Faculty of Dentistry
The British University in Egypt

The BRITISH UNIVERSITY IN EGYPT

Evaluation of Post Operative Pain after obturation using two different types of sealers

(A Randomized Clinical Trial)

Research proposal submitted to Department of Endodontics, Faculty of Dentistry, British University in Egypt, in partial fulfillment of the requirements of master's degree in Endodontics

Submitted by

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I. Administrative information:

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Introduction

Pain is one of the most common complications related to endodontic treatment and is defined as unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Endodontic postoperative pain has been defined as an unpleasant sensation of any degree of pain that occurs after initiating root canal treatment. The prevalence of post operative pain after endodontic treatment is 3-58%. [1]

Etiology of postoperative pain is multi-factorial and depends on the interaction between the host response, infection, and physical injury.

Including determination of working length, degree of foraminal enlargement, number of visits, analgesics consumption, gender [2-5], technique of filing and instrumentation system, kinematics, trauma of periapical tissue or bacterial extrusion and root canal sealer. specifically, extrusion of root canal sealer can disrupt periodontal tissues and cause inflammatory reactions. The intensity of this reaction depends on the composition of the sealer.

Different types of sealers can be used during obturation of root canals like zinc oxide and eugenol sealers, resin sealers or bio ceramic sealers. Resin sealers maybe epoxy, or methacrylate based, they are radiopaque, have low solubility and are biocompatible and have good flow while bio ceramic sealers contain alumina, zirconia particles, bioactive glass, calcium silicates, hydroxyapatite, and resorbable calcium phosphates [6]. These ingredients allow the sealers to resist bacterial leakage, rendering it biocompatible, simulating dynamic intratubular biomineralization. Bioceramic sealers release bioactive substances and enhance endodontic treatment outcomes by facilitating the differentiation of odontoblasts. However, resin sealers show higher bonding strength and radiopacity compared to bioceramic sealers.

Bioceramic sealers were introduced into the market as to cause less post operative pain after obturation compared to other sealers that is why studies were conducted to validate this fact with evidence.

The null hypothesis is that there is no difference in post operative pain between resin and bio ceramic sealers after endodontic treatment.

Review of Literature

Postoperative pain is defined as pain of any degree after initiation of root canal treatment either intra-appointment or post-obturation and is considered an undesirable occurrence for both patient and clinician.[7]

After cleaning and shaping of the canals Obturation can be performed using different types of sealers.

- Resin sealers are classified to epoxy resin based or methacrylate-based resin sealers. Epoxy resin-based sealers are commonly used due to their low solubility, micro-retention to dentin of root canal and their good apical seal. Currently modifications of the original formula are used widely [8]. Epoxy resin-based sealers are characterized by the reactive epoxide ring and are polymerized by these rings.

- Bio ceramic sealers are sealers that contain **calcium silicate and/or calcium phosphate** as their main compositions. Bioactive materials, such as glass and calcium phosphate, interact with the surrounding tissue to encourage the growth of more durable tissues [9], it can penetrate the dentinal tubules and interact with dentine moisture to create bonds between the dentin and core filling materials, an optimum dimensional stability, and the least amount of shrinkage. [10]

Pain is evaluated using visual analogue scale (VAS) [11]

- It is a pain rating scale. Scores are based on measures that are self-reported of symptoms that are recorded through a single handwritten mark placed at one point along the length of a 10-cm line representing a continuum between the two ends of the scale— on the left end of the scale (0 cm) means "no pain "and the on the right end of the scale (10 cm) "worst pain "

Pak and White [12]conducted a systematic review to assess the prevalence and severity of pretreatment, treatment, and post-treatment pain in patients receiving root canal treatment. They reviewed 72 studies for meta-analysis and concluded that pretreatment endodontic pain of high intensity dropped moderately within 1 day reaching minimal levels after 7 days & post-treatment pain prevalence was moderate or low stating that most included articles reported 7-day pain relief as the severity starts to drop from the first day till less than 10% after 7 days.

Ali et al., [13] investigated the prevalence of post-operative pain after single visit endodontic treatment in the Indian population using protaper rotary files in addition to hand instruments by evaluating the factors that might affect pain experience. Their study included One thousand three hundred and twenty-eight patients. post-operative pain was evaluated using visual analogue scale by each patient by well-defined categories at three-time intervals, 12, 24, and 48 hours. They concluded that the prevalence of post operative pain was low (4%) and the important prognostic determinants of post-operative pain were presence of pre-operative pain, old age, gender (females recorded higher), and mandibular teeth but the vitality of the tooth had no effect on the intensity nor the frequency of post operative pain.

Sadaf and Ahmad, [14] assessed postoperative pain and its associated clinical factors in endodontic therapy through a cross sectional study including one hundred and forty patients with premolars and molars requiring endododontic treatment and the treatment was performed in multiple visits. Results showed a significant difference in postoperative pain which was higher in females than males, mandibular teeth than maxillary teeth and in symptomatic than asymptomatic patients. There was no significant difference regarding tooth type, obturation length and sealer extrusion. So, gender, preoperative pain, maxillary, or mandibular teeth were considered risk factors affecting postoperative pain.

Mathew [15] reviewed and critically analyzed the influence of various factors on the incidence of postoperative pain.pain was evaluated through visual analogue scale (VAS) and facial gramice scale . A total of thirty-eight articles were included in the review, the articles were classified into variables affecting postoperative pain after endodontic treatment. Results showed high incidence of

postoperative pain in females, mandibular teeth, premolars when compared to anteriors, with positive correlation between preoperative and postoperative endodontic pain. Administration of premedication's (NSAIDs) decreases post operative pain. Step down instrumentation causes less debris extrusion and less pain. According to 13 different studies There was no significant difference between single or multiple visits. The effect of tooth vitality remained inconclusive.

Al-Rahabi [16] reviewed the effects of root canal treatment on postoperative pain and determined the possible predictive and related factors. Sixty-five studies were included in the review. Results showed a strong relationship existed between preoperative pain and postoperative pain, as well as high pain prevalence among women, mandibular and molar teeth. Application of intracanal medications may reduce the pain between visits. Moreover, recent advances in endodontics regarding magnification, instrumentation technique and alloy metallurgy in addition to activation of irrigant to reduce microbial load and disinfection for higher success rates of endodontic treatment reduced postoperative pain in terms of both intensity and duration. On the other hand, age of the patient and single or multiple visit root canal treatment showed no statistically significant differences.

Graunaite et al., [17] conducted a Split-mouth Randomized Controlled Trial to compare the effect of Resin-based and Bioceramic Root Canal Sealers on Postoperative Pain in sixty one patients with asymptomatic acute apical periodontitis (AAP) having at least 2 single rooted teeth requiring retreatment .Visual analogue scale was used to evaluate the pain .Obturation material was different for each tooth after retreatment ,they concluded that AH Plus and Total Fill perform similarly in terms of the occurrence and intensity of postoperative pain in teeth with AAP (acute apical periodontitis) with no material extrusion beyond the apex.

Nabi et al., [18] conducted a randomized controlled trial to compare the effect of different types of sealers on postoperative pain in single visit endodontic treatment. Ninety patients requiring primary endodontic treatment were selected for the study. Patients were treated in single visit endodontically using three different bio ceramic-based sealers (MTA plus sealer, iroot SP, Endo sequence BC) dividing the sample size to three groups. Heft–Parker Pain Rating

Scale was used to evaluate the pain for 48 hours postoperatively. They found that Post endodontic pain was reduced in all treatment groups and that the three bio ceramic sealers can be used for single-visit endodontics without fear of postoperative pain.

Fonseca et al., [19] Assessed extrusion and Postoperative Pain of a Bio ceramic and Resin-Based Root Canal Sealer on sixty-four patients requiring endodontic treatment in single rooted necrotic maxillary teeth, treatment was performed in a single visit and visual analogue scale (VAS) was used for pain assessment up to 1 week interval. Sealer extrusion was observed in 9 patients of the resin group and 19 patients of the bioceramic group concluding that Bio ceramic sealer presented significantly more extrusion than the Resin sealer and that sealer extrusion was not associated with pain. both groups had similar average pain level and the mean number of tablets taken for relief of pain.

Ferriera et al., [20] compared the occurrence and intensity of postoperative pain and analgesic intake after root canal treatment, using different root canal sealers on sixty single rooted necrotic asymptomatic teeth with apical periodontitis dividing the sample to three groups according to the type of sealer used for obturation(AH Plus, Endofill or MTA Fillapex) .Endodontic treatment was performed in two visits with placing calcium hydroxide dressing as intra canal medicament inter appointment . In terms of either incidence or intensity of postoperative pain or need for analgesic intake no significant differences were detected among the groups, at any timepoint. No pain was reported after 7 days. AH Plus, Endofill and MTA Fillapex used for filling root canals resulted in the same rate of postoperative pain and need for analgesic medication.

Shim et al., [21] compared the effects of bio ceramic sealer and resin-based sealer on the incidence and intensity of postoperative pain on one hundred and eight patients with anteriors and premolars and molars requiring endodontic treatment. In groups En1(premolars or anteriors) and En2(molars), root canals were obturated with Endo seal MTA using the single-cone technique. In groups AH (premolars or anteriors) and AH2(molars), the sealer used was AH Plus with the continuous wave technique. Pain was assessed through visual analogue scale over 7 days period. They found that: Endo seal MTA and AH Plus had similar

effects on the incidence and intensity of postoperative pain. The obturation time was shorter when using Endo seal MTA compared to AH Plus.

PICO

P: patients diagnosed with irreversible pulpitis age from 18-50 years old

I: obturation with bioceramic sealer

C: obturation with resin sealer

O: effect on post operative pain

Aim of the study

The aim of this randomized clinical trial is to evaluate the post-operative pain after obturation using Resin Vs. Bioceramic sealers.

Participants and Methods

I-Materials

Round bur/endo Z/tapered round stone
Rubber dam
#10 k files
Apex locator
#15 #20 k files
Side vented needle
5.25% sodium hypochlorite
Rotary files
Endo motor
Sensor
Paper points
Gutta percha points
Resin sealer
Bioceramic sealer
Torch
Condenser
Cotton and temporary filling

II-participants

A-Sample size determination:

Sample size calculation was performed using G power (3.1.9.4) software, based on a previous study [22] 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.

B-Patient's selection:

1-Eligibility criteria:

***Inclusion criteri*a:**

- Patients age ranges from 18-50 years old.
- Patients with teeth diagnosed with symptomatic irreversible pulpitis.
- Normal periapical condition confirmed by normal periapical radiograph or that with minimal widening of the PDL space
- The teeth are restorable
- Teeth are periodontally free.

Exclusion criteria:

- Teeth with immature roots
- Non restorable teeth
- Medically compromised patients with systemic complication that would alter the treatment.
- Necrotic teeth
- Teeth with apical periodontitis or periapical lesions
- Teeth that need multiple visits treatment

2-Ethical consideration:

Patient will be asked to follow general instructions and to sign a printed informed consent explaining the aim of study, brief of study methodology, benefits and complications of the procedure and requesting that they allow clinician to follow up after performing the treatment. This study will be performed in compliance with the ethical standards laid down in the 2013 Declaration of Helsinki

Adverse events during the trial will be reported to supervisor and co supervisor and monitors of ethical committee

C-Patient allocation:

Using computer generated randomization, the participants will be allocated randomly into two equal groups.

The sequentially numbers that will be generated, will be placed in opaque envelope until the intervention and each participant will be asked to select an envelope that determine which group of intervention he will be assigned.

D-Patient Classification:

Patients were randomly divided into two groups according to material used for obturation . each patients name will be replaced with a case number within the group to protect the privacy of medical information and data of the patients

Group (1) resin sealers

Group (2) bio ceramic sealer

Methods

Procedural steps:

- Pain scale chart will be given to each patient to rate his /her pain level before endodontic treatment as preoperative reading on a visual analogue scale (VAS)
- Tooth will be anaesthetized using Local anesthesia containing Articaine with epinephrine 1:100,000.
- Access cavity will be performed using a carbide round steel bur and tapered diamond stone until complete deroofing.
- Rubber dam isolation of tooth
- Patency is gained and working length is recorded using apex locator and confirmatory radiograph.
- Cleaning and shaping using rotary system
- Irrigation using 5.25% sodium hypochlorite introduced using side vented needle
- Activation of the irrigant
- Master cone check
- obturation
- temporary restoration will be placed

Methods of evaluation

Post operative pain

Each patient will be asked to fill the visual analogue scale (figure 1) to rate the pain level postoperatively at 6, 24, 48, and 72 hours following the end of the procedure.

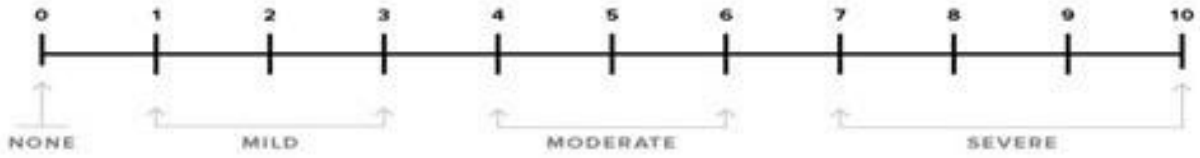

Figure 1: Visual analogue scale used by the patient to report pain level at different time intervals

G-Statistical analysis:

Data obtained will be tabulated in the form of groups and case numbers to protect patient's confidentiality.

Data will be statistically analyzed using non-parametric tests to compare numerical variables (age, VAS scores) amongst the groups. other test will be used to evaluate the changes in pain scores over time. Categorical variables (gender, type of teeth) will be compared amongst the groups . Also, the correlation assessments between age factor and postoperative pain, and gender factor and postoperative pain will be done.

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