"COMPARATIVE EVALUATION OF POSTOPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC TREATMENT USING NEOLIX NEONITI AND E3 AZURE FILE SYSTEM A RANDOMIZED CLINICAL TRIAL"

By

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LIST OF ABBREVIATIONS

NiTi	Nickel – Titanium
NaOCl	Sodium Hypochlorite
K file	Kerr file
EDTA	Ethylenediamine Tetracetic acid
0	Degree
#10	Tip diameter – 0.10mm
#15	Tip diameter – 0.15mm
mm	Millimeter
%	Percentage
i.e	That is
ISO	International Organization for Standardization
EDM	Electric Discharge Machining
GP	Gutta percha
PP	Paper point
EAL	Electronic Apex Locater
WL	Working length
M	Male
F	Female
VAS	Visual Analogue Scale

Post op	Post operative
min	minutes
hrs	hours
yrs	years
<	Less than
>	Greater than
=	Equal to
Fig.	figure
vs.	versus
IOPAR	Intraoral periapical radiograph

ABSTRACT

Title of the article: Comparative Evaluation of Postoperative Pain After Single Visit Endodontic Treatment Using Neolix Neoniti and E3 Azure File System: A Randomized Clinical Trial

Context:

Root canal preparation can cause postoperative pain and swelling due to the inadvertent extrusion of debris, which varies depending on the instrumentation technique and design characteristics. Dental companies have been introducing NiTi rotary equipment for the past ten years, including M wire, CM wire, Max wire, EDM, and gold and blue coated NiTi files. However, even the newly introduced spectra of instruments succumb debris's apical extrusion. Thus, that instrument which cause minimal extrusion becomes prudent as it causes less pain. Therefore study aims to asses and compare post-operative pain after single-visit endodontic treatment employing Neolix Neoniti and E3 Azure rotary file systems

Methods and Material:

68 patients in need of endodontic therapy wrt maxillary premolar teeth, diagnosed as asymptomatic irreversible pulpitis were randomly allocated in to 2 Groups according to instrument used: GroupA Neolix Neoniti (EDM) and GroupB E3 Azure (Azure HT) and RCT was done in single session, modified VAS was used to measure post-operative pain at various time intervals and Additionally, the groups' associations with age, sex, and the amount of time needed for root canal preparation were assessed and compared.

Results: Significantly more postoperative pain occurred in the Neolix Neoniti group than in the E3 Azure group. At 6 hrs, both Groups had the highest mean pain levels; however, at observation intervals, there was a notable decrease in pain and no pain at 72hrs.In the variables age and gender severity of pain did not differ significantly, and no statistical difference noted in preparation time

Conclusions: It may be inferred that patients undergoing canal instrumentation using the Neolix Neoniti rotary file experienced much more postoperative pain than those using the E3 Azure rotary file.

Key-words:Neolix Neoniti,E3 Azure,single sitting, post operative pain

Key message: In order to address the limitations of this study and extrapolate the RCT's findings to all clinical cases, larger sample sizes, longer follow-up times, and the inclusion of more factors will be needed in future clinical studies

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INTRODUCTION

Life Is Full of Evolution, And Endodontics Is No Exception!!!!

Even with greater knowledge of the internal anatomy of teeth, path breaking innovations in radiology backed with the evolution of instruments and technology one continues to be challenged while we shape root canals.[1] Postoperative pain which is a significant concern in endodontics, occurs in the ranges between 3% and 58%, of all endodontic patients, the most important causative factors for post-operative pain is an outcome of these challenges.[2]

Dental companies have been introducing NiTi rotary equipment for the past ten years in an effort to enhance preparatory methods, reducing time, to treat complexity such as curved canal. Niti's excellent shape memory and super elasticity have a positive impact on root canal shaping outcomes. Many innovations, including M wire, CM wire, Max wire, EDM, and gold and blue coated NiTi files precision and perfection is promising.[3 4]

However, even the newly introduced spectra of instruments succumb debris's apical extrusion. The quantity of debris varies with every different instrumentation technique and design characteristics.[5 6] This debris may create an injury that results in inflammation if it is extruded into the periapical tissues. This debris includes dentin filings, pulp tissue fragments, necrotic tissue, microbes, or intracanal irrigants. Some publications have referred to the extruded material as worm of necrotic detritus. The inflammatory response in periodontal ligaments is triggered by neurogenic sources, substance ,CGRP these neuropeptides trigger vasodilation, plasma extravasation, and activation of inflammatory cells, growth factors, and

inflammatory mediators, causing pain and escalating inflammation.[7] Thus that instrument which cause minimal extrusion becomes prudent as it causes less pain.

Manufacturers and researchers have been experimenting to create newer models that would use the best-tested design elements from the past along with the newest technology, in order to create safer, more effective, and simpler file systems .[8] [9] [10] Two such instrument have been newly introduced into the market that is Neolix Neoniti and E3 Azure.

Neoniti Neoniti (Neolix, Châtres-la-Forêt, France) launched in the year 2014 is a type of full-sequence, single-file rotary NiTi instrument developed to prepare a root canal all with one instrument.[11] The electrical discharge machining method used to create the Neoniti A1 has several benefits, including high precision, the ability to create a wide range of designs without tool constraints, and minimal manufacturing stress to the file surface. It also results in a rough surface that can improve the file's cutting capabilities.[12]

In-vitro studies done on these file systems have claimed that the Neolix Neoniti rotary file system has a decreased apical debris extrusion attributed to its variable pitch and helical angle. [13]

In vivo study comparing ProTaper Next to Neolix Neoniti file system for treating necrotic pulps in maxillary and mandibular teeth found that Neolix Neoniti file system was superior in postoperative pain.[14]

Endostar E3 Azure®, which was newly debuted in the year 2019 has been produced by Azure HT Technology, which alter their crystal structure and enable the change from martensite to austenite at temperatures close to body temperature. In

addition to it has altered S-shaped cross-section with two 90-degree cutting edges to minimize suck-down of debris, it facilitates more effective debris transportation up the canals while instrumentation is being done.[15]

In-vitro studies on E3 Azure file system comparing debris extrusion from continuous rotation and optimum torque reverse showed no statistical significance.[16]

In vivo, Studies using the E3 Azure file system with and without apical patency with modified S shape cross section showed no substantial variation in pain following procedure.[17]

The introduction of single-file systems in recent years with different kinematics and file designs has greatly streamlined the multistep rotational instrumentation process into a single step[18] [19].as single file systems lower the risk of cross-contamination between patients and save the operator time and money.[20]

Both of these instruments could be options for clinicians to choose from and there is no invivo study done to compare these two systems, The best kind of data to support evidence-based clinical therapy is a randomized clinical trial. [21]

Therefore,a study was conducted using the Neolix Neoniti and E3 Azure rotary file systems to assess and compare post-operative pain following a single visit endodontic treatement.

AIM & OBJECTIVE

STUDY AIM

Employing Neolix Neoniti and E3 Azure rotary file systems assess and compare post-operative pain after single-visit endodontic treatment.

STUDY OBJECTIVES

- Using visual Analogue Scale assess the occurance of post-operative pain at 6-, 24-, 48-, and 72 hrs following single-visit endodontic treatment performed using Neolix Neoniti and E3 Azure rotary file systems.
- Using visual Analogue Scale to assess the severity of post-operative pain at 6-, 24-, 48-, and 72-hrs following single-visit endodontic treatment performed using Neolix Neoniti and E3 Azure rotary file systems.
- Using visual Analogue Scale to compare the occurrence of post-operative pain at 6-, 24-, 48-, and 72- hrs following single-visit endodontic treatment performed using Neolix Neoniti and E3 Azure rotary file systems.
- Using visual Analogue Scale to compare the severity of post-operative pain at 6-, 24-, 48-, and 72 hrs following single-visit endodontic treatment performed using Neolix Neoniti and E3 Azure rotary file systems.
- To assess and compare how age and sex are associated with the groups using Neolix Neoniti and E3 Azure rotary file systems.
- To assess and compare time needed to instrument both canals

RESEARCH HYPOTHESIS

NULL HYPOTHESIS

Post-operative pain will not differ following single-visit endodontic treatment with Neolix Neoniti and E3 Azure rotary file systems.

ALTERNATE HYPOTHESIS

Post-operative pain will differ following single-visit endodontic treatment with Neolix Neoniti and E3 Azure rotary file systems.

REVIEW OF LITERATURE

1. A prospective study examined the factors that influence post-preparation pain during root canal therapy. The researchers determined that postoperative discomfort was common, and that it was influenced by preoperative edema, systemic steroid treatment, tooth type, and preoperative discomfort.[22]

2. A study compared the occurrence, severity, and duration pain of 300 endodontically treated patients after procedures with and without apical patency, taking into account diagnostic criteria such as viability, preoperative pain, group, and morphology. When all variables are taken into account, it was determined that maintaining apical patency does not affect the incidence, severity, or duration of postoperative pain.[23]

3. A randomized controlled trial compared post-operative pain following single or two visits root canal treatment (RCT) for anterior teeth with important pulps and a single root and canal. There was no significant difference in the incidence and intensity of post obturation discomfort experienced after a one- or two-visit RCT on teeth with important pulps and a single canal.[24]

4. According to a study, pre-operative discomfort, gender, age, and mandibular teeth are important predictors of the low (4%), post-obturation pain following root canal therapy. The degree of pain is independent of the state of the tooth.[25]

5. An in-vivo study evaluated the frequency and severity of pain following treatment utilizing three nickel-titanium instrumentation techniques: rotary crown-down with Twisted Files (TF) instruments, reciprocating single-file with Wave One instruments, and a novel combination of reciprocation and continuous rotation. Postoperative pain was assessed using the Visual Analogue Scale. This study found that the reciprocating single file approach resulted in a significantly higher incidence of symptoms.[26]

6. A study assessed the impact of working length measurement techniques (digital radiography and electronic apex locator). on postoperative discomfort. It was determined that there was no difference in postoperative pain between working length measurements utilizing an electronic apex locator and digital radiography.[27]

7. Prospective randomized clinical research compared postoperative pain and analgesic drug use after endodontic treatment of posterior teeth using two reciprocating systems and a continuous rotating system. It was determined that the reciprocating and continuous rotary systems were equal in terms of postoperative pain incidence and analgesic medication intake at the time points studied.[28]

8. Endodontic treatment is commonly done in multiple visits as preferred by many clinicians, but now, the scenario is changing with the advent of single visit endodontics. Studies conducted comparing multiple visit and single visit endodontics reported statistically insignificant difference between them in regard to survival rate, post-operative pain or flare ups and long-term prognosis.[29]

9. The introduction of single-file systems in recent years with different kinematics and file designs has greatly streamlined the multistep rotational instrumentation process into a single step.[7] Single file systems lower the risk of cross-contamination between patients and save the operator time and money.[30]

10. Another significant development was the inclusion of reciprocating motion as opposed to the previously employed 360-degree rotation motion used with files. However, it was shown that reciprocating motion extruded more debris apically than files in continuous motion.[31]

11. A Clinical trial was done to evaluate post operative pain both when apical patency is maintained and not using E3Azure.The result showed that there There was no statistical difference in postoperative discomfort in the groups.[32]

12. Among the other kinematics, no discernible variation was seen. While reciprocal motion seemed to enhance debris transportation toward the apex, continuous rotation—which functions similarly to a screw conveyor—seems to encourage coronal transportation of dentine chips and debris. [33]

13. A study evaluated the impact of various kinematics and equipment designs based on effectiveness of cutting of two heat-treated nickel-titanium systems. I; Azure rotary system in rotation motion, group II; Azure rotary system in Reciprocation motion, group III; Fanta AF One rotary system in rotation motion and group IV; Fanta AF One rotary system in reciprocation motion. Forty resin canals were divided into four groups based on the instrument and operating kinematic. Blocks were labeled, weighed, and analyzed for

statistical evaluation. It was found that the instrument's cross section had a greater effect on cutting efficiency compared to the motion utilized. [34]

14. A comparative clinical investigation was carried out to assess pain after single session of endodontic treatment in vital and non-vital with and without periapical radiolucency. It was concluded that none of the teeth in any of the groups had severe pain. There was no statistical difference between the incidence of pain in vital and non-vital teeth without periapical radiolucency.[35]

15. A clinical trial was done to assess Post-operative pain after single appointment RCT using protaper Next and Neolix Neoniti which concluded that the Neolix Neoniti group showed superiority in terms of postoperative pain. These results were attributed to the variable helical angle of 28˚ to 16˚ from tip to rear of Neoniti files.[36]

16. A quantitative analysis of apical debris extrusion was conducted in vitro comparing Mtwo, Hyflex EDM, Neolix Neoniti and Protaper files. The results showed that Hyflex EDM showed maximum amount of apical debris extrusion and the lowest values were seen with the Mtwo and the Neolix file system,[37]

17. A study was done as the Comparative analysis of extruded debris from the apex root canal using two Ni-Ti single file rotary systems which evaluated NEOLIX Neoniti and One shape system. The study concluded that Neolix Neoniti extruded less debris as compared to the One shape system. The results were attributed to the variable pitch of 2.25- 6.00 mm over the length of the file and varying helical angle of 28˚ to 16˚. Also, the three-point contact of one

shape having a triangular cross-section resulted in the greater generation of the debris.[38]

18. An in-vitro study compared the ability to shape by ten rotary and reciprocating file systemand the authors came to the conclusion that the Neolix Neoniti system and the Reciproc system gave superior results in shaping.[39]

19. A study evaluated the The impact use of rotary and reciprocating single file methods on pericervical dentin, it was concluded that the Neolix Neoniti system removed the least pericervical dentin and hence contributed to a longer survivability of the tooth.[40]

20. An in-vitro investigation examined the establishment of dentinal fractures.using four different rotary systems, Neolix Neoniti, Reciproc, Mtwo, and Protaper system which concluded that the Neoniti systems showed a statistically significant lower frequency of cracks in comparison to the other systems.[41]

21. A prospective randomized control study evaluated and Compared postoperative discomfort after single-visit root canal therapy.with Reciproc Blue and Hyflex EDM file systems. The authors used a verbal rating scale and evaluated pain after 24h, 48h, 72h, and 7 days. The Postoperative pain was found to be higher in the RBlue than in the Hyflex EDM and manual file system when the file was used in reciprocating motion.[42]

22. A study assessed the. of The material was extruded apically utilizing three different reciprocating single endodontic file systems.The authors used 45 human upper first molars randomly assigning them to 3 groups; Reciproc

Blue, R- motion, and Edge One. The amount of apical extrusion of debris was assessed using the empty tube model of Myers and Montgomery. Within the limitations of the study, R-Motion showed the most amount of apically extruded debris followed by Reciproc Blue and Edge One [43].

23. The findings of this in vivo trial found no significant change in the incidence of postoperative pain among the three groups.A prospective randomized controlled study compared postoperative pain in single visit endodontics using heat-treated nickel − titanium file systems (ProTaper Gold, HyFlex EDM, V Taper 2H). 60 patients requiring endodontic therapy were divided into three groups Group 1 teeth prepared with ProTaper Gold (Dentsply), Group 2 HyFlex EDM (Coltene), and Group 3-V Taper 2H (SS WHITE). Treatment was performed in a single visit.. The Visual Analog Scale was used to measure the intensity of postoperative pain after 2, 4, 8, 12, 24, and 48 hours.[44]

24. An in vitro study compared the effect of continuous rotation and optimum torque reverse on the amount of apically extruded debris using EdgeFile X7 and Endostar E3 Azure files. 40 mandibular single rooted premolars were chosen. Canals were divided into two groups (n=20). An analytical microbalance assessed the weight of debris. According to motion kinematics; with continuous rotation EdgeFile X7 had a higher value than Endostar E3 Azur while with Optimum torque reverse motion, Endostar E3 Azur had a higher value with no statistically significant differences. According to the file used, EdgeFile X7 showed a higher significant value with continuous rotation than with optimum torque reverse. In contrast, Endostar E3 Azur showed a higher value with continuous rotation than with optimum torque reverse with

no statistically significant difference. Within the study's limitations, it was concluded that kinematics impacts the amount of extruded debris regarding the type of rotary files used. [45]

25. In an in vitro study, the amount of material ejected apically via TruNatomy, ProTaper Next, HyFlex electric discharge machining, and HyFlex controlled memory was compared. The TN file system produced significantly less debris extrusion compared to other systems.[46]

26. An in vitro study looked at the amount of apically extrudeddebris following two distinct file system instrumentation. Wave One Gold and Hyflex EDM. 30 premolar teeth were utilized for the study. Extruded debris and irrigants were collected in preweighed test tubes and weighed. Hyflex EDM showed more debris extrusion than Wave One Gold.[47]

27. A study evaluated the amount of Apical debris extrusion and centering abilities of multifile NiTi systems and single-file systems. 70 3D-printed resin teeth were used, and the apically extruded debris was collected. The study found that RCB had the highest apical extrusion of debris, while problems such as transportation of root canals and ratio of centering were lowest in ROT, PTG, and PTG. The study concluded that the cross-section design and mode used for the motion were the most significant factors affecting debris extrusion.[48]

28. EdgeFile, a reciprocating and multiple-file system, exhibited significantly less postoperative discomfort compared to other systems in a research comparing

heat-treated rotary and reciprocating nickel titanium file systems for acute irreversible pulpitis in maxillary premolars.[49]

29. A study comparing two Ni-Ti single file rotary systems, One-Shape and Neo-Niti, found that the Neolix Niti single file system had less extrusion during root canal instrumentation compared to the One Shape system. The study used preweighed Eppendorf tubes for each tooth and irrigated them with distilled water.[13]

30. A study on dentinal fractures after root canal instrumentation with One hundred and eighty intact lower central incisors were selected and randomly divided into fourteen groups, The root canals were prepared with fourteen different rotary systems after decoronation With water cooling all teeth were sectioned found that canals with instrumentation showed dentinal cracks, while uninstrumented ones did not. The study examined teeth sectioned 3, 6, and 9 mm from the apex and examined under a stereomicroscope. Crack formation occurred in both rotary and reciprocating file systems.[50]

MATERIALS AND METHODS

Study Comparative evaluation of post-operative pain after single visit endodontic treatment using Neolix Neoniti and E3 Azure file systems rotary file systems-A randomized clinical trial was carried out at Department of Conservative Dentistry and Endodontics, KAHER's V.K. Institute of Dental Sciences, Belagavi, Karnataka, with approval of Research and Ethical Committee of KLE University's VK Institute of Dental Sciences.With reference number 1599 dated 03.04.2024, and with the CTRI number CTRI/2023/05/052543.

MATERIALS USED IN THE STUDY: -

- LA 2% lignocaine 1:80,000 adrenaline (ICPA),15%EDTA gel (Well-Prep), Povidine Iodine5% w/v (Sun Pharmaceutical Ind),30% w/v Hydrogen Peroxide30% w/v (Thermo Fisher Scientific Pvt. Ltd),Sodium Thiosulphate (Ranbaxy Fine Chemicals Limited), Saline :0.9% w/v (AH Ltd.Ind),Naocl 3% (Vishal Dentocar Ltd)Di sodium edetate solution17% (Canalarge)IOPA Films (Noisy-Le-Grand Cedex, France),Sterile cotton,Paper points (DiaDent MMPP),Guttapercha (Neolix Neoniti and E3 Azure matching gutta-percha points),AH Plus® Sealer (Dentsply,Germany),Cavit G (3M ESPE Germany),Tab Ibuprofen 400mg (Abbott India.)

- The DG-16 probe (GDC®, Germany), the mouth mirror (GDC), the rubber dam kit (Hygienic, Coltene-Whaledent), electric pulp vitality tester (Parkell Inc, NY), Disposable saliva ejector; Airotor (NSK AIR); spoon excavator (GDC),Disposable syringes (Unlock); Endo Z bur (Dentsply); Mini Endo block

(Dentsply); X-SmartTM (Dentsply); Endo access bur (Dentsply); Stainless steel K-files # 10, 15,(Mani Inc); Neolix Neoniti rotary file system (Neolix France) – A1 (6%, 0.25 mm); E3 Azure rotary files system (Endostar) – A1 (6%, 0.25 mm) and matching GP.

METHODOLOGY

Based on the specific inclusion and exclusion criteria 68 patients in need of endodontic therapy with respect to maxillary premolar teeth, diagnosed as asymptomatic irreversible pulpitis were chosen from the normal patient pool of Department Of Endodontics and Conservative Dentistry, the KLE VKIDS Belagavi. A signed informed consent agreement was obtained from patient after being informed about the procedure in his or her native tongue.

INCLUSION CRITERIA: -

Patients in need of root canal therapy for their 2-root canalled maxillary premolar teeth, identified clinically with pulp sensitivity tests as asymptomatic irreversible pulpitis, patients in age range of 18-50 years, having an insignificant past medical history, without any pre-operative pain, and sufficient coronal structure for isolation

EXCLUSION CRITERIA: -

PATIENT SPECIFIC:

Patient who decline to provide their consent ,Individuals with immunocompromised states, pregnancy, any systemic diseases, Patients receiving antibiotic treatment within the last three months, Patients who have used analgesic

medications within the last seven days, Patients with lignocaine allergies adrenaline concentration of 1:80,000,Ibuprofen-allergic patients, as well as those in need of root canal therapy for two or more teeth on the ipsilateral side (because pain from any of these teeth may provide a false positive reading).

SPECIFIC TO DIAGNOSIS:

Teeth with severe apical periodontitis, acute periapical abscess in teeth, teeth whose diameter of periapical radiolucency is more than 0.5 cm (5 mm), teeth where the canal is being drained of an inflammatory exudate, painful teeth without a sinus canal for drainage, cases involving retreatment, Dilacerated teeth, teeth with grade III mobility or severe periodontitis.

C. TOOTH SPECIFIC:

Teeth with internal and external resorption, an immature apex, and calcified canals, With two root canals and one apical foramen at the end, Teeth with such canals will not be accepted if a 10 K-file moves very slowly ,20 K-file extends readily (apical gauging),severe labially or lingually incorrectly positioned teeth that make it challenging to gain straight-line access,

DETAILS OF THE PROCEDURES CONDUCTED IN THE RESEARCH –

A single clinician evaluated each patient based on radiographic and clinical data, and then each case was treated. The exclusion criteria were strictly adhered to, and computer-generated random number tables were used to handle confounding variables through random allocation

The patient was given LA (1:80,000 adrenaline 2% lignocaine), For tooth isolation, a rubber dam (Hygienic, Coltene) was used. After the patient provided written informed consent (Annexure III) for their participation in the study. Following isolation, the tooth crown was cleaned with regular saline and pumice, with sterile cotton rolls and pellets the tooth was disinfected for 60 seconds each with 30% w/v hydrogen peroxide and 5% w/v Povidine iodine, Sodium thiosulphate was applied subsequently rendered the iodine inactive.[51]

Following the procedure of disinfection, a standard endodontic access cavity preparation was carried out, and the #10 K-file was used to evaluate the patency of the canals. Then apex locator was used to estimate working length (WL), then validated by radiograph and 15 K-file (Mani Inc, Japan) was used as glide path.

Following the manufacturer's guidelines, Group A (n = 34) used a full sequence of Neoniti rotary files up to size A1 for root canal preparation, whereas Group B (n = 34) utilized E3 Azure files up to size A1.

Group A: Neoniti Rotary Files (Neolix, Châtres-La-Forêt, France) – A1 (6%, 0.25 mm) The instrumentation was executed according to the manufacturer’s instructions. Neoniti A1 single rotary file was used to shape canals until they reach the apex. with 2-3 pecks were cautiously injected into the canal, followed by upward circumferential brushing motions from the bottom upward. After rinsing thoroughly, K file #10 was used to check canal patency,sodium hypochlorite was used to wipe the Neoniti A1 flutes,Neoniti A1 should be rerouted after achieving WL only pecking motion was used last 3-4mm at apex Neoniti file system was used in continuous motion,torque limit of 1.5 Ncm , speed of 300 to 500 rpm

Group B E3 Azure Rotary Files (Endostar) – A1 (6%, 0.25 mm) The instrumentation was executed in compliance with the manufacturer's guidelines E3 Azure single rotary file was used to shape canals until they reach the apex E3 Azure A1 is cautiously injected into the canal with upward and downward motion. 2/3 of the WL; use an apex locator and a size 15 hand file to examine the WL. After that, insert A1 at its maximum working length. Rinse well, then use a K file #10 to check canal patency. E3 Azure A1 should be thoroughly cleaned. Repeat the above method until the WL is not reached The E3 Azure file was rotated continuously with a torque limit of 2.1–3 N. cm, speed of 300 rpm During preparation, all teeth's canals were irrigated with NaOCl 3% and EDTA 17% using the methodology outlined below.

Flush the access cavity with 3% NaOCl ,in middle of each instrument add 2 mL of 3% NaOCl each canal.Following shaping, add 5 mL of 3% NaOCl and 5 mL of 17% EDTA each canal, then irrigate with 3 ml saline and dry with help of sterile PP after completion of procedure

Following the placement of a master cone and confirmation with intraoral periapical radiograph (IOPAR), both groups underwent single cone obturation using Neolix Neoniti and E3 Azure matching GP points, with resin-based sealer (AH Plus) .After obturation a temporary restoration (Cavit G) was placed and radiograph was obtained. The canals were obturated in a single visit.

The amount of time needed for canal preparation was calculated for each group starting with the first file used for evaluating canal patency and ending with the final file used to instrument the canal. This covered the time needed for irrigation and canal preparation for a single file.

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The participants were told to take 400 mg of ibuprofen, a mild painkiller, only in the event that they felt pain. A revised Visual Analogue Scale (VAS), verified in earlier research [52], was used to record the degree of pain, whether it was none, mild, moderate, or severe, following procedure.[53]

No pain (0) - The treated tooth appeared normal, and patients reported no pain.

Mild pain (1) - Pain was noticeable but not distressing, and did not require any pain relievers.

Moderate pain (2) - Pain was uncomfortable yet tolerable, and any painkillers used were effective in alleviating the discomfort.

Severe pain (3)- Pain was hard to endure (analgesics were minimally effective or ineffective at relieving the pain

Visual Analogue Scale (VAS) grading standards were taught to the patients. Following treatment, the patient brought the VAS form (Annexure VII) with them to record their pain levels at 6-, 24-, 48-, and 72-hours following surgery. The patient received frequent reminders to record their pain levels and to submit the completed VAS form. If an analgesic was used, the dosage was noted at that specific moment. In the event that the recommended medication was insufficient to relieve the pain, patients were instructed to get in contact with the clinic.

For the statistical analysis, SPSS software (version 20) was utilized [54]

The following methods were used to compare VAS scores: the Mann-Whitney U test was used to compare VAS scores between groups; the Wilcoxon matched pairs test was used to compare VAS scores within groups; the Chi-square test to explore the relationship between age and sex with VAS scores; independent t-test compared the amount of time needed to instrument the canals in each group.

PHOTOGRAPHS

Fig.1 Diagnostic Instruments

Fig.2 LA and rubber dam armamentarium

Fig 3 Administration of LA

Fig.4 Rubber Dam Isolation

Fig.5 Material for sterilization protocol

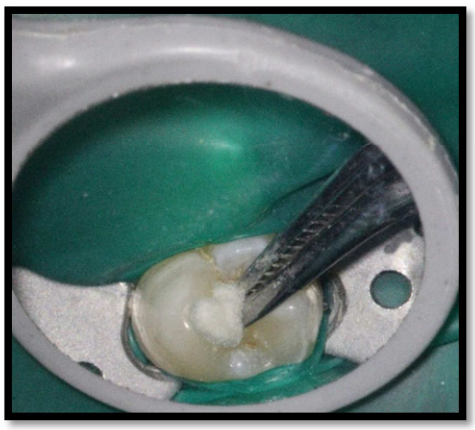


Fig.6. Sterilization Protocol; Step 1 - 30% Hydrogen *Peroxide*

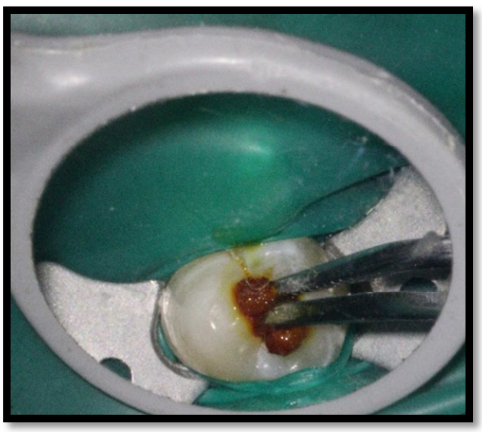


Fig7.Sterilization Protocol; Step 2 - 5% Povidine Iodine

Fig.8. Sterilization Protocol; Step 3 – Sodium Thiosulphate

Fig. 9 Access cavity preparation armamentarium

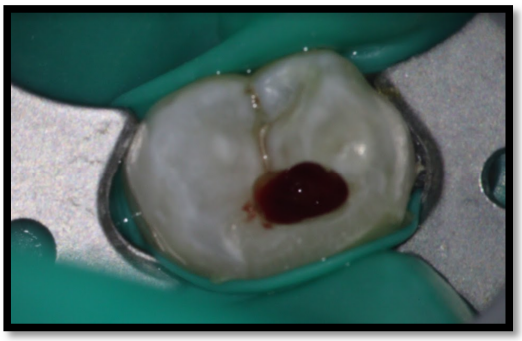


Fig.10 Access cavity preparation

Fig.11 prepared access cavity

Fig.12 Biomechanical preparation armamentarium

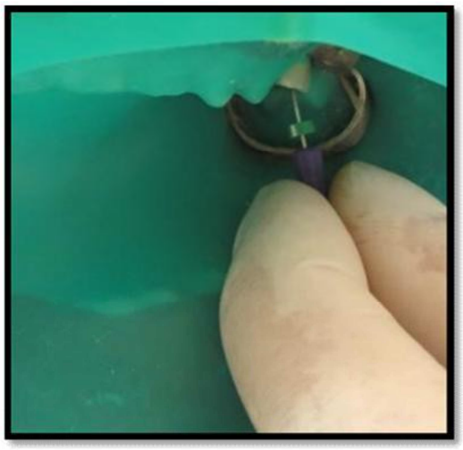


Fig. 13 Checking canal patency by #10 K-File

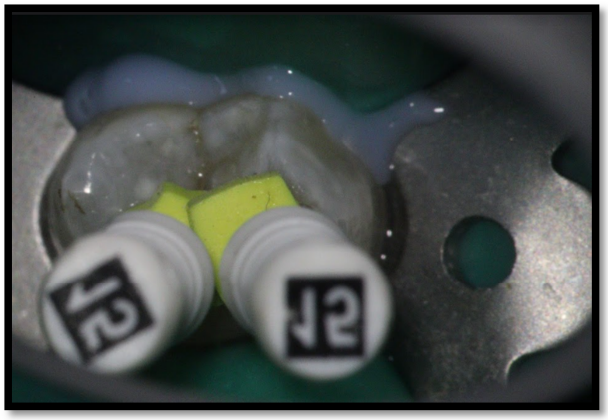


Fig.14 Working length files

Fig.15 Working length determination using EAL

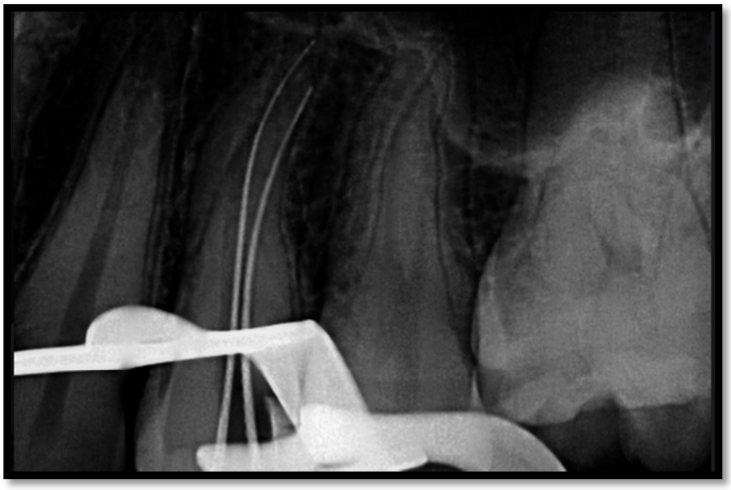


Fig.16 Working length radiographic confirmation

Fig.17 Glide path with 15k file

Fig.18 Instrumentation using Neolix Neonit rotary file system (Group A)

Fig.19 Speed and torque Neolix Neoniti rotary file system

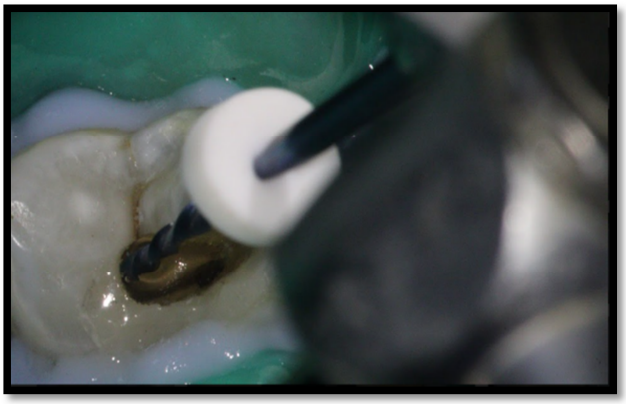


Fig.20 Instrumentation using E3 Azure rotary file systems (Group B)

Fig.21 Speed and torque E3 Azure rotary file systems

Fig.22 Obturation materials and armamentarium

Fig.23 Master cone IOPAR with corresponding gutta-percha points

Fig.24 Post obturation IOPAR

RESULTS

Table 1: VAS scores for individual patients in group A

Sl.No	Sex	Age	6hrs	24hrs	48hrs	72hrs	Time In Sec
1	F	41	2	1	0	0	136
2	M	28	0	0	0	0	144.8
3	M	25	1	1	1	0	138.8
4	F	35	0	0	0	0	136.92
5	F	29	0	0	0	0	147.2
6	F	35	0	0	0	0	128.4
7	M	33	2	2	0	0	135
8	F	29	1	0	1	0	141
9	M	35	0	0	0	0	129
10	F	30	1	1	0	0	136.4
11	F	34	0	0	0	0	137
12	M	29	0	0	0	0	142.5
13	F	35	0	0	0	0	141
14	M	48	1	1	0	0	130
15	M	46	1	1	0	0	126.4
16	F	34	1	1	0	0	128.3
17	F	30	0	0	0	0	125.1
18	F	28	1	1	0	0	133
19	F	22	0	0	0	0	146
20	F	32	1	1	0	0	120
21	F	27	0	0	0	0	135
22	F	40	2	2	1	0	124.4
23	F	32	1	1	0	0	138
24	F	36	1	0	0	0	134.1
25	F	29	0	0	0	0	129.2
26	F	28	0	0	0	0	124
27	F	37	1	1	0	0	146.1
28	M	25	1	1	1	0	142
29	F	32	0	0	0	0	150.4
30	M	48	0	0	0	0	159.3
31	F	29	1	1	0	0	142.2
32	M	29	0	0	0	0	123
33	M	30	1	1	0	0	128
34	M	32	0	0	0	0	126

Table 2: VAS scores for individual patients in group B

L NO	Sex	Age	6hrs	24hrs	48hrs	72hrs	Time In Sec
1.	F	42	1	0	0	0	148
2.	M	32	0	0	0	0	160.2
3.	M	30	0	0	0	0	138
4.	M	38	2	2	2	0	129.3
5.	M	35	1	0	0	0	142.2
6.	F	26	0	0	0	0	144
7.	M	31	0	0	0	0	128
8.	F	45	0	0	0	0	123
9.	F	25	1	0	0	0	133
10.	F	28	1	0	0	0	132.4
11.	F	20	0	0	0	0	130.1
12.	F	39	0	0	0	0	146.2
13.	M	37	0	0	0	0	129
14.	F	27	0	0	0	0	136.4
15.	F	35	1	0	0	0	137
16.	M	20	0	0	0	0	142.5
17.	M	26	0	0	0	0	141
18.	F	21	0	0	0	0	130
19.	F	24	0	0	0	0	126.4
20.	F	24	0	0	0	0	128.3
21.	F	35	1	o	0	0	125.1
22.	F	33	2	1	0	0	133
23.	F	26	0	0	0	0	147.4
24.	F	32	2	1	0	0	138.3
25.	F	25	1	0	0	0	125.8
26.	F	26	0	0	0	0	135
27.	F	25	0	0	0	0	136
28.	M	37	2	2	1	0	156.4
29.	F	28	1	0	0	0	132
30.	F	23	0	0	0	0	128
31.	M	27	0	0	0	0	141
32.	M	31	0	0	0	0	132.4
33.	F	27	1	0	0	0	163.2
34.	M	28	0	0	0	0	132

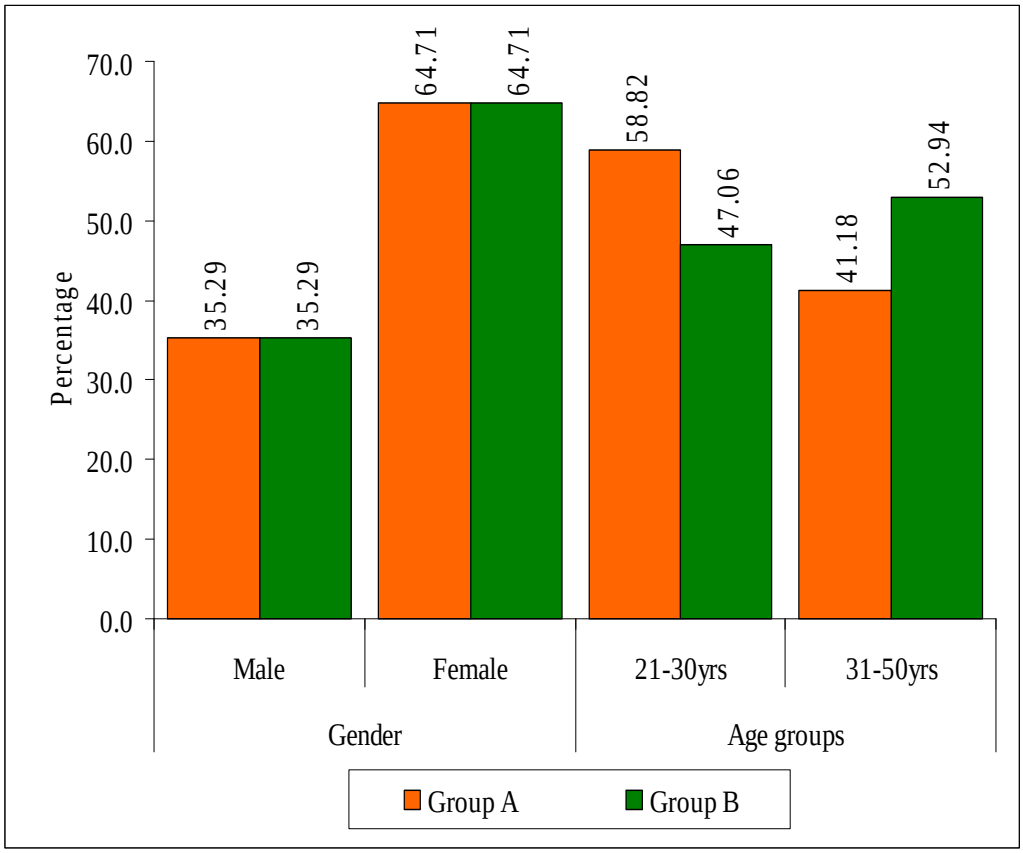
Table 3: Age and gender comparison between two groups (Groups A and B)

	Group A	%	Group B	%	Total	%	Chi-square	p-value
Gender								
Male	12	35.29	12	35.29	24	35.29	-	1.0000
Female	22	64.71	22	64.71	44	64.71		
Age groups								
21-30yrs	20	58.82	16	47.06	36	52.94	0.9440	0.3310
31-50yrs	14	41.18	18	52.94	32	47.06		
Mean	32.71		29.71		31.21			
SD	6.18		6.14		6.30			
Total	34	100.00	34	100.00	68	100.00		

Table 4: Comparison between Groups A and B using the Mann-Whitney U test for VAS scores at various time points

Time points	Group A	%	Group B	%	Total	%	Z-value	p-value
6hrs								
Score 0	17	50.00	21	61.76	38	55.88	0.6501	0.5156
Score 1	14	41.18	9	26.47	23	33.82		
Score 2	3	8.82	4	11.76	7	10.29		
24hrs								
Score 0	19	55.88	30	88.24	49	72.06	2.1526	0.0314*
Score 1	13	38.24	2	5.88	15	22.06		
Score 2	2	5.88	2	5.88	4	5.88		
48hrs								
Score 0	30	88.24	32	94.12	62	91.18	0.3864	0.6992
Score 1	4	11.76	1	2.94	5	7.35		
Score 2	0	0.00	1	2.94	1	1.47		
72hrs								
Score 0	34	100.00	34	100.00	68	100.00	0.0000	1.0000
Score 1	0.00	0	0.00	0	0.00	0.00		
Score 2	0.00	0	0.00	0	0.00	0.00		
Score 3	0.00	0	0.00	0	0.00	0.00		
Total	34	100.00	34	100.00	68	100.00		

Figure 25: Age and gender comparison between two groups (Groups A and B)



*p<0.05

Figure 26: Comparison of the VAS scores for Groups A and B at various intervals

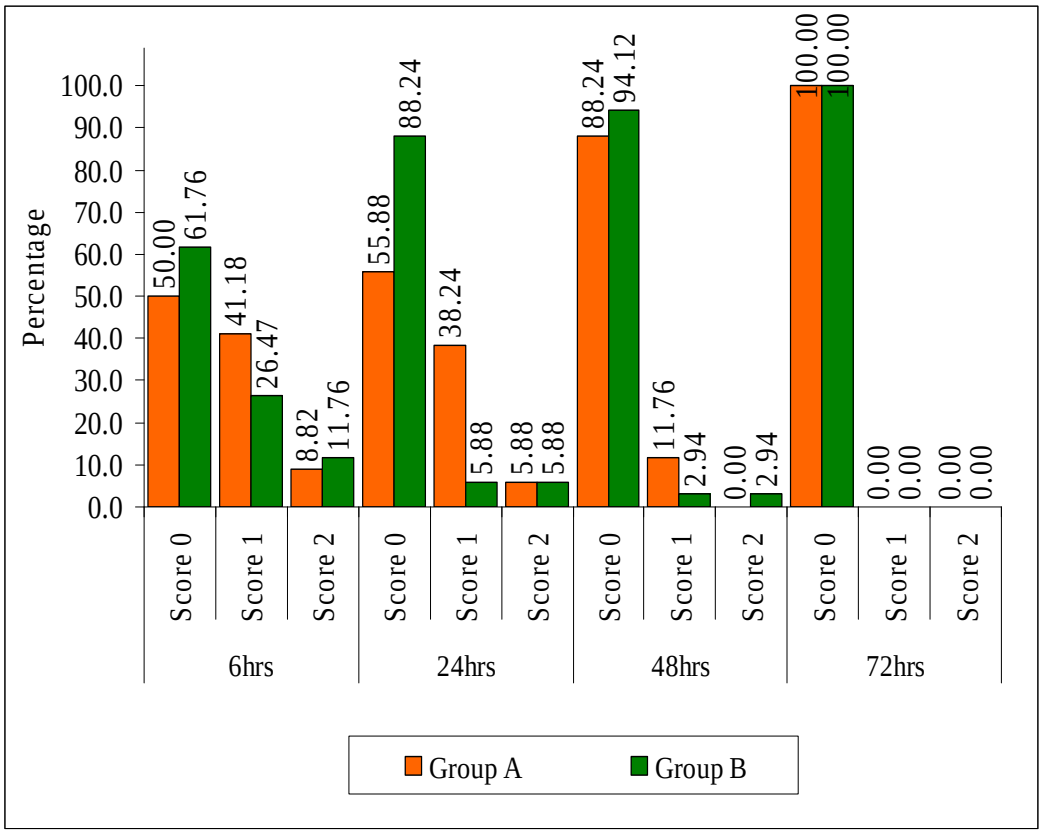
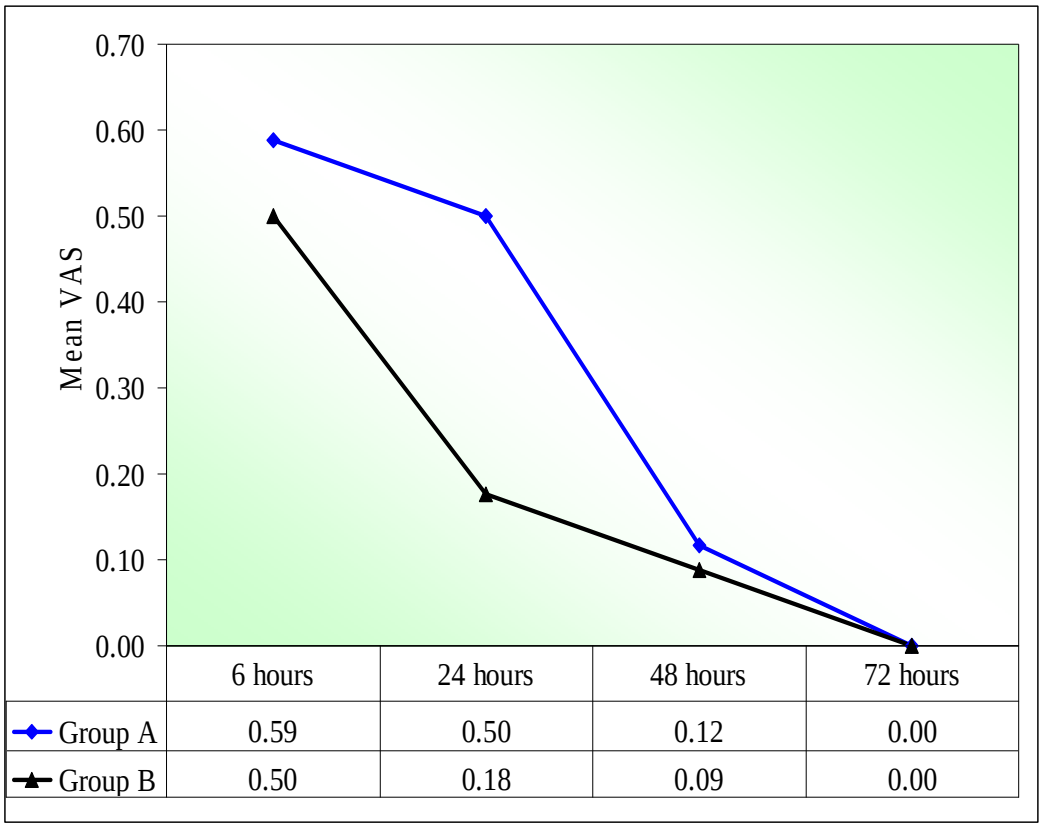


Figure 27: Comparison of the VAS scores for Groups A and B at various intervals



	6 hours	24 hours	48 hours	72 hours
Group A	0.59	0.50	0.12	0.00
Group B	0.50	0.18	0.09	0.00

Table 5: Within-group comparison of VAS scores at 6, 24, 48, and 72 hours for Group A and Group B using the Wilcoxon matched pairs test:

File system	Changes from	% of change in VAS	T-value	Z-value	p-value
Group A	6 hours vs 24 hours	-17.65	0.0	1.6036	0.1088
	6 hours vs 48 hours	70.59	0.0	3.2958	0.0010*
	6 hours vs 72 hours	100.00	0.0	3.6214	0.0003*
	24 hours vs 48 hours	75.00	7.0	2.8563	0.0043*
	24 hours vs 72 hours	100.00	0.0	3.4078	0.0007*
	48 hours vs 72 hours	100.00	0.0	1.8257	0.0679
Group B	6 hours vs 24 hours	46.67	0.0	2.9341	0.0033*
	6 hours vs 48 hours	80.00	0.0	3.0594	0.0022*
	6 hours vs 72 hours	100.00	0.0	3.1798	0.0015
	24 hours vs 48 hours	62.50	0.0	1.6036	0.1088
	24 hours vs 72 hours	100.00	0.0	1.8257	0.0679
	48 hours vs 72 hours	100.00	0.0	1.3416	0.1797

*$p<0.05$

Table 6: Comparison of the amounts of time needed in each group for canal instrumentation independent t test in sec

Group	n	Mean	SD	SE	t-value	P-value
Group A	34	135.43	8.99	1.54	-0.5919	0.5560
Group B	34	136.78	9.87	1.69		

Figure 28: Comparison of the amounts of time needed in each group for canal instrumentation independent t test in sec:

Since this was a randomized clinical trial, we had no influence over how the age and sex variables were distributed.

Distribution of ages within groups:

Within Group A, 58.82 percent of samples belonged to the 18–30 age range, whereas 41.18 percent fell into the 31–50 age range (Table 3; Figure 25).

47.06 percent of samples were between the ages of 18 -30 ,52.94 percent samples in Group B were between the ages of 31- 50(Table 3; Fig. 25).

The average age for Group A was 32.71 years with a SD of 6.18 years ,while the patients' mean age in Group B was 29.71 years with a standard deviation of 6.14 years. The differences in mean ages between the two groups were found to be not statistically significant. (Table 3) (Fig. 25)

Distribution of genders within groups:

(Table 3) (Figure 25) shows that in Group A, consisting of 34 participants, 35.29% were male, while 64.71% were female.

In Group B (n = 34), 35.29% of the participants were male and 64.71% were female, as shown in (Table 3)and (Figure 25).

Distribution of Visual Analog Scale Scores in Groups A and B at various time points:

The Severity of post obturation pain at 6hrs, 24hrs, 48hrs, and 72hrs intervals was assessed. significant difference(p=0.0314*) at the 24hr interval between Groups. In Group A 55.88% of participants had no pain, and 38.24%experienced mild pain,

5.88% experienced moderate pain whereas, in Group B, 88.24 %reported no pain, and 5.88 % had mild pain ,5.88% experienced moderate pain (Table4) (fig 26)

The findings from the current study, shown in Table 4 (Figure 26), indicate a trend in the pain severity experienced by patients in both groups. The peak level of pain was recorded at six hours post-therapy, affecting 33.82% of the patients. This was followed by a statistically significant reduction in pain, with 22.06% of patients still experiencing discomfort at 24 hours and only 7.35% at 48 hours. By 72 hours, none of the patients in either group reported any pain.

Within-group comparison of VAS scores at 6, 24, 48, and 72 hours for Group A using the Wilcoxon matched pairs test:

At the end of 6hrs, ($p = 0.5156$), 48 hrs ($p = 0.6992$), 72hrs ($p = 1.0000$). While not statistically significant, VAS scores were more in Group A compared to Group B,

a difference that was clinically significant (Table 4). (Fig. 26) But at the end of 24hrs, statistical significance (0.0314*) was noted, Group A exhibited higher VAS scores compared to Group B. (Table 4) (Fig26)

When comparing baseline, statistically significant differences ($p<0.05$) were found.

VAS scores to those at subsequent time intervals—6 hrs vs 48 hrs, 6 hrs vs 72 hrs, 24 hrs vs 48 hrs, and 24 hours vs 72 hrs. (Table 4), However, no significant differences were found between the 6 hrs vs. 24 hrs ($p= 0.1088$) and 48 hrs vs. 72 hrs comparisons ($p= 0.0679$).

Pair-wise intra-group (Group B) comparison of VAS scores using the Wilcoxon matched pairs test at six, twenty-four, forty-eight, and seventy-two hours after procedure:

With the exception of 24 hours vs. 48 hours (p=0.1088), 48 hours vs. 72 hours (p=0.1797), and 24 hours vs. 72 hours (p=0.0679), Statistically significant differences ($p<0.05$) was noted in VAS scores across all time intervals—6 hrs vs. 24 hrs, hrs vs. 48 hrs, 6 hrs vs. 72 hrs, and 6 hrs vs. 72 hrs—as shown in (Table 5 and Figure 27) From 6 hours to 24 hours and hours to 48 hours, Group A's pain score was higher, indicating that Group B performed better.

Comparison of the amounts of time needed in each group for canal instrumentation:

There was no significant variation in the canal preparation time (8.99+/-1.54min versus 9.87+/-1.67min; p=0.5560) between Group A and Group B. (Fig. 28, Table 6)

DISCUSSION

The measure of intelligence is the ability to change -Albert Einstein

The twentieth century saw considerable developments in endodontic instrumentation and technique. The invention of root canal devices, such as the K-file and the rotary system, transformed the way root canal procedures were performed, boosting efficiency and precision[56] The instrument design significantly influences neuropeptide expression following root canal preparation, independent of movement type or file number. Neuropeptide expression is influenced by debris extrusion, movement type, speed, and other factors causing periodontal ligament inflammation.[55]

Endodontics has evolved into a specialized specialty that aspires for excellence in patient treatment through a combination of historical knowledge, scientific discoveries, and technology improvements. Recognizing past accomplishments allows us to look forward to an even more hopeful future

A manual file was the sole instrument available in the past which was made up of stainless steel for biomechanically preparing root canals; this made filing laborious and prolonged the treatment period, leading to uneven root canal preparation, ledges and transportation[5657] Due to their cutting tips, square or triangle cross sections, consistent 2% taper, and efficient filing action (up and down into the canal), they generated an enormous quantity of debris. (1998, Reddy & Hicks; 2009; Adl et al.; 2014; Sowmya et al.)[18]

In order to overcome these hurdles Dental companies introduced NiTi rotary instruments drastically improvising preparation procedures, reducing time, complexity, and clinician fatigue [59]The evolution of NiTi rotary files is a testament to the dynamic nature of dental technology, Although NiTi alloys have better mechanical qualities, there is still a chance of fracture. In the past ten years, many exclusive processing techniques have been implemented to enhance the cleaning effectiveness, shaping capacity, and mechanical characteristics of NiTi alloys. The fatigue resistance, whether it be torsional or cyclic fatigue, is then modified by various procedures, which include of electropolishing, thermal, mechanical, and the more contemporary electric discharge machining [60]

However, it has been shown that all instrumentation methods, whether mechanical or manual, result in the accidental extrusion of debris into the area surrounding the periapex.[61]

It is speculated that postoperative pain is caused by the debris thrusting outside the root canal during procedure. This debris's apical extrusion induces an immediate inflammatory reaction due to localized disruption of the equilibrium during root canal instrumentation between host defense and root canal microorganisms.[62] This inflammatory response in periodontal ligaments is triggered by neurogenic sources, like calcitonin gene-related peptide and substance [63]

Another significant development was the inclusion of reciprocating motion as opposed to the previously employed 360-degree rotation motion used with files.[64]However, it was shown that reciprocating motion extruded more debris apically than files in continuous motion.[65]Burkin et al. concluded that less debris extrusion resulted in reduced postoperative pain when utilizing continuous rotating motion compared to reciprocating action[66]

Since the first generation of endodontic files to the current fifth generation, the market has continued to upgrade with new files. However, a variety of characteristics, such as the instrument's radial land, cross-section, and blade design, core diameter, rake angle, variable distance between flutes and variable taper or pitch or specific preparation methods like reciprocation, continuous rotation, or adaptive motion, may also affect the amount of debris extrusion. [67]

Offsetting the center of rotation has improved the canal shaping efficiency of the fifth generation. Compared to a centered mass rotating instrument, the offset-designed files increase cutting and debris removal by propagating a motion wave that runs the entire distance of the NiTi file. [68] among which is neolix neonti and E3 Azure [69]

Endodontic treatment is commonly done in multiple visits as preferred by many clinicians, but now, the scenario is changing with the advent of single visit endodontics. Studies conducted comparing multiple visit and single visit endodontics reported statistically insignificant difference between them in regard to survival rate, post-operative pain or flare ups and long-term prognosis [70]

Ideally,Chemomechanical treatments ought to be finished in a single visit.Since as many irritants as possible are removed from the root canal system, the chance of discomfort between appointments due to surviving microbial species growing larger or becoming more virulent due to environmental condition changes may be decreased.[71]

The recent developments in root canal preparation have been dominated by the idea that less is more. The root canal was completely shaped utilizing a single file system. Among its advantages are their lower cost and shorter shaping time, which allows the greater time to be spent by the clinician cleaning the canal Moreover, the method uses a single instrument instead of multiple files, which eliminates procedural problems.[13,69]

A single file system is offered by Neolix neoniti (Neolix, Châtres-la-Forêt, France) that has been handled with Electro Discharge Machining (EDM), boosting the file's flexibility. It has a nonhomothetic rectangular cross section with two points of contact, a rounded gothic tip, variable pitch, and a helix angle ranging from 28 to 16° from tip to rear, decreasing screwing effect. [72]

In-vitro studies done on these file systems have claimed that the Neolix Neoniti system has a decreased apical debris extrusion attributed to its variable pitch and helical angle.[14]

In vivo study comparing ProTaper Next to Neolix system for treating necrotic pulps in maxillary and mandibular teeth found that Neolix rotary system superior in postoperative pain.[13]

Novel Endostar E3 Azure® is manufactured with Azure HT technologyIt features a safe cutting tip, a variable pitch, and a redesigned S-shaped cross section that lessens the file's core and improves flexibility and debris removal. When CM wire is paired with a titanium oxide surface treatment, it improves hardness, flexibility, and fracture resistance. (Shangahai Fanta 2018–2019 catalog.pdf)

In-vitro studies on file systems comparing debris extrusion from continuous rotation and optimum torque reverse showed no statistical significance. [16]

In vivo studies using the E3 Azure file system with and without apical patency with a modified S shape cross section showed no significant difference in post-operative pain.[17]

A painful root canal might lower one's quality of life. When compared to multiple visits, single-visit endodontic treatment had an equivalent success rates. However, it offered several advantages such as shorter treatment time, fewer risks from repeated injections, and the possibility of microleakage. It was also preferred by patients as it shortened time, expense, and operative procedures. in addition to that it is more economical and time-efficient, allowing clinicians to focus on providing patients with the best endodontic care available.[7374]

Therefore, a prospective randomized clinical trial was conducted using a file system made of EDM and Azure HT technologies to clinically assess postoperative pain after a one-visit endodontic treatment.

This study also investigated the association of characteristics such as age and sex on the post-operative pain within the groups, as well as the time required for canal instrumentation in both groups.

68 patients meet the precise inclusion and exclusion criteria. in need of endodontic therapy with respect to maxillary premolar teeth, diagnosed as asymptomatic irreversible pulpitis were chosen from the normal patient pool of the Department of Conservative Dentistry and Endodontics at the KLE V.K. Institute of Dental Sciences in Belagavi

Sample size was estimated using the formula [75]

p_1 : Percentage of change in the 1st group= 0.63

p_2 : Percentage of change in the 2nd group= 0.28

α : Level of significance = 5%

1 – β : Power = 80%

Formula

$$n = \frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 \quad (p_1 q_1 + p_2 q_2)}{(p_1 - p_2)^2}$$

Estimated sample size for each group = 31

Considering 10 % dropouts in each group,

n = 34 in each group

Clinical trial's reliability and validity were assessed with a 10% dropout rate, as a higher rate could potentially impact the study's effectiveness.[76]

An age range of 18 to 50 years old was chosen for this investigation. As the connection between a dentist and patient is fundamentally a contract, it follows that

only those who are at least 18 years old are eligible to sign a doctor-patient agreement and provide consent for medical treatment.[77]Furthermore, it has been noted that 90% of people over 50 have some form of calcification in their root canals.[7879]

This study selected two-rooted or two canalled maxillary premolar teeth with straight roots to minimize frictional stress and torque demand, and an apical preparation up to ISO size 25 suffices. Hence, the root canals were instrumented with E3 azure instruments upto size A1 or Neolix Neoniti instruments upto size A1 both having 0.25mm tip diameter. The standardization of instruments with the same tip diameter reduced a variable that could affect debris extrusion and postoperative pain.[80]

Teeth where a #20 K-file easily reached working length or where a #10 K-file was very difficult to move, were excluded. To prevent interpersonal differences in care between clinicians, a single clinician handled every case. Glennon et al5 found preoperative pain significantly influences postoperative pain therefore focusing on teeth with asymptomatic irreversible pulpitis or healthy pulp that has been treated for prosthetic purposes.[81]

The research comprised teeth with adequate coronal structure for proper isolation, excluding asymptomatic non-vital teeth due to increased postoperative pain. Patients with several ipsilateral teeth in need of root canal therapy were excluded due to potential false positive readings due to the inability to differentiate the pain caused by these teeth.[82]

This study excluded teeth with chronic apical periodontitis, necrotic teeth, symptomatic acute conditions, and intracanal medicament cases like retreatment and

weeping canals due to increased postoperative pain risk. Since Glennon et al. discovered that periapical radiolucency's with a diameter more than 5 mm were related to increased post-operative pain, they were also excluded.[83]

This study eliminated patients taking antibiotics that suggested immunological incompetence or a systemic illness, as well as those taking analgesics that could provide inaccurate VAS scores because of elevated pain thresholds. Since steroids greatly lower the frequency and intensity of postoperative pain, they were also eliminated from the study.[84]

A table of random numbers was used to randomly allocate the confounding variables of age and sex. There were two groups of patients:

Group A: Neoniti rotary files(Neolix, Châtres-la-Forêt, France) – A1 (6%, 0.25 mm) consisted of 34 teeth The instrumentation was executed according to the manufacturer's instructions. Neoniti A1 single rotary file was used to shape canals until they reach the apex. with 2-3 pecks were cautiously injected into the canal, followed by upward circumferential brushing motions from the bottom upward. After rinsing thoroughly, K file #10 or 15 was used to check canal patency. sodium hypochlorite was used to wipe the Neoniti A1 flutes, Neoniti A1 should be rerouted after achieving WL, only pecking motion was used last 3-4mm at apex Use Neoniti file system in continuous motion, torque 1.5 Ncm, speed range of 300 to 500 rpm.

GROUP B: E3 Azure rotary files (Endostar) – A1 (6%, 0.25 mm) consisted of 34 teeth The instrumentation was executed in compliance with the manufacturer's guidelines. E3 Azure single rotary file was used to shape canals until they reach the apex E3Azure A1 is cautiously injected into the canal with upward and downward

motion.2/3rd of working length, check WLwith an apex locator, 15k hand file.After that, insert A1 at its maximum working length. Rinse well, then use a K file #10 or 15 to checkcanal patency. E3Azure A1 should be thoroughly cleaned. Repeat the above method until the WL is not reached

Use E3 Azure file in continuous rotation at a maximum torque of 2.1 to 3 N. cm at 300 rpm.

The procedure maintained apical patency by passively moving a small #10 K-file through the procedure without binding or enlarging the apical foramen, preventing post-operative pain. [85]

WL was ascertained by means of an apex locator and validated by a radiograph, combination of electronic- radiographic methods is more accurate than radiography alone, as suggested by the European Endodontic Society. [86] [87]Unintentional overextensions of #15 K-file root canal files did not affect postoperative pain incidence. According to Torabinejad et al., the incidence of postoperative pain is unaffected by unintended root canal files being overextended when determining working length.[88]

According to Ruddle's method, a feed it in and pull motion was used to complete the glide path in this investigation using hand #15 stainless-steel K-files (Mani Inc., Tochigi, Japan) at the established WL. This method lessens the possibility of pain during treatment by reducing the pushing of debris past the apical foramen and facilitating its suspension in the irrigating solution. [89]

The choice of irrigants for this study were 3% sodium hypochlorite (NaOCl), 17% ethylene diaminetetracetic acid (EDTA),0.9% normal saline according to the following protocol [90]

3% sodium hypochlorite is supplied by Vishal Dentocare PVT LTD in India. was used [89]as a potent antibacterial also dissolves pulp remains, Concentrations greater than 2% possess the dissolving properties required to remove necrotic and essential tissue. [90] Sodium hypochlorite exhibits strong antimicrobial activity, killing bacteria rapidly even at weaker concentrations, particularly against most bacteria found in the root canal. Since 17% EDTA solution (Canalarge; Ammdent, Chandigarh, India) chelates inorganic tissue and aids in removing debris that becomes packed into dentinal tubules during root canal instrumentation, it was employed as an irrigant. The smear layer is this material that contains soft tissue and dentine components and keeps the root canal system from being thoroughly cleaned (Violich and Chandler [91]When employed with sodium hypochlorite as part of the same irrigating regimen, EDTA has also been demonstrated to boost the antibacterial efficacy of the solution. (Bystrom and Sundqvist 1985).[53]

As a final flush, 0.9% sterile normal saline (Amanta Healthcare Ltd., Gujarat, India) was employed, which had the flushing effect of neutralizing the different compounds of the irrigants. This study utilized 15% EDTA gel as a lubricant to facilitate root canal instrumentation and negotiation, aiding file movement within the root and assisting with stainless steel and nickel titanium file systems.[92]

The obturation process was performed using GP and resin-based sealer (AH Plus[) [9394] Temporary restoration was administered following obturation, IOPAR was taken after postobturation. In a single visit, each canal was shaped, cleaned, and

obturated.

A frequent challenge in pain research is the patient's subjective assessment and quantification of pain. The perception of pain varies greatly from person to person. and dynamic phenomenon that is influenced by a range of physiological and psychological elements. [95] According to Turk and Melzack (1992), the patient's interpretation of the pain and its anticipated length have an impact on its intensity[96] also including the environment, expectations, attitudes, and beliefs all affect how pain is experienced.

Instead of utilizing a full spectrum of measure values, using a modified Visual Analogue Scale (VAS) of 0–3, rate the severity of pain since it has more clinical relevance for comparisons due to the limited number of categories (Bodian et al. 2001). [97]The escalating pain intensities were represented by a list of adjectives, such as no pain (number (0)), mild pain (number 1), moderate pain (number 2), and severe pain (number 3).

These descriptors were given numbers for convenience of recording, which were supported by earlier research.[98] The Cochrane database recommends a pain scale for post-endodontic pain, rated in advanced order and accurately described using analgesics, making it an effective method for quantifying pain.[83]The pain score was recorded 6, 24, 48, and 72 hours following endodontic therapy with the 12-hour period excluded due to inconvenient patient contact. In this study, no time frame beyond 72 hours was considered. as, it has been documented that. Regardless of the method or drug utilized, 4 days after endodontic treatments, the prevalence of pain was minimal.[99]

Following endodontic treatment. for the treatment of postoperative pain, nonsteroidal anti-inflammatory drugs have been recommended as the first line of treatment.

Numerous studies have examined the efficacy of ibuprofen to reduce pain during root canal therapy. [100]Because regular prescriptions could affect the study's outcome measure, it was only prescribed when necessary.[101]

Additional operator-dependent variables, such as chemical (irrigant extrusion) and mechanical (erroneous working length determination resulting in over-instrumentation and over-filling) injuries during root canal preparation, were addressed by measuring accurate working length (electronic apex locator reading taken twice and confirmed with an IOPA, preventing wedging of the irrigating needle during irrigation, and taking a master cone IOPA prior to obturation.[101]

Therefore, the accidental extrusion of debris at the root apex during root canal instrumentation is the likely source of the post-operative pain seen in this current study.[102]

Study's findings show that, when using the Neolix Neoniti rotary file system for root canal instrumentation (Group A), postoperative discomfort was consistently higher than when using the E3 Azure file system (Group B). Consequently, the null hypothesis was disproved

The outcome might be explained by the way E3 Azure is designed, with a redesigned S-shaped cross section that reduces the file's core and improves the elimination of debris (Shangahai Fanta catalogue 2018 2019.pdf). [103]

In addition, it has two sharp cutting edges for efficient performance, and upward transportation of debris, where debris can be swept via vertical blades from flutes to the safe-side relief area and subsequently outside the canal. Studies by (Mohamed Mokhtar Nagy 2021; Mohamed Kataia et al. [104]shiwangi et al[105] , shaimaa Nasr Abd el-ghaffar 2024) also shared similar results.

Conversely, the Neolix Neoniti file's rectangular cross-section design offers less room for the buildup and removal of debris towards the coronal. The file has a greater area of interaction between the wall of the root canal and preparation. resulting in a regular buildup of debris and a smear layer positioned between the root canal wall and the instrument. Thus, increasing the possibility of extrusion of debris beyond the apex.[106 107 108]

Contradictory research has been reported for both long and short pitches on the suckdown of debris in earlier studies by (Franck Diemer, et al[109], Elham et al [110]). E3 Azure is created with varied pitches and varying helix angles in an effort to lessen the negative effects of both long and short pitches, as well as the suck-down that is sometimes associated with constant pitch relating to lesser extrusion of debris.

The unique blue color of the instruments is caused by a visible layer of titanium oxide, which is produced by a unique and exclusive procedure called HT technology of NiTi wire processing. Previous studies (Abdelnaby, P.,et al [111], Doğanay Yıldız E et al [112])suggest that alloy heat treatments that produce controlled memory effect and flexibility will decrease the amount of debris that is apically extruded. [113 114]

Electrical discharge machining (EDM) technology is used in the manufacturing of Neoniti (Neolix, Châtres-la-Forêt, France). Neoniti features an integrated abrasive property, frontal and tangential edges, and high cutting efficiency, according to the manufacturer. It could lead to overcutting, aggravating the volume of dentin and debris extrusion. [115] [108]

Both E3 Azure and Neolix Neoniti has safe cutting tip.[111] [112] In addition to that Neoniti A1 has an abrasive property integrated right into the tip design, characteristic of Gothic design. Such features could reduce the amount of torque needed to cut the canal walls, but it may also cause more debris to extrude from the apical foramen. [116]

The severity of post obturation pain at 6hrs, 24hr, 48hr, and 72hr intervals was assessed. At the 24-hour period, there was a significant difference (p=0.0168) between Neolix neoniti Group and E3 Azure Group. In Neolix neoniti Group 48.48, % of participants had no pain, and 39.39%experienced mild pain, 6.06% experienced moderate pain whereas, in E3Azure Group, 84.85% reported no pain, and 9.09% had mild pain, 3.03% experienced moderate pain suggesting that E3 Azure rotary file system was better, results in both groups experiencing no pain at all after 72 hours.

Both groups' patients reported pain, but there was no statistically significant difference.

(p=0.4967) at 6 hours. Hawthorne effect may be an important contributing element to this non-significant difference. This effect is the shift in a subject's behavior as a result of the extra attention and status they receive by taking part in an experiment. It may cause them to first overestimate their pain threshold, which may generate an apparent discordance until a day has passed.[117]

These findings align with those of Kherlakian et al. [118]and Relvas et al.[119] The wear-off of the local anesthetic effect in the first six hours after the endodontic procedure is a further explanation for this outcome, apart from the Hawthorne effect.[120]

During the 72-hour follow-up, neither group reported any pain. Which is in line to earlier research, if endodontic pain occurs, it usually subsides in less than 72 hours. [121]

Because it affects the patient's overall comfort and the amount of time available When utilizing an instrumentation system for irrigation, the amount of active time required for canal preparation is a crucial consideration that the majority of clinicians.[122] Amount of needed for canal preparation was calculated for each group starting with the first file used to assess canal patency and ending with the final file used to instrument the canal. This covered the time needed to prepare the canal, with a single file system and irrigation.[123]

It was noted in the current investigation that the difference in the canal preparation time was not highly significant, as both are single file rotary systems.[124] The time required for GroupA (Neolix) in comparison with the Group B (E3 azure) (8.97+/-1.56min versus 9.99+/-1.74min (p=0.6051)

The current investigation found that the degree of pain was unaffected by an individual's age. These findings are consistent with those of R Ocalan et al,[125] who found no connection between the patients' self-reports of postoperative pain and sociodemographic factors such age and educational attainment.

It was found in this study that patients, both male and female, felt similar pain, the findings are similar to those of Clem 1970; Maddox et al. 1977; Oliet 1983who found no connection between gender and pain following procedure. [126]

In the near future clinical research with a larger sample size, longer follow-up, and the association of more variables is needed to overcome the shortcomings of this study so that one can be extended the findings of this RCT to all clinical instances.

CONCLUSION

In conclusion, this study evaluated pain after a single endodontic visit using two different types of single file systems within the parameters of the current investigation. In the variable age and gender pain did not differ significantly, but there was a significant difference in the VAS score at the 24-hours ($p=0.0168$), suggesting that the E3 Azure file system, produced less postoperative pain when it was compared with the Neolix Neoniti file system. In order to address the limitations of this study and extrapolate the RCT's findings to all clinical cases, larger sample sizes, longer follow-up times, and the inclusion of more factors will be needed in future clinical studies.

SUMMARY

The present randomized clinical trial Compared and evaluated postoperative discomfort following a single-session endodontic procedure using Neolix Neoniti and E3 Azure file system abiding strictly to the inclusion and exclusion criteria, 68 individuals with maxillary premolar teeth in need of endodontic therapy, diagnosed with asymptomatic irreversible pulpitis were chosen from the normal patient pool from Department of Conservative Dentistry and Endodontics at the KLE VKIDS Belagavi.

They were split up into two groups at randomly:

Group A included 34 teeth that were treated using Neoniti (Neolix, Châtres-la-Forêt, France) files with a size of 25 and a 6% taper.

Group B consisted of 34 teeth that were treated using Neoniti (Neolix, Châtres-la-Forêt, France) files with a size of 25 and a 6% taper.

Age and gender were among the significant predictive variables (variables) of postoperative pain that were noted.

After the patient's signed consent was obtained. LA (1:80,000 adrenaline, 2% lignocaine) was given, and a rubber dam (Coltene) was used to isolate the teeth. A typical endodontic access cavity was made following the sterilizing process. An apex locator (J. Morita, Japan) was used to establish WL, which was then confirmed using radiograph.

One of the two single file instrumentation system listed below was then used to prepare the root canal: either Neoniti Neoniti (Neolix, Châtres-la-Forêt, France)

files up to size A1 25 6%, or Endostar E3 Azure® files up to size A1 25 6%, as directed by the manufacturer. For standardization, the apical diameter of both procedures was kept at 0.25mm, the amount of time it took for each group to prepare the canal was also measured.

A sealer based on epoxy resin (AH Plus) was used for obturation utilizing a single cone obturation technique (Neolix Neoniti or E3 Azure matching gutta-percha points). In a single visit, every canal was cleaned, shaped, and obturated.

Postoperative pain in patients was assessed using a Visual Analogue Scale. at 6-, 24-, 48-, and 72 hours. The rising levels of pain were indicated by a list of adjectives, such as no pain (number (0), mild pain (number 1), moderate pain (number 2), and severe pain (number 3). The descriptors were given numbers to make documenting the pain easier.

Using the Mann-Whitney U test Intergroup pairwise comparison of the Wilcoxon matched pairs test was used to compare pairings within the same group after the VAS scores at various time points were obtained. The unpaired t-test was used to compare how long it took for canal instrumentation in the two groups.The chi-square test was used to compare each group's parameter associations with postoperative pain.

The severity of post obturation pain at 6hrs, 24hrs, 48hrs, and 72hrs intervals was assessed. There was a distinct difference. ($p = 0.0314$ *) at the 24hr interval between Groups In Group A 55.88% of participants had no pain, and 38.24%experienced mild pain, 5.88% experienced moderate pain whereas, in Group B, 88.24 %reported no pain, and 5.88 % had mild pain ,5.88% experienced moderate

pain (Table4) (fig 26) suggesting patient experienced less postoperative pain after the use of E3 Azure.

When age and sex were taken into consideration, there was no statistically significant variation in the VAS scores. and also, preparation time in both Group A and Group B had no statistical significant difference (8.99+/-1.54min versus 9.87+/-1.67min (p=0.5560)

It may be inferred that patients undergoing canal instrumentation using the Neolix Neoniti rotary file instrument experienced much more postoperative pain than those using the E3 Azure rotary file instrument.

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ANNEXURE – I – ETHICAL APPROVAL CERTIFICATE

Research and Ethics Committee
KLE VK INSTITUTE OF DENTAL SCIENCES
A Constituent Unit of KLE Academy of Higher Education & Research
Accredited 'A' Grade by NAAC Placed in Category 'A' by MHRD (GoI)
Nehru Nagar, Belagavi - 590 010, Karnataka State
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Sl. No. : 1599

CERTIFICATE

EC/NEW/INST/2021/2435
Research & Ethics Committee

This is to Certify that the synopsis titled

Comparative Evaluation of Postoperative Pain after Single visit Endodontic Treatment using Neolix Neonix and E3 Azure File System *Submitted by*

Dr. **REG. NO. IE0221001** *P. G. Student / Staff, Guided by* Dr. _____ *from Department of* Conservative and Endodontics *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

Date : 3/4/24

Member Secretary
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

ANNEXURE – II – BIOSTATISTICS CLEARANCE LETTER

KLE V.K. Institute of Dental Sciences
(A Constituent unit of KLE Academy of Higher Education & Research
Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi-590 010 INDIA
Accredited 'A+' grade by NAAC (3rd Cycle) & Placed in Category 'A' by MHRD (GoI)
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FAX: 0831-2470640
Web: http://www.kledental-bgm.edu.in
E-mail: principal@kledental-bgm.edu.in

Biostatistics Clearance Certificate

This is to certify that the Biostatistics aspect of this dissertation/ Thesis work of **REG. NO. IE0221001**, post-graduate student, under the guidance of & Head of Department, **Department of Conservative Dentistry and Endodontics, entitled "Comparative Evaluation Of Postoperative Pain After Single Visit Endodontic Treatment Using Neolix Neoniti And E3 Azure File System:A Randomized Clinical Trial"** has been done under my guidance and completed satisfactorily.

Place: Belagavi
Date:

Name & Signature of Biostatistician

Dr. S. B. JAVALI Ph.D.
Sr. Associate Professor in Statistics
Department of Community Medicine
USM KLE International Medical Program.
BELAGAVI-590010.

ANNEXURE – III – PLAGIARISM CERTIFICATE

Scientific Correspondence and Review Committee

KLE VK Institute of Dental Sciences

A Constituent Unit of KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi - 590 010, Karnataka State

Accredited 'A' Grade by NAAC (2nd Cycle) | Placed in Category 'A' by MHRD (GoI)

☎: 0831-2470362
FAX: 0831-2470640

Web: http://www.kledental-bgm.edu.in
E-mail:principal@kledental-bgm.edu.in

Date :

Serial No. : 197

PLAGIARISM CHECK REPORT

Name of the Applicant : **REG. NO. IE0221001**
UG / PG / Ph.D / Staff : POST GRADUATE
Batch & Year : 2021 - 2024
Department : CONSERVATIVE DENTISTRY AND ENDODONTICS

The soft copy of Research Work / Manuscript by [redacted] entitled

"..COMPARATIVE..EVALUATION..OF...POST..OPERATIVE..PAIN..AFTER..SINGLE VISIT ENDODONTIC TREATMENT USING NEOLIX NEONITI AND E3 ....AZURE...FILE...SYSTEM:..A..RANDOMIZED...CLINICAL....TRIAL....."

under the guidance of ...[redacted]..... has been submitted for Anti-Plagiarism check to the Scientific Correspondence & Review Committee of KLE VK Institute of Dental Sciences using "Turn-it-in" software.

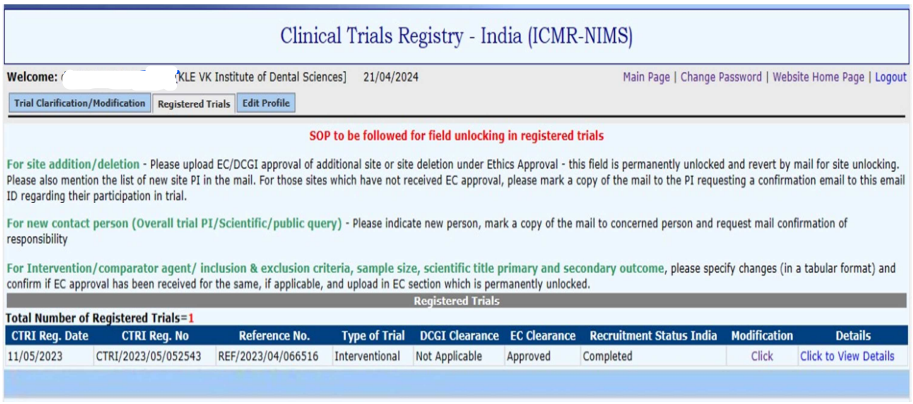
The scan has been carried out and the scanned output reveals a Similarity Index of .....4.....%, which is **within / not within** the acceptable limits of 10% as per the UGC guidelines.

22/Oct/2024

Member Secretary
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER-Belagavi

Chairman
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER - Belagavi

ANNEXURE – VI CTRI REGISTRATION CERTIFICATE



Clinical Trials Registry - India (ICMR-NIMS)

Welcome: [redacted] KLE VK Institute of Dental Sciences] 21/04/2024 Main Page | Change Password | Website Home Page | Logout

Trial Clarification/Modification | Registered Trials | Edit Profile

SOP to be followed for field unlocking in registered trials

For site addition/deletion - Please upload EC/DCGI approval of additional site or site deletion under Ethics Approval - this field is permanently unlocked and revert by mail for site unlocking. Please also mention the list of new site PI in the mail. For those sites which have not received EC approval, please mark a copy of the mail to the PI requesting a confirmation email to this email ID regarding their participation in trial.

For new contact person (Overall trial PI/Scientific/public query) - Please indicate new person, mark a copy of the mail to concerned person and request mail confirmation of responsibility

For Intervention/comparator agent/ inclusion & exclusion criteria, sample size, scientific title primary and secondary outcome, please specify changes (in a tabular format) and confirm if EC approval has been received for the same, if applicable, and upload in EC section which is permanently unlocked.

Registered Trials

Total Number of Registered Trials=1

CTRI Reg. Date	CTRI Reg. No	Reference No.	Type of Trial	DCGI Clearance	EC Clearance	Recruitment Status India	Modification	Details
11/05/2023	CTRI/2023/05/052543	REF/2023/04/066516	Interventional	Not Applicable	Approved	Completed	Click	Click to View Details

ANNEXURE – V – CONSENT FORM

Department of Conservative Dentistry and Endodontics,
K.L.E. V.K. Institute of Dental Sciences, Belgaum

CONSENT FORM
COMPARATIVE EVALUATION OF POSTOPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC TREATMENT USING NEOLIX NEONITI AND E3 AZURE FILE SYSTEM
A RANDOMIZED CLINICAL TRIAL

ನಾನು.....ವಯಸ್ಸಿನ ವಯಕ್ತಿಯಾಗಿದ್ದಾನನಗೆ ತಿಳಿದಿರುವ ಭಾಷೆಯಲ್ಲಿ ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ನನನ ಭಾಗವಹಿಸುವುದ್ರ ಬಗೆನನಗೆ ತಿಳಿಸಲಾಗಿದೆ

೧. ನಾನು ಕೆಲವು ಖಾಸಗಿ ಮಾಹಿತಿಗಳಾದ್ ಹೆಸರು ವಯಸು ಲ್ಲಂಗ ವಿಳಾಸ ಹಲ್ಲಿನತಪಾಸಣೆಯ/ ಚಿಕ್ತತ್ಸೆಯ ಮಾಹಿತಿಯನುನ ಮತು ಈ ಅಧಯಯನಕಾಾಗಿ ಬೋಕಾದ್ ಎಲಿವಿವರಣೆಗಳನುನ ಕೊಡಲು ಒಪ್ಪಿಕೊಳಳುತ್ತಿರೋನೆ.
೨. ನನನ ರೊೋಗದ್ ಪರಿಸ್ಸಿತಿಗೆಬೋಕಾದ್ ಚಿಕ್ತತ್ಸೆಯ ವಿಧಾನಗಳನುನನನಗೆ ಸಂಪೂರ್ಣವಾಗಿ ತಿಳಿಸಲಾಗಿದೆ.

೩. ನನಗೆ ನೋಡುವ ಚಿಕ್ತತ್ಸೆ ಅದ್ರಿಂದ್ ಉಂಟಾಗುವ ತ್ರಿೊಂದ್ರೆ ಹಾಗೊ ಅದ್ಾಂಾಗಿ ಬೋಕಾಗುವ ಚಿಕ್ತತ್ಸೆಗಳ ಬಗೆ ವೈದ್ಯರನುನ ಪರಶ್ನನಸಲು ಸಾಕಷ್ಾಾ ಅವಕಾಶಗಳನುನ ನೋಡಲಾಗಿರುತಿದೆ.
೪. ಈ ಅದ್ಯಯನಕಾಾಗಿ ನನನ ದ್ಂತ ವೈದ್ಯರು ನನನನುನ ಕರೆದಾಗಲೆಲಿ ನಾನು ಬರುವೆನೆಂದ್ಾ ಒಪ್ಪಿಕೊಂಡಿರುತ್ತಿರೋನೆ.
೫. ನಾನು ನನನ ದ್ಂತ ವೈದ್ಯರಿಗೆ ನನನ ಬಗೆನೋಡಿರುವ ಮಾಹಿತಿಯನುನ ಈ ಅಡ್ಾಯನದ್ ಫಲ್ಲತ್ಾಾಂಶದ್ಲ್ಲಿ ಅಳವಡಿಸ್ಸ ಪರಸುತಿಸಲುಮನವಿ ನೋಡಿರುತ್ತಿರೋನೆ.
೬. ನಾನು ನನನ ದ್ಂತ ವೈದ್ಯರು ನನಗೆ ಈ ಅಧಯಯನದ್ಲ್ಲಿನೋಡುವ ಸೊಚನೆಗಳನುನ ತಪಿದೆ ಪಾಲ್ಲಸುತ್ತಿರೋನೆ. ೭. ಯಾವುದೋ ಕಾರಣದಿಂದಾಗಿ ನಾನು ಈ ಅಧಯಯನದ್ಲ್ಲಿಭಾಗವಹಿಸಲು ಅಸಫಲನಾದ್ರೆ/ ಅಸಫಲಳಾದ್ರೆ ಅಧಯಯನದಿಂದ್ ಹೊರಬರಲು ನನಗೆ ಅನುಮತಿ ನೋಡಲಾಗಿದೆ.
ಮೋಲಾಂಡ ಮಾಹಿತಿಯನುನ ನಾನು ಓದಿ ತಿಳಿದ್ಾಕೊಂಡಿದುೋನೆ ಹಾಗೊ ನಾನು ಈ ಅರ್ಜಣಯಲ್ಲಿ ಸಹಿ ಮಾಡಿದುೋನೆ.

ದ್ಂತ ವೈದ್ಯ ರಹೆಸರು: ಅಭ್ಯರ್ಥಣಯ ಹೆಸರು ಮತುಸಹಿ

ವಿಳಾಸ:

ದ್ೊರವಾಣಿ ಸಂಖೆಯ: ದ್ಂತ ವೈಧಯರ ಸಹಿ:

DEPARTMENT OF CONSERVATIVE DENTISTRY AND ENDODONTICS,

KLE. V.K. INSTITUTE OF DENTAL SCIENCES, BELGAUM

CONSENT FORM

COMPARATIVE EVALUATION OF POSTOPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC TREATMENT USING NEOLIX NEONITI AND E3 AZURE FILE SYSTEM :A RANDOMIZED CLINICAL TRIAL

मी.....वय.....सहभागी होत असलेल्या वरील संशोधना बद्दल मला समजत असलेल्या भाषेत सर्व माहीती दिली आहे.

1. मी माझी माहीती जसे की नांव वय, लिंग, पुर्व दंत उपचार महिती आणि इतर लागणारी माहीती देण्यास तयार आहे.

2. माझी दंत वैद्याकीय तपासणी करणार असल्याची मला कल्पना आहे.आणि दिलेली माहीती मला समजली आहे.

3. मी या संशोधना बद्दल माहिती विचारु शकतो/शकत.

4. मी परिक्षणा वेळी दंत वैद्याकानी दिलेल्या सुचना पाळेन.

5. मी दिलेली माहीती आणी यांचा-या निकल वापरण्यास, मांडण्यास आणि प्रकाशीत करण्यास पुर्ण सम्मती देत आहे.

6. जरी एखाद्या एजेन्सीन.मी दिलेली माहीती वापरली तरी मी कोणतीही फर मागणी करणार नाही

7. मी या संशोधनात स्वइच्छेने.भाग घेण्याची परवानगी देत आहे.
8.कोणत्याही कारणास्तव माझा सहभाग मी माघारी घेऊ शकतो / शकत.
9. दंतवैद्यकाने.दिलेली वरील महिती मी वाचली आहे.आणि ती मला समजली आहे.म्हणुन मी या अर्जावर नोंदणी व स्वाक्षरी केली आहे.

दंतवैद्यकाचे.नांव : **पालकांची सही:**
दंतवैद्यकाची स्वाक्षरी : **स्थळ**
तारीख:

KLE Vishwanath Katti Institute of Dental Sciences, Belagavi

Department of Conservative & Endodontics

CONSENT FORM

POSTOPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC TREATMENT USING NEOLIX NEONITI AND E3 AZURE FILE SYSTEM A RANDOMIZED CLINICAL TRIAL

Patient Information Sheet

Title of the study – comparative evaluation of postoperative pain after single visit endodontic treatment using neolix neoniti and E3 azure file system :A randomized clinical trial

Aim of the study:

Although, the root canal treatment has been widely followed and is able to cure the patients of pain, the post-operative pain is still a discomforting phenomenon. One of the factor responsible to cause it and under control of the clinician is the files used for the preparation during the treatment. This study intends to compare two rotary instruments and to evaluate which instrument causes less post-operative pain

Description of the study:

The patients that can be included in this study and are interested to participate will be informed about the study and the protocol that will be followed. We are aiming to include 68 patients requiring root canal treatment of maxillary premolar teeth. The patients will be randomly allocated to the two groups. Root canal treatment will be completed in a single visit and the patient will have to report about the post-operative pain he/she experiences at 6 hrs, 24 hrs, 48 hrs. and 72 hrs. If pain occurs the patient is advised to take 400 mg ibuprofen to relieve the pain. If the pain is unbearable, he/she can report to the study person immediately and the necessary treatment and relief will be provided.

Participation and Termination: Your participation in the study is voluntary. You can refuse to participate or ask your study doctor to end your participation before the final closure of the study at any time. Refusal to participate or early termination will not in any way, influence your relationship with and or your treatment by the doctor. If you agree to participate, you will be asked to sign the informed consent form. You have the right to ask questions about this study at any time.

Cost of participation:

Participating in this trial will not result in any additional cost to you.

Confidentiality:

In accordance with Belgian Law concerning private life protection (1992) and patient's rights, information collected from your participation in this study is protected. If you agree to participate in this study, your personal data and clinical information will be collected and coded. When the results of this study will be published, your identity will remain confidential.

KLE Vishwanath Katti Institute of Dental Sciences, Belagavi

Department of Conservative & Endodontics

CONSENT FORM

COMPARATIVE EVALUATION OF POSTOPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC TREATMENT USING NEOLIX NEONITI AND E3 AZURE FILE SYSTEM

A RANDOMIZED CLINICAL TRIAL

I, _____ aged _____ years have been informed about my involvement in the study.

1. I agree to give my personal details like Name, Age, Sex, Address, previous dental history
    a. and the details required for the study to the best of my knowledge.
2. The procedures necessary to treat the condition have been explained to me and I understand the nature of the procedure to be performed.
3. I have been given the opportunity to question the doctor concerning the nature of the
    a. treatment, the inherent risks of the treatment and alternatives to this treatment.
4. I will visit the dentist as and when required for the study, at the given appointment (date and time).
5. I permit the operator to utilize the information given by me and results obtained from the
    a. study for presentation and publication.
6. I will follow the instructions given by the doctor during the study.
7. I have been informed about the nature of treatment, its advantages and disadvantages.
8. If for any reason I am unable to participate in the study, for reasons unknown, I can
    a. withdraw from the study.
9. I have read, gone through and understand the above information given by the Doctor about the study.

I have entered and signed this application

Dentist's Name:	Witness' Name:
Address:	Address:
Ph. No:	Ph. No:
Signature:	Signature:

ANNEXURE – VI – PROFORMA
Department of Conservative Dentistry and Endodontics

K.L.E. V.K. Institute of Dental Sciences, Belgaum

Proforma

"Comparative Evaluation Of Post - Operative Pain After Single Visit EndodonticTreatment Using Neolix Neoniti AND E3 Azure Rotary File Systems:*A Randomized Clinical Trial*"

Case History, Patient Assessment, Diagnosis And Treatment Plan

Name of the Patient :

O.P.D. Number :

Sex :

Age :

Address :

Chief Complaint :

History Of Present Illness :

Past Dental History :

Medical History :

History Of Allergy :

Clinical Examination :

Clinical Diagnostic Tests :

Pulp Vitality Test [Electric Pulp Test] :

Percussion :

Mobility :

Radiographs [IOPA] :

Diagnosis :

Treatment plan :

ANNEXURE – VII

'VISUAL ANALOGUE SCALE' SCORE SHEET

DEPARTMENT OF CONSERVATIVE DENTISTRY AND ENDODONTICS
K.L.E. V.K. INSTITUTE OF DENTAL SCIENCES, BELGAUM

Proforma (to be handed over to the patient)

"Comparative Evaluation Of Post - Operative Pain After Single Visit Endodontic Treatment Using Neolix Neoniti AND E3 Azure Rotary File Systems:A Randomized Clinical Trial"

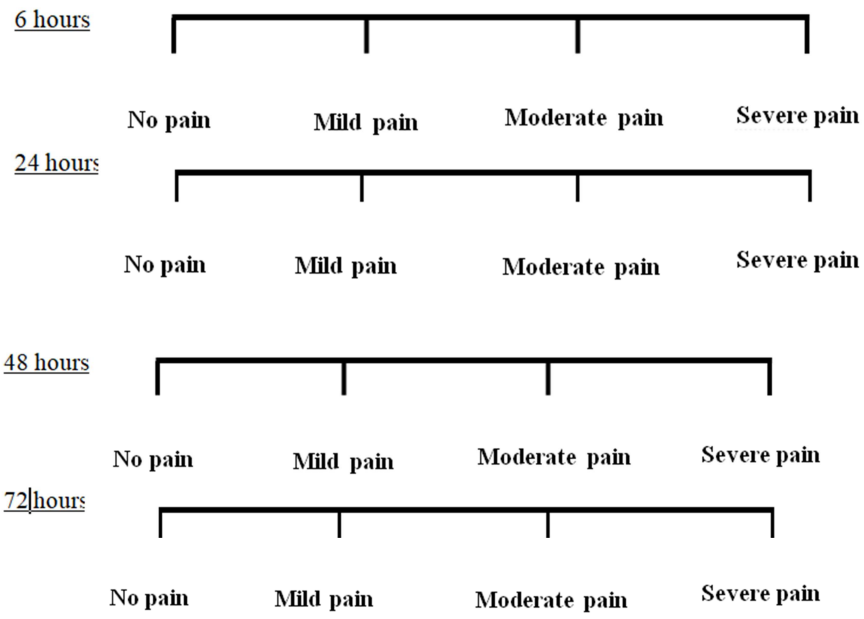
Name of the Patient :

O.P.D. Number :

Sex :

Age:

Address :



Medication taken, if any, when:_____

Signature of the patient

Thank you for your participation in the study