Endodontic files are used to remove intracanal pulpal tissues, microbial biofilm, and toxic by-products and to develop a continuously tapering canal while maintaining the canal geometry that ultimately allows for the delivery of irrigating solutions and intracanal medicaments as well as the three-dimensional filling of the root canal system. Historically, stainless steel hand files have been used to perform canal shaping. However, these files are stiff and associated with increased operator fatigue, and when used in the preparation of curved root canals, the restoring forces of the files tend to return the file back to its original shape, resulting in canal transportation.

More recently, nickel-titanium (NiTi) files have been introduced and are broadly used to shape the root canals owing to their increased flexibility, rapid and centered canal preparation, safer preparation of curved canals, improved cutting efficiency, and improved treatment outcome. In spite of all these advantages, the main limitation in the use of a NiTi file is the risk of their fracture, especially when it is autoclaved and reused.

XP-Endo Shaper is a single-file system that is used in a continuous rotary movement. This file is snake-shaped with a triangular cross-section. It has an apical diameter of 0.27 mm and a fixed taper of 0.01. The MaxWire technology involved in the production of this file provides it with superelasticity and shape memory properties that make it ideal for use in both straight and curved canals.

Emara and colleagues (2021) reported on a trial that sought to evaluate whether root canal instrumentation using XP-endo Shaper in comparison with conventional rotary instrumentation using iRaCe files would result in a difference in postoperative pain, and intracanal bacterial count in mandibular premolars with single oval canals and necrotic pulps.

INTRODUCTION

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MATERIALS AND METHODS

This study was designed as a parallel, randomized, double blinded clinical trial. The inclusion criteria for the participants were healthy men and women of 20-60 years reporting no to mild preoperative pain and having mandibular premolars with single oval root canals and necrotic pulps, and with (smaller than 3 mm) or without periapical radiolucency. The exclusion criteria were pregnant women, if analgesics or antibiotics had been consumed by the patient during the past 12 h, teeth that did not have a normal occlusal contact on verification using an articulating paper, association with acute periapical abscess, greater than 5mm periodontal pockets, greater than grade I mobility, alveolar bone loss exceeding 50%, and non-restorable teeth.

The diagnosis was confirmed through history of chief complaint, negative response to both thermal test and electrical pulp tests and radiographic examination using the digital imaging. After opening the access cavity to confirming the diagnosis by absence of bleeding, each patient selected an envelope and was allocated either to the XP-endo Shaper group (A) or the iRaCe group (B). The patients and outcome assessors were blinded to the assigned treatment group throughout the study.

Each patient was given pain scale chart (modified visual analogue scale) to record the presence and severity of pain before treatment. The modified VAS consisted of 10 cm line and was illustrated visually, verbally and numerically to the patients. Four categorical scores expressed the pain level: 1. None (0); 2. Mild (1–3); 3. Moderate (4–6); 4. Severe (7–10). Root canal treatment was completed in a single visit using a standardized approach in both groups. After local anaesthesia and application of rubber dam, the
access cavity was then prepared using another sterile round carbide bur and Endo-Z bur under sterile saline irrigation. The operative field and pulp chamber were disinfected and 5% sodium thiosulfate was used to neutralize the effect of NaOCl then dried using sterile cotton wool. Sterility was checked by collecting control samples from the external surface of the crown as well as the access cavity using sterile paper points and culturing them aerobically and anaerobically.

Stainless steel size 15 K-files were used to confirm the patency of the root canals. Working length was determined using an electronic apex locator then confirmed radiographically to be 0.5mm shorter than radiographic apex. In the intervention group, the Xp-endo Shaper single file was used for instrumentation in an endodontic motor at a speed of 800rpm and a torque of 1Ncm starting at size 30, .04 taper. The file was operated in 5 up and down strokes of 3-5mm amplitudes until reaching working length then 10 brushing strokes of 5-7mm for the full length of the canal and an extra 45s of instrumentation was continued at the working length to enlarge the canal to size 40, .04 taper. After each 5 strokes, the canal was irrigated using 3mL of 2.5% sodium hypochlorite and EDTA gel was used as a lubricant. In the control group, mechanical preparation was completed using rotary iRace files sizes 15, .06 taper, 25, .04 taper, 30, .04 taper, and 40, .04 taper at a speed of 600 rpm and a torque of 1.5 Ncm and the canal was irrigated after the use of each instrument.

All canals received the same volume of irrigant (30 mL) using a syringe with 27 gauge open ended bevelled needle placed at 3 mm from the working length. The canals were then dried using sterile paper points and flushed with 5 mL of 5% sodium thiosulfate to inactivate the NaOCl. The final preparation was then checked by adapting master cones of size 40, .04 gutta-percha at the working length and a radiograph was taken to verify proper length. The post-instrumentation root canal samples (S2) were then taken from the canals. The microbiological samples were transferred to the laboratory. Canal filling was completed using a modified single cone technique with a resin-based root canal sealer. The access cavities were restored with core-build up composite resin and occlusal contacts were adjusted.

Patients were asked to record the incidence and severity of their postoperative pain on the modified visual analogue scale (VAS) at 6, 12, 24 h, 2, 3, 4, and 5 days. The patients were prescribed Ibuprofen (400 mg) to be consumed in one tablet every 6 h for a maximum of 5 days in the event of persistent moderate to severe pain. Patients recorded the incidence and number of analgesic tablets taken.

Intracanal bacterial counts were determined using a culture technique and the resultant growth was visually quantified by counting the number of colony forming units per millilitre (CFUs/mL) under the microscope. Only plates with 30-300 colonies were counted.

If swelling occurred, the patient was seen to assess the severity by a blinded assessor on a four point swelling rating scale expressed as none (n); small swelling intraorally adjacent to the treated tooth (s); moderate (m); or large severe swelling visible extraorally (!). The blinded assessor also determined if systemic antibiotics (Augmentin 625 mg/8 h/5 days) or drainage were needed. The incidence of flare-up was recorded as a binary outcome (Yes/No) when patients reported moderate to severe postoperative pain and/or moderate to severe swelling that began 12-48h after treatment and lasted at least 48 hours.

**RESULTS**

Sixty patients were included in the statistical analysis. The demographic data and clinical features of the patients were similar in both groups.

The incidence of postoperative pain was significantly lower in the intervention group compared with the control group at 6, 12 and 24h (P=0.039, 0.047, and 0.026, respectively). The mean postoperative pain scores were lower in the intervention group at all follow-up periods with a significant difference at 6h (mean difference: 1.33, 95% CI: 0.307-2.352, P=0.02), 12h (mean difference: 1.1, 95% CI: 0.263-1.936, P=0.007), 24h (mean difference: 0.94, 95% CI: 0.178-1.701, P=0.008) and 48h (mean difference: 0.97, 95% CI: 0.192-1.747, P=0.038).

There was a significant decrease with time in mean pain scores at all evaluation periods in relation to preoperative pain in the intervention group (P=0.01 at 6h and <0.001 at 12h, and 1-5 days) while in the control group a significant decrease in mean pain scores occurred at 3 to 5 days evaluation periods (P=0.9 at 6, 12, 24 h, 0.37 at 2 days, and <0.001 at 3-5 days).

There was no significant difference in the incidence of analgesic intake (3.3% in the intervention group versus 16.7% in the control group [P=0.085]). Regarding number of analgesic tablets in the intervention group, 1 patient took 2 tablets; while in the control group, 3 patients took 2 tablets and 2 patients took 3 tablets with no significant difference between them (P=0.08).

All sterility control samples were negative for bacterial growth. Both groups were associated with a significant reduction in the bacterial counts following canal instrumentation compared to pre-instrumentation samples with no significant difference between them. S2 anaerobic bacteria counts represented 16.31% of S1 (i.e. 83.68% reduction) in the XP-endo Shaper group, and 19.48% of S1 (i.e. 80.5% reduction) in the iRaCe group. The number of root canals free of cultivable anaerobic bacteria were 8 (26.67%) in the XP-endo shaper group and 3 (10%) in the iRaCe shaping group. There was a weak correlation between postoperative pain severity and anaerobic bacterial counts (rs=-0.079, P=0.54).

Flare-ups occurred in 2 cases in the control group in the form of moderate swelling occurring 24h after treatment and lasting for 48h. Flare-ups were controlled by systemic antibiotics with no need for drainage or retreatment. No flare-up occurred in the intervention group. The overall incidence of flare-up was 3.3%.

There was no correlation between age and postoperative pain (rs=0.111, P=0.39) nor preoperative and postoperative pain (rs=0.085, P=0.51). None of the clinical variables (i.e. gender, presence or absence of periapical lesion)
had a significant effect on neither incidence nor intensity of postoperative pain ($P>0.39$).

**CONCLUSIONS**

XP-endo shaper significantly reduced the incidence (at 6, 12, and 24 h) and severity (at 6, 12, 24, and 48 h) of postoperative pain compared with iRaCe rotary files. Both instrumentation systems succeeded in significantly reducing bacterial levels in primary infected root canals with no significant difference between them.

**MATERIALS AND METHODS**

Mechanical canal instrumentation and irrigation with antibacterial solutions constitute the basis of root canal treatment. Irrigating solutions are crucial in order to flush away debris, remove the smear layer and further disinfect the noninstrumented areas of the root canals. Sodium hypochlorite (NaOCl) is the most commonly used irrigant, due to its antimicrobial and antibiofilm potency and organic tissue dissolution capacity. However, it has been shown to be cytotoxic to the periapical tissues.

Irrigation with a syringe and a needle remains the most commonly used technique for irrigation in endodontics but fluid penetration at the apical region is limited. Efforts to surmount this problem have been made via the introduction of various irrigant activation devices or methods to improve irrigant distribution within the root canal system and augment disinfection. Sonic and ultrasonic agitation techniques are being used, but other forms of activation such as laser-activated irrigation (LAI) and manual-dynamic activation (MDA) have also been introduced more recently. Ultrasonically activated irrigation (UAI) implies the ultrasonic activation of irrigant in the centre of the instrumented root canal by a noncutting, oscillating instrument. The working mechanism primarily is the generation of steady, unidirectional circulation of fluid in the vicinity of the vibrating instrument, called acoustic microstreaming. Laser-activated irrigation (LAI) with a pulsed Er:YAG laser is another method of irrigant activation. Pulsed erbium lasers produce optical cavitation in the irrigant, resulting in expanding and imploding vapour bubbles at the fibre tip and smaller secondary bubbles deeper in the canal that undergo acoustic streaming. These events occur extremely rapid (within the microsecond region), resulting in very fast liquid movement throughout the entire canal. However, there have been reports of irrigant extrusion with LAI leading to possible post-operative pain.

**References**


**Implications of practice**

The XP-endo shaper system performed significantly better for the outcomes post-operative pain than the rotary system.

**CONCLUSIONS**

**MATERIALS AND METHODS**

This was a double-blind, single-centre, superiority parallel design randomized controlled trial which was reported in accordance with the Preferred Reporting Items for Randomized Trials in Endodontics (PRIPATE) 2020 guidelines. Healthy patients over the age of 18 years who required root canal treatment of an asymptomatic tooth with vital or necrotic pulp, or with a previously initiated therapy on the emergency dental department, with or without radiographic apical rarefaction, were considered for enrolment. Patients were excluded if they had pain, a history of sensitivity or adverse reactions to any of the medications (nonsteroidal anti-inflammatory drugs) or materials used in this study. Teeth with incompletely formed roots or open apices, retreatment cases or patients presenting with pain in another area and/or tooth of the oral cavity or patients who took medication that could alter pain perception (e.g. analgesics) within at least 12 h before treatment were also excluded, as well as pregnant or breastfeeding females.

Medical and dental history of every individual was recorded, and clinical and radiographic examination was performed. Clinical examination included visual inspection of the tooth and surrounding tissues, assessment of restorability, periodontal probing, palpation and percussion tests. Sensibility testing was done using cold test.
Periapical radiographs were taken using the parallel technique. This information resulted in establishment of the pulpal and apical diagnosis. Each patient was asked to determine the level of preoperative pain by drawing a line on a VAS (0–100 mm), with 0 meaning ‘no pain’ and 100 ‘unbearable pain’. Healthy patients indicating a level of pain between 0 and 4 mm on the VAS were asked to participate in the study.

Complete chemo-mechanical preparation and canal filling were performed by the same operator in a single visit using a standardized approach. The working length (WL) was determined by an electronic apex locator. After initial shaping, the final apical preparation size of each canal was determined as 3 sizes larger than the first binding file at the WL, using hand files. The canal preparation was completed using ProTaper Next (PTN) instruments, with a minimum apical diameter of size 25. Irrigation was done using a 27-gauge notched needle adapted to a 3ml syringe with 2 mL of 3% NaOCl in between instruments. The needle was inserted to a depth of 2-3 mm short of WL. Before the final irrigation procedure, each canal was rinsed with 2ml EDTA 17%.

Each patient received a pain diary to record their pain on the following moments: 6, 24, 48 and 72h after the intervention. A visual analogue scale (0–100 mm) was used to indicate the pain intensity. The VAS was thoroughly explained to the patients, who were then instructed to place a mark on the horizontal VAS line corresponding to the intensity of postoperative at the various moments. The time at which the treatment was finished was written on the pain diary to facilitate the completion of the pain record. Patients were advised to use the prescribed medication only if they felt that pain was affecting their normal life. The pain diary also contained a part to keep a record of their analgesic intake.

Patients were instructed to return the reports either via post, via email or at their next visit at the dental school. When reports were sent via email, the pictures were printed. Measurements were done using a ruler and when necessary, the rule of three was used to determine the level of pain.

RESULTS

A total of 88 subjects were initially screened for inclusion, and 56 patients were finally enrolled in the study. The random allocation resulted in 28 patients (18 males and 10 females) in the UAI group and 28 patients (13 males and 15 females) in the LAI group. Fifty-five patients returned their VAS forms, one patient from the UAI group failed to do so. The mean age of the patients in the UAI group was 41 years, whilst in the LAI group, it was 43 years. Ten teeth in the UAI group and 15 teeth in the LAI group displayed a preoperative radiolucency. There were no significant differences between the two arms regarding gender (P=0.179), age (P=0.712) and the presence of an apical radiolucency (P=0.179).

Overall, mean postoperative pain intensity was low (overall mean of 9.4 after 6h and 6.55 after 24h), with the majority of patients having no or minimal pain 24h postoperatively. Six hours postoperatively, pain intensity was significantly lower in the LAI group compared to the UAI group (P<0.05). Whilst this difference was statistically significant, it was below the value considered as clinically relevant, as determined in the power calculation. At 24, 48 and 72h, no statistically significant differences between the activation groups were observed (P>0.05).

In the UAI group, the pain at 24h was significantly lower than the pain at 6h (P<0.05). At 48 and 72h, the pain levels were significantly lower compared with the preceding time interval. In the LAI group, the mean postoperative score at 24h was slightly higher than that at 6h, but this difference was not significant (P>0.05). At 48 and 72h, a further significant decrease compared to the previous time-points was noted (P<0.05).

One patient from the UAI group reported severe pain up to 78 mm on the VAS till 48h postoperatively. This case was associated neither with swelling nor with an emergency visit. No other untoward effects were reported.

Logistic regression analysis of the incidence of postoperative pain revealed a significant association between the presence of postoperative pain at 6h and the final irri-
gation protocol, whilst no association was observed with age, gender, tooth type and presence of radiolucency.

Six hours after treatment, 26% of the patients (7 of 27) in the UAI group and 7.7% (2 of 28) in the LAI group required analgesics for pain control, but this difference was not significant. No significant differences in analgesic intake between the two groups were found at the other time intervals.

**CONCLUSIONS**

Ultrasonically and laser-activated irrigation resulted in low and comparable levels of postoperative pain in asymptomatic patients receiving primary root canal treatment.

**Implications for practice**

These new modes of irrigant administration show promise for routine clinical application compared to the current needle and syringe method for the outcome of lower post-operative pain.

**Reference**