.001*			
Effect size (w)	0.337		0.441			

^{*:} Significant at $P \le 0.05$, The different superscripts in the same column indicate statistically significant change by time

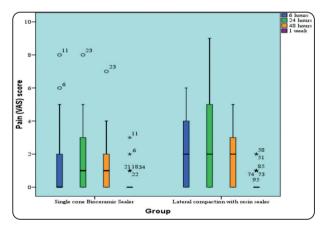


Fig. (1): Box plot representing median and range values for pain (VAS) scores in the two groups (Circles and stars represent outliers)

DISCUSSION

Root canal filling materials coming into direct contact with the periapical tissues result in post-operative inflammation, so the biocompatibility of endodontic sealers is of great importance when we aim to minimize the postoperative pain of root canal filled cases (12). Bio ceramic sealers are bioactive materials that help in osteoblastic differentiation and have a biologically acceptable soft tissue reaction (13). Post-operative pain of nonsurgical retreat-

Table (2): Mean, standard deviation (SD), frequencies (n), percentages and results of Student's t-test and Chi-square test for comparison between demographic data in the two groups:

	Single cone Bioceramic Sealer (n = 50)	Lateral compaction with resin sealer (n = 50)	P-value
Age (Years)			
Mean (SD)	8.7) 35)	8.9) 34.4)	0.709
Gender [n (%)]			
Male	(60) 30	(56) 28	0.685
Female	(40) 20	(44) 22	

^{*:} Significant at $P \le 0.05$

ment cases is common and frustrating, and can have an adverse effect on the patient dentist relationship. Several studies confirmed that there is no difference in the outcome of the non-surgical retreatment cases between single and multiple visits. (14).

According to multiple studies, the degree of postoperative pain incidence in single-visit retreatments was lower than that in multiple-visits. (10,11). Pain has multifactorial reasons to happen as the endodontic procedure comprises multiple steps in-

cluding the chemo mechanical preparation along with the obturation. It is prudent to use materials with acceptable biological properties if we are aiming to decrease the incidence of postoperative pain and inflammation in nonsurgical retreatment cases. AH Plus (Dentsply Sirona, York, USA) is an epoxy resin-based sealer that is readily used worldwide. This resin sealer has shown high levels of postoperative pain especially after unintentional material periapical extrusion. This epoxy resin sealer is considered the gold standard against which other sealers are compared and that's why it was chosen in the current study (15). Currently, calcium silicate-based materials are readily used, mainly because of their biocompatibility and bioactive properties (16). Thus the calcium silicate based bio ceramic sealer (Endosequence) was chosen in the current study in an attempt to discover whether the postoperative pain would decrease after obturating the teeth with this bioactive sealer or not.

The visual analog scale (VAS) is considered to be a reliable scale for measuring the degree of postoperative pain in dental research. Some studies have used the VAS, and others have used the verbal rating scale (VRS) for pain assessment. In the current study, the level of discomfort and pain was measured using the VAS as it can reproducibly predict the pain intensity using a well defined numerical ratio far more accurate than the VRS (17-20).

Patients were informed the aim of the study after self recorded their pain level. In this manner, the Hawthorne effect i.e. the mere awareness of participants in an inves-tigation can alter the way in which a person behaves, was minimized (15)

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after self recorded their pain level. In this manner, the Hawthorne effect i.e. the mere awareness of participants in an investigation can alter the way in which a person behaves, was minimized ⁽¹⁵⁾. De Amici D, Klersy C, Ramajoli F, Brustia L, et al. Impact of the Hawthorne effect in a longitudinal clinical study: the case of anesthesia. Control Clin. Trials. 2000 Apr; 21 (2): 103-114.

Mandibular molars were chosen in the current study as previous studies showed increased pain levels postoperatively in molars. All treatments were done by the same clinician who has sixteen years of clinical experience in endodontics as a specialist to exclude the operator as a variable influencing the degree of postoperative pain and to be able to overcome any complexities in the canal anatomy during retreatment in a single session. Patients receiving analgesics twenty-four hours prior to treatment were excluded from the current study to avoid any influence on the postoperative pain (21, 22). The presence of preoperative pain was found to have a direct correlation with the degree of postoperative pain, so asymptomatic patients only were recruited in the present study (23).

Warm vertical obturation techniques result in a greater amount of apical extrusion of filling materials compared to the cold lateral condensation technique (24). This overextension results in postoperative pain (25), thus the lateral condensation obturation technique was selected in the current study to decrease the impact of overextended periapical filling materials on the degree of postoperative pain. In a recent randomized clinical trial comparing the obturation when using single cone calcium and silicate sealers as opposed to continuous wave compaction with epoxy resin sealers, it was found that sealer extrusion results in a reduced success rate and an increased postoperative pain (30).

The hypothesis that the intensity of postoperative pain is less in single cone bioceramic based obturation retreatments in comparison to the lateral compaction epoxy resin based obturation retreatments was not fulfilled. There was no statistically significant difference regarding the postoperative pain between the two groups. Several studies have also found that there was no significant difference between the different sealer groups (26-28). In another study an epoxy resin sealer (AH plus) group was found to have less postoperative pain compared to the bioceramic group however in this study the teeth were vital and primary treatment was the treatment approach and not retreatment (29).

In both groups, there was a statistically significant decrease in the pain scores after one week, which is normal owing to the span of time that has passed allowing the pain and the inflammation to subside. Although both groups did not show a significant difference in the pain scores, however the AH plus resin group showed a significant postoperative pain increase after six hours, which was not the case in the bioceramic group. A recent meta-analysis also found that the postoperative pain (POP) was not significantly different when comparing retreatment cases obturated with bioceramic sealer versus traditional gutta percha and sealer, although numerically the bioceramic group showed a higher POP value in the 24 and 48 hours period (31). Another meta-analysis also concluded that there was no difference between the postoperative pain in resin-based and bioceramic root canal sealers at 24 and 48 hours (32). In the current study both the age and gender did not have a significant effect on the intensity of postoperative pain. A study found that females had a significantly greater postoperative pain compared to males when bioceramic sealer was used; however, they compared the postoperative pain in retreatment, vital and necrotic cases (33).

CONCLUSIONS

Under the limitations of the current study, the following conclusions were withdrawn:

1. There is no difference in the postoperative pain incidence between the bioceramic single cone technique and cold lateral compaction with

- resin sealer.
- 2. Both the gender and age did not have an effect on the outcome of the postoperative pain in both groups.
- 3. Single cone obturation with bioceramics can be used safely in single visit retreatment cases, when postoperative pain is being considered.

Recommendations:

Observational follow-up cohort studies are needed to determine the long-term effect of the single cone obturation with bioceramics upon the clinical and radiographic outcome.

Conflict of Interest

The authors deny any conflict of interest

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