Research article

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Intraoperative discomfort associated with the use of a rotary or reciprocating system: a prospective randomized clinical trial

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Objectives: The aim of this randomized, controlled, prospective clinical study was to evaluate patients' intraoperative discomfort during root canal preparations in which either multi-file rotary (Mtwo) or single-file reciprocating (Reciproc) systems were used. ***Materials and Methods:*** Fifty-five adult patients, aged between 25 and 69 years old, with irreversible pulpitis or pulp necrosis participated in this study. Either the mesiobuccal or the distobuccal canals for maxillary molars and either the mesiobuccal or the mesiolingual canals for mandibular molars were randomly chosen to be instrumented with Mtwo multi-file rotary or Reciproc single-file reciprocating systems. Immediately after each canal instrumentation under anesthesia, patient discomfort was assessed using a 1 - 10 visual analog scale (VAS), ranging from 'least possible discomfort' (1) to 'greatest possible discomfort' (10). The Wilcoxon signed-rank test was used to determine significant differences at $p < 0.05$. ***Results:*** Little intraoperative discomfort was found in all cases. No statistically significant differences in intraoperative discomfort between the 2 systems were found ($p = 0.660$). ***Conclusions:*** Root canal preparation with multi-file rotary or single-file reciprocating systems had similar and minimal effects on patients' intraoperative discomfort. (*Restor Dent Endod* 2017;42(2):140-145)

Key words: Endodontics; Instrumentation; Pain

Introduction

The recent introduction of single-file reciprocating systems to the market has raised new perspectives for root canal preparation. The reciprocating motion relieves the stress on the instrument by special counterclockwise (cutting action) and clockwise (release of the instrument) movements and therefore increases its resistance to fatigue in comparison to systems with continuous rotary motion.[1] Overall, research findings on reciprocating systems have reported a decrease in preparation time, increased cyclic fatigue life, and a similar shaping ability to rotary systems.[2-8] Despite these advantages, during root canal preparation with reciprocating instruments, the clinician can feel a disturbing trepidation associated with a pronounced 'click sound,' which raises doubts regarding patients' discomfort during endodontic treatment, especially as a consequence of the kinematics. This might lead the patient to have the sensation that the treated tooth is in danger of fracturing.

This is the background of the current clinical trial, which was conducted to evaluate patients' intraoperative discomfort during root canal instrumentation by rotary (Mtwo, VDW, Munich, Germany) and reciprocating (Reciproc, VDW) systems. The null hypothesis

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tested was that there would be no difference in patients' intraoperative discomfort between the tested systems.

Materials and Methods

This was a randomized, controlled, single-blinded, split-mouth, prospective clinical study with an equal allocation rate between the groups. This clinical trial was registered in the ISRCTN (registration number, ISRCTN11624674). The Ethics Committee in Research of the Piracicaba Dental School, University of Campinas (FOP-UNICAMP) approved the study with the protocol 058/2015, and written informed consent was obtained from each volunteer. All volunteers invited to participate in this clinical trial were informed of the protocols of the procedures, which were conducted by an endodontist/PhD student, the risks and benefits, and their right to self-determination regarding participation. After signing a written consent form, a copy was delivered to all volunteers.

Sample size calculation

A Wilcoxon signed-rank test from the *t*-test family was selected (G*Power 3.1.9.2 for Macintosh; Heinrich-Heine, Düsseldorf, Germany). Using the results of Relvas *et al.*,[9] as a reference, who found no difference in postoperative pain after 24 hours comparing a reciprocating and a rotary system, an effect size of 0.81 was input together with an alpha-error of 0.05 and a power beta of 0.95. The estimation of participants indicated a minimum sample size of 23 individuals in order to achieve 95% confidence for a true difference between the groups.

Patient selection

The inclusion criteria were defined as follows: healthy (American Society of Anesthesiology [ASA] I patients) adults older than 18 years of age who had been admitted to the Endodontics Department of FOP-UNICAMP from January 2015 to December 2015, with a clinical diagnosis of irreversible pulpitis or necrosis in the first or second maxillary and mandibular molars. The clinical diagnosis of asymptomatic irreversible pulpitis was based on an increased response to the cold test with Endo-frost (Coltène-Whaledent, Langenau, Germany) and the presence of deep caries on radiography, extending to the pulp space, without any spontaneous symptoms. Diagnosis of pulp necrosis was based on the absence of response to the cold test after 10 seconds. None of the patients enrolled in this clinical trial were taking any medications that could alter their perception of pain, such as analgesic or nonsteroidal anti-inflammatory drugs. The radiographic findings included the absence of periapical radiolucencies except for a widened periodontal ligament. The mesiobuccal canals or the distobuccal canals for maxillary molars, as well as the mesiobuccal canals or the mesiolingual canals for mandibular molars, were chosen. During the root canal treatment procedure, teeth failing to be treated in a single appointment or patients who discontinued treatment were omitted from the study.

Approximately 190 patients attending consultations each month at the Endodontics Department, which operates for 9 months per year. The recruitment process for this study lasted for 1 year, during which 1,700 patients were estimated to have undergone any procedure. Of these patients, 55 were selected to take part in this clinical trial by meeting the inclusion criteria (Table 1) and signing the consent form. The exclusion criteria also included other endodontic diagnoses such as reversible pulpitis, abscess, retreatment, endodontic treatment in other teeth, patients taking medications that could interfere with the trial, pregnancy, and patients not defined as ASA I (Figure 1).

Study intervention

After local anesthesia using posterior superior alveolar nerve block for maxillary molars and inferior alveolar nerve block for mandibular molars with 2% lidocaine with 1:100,000 epinephrine (Alphacaine, DFL Indústria e Comércio Ltda, Rio de Janeiro, RJ, Brazil), a rubber dam was placed and the access cavity was prepared using sterile diamond burs. If patients recorded any sensation of pain during the procedure, a supplemental injection providing local infiltration with 1.8 mL of 2% lidocaine with 1:100,000 epinephrine was administered.

An initial exploration of the root canals was performed with size 10 K files (VDW), to establish the root canal length using an electronic apex locator (Root ZX II, J. Morita Corp., Tokyo, Japan). Working length (WL) was established by deducting 1 mm from the canal length. Only cases where a size 10 K file went passively and a size 15 K file did not go passively to the WL in both canals - that is,

Table 1. Demographic and clinical characteristics of participants

Gender	Male	26
	Female	29
Age, years		46 ± 18
Mandibular first molar		15
Mandibular second molar		10
Maxillary first molar		25
Maxillary second molar		5
Total		55

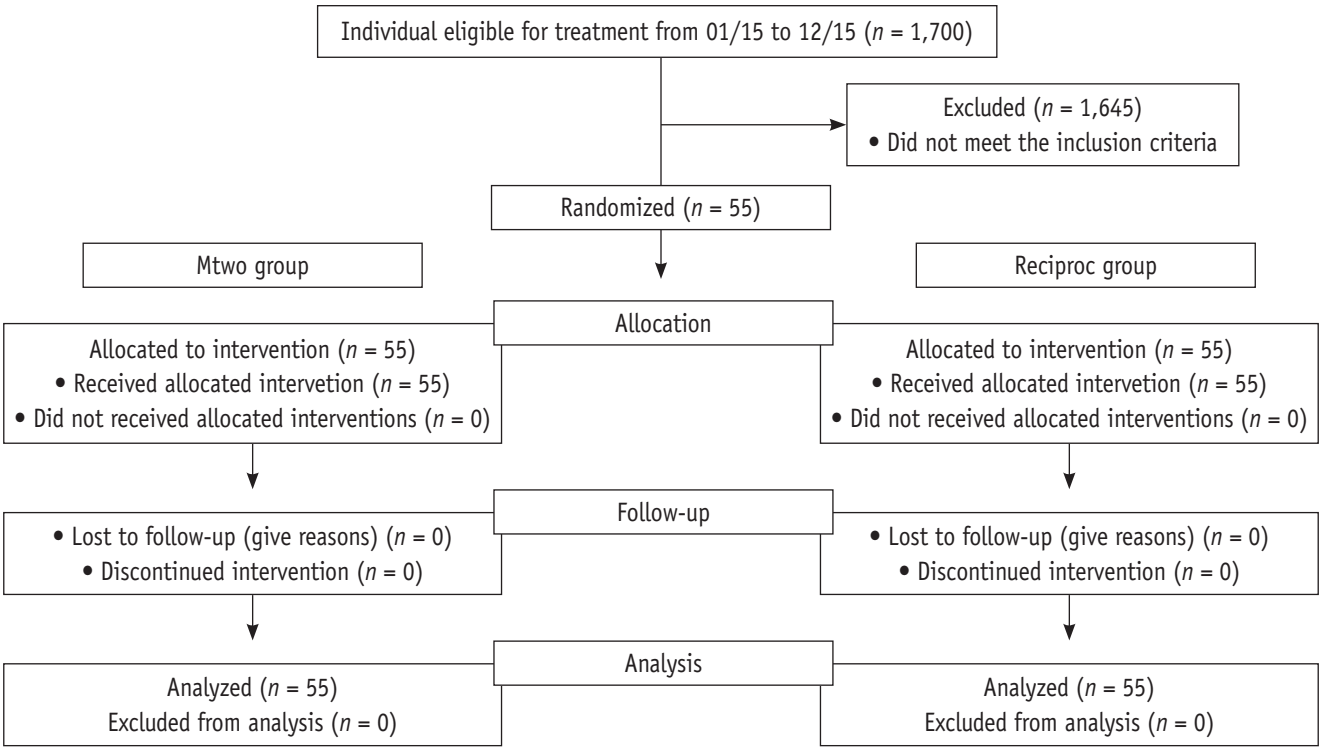

Figure 1. CONSORT flow diagram for randomized clinical trials. Mtwo, multi-file rotary; Reciproc, single-file reciprocating.

the mesiobuccal and distobuccal canals for the maxillary molars and the mesiobuccal and mesiolingual canals for the mandibular molars - were selected. These cases were classified as narrow and R25 was recommended, according to the manufacturer's protocol. All teeth received both instrumentation protocols (the Mtwo rotary system or the Reciproc reciprocation system). In this way, each patient experienced the 2 different file systems in the same teeth. A web-based program determined the randomized allocation of the instrumentation systems per canal. While the endodontist was not blinded to the allocated file system, patients were kept blinded to the allocation. Instruments were driven with the VDW Silver motor (VDW) according to each manufacturer`s instructions.

The Mtwo instruments were used according to the manufacturer's instructions in the following sequence: sizes 10/0.04, 15/0.05, 20/0.06, and 25/0.06. The motor was adjusted to 500 - 600 rpm and 1 N·cm. After 3 gentle in-and-out motion strokes, the instrument was removed from the canal and cleaned until the WL was reached.

Reciproc R25 (size 25/0.08) was introduced into the canal until resistance was felt and then activated in reciprocating motion. The instrument was moved in an apical direction using an in-and-out pecking motion of about 3 mm in amplitude with light apical pressure. After 3 pecking motions, the instrument was removed from the canal, and its flutes were cleaned off. This procedure was performed until the instrument reached the WL.

In both systems, before each file, 2% chlorhexidine gel was inserted into the canal. After each file, the root canals were irrigated with 2 mL of 0.9% sterile saline solution dispensed using a 30 G Max-i-Probe needle (Dentsply-Rinn, Elgin, IL, USA) up to 3 mm from the WL. After canal preparation, an additional rinse with 5 mL of 0.9% saline solution was performed. The total amount of solution used per canal was 20 mL. A final rinse with 5 mL of 17% ethylenediaminetetraacetic acid (EDTA) delivered for 3 minutes, followed by a 5 mL rinse with 0.9% saline solution, was performed for both groups. Then, canals were dried with absorbent paper points (VDW) and filled with gutta-percha (Dentsply, Rio de Janeiro, RJ, Brazil) and Endomethasone N (Septodont, Saint-Maur-des-Fossés Cedex, France) using warm vertical compaction with the continuous-wave technique and gutta-percha backfill. The study was finished when the endodontic treatment was completed in all subjects.

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Evaluation of intraoperative discomfort and statistical analysis

Patient discomfort was assessed using a 1 to 10 visual analog scale (VAS), ranging from 'no discomfort' (1) and 'highest possible discomfort' (10). The assessment of intraoperative discomfort was conducted immediately after receiving the treatment with each of the instrumentation protocols. The scale was presented to patients after the end of the instrumentation process with each file system.

The findings were recorded in an Excel spreadsheet (Microsoft Corp., Redmond, WA, USA) for statistical evaluation using SPSS software version 19.0 (IBM Corp., Armonk, NY, USA). The Wilcoxon signed-rank test was used to compare the number of cases recorded in each VAS score between the 2 instrumentation systems tested, and univariate analysis of variance was used to investigate the effect of demographic variables (age, gender, and tooth arc) on the VAS scores reported for the Reciproc and Mtwo systems. An alpha-type error of 5% was set as the cut-off level for significance.

Results

In the Reciproc group, the lowest discomfort value reported was 1 and the highest value was 5, while for the Mtwo group, the scores varied from 1 to 4 (Table 2). No patient experienced any adverse event.

No statistically significant difference in intraoperative discomfort between the 2 different instrumentation groups was found (Reciproc, -2.18 ± 1.02; Mtwo -2.24 ± 1.00, p = 0.660). Little intraoperative discomfort was found in all treated cases in both groups.

None of the demographic variables were found to have a statistically significant effect on the scores reported either for the Reciproc system (age, p = 0.788; gender, p = 0.988; tooth arch, p = 0.387) or the Mtwo system (age, p = 0.642; gender, p = 0.853; tooth arch, p = 0.306). The number of patients who described the same degree of discomfort was 29, while 14 patients described more discomfort for the Mtwo system and 12 patients described more discomfort for the Reciproc system.

Table 2. Descriptive outcome of the pain scores of VAS

Score	File used (%)	
	Mtwo (n = 55)	Reciproc (n = 55)
0	0 (0)	0 (0)
1	15 (27.27)	16 (29.09)
2	19 (34.54)	20 (36.36)
3	14 (25.45)	13 (23.64)
4	7 (12.73)	5 (9.09)
5	0 (0)	1 (1.82)
6	0 (0)	0 (0)
7	0 (0)	0 (0)
8	0 (0)	0 (0)
9	0 (0)	0 (0)
10	0 (0)	0 (0)
Total	55 (100)	55 (100)

VAS, visual analog scale; Mtwo, multi-file rotary; Reciproc, single-file reciprocating.

Discussion

The present study was unable to detect significant differences in intraoperative discomfort during chemomechanical preparation using the Mtwo full-sequence rotary system and the Reciproc single-file reciprocating system. Therefore, the null hypothesis was clearly accepted. A previous study evaluated the influence of rotary versus reciprocating motion on postoperative pain;[9] however, to the best of the authors' knowledge, there are no data on intraoperative discomfort evaluating different root canal preparation kinematics. Although it is possible for the clinician to notice that root canal preparation with multi-file rotary and single-file reciprocating mechanisms have marked differences, the results of the present study demonstrate that these differences did not cause pronounced discomfort in patients.

Mtwo and Reciproc are manufactured from different types of NiTi alloy (Mtwo, conventional NiTi; Reciproc, M-Wire). Moreover, ISO size 25 Mtwo and Reciproc files have a slight difference in the taper (0.06 and 0.08, respectively). However, these files have the same cross-sectional design.[2] Thus, it is expected that the minute patient discomfort reported in this study was possibly related to the number of files in the rotary system and the reciprocating movement kinematics used during root canal instrumentation with Reciproc.

One of the main concerns about studying discomfort is the subjective nature of this evaluation. Each person's threshold for discomfort is unique and may be remarkably distinct from that of others. For that reason, and to provide a robust methodological comparison, maxillary and mandibular molars with similar buccal and mesial root canals were selected to provide a similar anatomically reliable baseline. This selection allowed performing root canal instrumentation using these 2 systems in the very same tooth using a split-mouth design, thereby reducing the individual subjective bias that naturally occurs in parallel-group designs. Moreover, the schematic of the discomfort evaluation is critical, and it is essential to ensure that the questions will be fully understood by the

patients and easily interpreted by researchers. For this, a simple 1-to-10 VAS was used in the feedback evaluation, where 1 represented the 'least possible discomfort' and 10 represented the 'greatest possible discomfort.' This scale has been used in several clinical studies evaluating postoperative pain. Moreover, there is considerable evidence indicating that the VAS has advantages over other methods in terms of feasibility and reliability.[10-12]

Postoperative pain related to root canal instrumentation has been reported to vary from low to high incidence.[13-19] The methodological differences related to preoperative pain, variability in protocols, and differences in the collection of clinical findings may explain this variation. In the present study, rather than postoperative pain, intraoperative discomfort was evaluated, which makes comparison among studies non-reliable. Moreover, the intraoperative evaluation is a singular study condition that may make irrelevant some demographic aspects, such as pre-treatment diagnosis, age, and gender of the patients. Intraoperative discomfort was found to be low for both the Reciproc and Mtwo systems, regardless of demographic factors.

Conclusions

Based on the findings of the present study, it can be concluded that root canal preparations with the full-sequence Mtwo rotary system or the single-file Reciproc system had a similar, and small, effect on intraoperative discomfort.

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Conflict of Interest: No potential conflict of interest relevant to this article was reported.

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