Effect of Reciprocating versus Rotary Instrumentation on Post-endodontic Pain and Endotoxins Level in Infected Root Canals: A Randomised Clinical Trial

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Abstract

Background: This randomised, prospective, controlled trial aimed to assess the effect of reciprocating single-file and rotary instrumentation on the intensity of postoperative pain and the amount of endotoxins in primarily infected root canals.

Methodology: Forty participants were randomly assigned into two equal groups according to root canal instrumentation technique (n = 20), control group: root canals were instrumented using ProTaper Next rotary system and intervention group: canals were instrumented using WaveOne Gold reciprocating instrumentation system. Root canal treatment was carried out on two visits and postoperative pain of participants was measured using a numerical rating scale (NRS) at predetermined time intervals 6, 12, 24, 48 hours after instrumentation and obturation appointments. Quantification of endotoxins was done using the Sandwich-ELISA method at predetermined time intervals (after access cavity preparation and after completion of instrumentation). Pain score data were summarised as mean and standard deviation.

Results: No statistically significant difference was noted between the single-file reciprocating system (WaveOne Gold) and the multiple-file rotary system (ProTaper Next) regarding postoperative pain and reduction in the amount of endotoxins (P > 0.05).

Conclusion: Both single-file reciprocating instruments and multi-file rotary instruments resulted in mild to moderate postoperative pain and comparable reduction of endotoxins level.

Keywords: *endotoxins, post-endodontic pain, primary endodontic infection, ProTaper Next, WaveOne Gold.*

Introduction

Post-endodontic pain is defined as the pain of any degree that occurs after initiation of root canal treatment and it remains to be a significant problem in the dental profession.(1)

Post-endodontic pain is caused by a multitude of factors, one of which is the apical extrusion of debris during root canal treatment both with manual stainless steel and nickel-titanium rotary instrumentation techniques.(2)However, reciprocating instrumentation techniques claimed to significantly increase the amount of debris extruded beyond the apex and, consequently, the risk of postoperative pain.(3,4)

It is well known that one of the main goals of root canal treatment is to reduce the amount of bacteria and their by-products, all contributing to the perpetuation of apical periodontitis.(5,6) Lipopolysaccharides (LPS), generally referred to as endotoxins, can egress into periapical tissue contributing to the initiation and perpetuation of an inflammatory process, therefore endodontic treatment should not only rely on bacterial elimination but also the reduction or elimination of endotoxins.(7)

The concept of using single-file systems to shape

the root canals completely from start to finish has been questioned for achieving proper cleaning and disinfection.[8]

In this study, root canal preparation was done using ProTaper Next (PTN) and WaveOne Gold (WOG) NiTi Systems. PTN is manufactured from M-Wire nickel titanium alloy to enhance flexibility and cyclic fatigue resistance. It is designed with progressive and regressive percentage tapers, and an off-centered rectangular cross section for superior strength to improve canal shaping efficiency.[9]

WaveOne Gold is characterized by a new thermally treated nickel-titanium alloy named "Gold". The gold process is a post-manufacturing procedure in which the ground NiTi files are heat-treated and slowly cooled. This process results in a distinctive gold finish that improves its resistance and flexibility far in excess of its predecessor.[10]

So the objective of the current study was to test the null hypothesis whether the use of a reciprocating single-file system (WaveOne Gold) for cleaning and shaping of primarily infected root canals differ from rotary instrumentation (ProTaper Next) in the intensity of postoperative pain and level of endotoxins.

Materials and Methods

Study design and setting: The study protocol was registered on pactr.org and the registration number is PACTR201808614861015. The protocol was approved by theResearch Ethics Committee (approval # 14-10-15). Participants were asked to sign a printed informed consent that explained the study aim, benefits, and possible side effects of the treatment, and the investigator's instructions.

Sample size calculation: Prior data[11] indicated that a minimal clinical difference of 1 in pain score between test and control groups would be clinically relevant. Using a power of 80%, a level of significance of 5%, and considering a standard deviation of 1.0, 17 participants per group would be necessary. The number had to be increased to a total sample size of 20 per group to allow for losses during follow up.

Participants and eligibility criteria: After enrollment of 56 patients, only 40 medically-free participantswith an age range of 13-60 years who met the inclusion criteria and diagnosed with non-vital permanent mandibular molars and pain on palpation or tenderness to percussion were enrolled from the outpatient clinic of the Department of Endodontics(Figure 1).

Exclusion criteria comprised of a history of medicine intake including corticosteroids, opioids, and nonsteroidal anti-inflammatory drugs (NSAIDs) in the past 12 h or antibiotic treatment during the last 3 months, patients with a history of intolerance of nonsteroidal anti-inflammatory drugs, or those with systemic disorders or pregnant females; teeth with periodontal pockets deeper than 4 mm, previous endodontic treatment, grade II or III mobility. Before treatment, a list of information regarding age, gender, type of tooth was gathered from each patient, and the treatment was performed on two visits.

Treatment procedures: Endodontic procedures were accomplished by one trained postgraduate student. An electrical pulp tester (Denjoy DY310 Dental Pulp Tester; Denjoy, Henan, China) was used to determine pulp sensibility. Radiographic examination was done using the bisecting angle technique with a photostimulable phosphor plate wireless sensor (SOREDEX, DIGORA). A final diagnosis of necrotic mandibular permanent molar teeth with symptomatic apical periodontitis was confirmed before enrollment in the study.

Preoperative pain was recorded using NRS where 0 indicates no pain and 10 indicates pain as terrible as it could be. Pain intensity was categorised into either: none (0); mild (1–3); moderate (4–6); and severe (7–10).[12]

The tooth was anaesthetised using inferior alveolar nerve block by local anaesthesia (Mepivacaine HCl 2% with Levonordefrin 1:20,000) (Mepivacaine, Alexandria Co. for pharmaceuticals & chemical industries, Alex., Egypt). The tooth was properly isolated with a rubber dam and its external surface was disinfected. Access cavity preparation was performed and the first endotoxin sample (S1) was taken by introducing sterile paper points #15 (DentsplyMaillefer, Ballaigues, Switzerland) into

the largest canal or the one related to apical periodontitis.[13]

Establishing a glide path to all root canals was done and coronal flaring was performed. The working length was determined using an electronic apex locator (Denta Port Zx J. Morita, Kyoto, Japan) and confirmed radiographically.

Randomisation and allocation concealment: At this step, the participants were divided randomly into two groups by an investigator not involved in participant enrollment usinga computer software (http://www.random.org/). Numbers from 1 to 40 were written on 40 pieces of paper folded eight-times. Each paper was placed separately in a closed opaque envelope. Each participant was asked to pick one of the envelopes and the participant was assigned to the groups based on the number in the envelope.

For the control group, canals were instrumented using ProTaper Next (PTN) rotary system (DentsplyMaillefer, Ballaigues, Switzerland) according to the manufacturers´ instructions. In the presence of NaOCI, X1 file was used in one or more passesuntil the working length was reached. X2 file was exactly used as described for the X1 file until the working length was passively reached. Afterward, the canal was gauged with a size 25 K-file and, if this file was snug at length, the preparation was considered adequate. If the size 25 K-file was loose at length, canal shaping was continued with X3 and, when necessary, with X4 gauging after each instrument with the 30 or 40 hand files, respectively.

For the intervention group, canals were instrumented using WaveOne Gold (WOG) reciprocating instrumentation system (Dentsply Maillefer, Ballaigues, Switzerland) according to the manufacturers´ instructions. In the presence of NaOCI, the canal shaping procedure was initiated with the Wave One Gold primary file using 3 mm amplitude strokes in a gentle inward motion to passively advance the file to the full working length. If the primary file didn't progress, the small file was advanced to the working length followed by the primary file to optimize the shape.If the primary file was loose at length with no dentinal debris in the apical flutes, shaping was continued with the medium or the large file.

Canal irrigation was performed with 5 ml of 2.5% NaOCl solution (Clorox, 10th of Ramadan, Egypt) using a side vented 27-gauge needle (C-K Dental Ind. Co, Ltd, Korea) after each file use. After completion of instrumentation, the root canals were thoroughly flushed using 5 ml of sterile saline solution.

A continuous rinse with 5 ml of 17% EDTA solution (MD-Cleanser, Meta Biomed Co, Ltd, Korea) for 3 minutes followed by a final rinse with 5 ml of sterile saline solution was performed before taking the second endotoxin sample (S2).

At the second appointment, 1 week after the first appointment, the temporary filling was removed and the root canals were irrigated using 5ml saline followed by 1ml of 17% EDTA to remove the smear layer, and then obturation of the root canals was done.

In both groups, root canals were obturated using matching gutta-percha points and a resin-based root canal sealer (Adseal, Meta Biomed CO, LTD, Korea). Finally, the tooth was sealed by a reinforced zinc oxide-eugenol cement.

Endotoxin sampling procedures: The first endotoxin sample (S1) was taken after access cavity preparation by introducing the paper point into the full length of the canal and retained in position for 60 seconds. This procedure was repeated with 3 paper points. Immediately afterward, the samples were placed in a sterile plastic epindorff and stored at -20^0C.[14]

The second endotoxin sample (S2) was taken just after completion of instrumentation and irrigation with saline solution using the same protocol.

Outcomes: Primary outcome: Postoperative pain was measured using NRS at predetermined time intervals 6, 12, 24, 48 hours after the end of each appointment. Secondary outcome: Quantification of endotoxins was done using the Sandwich-ELISA method at predetermined time intervals (after access cavity preparation and after completion of instrumentation).

Statistical analysis: All the data was collected and tabulated. Statistical analysis was performed by Microsoft Office 2013 (Excel) and statistical package SPSS version 22. Pain score data were summarised as mean and standard deviation. Comparisons between the two groups were done using Mann-Whitney test for analysis of the intensity of pain. Unpaired t-test was used when comparing variables between the two groups while paired t-test was used when comparing variables within the same group. The significance level was set at p-value < 0.05.

Results

Demographic data for gender distribution, age of participants, and tooth type showed no statistically significant difference between the two tested groups (Table 1).

Regarding the intensity of post-instrumentation pain at the predetermined time intervals, the control group (PTN) showed the highest mean score of post-instrumentation pain intensity at 6 hours which decreased gradually to reach the least value at 48 hours postoperatively. While the intervention group (WOG) showed the highest mean score at 6 and 12 hours postoperatively which decreased gradually to reach the least value at 48 hours postoperatively. The control group showed less mean pain scores at all time intervals than the intervention group but didn't reach the level of statistical significance. Also, the intensity of post-obturation pain was not significantly different between the two groups at the predetermined time intervals (Table 2). Intragroup data analysis revealed that the intensity of post-instrumentation and post-obturation pain significantly decreased at different time intervals within each group at different follow up periods ($p < 0.05$; Graph 1).

The comparison between the first (S1) and second (S2) endotoxin samples within each group revealed a statistically significant decrease in the mean value of endotoxin level from S1 to S2. Root canal instrumentation using the ProTaper Next system was able to decrease endotoxin level by approximately 33% while 31% reduction in the endotoxin level was achieved using WaveOne Gold instrumentation system. Regarding the mean values of different endotoxin samples, the comparison between the control and intervention groups showed no statistically significant difference between the two groups at S1 and S2 mean scores ($p > 0.05$; Table 3).

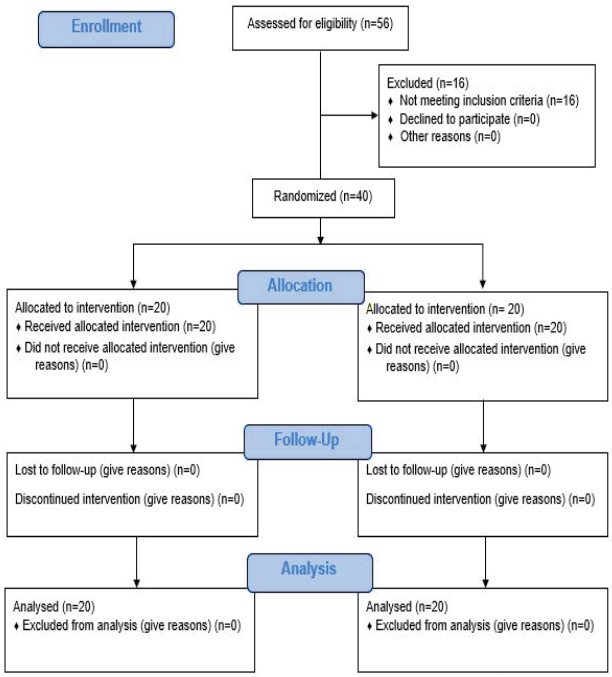
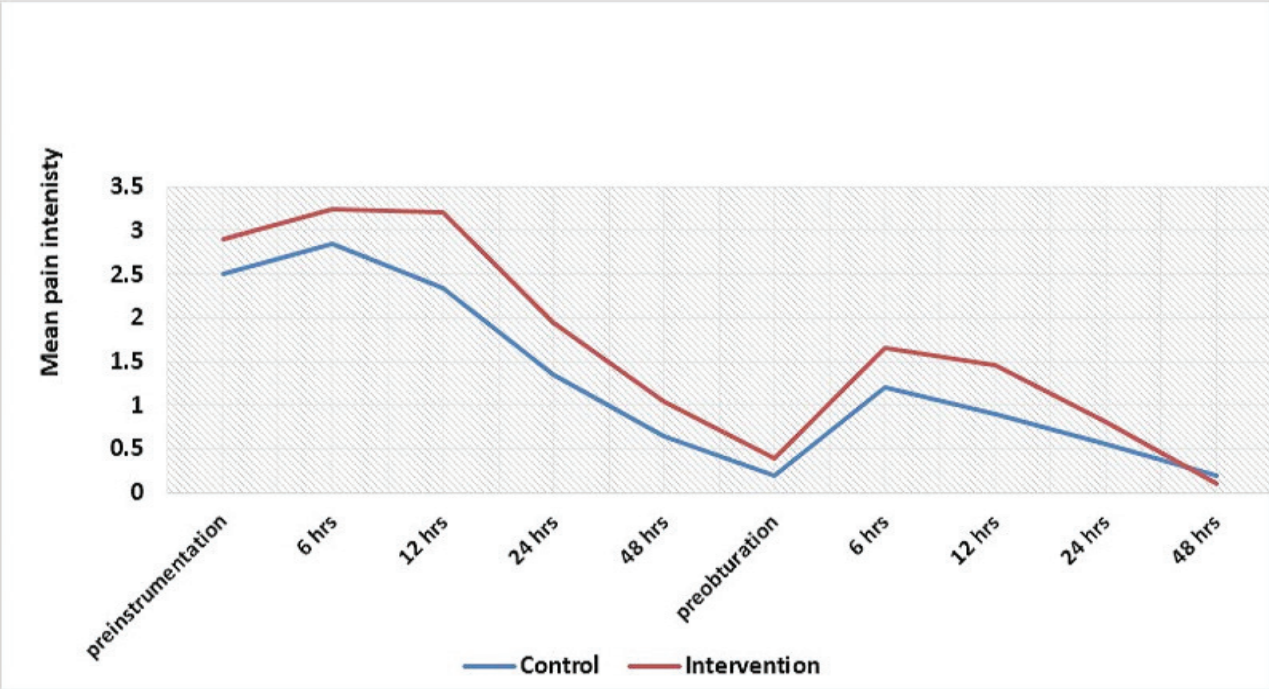


Figure 1: CONSORT flow chart showing the flow of participants along the study



Graph1: Line chart representing the changes in the intensity of pain at different time intervals for each group

Table 1: Baseline characteristics of the included study participants

Variables		Control (PTN) (n=20)	Intervention (WOG) (n=20)	P-value
Gender [n (%)]	Female Male	10 (50%) 10 (50%)	10 (50%) 10 (50%)	1
Age (Mean+ SD)		36.9+13.3	30.9+11.3	0.135
Tooth type [n (%)]	Lower 6 Lower 7	14 (70%) 6 (30%)	13 (65%) 7 (35%)	0.87

SD, standard deviation

Table 2: Intensity of pain (mean±SD) of the two groups at predetermined time intervals using Mann-Whitney test

Time-point	Control (PTN) (n=20)	Intervention (WOG) (n=20)	P-value
Preinstrumentation	2.5±1.4	2.9±1.16	0.42
After 6 hrs	2.85±1.63	3.25±1.29	0.353
After 12 hrs	2.35±1.63	3.2±1.5	0.058
After 24 hrs	1.35±1.42	1.95±1.5	0.151
After 48 hrs	0.65±1.03	1.05±1.31	0.257
Preobturation	0.2±0.52	0.4±0.68	0.429
After 6 hrs	1.2±1.1	1.65±0.98	0.187
After 12 hrs	0.9±0.91	1.45±0.94	0.062
After 24 hrs	0.55±0.75	0.8±0.83	0.292
After 48 hrs	0.2±0.52	0.1±0.3	0.604

Table 3: Endotoxin levels (mean±SD) in the two tested groups

	S1	S2	Percentage of reduction
PTN group Mean+ SD	376.6+150a	252+130b	33%
WOG group Mean+ SD	451+140a	311+120b	31%

[Different lower-case letters represent a significant difference]

Discussion

During chemo-mechanical preparation of the root canals, all instrumentation techniques can produce apical extrusion of debris. However, some studies have stated that full-sequence rotary instrumentation was associated with less debris extrusion compared with the use of reciprocating single-file systems and suggested that this factor could be associated with less postoperative pain.

(15,16)

Bacterial lipopolysaccharides produced by gram-negative bacteria, which were predominantly involved in root canal infections, have been shown to enhance the sensation of postoperative pain.[13,17] Single-file instrumentation systems have been developed with the advantage of cleaning and shaping root canals in a shorter time, however, their ability to properly remove bacteria and bacterial by-products from infected root canals is questionable.

In the present study, postoperative pain was recorded using NRS which was considered a consensus-based, standardised assessment measure, and reported better compliance when compared to other scales.[12]

The time of assessment of postoperative pain intensity in this study was 6, 12, 24, 48 hours after instrumentation and obturation as the exudative process begins within 6 hours, where polymorphonuclear leukocytes (PMNs) begin to enter the injured site and increases steadily, peaking at about 24 to 48 hours after the injury increasing the release of inflammatory mediators and neuropeptides. Then, the proliferative process begins after 48 to 96 hours, which is characterised by declining the PMN population, and the beginning of macrophages to enter the wound site.[18]

In the current study, the intensity of post-instrumentation and post-obturation pain did not differ statistically to a significant level between the two tested groups. This finding resembles the results ofÇIÇEK et al.[9], Relvas et al.[19],Farhad et al.[20] and Saha et al.[21] who found no significant difference in postoperative pain between the rotary and reciprocating instrumentation techniques during endodontic treatment.However, our results were in contrast to those of Krithikadatta et al.[22] and Mehdi et al.[23]who found that reciprocation techniques produced a more significant postoperative pain when compared to rotary instrumentation techniques.

On the other hand, Neelakantan et al.[24]and Shokraneh et al.[25]reported that postoperative pain was significantly lower in patients treated with reciprocating instrumentation techniques in comparison to rotary instruments.

The wide contrast in the results of the different studies might be attributed to differences in sample size, periapical condition, tooth type, preoperative pain score, and discrepancies of instrumentation techniques and systems used for instrumentation of the root canals.[26]

Quantification of bacterial endotoxins was performed with human endotoxin ELISA kit using the Sandwich-ELISA method. The key advantage of a Sandwich-ELISA is its high sensitivity; as it is 2-5 times more sensitive than direct or indirect ELISAs. In addition to this, it delivers high specificity as two antibodies were used to detect the antigen.[27]

Regarding the comparison between different samples of endotoxins (S1 and S2) within the same group of the present study, both groups showed a statistically significant decrease in the mean value of endotoxin between every two samples.

Root canal preparation with both instrumentation techniques in the present study was able to reduce LPS content by about 31-33%. Endotoxin reduction after chemo-mechanical preparation was previously reported to be 60%by Martinho et al.[14], 44% by Vianna et al.[28] using manual instruments for apical preparation, and 29%by Adl et al.[29]using rotary ProTaper instruments.

According to the current study, no statistically significant difference was found between both groups regarding the ability to reduce the amount of endotoxins in primarily infected root canals. Similar findings were reported in other studies conducted by Martinho et al.[13], Marinho et al.[17]and Cavalli et al.[30]

Interestingly, these findings support the efficacy of root canal preparation with a single file for the removal of endotoxins. Therefore, it seems reasonable to assume that the mechanical action of endodontic instruments on dentine together with copious irrigation is more relevant for endotoxin removal than the number of files included in an instrumentation system.[17]

Conclusion

Within the limitation of this randomised clinical study, it could be concluded that; the use of single-file reciprocating instruments or multi-file rotary instruments in primarily infected teeth resulted in a comparable level of postoperative pain and comparable ability of root canal disinfection. However, neither of them rendered the root canals free of endotoxins.

Ethical Clearance: Ethical approval was taken from the Research Ethics Committee of the Faculty of Dentistry, Cairo University, Egypt.

Source of Funding: Self-funded research.

Conflict of Interest: The authors deny any conflicts of interest related to this study.

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