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Research title: Comparative Evaluation of Post-operative pain with different apical finishing sizes after single visit root canal treatment

Research approved by Research ethics committee the British university in Egypt Research Approval Number: 7/3 /2023 Number 23-002 Comparative Evaluation of Post-operative pain with different apical finishing sizes after single visit root canal treatment

Introduction:

Apical preparation size is a very important variable in the process of root canal preparation. There have been many conflicts regarding the proper size and how it affects bacterial reduction, root canal dentine strength in terms of conservation and even postoperative pain. Post-operative pain as a patient related outcome, with different apical sizes is very important. In this study, we will evaluate the postoperative pain after root canal enlargement with two sizes after the binding file compared to three sizes after the binding file without disregard of mechanical principles of root canal preparation.

Materials E3 Azure Poldent files Resin sealer k-files Mani

Subjects:

This is a proposed randomized controlled parallel clinical, prospective split mouth, triple blinded study. Sample size calculation was conducted using G\*Power 3.1.9.4 software based on data obtained from a previous study.[hala's paper which compared the effect of different kinematics on post operative pain(patients) ] It was estimated that a minimum sample size of 19 subjects (sides) per group for a total of 38 sides would be essential for an effect size of 0.97 with an alpha error of 0.05 and a power beta of 0.90 to achieve 95% confidence of a true difference between the groups. Sample size was increased by 25% to 25 subjects per group for a total of 50 sides to compensate for dropouts.

Inclusion criteria:

Of the 25 patients all must have the following: Age: 20-50 Gender: Males and Females, random selection.

Systemic status: healthy patients (Category: American Society of Anaesthesiologists class 1)

Bilateral exposed mandibular first or second permanent molars Molars should have separate mesial and distal roots

Mesial roots confirmed to be type three root canal system

Distal root confirmed to be type one root canal system

Normal periapical radiograph and no bone changes

Symptomatic irreversible pulpitis

I.B.F. in mesial roots not more than #20, and distal root not more than #30

Exclusion criteria:

Type two root canal system in mesial roots Type two or three root canal systems in distal roots Signs of apical involvement in the radiograph Any systemic conditions altering the treatment or requiring medications or precautions

## Patient selection and preparation:

All root canal treatments were performed by a single endodontic consultant. All subjects were selected from walk in patients presented to the endodontic clinic of the British university in Egypt. Cases that were diagnosed and did not meet the inclusion criteria were referred to the intern clinic for dental care. Cases that met the inclusion criteria where selected for this study. All patients were verbally informed about the procedure's benefits and that the results of the treatment will be used to this study and the risks of the procedure was explicitly explained to them. After the verbal consent patients were handed a written form consent to sign upon.

## Procedure:

Radiographs were taken by a Paralleled long cone periapical radiography. To ensure a visible root canal  $\leq 30^{\circ}$  of canal curvature and a periapical index (PAI score) of 3–5 according to Orstavik et

al., (1986) in addition of initial confirmation of root canal types. All patients were anesthetized, rubber dam applied, and access cavities were performed. After root canal exploration and scouting, root canal systems were reconfirmed to be the types selected for this study.

Initial binding file was selected for all root canals to ensure it met the inclusion size of mesial roots #20 and distal #30. After patency and glide path were performed by K-files up to size #20, engine driven canal enlargement was applied using E3 Azure files to final finishing size according to the grouping.

Group A: (left side of the patient) will be prepared 2 sizes larger than the IBF, to size 35#/.04 mesial canals and 40#/.04 distal canals.

Group B: (right side of the patient) will be prepared 3 sizes larger than the IBF, to size 40#/.04 mesial canals and 45#/.04 distal canals.

All data of post-operative pain will be recorded by a second blinded clinician through a visual analog scale (VAS). Postoperative monitoring periods will be recorded in 12 hours, 24 hours, 3 days and 1 week.

Data will be sent to the statistician with group names only to fulfill the triple blinding criteria and results will be interpreted