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Postoperative quality of life following single-visit root canal treatment performed by rotary or reciprocating instrumentation: a randomized clinical trial

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Abstract

Pasqualini D, Corbella S, Alovisi M, Taschieri S, Del Fabbro M, Migliaretti G, Carpegna GC, Scotti N, Berutti E. Postoperative quality of life following single-visit root canal treatment performed by rotary or reciprocating instrumentation: a randomized clinical trial. *International Endodontic Journal*.

Aim To compare the impact of rotary and reciprocating instrumentation on postoperative quality of life (POQoL) after single-visit primary root canal treatment.

Methodology A randomized controlled clinical trial was designed and carried out in a University endodontic practice in northern Italy. Healthy subjects with asymptomatic irreversible pulpitis, symptomatic irreversible pulpitis or pulp necrosis with or without apical periodontitis (symptomatic or asymptomatic) scheduled for primary root canal treatment were enrolled. Single-visit root canal treatment was performed with ProTaper™ S1-S2-F1-F2 (rotary group, $n = 23$) and WaveOne™ Primary (reciprocating group, $n = 24$). Irrigation was performed with 5% NaOCl and 10% EDTA. Root canal filling was performed with the continuous-wave technique and ZOE sealer. POQoL indicators were evaluated for 7 days post-treatment. The variation of each indicator over time was compared using ANOVA for repeated measures ($P < 0.05$). The impact of each variable on POQoL was analysed with a multivariate logistic regression model ($P < 0.05$).

Results Pain curves demonstrated a more favourable time-trend in the rotary group (mean, $P = 0.077$; maximum, $P = 0.015$). Difficulty in eating ($P = 0.017$), in performing daily activities ($P = 0.023$), in sleeping ($P = 0.021$) and in social relations ($P = 0.077$), was more evident in the reciprocating group. Patients' perception of the impact of treatment on POQoL was more favourable in the rotary group ($P = 0.006$). Multirooted tooth type and pre-existing periradicular inflammation were associated with a decrease in POQoL.

Conclusion Reciprocating instrumentation affected POQoL to a greater extent than rotary instrumentation.

Keywords: endodontics, quality of life, reciprocating, root canal therapy, self-report.

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Introduction

Root canal treatment is a conservative treatment modality yielding long-term retention of teeth with pulpal or periradicular disease (Friedman 2002). Postoperative pain may affect the quality of life of patients (QoL) and influence their subjective evaluation of treatment alternatives (Iqbal & Kim 2008). QoL is a complex phenomenon related to health (Raphael *et al.* 1994), socio-economic and cultural needs in the context of individual's expectations and standards (WHO 1995). Patient satisfaction is an important

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consideration in the delivery of dental care (Iqbal & Kim 2008, Hamasha & Hatiwsh 2013), and QoL following dental treatment can be evaluated (Iqbal & Kim 2008, Gatten *et al.* 2011) through self-assessing questionnaires (Dugas *et al.* 2002).

QoL in dentistry can be investigated by two approaches: oral health-related quality of life (OHIP) (Dugas *et al.* 2002, Gatten *et al.* 2011, Liu *et al.* 2014a) and postoperative quality of life (POQoL) surveys (Tsesis *et al.* 2005, Del Fabbro *et al.* 2012). OHIP analyses the influence of health and mouth status on general QoL in a social context (Slade & Spencer 1994, Dugas *et al.* 2002, Gatten *et al.* 2011). POQoL assessment relies on the subjective perception of the impact of treatment on QoL for 7 days post-treatment and measures the impairment of daily activities such as eating, speaking, sleeping and social relations (Taschieri *et al.* 2014, Del Fabbro *et al.* 2015).

Postoperative pain is a frequent complication of root canal treatment (Pak & White 2011) and can be influenced by preoperative status, treatment techniques and clinician experience (Pasqualini *et al.* 2012, Hamasha & Hatiwsh 2013). Post-treatment pain may result from apical instrumentation and inflammatory responses, especially in the presence of pre-existing periradicular inflammation (Torabinejad *et al.* 1994, DiRenzo *et al.* 2002, Fillingim 2005, Liu *et al.* 2012, 2014b). In addition, apical extrusion of infected debris during chemomechanical instrumentation may generate an acute inflammatory response and subsequently worsen the perception of postoperative pain (Pak & White 2011, Tanalp & Güngör 2014). All instrumentation techniques, manual or mechanical, can cause apical extrusion of infected debris, even when the preparation is maintained at the apical terminus (Tanalp & Güngör 2014). However, some techniques extrude less debris than others (Nair *et al.* 2005, Tanalp & Güngör 2014).

Nickel–titanium (NiTi) shaping instruments used in a reciprocating motion may decrease the impact of cyclic fatigue while improving root canal centring ability (Berutti *et al.* 2012). Compared to rotary instrumentation, reciprocating motion may increase the amount of debris extruded beyond the apex and consequently the risk of postoperative pain (Bürklein & Schäfer 2012, Caviedes-Bucheli *et al.* 2015). There are no clinical data that compare rotary and reciprocating systems in terms of patient QoL following single-visit root canal treatment. The objective of this study was to evaluate the impact of rotary and reciprocating file shaping techniques on immediate POQoL. This study tested the null hypothesis that rotary and reciprocating instrumentation would impact postoperative QoL to the same extent.

Materials and methods

This randomized controlled clinical trial (two parallel groups design) was prepared and reported following CONSORT guidelines (Schulz *et al.* 2010). The study was authorized by S.G. Battista University Hospital Ethics Committee and Review Board. All subjects gave informed written consent for participation in the study, which was performed according to the principles of the last update of the Helsinki Declaration (WMA 2000).

Eligibility criteria

Consecutive informed and consenting healthy subjects of both genders who presented at the Endodontic Department of Turin Dental School between June and October 2013 were enrolled until the required sample size was reached. Subjects had one single or multi-rooted tooth with asymptomatic irreversible pulpitis (deep caries in the pulp after excavation, with preoperative absence of symptoms and normal response to thermal tests), symptomatic irreversible pulpitis or pulp necrosis with or without apical periodontitis (symptomatic or asymptomatic). Each was scheduled for primary root canal treatment and had not previously undergone emergency endodontic care. Patients with sinus tract, periapical abscess or facial cellulitis were not enrolled due to the possibility of confounding quality of life perception independently from the treatment. Patients with physical or psychological disabilities or inability to understand study instructions were excluded.

Interventions

The medical and dental status and history of each patient were collected. Intra-oral examinations were performed using 3.5X loupes. Pulpal and periradicular status were assessed with thermal and electric pulp tests (Diagnostic Unit, Sybron, Orange, CA, USA), palpation and percussion. Periodontal status was also recorded. Periapical radiographic examination was performed using Rinn XCP devices (Rinn Corp., Elgin, IL, USA) and PSP imaging plate. The data were processed and archived by a dedicated scanner and software interface (OpTime Soredex, Tuusula, Finland).

Teeth with a loss of lamina dura and periodontal ligament enlargement of >2 mm were classified as having lesions of endodontic origin (LEO). Clinical and radiological data were analysed by three blinded examiners selected from the clinical assistant professors within the Endodontic Department. When opinion was not unanimous, agreement was reached through discussion. Examiners were calibrated to the evaluation criteria through a case series presentation, and examiner concordance was analysed by the Fleiss' K score until interexaminer reliability ($K > 0.70$) was expected. Clinical cases were classified as minimal, moderate or high difficulty according to American Association of Endodontists (AAE) Endodontic Case Difficulty Assessment (http://www.aae.org/uploadedfiles/publications_and_research/guidelines_and_position_statements/2006casedifficultyassessmentformb_edited 2010.pdf).

All treatments were performed by experienced operators that followed a postgraduate course in Endodontics and with more than 3 years of experience.

After local anaesthesia and rubber dam isolation, access cavity and endodontic pre-treatment to create an adequate reservoir for irrigant solutions were performed. A mechanical glide path was created with PathFile 1, 2 and 3 (Dentsply Maillefer, Baillagues, Switzerland), with an endodontic motor (X-Smart, Dentsply Maillefer), 16 : 1 contra angle, at the suggested settings (300 rpm on display, 5 Ncm), at working length (WL). Electronic WL was recorded with an apex locator (Diagnostic Unit, Sybron) and checked thrice during treatment. Initial WL was recorded with a size 10 stainless-steel K-File during canal scouting and initial glide path, using an electronic apex locator. A second WL was recorded after the definitive glide path with PathFile 1-2-3 with a size 17 K-File using an electronic apex locator and periapical radiographs.

Patients were then randomized to rotary or reciprocating instrumentation treatment arm.

In the rotary group, each canal was shaped using ProTaper™ (Dentsply Maillefer) S1-S2. Definitive WL was checked with a size 17 K-File and shaping was accomplished with F1-F2 at WL, with X-Smart motor set at the suggested settings. Apical patency was established and confirmed with a size 10 K-File 0.5 mm beyond the apex.

In the reciprocating group, canals were shaped with WaveOne™ Primary reciprocating files (Dentsply Maillefer) using a gentle inward motion, withdrawing the file every 3 mm to remove debris, as suggested by the manufacturer's instructions (http://www.tulsadentalspecialties.com/Libraries/Tab_Content_-_Endo_Access_Shaping/WaveOne_Reciprocating_File_DFU.sflb.ashx). Shaping was achieved at the definitive WL following assessment once the instrument reached the limit between the middle and apical third. The dedicated reciprocating motor of WaveOne™ file was used with the manufacturer's configuration set-up. Apical patency was established and confirmed with a size 10 K-File 0.5 mm beyond the apex.

Irrigation was performed with a syringe and 30-G endodontic needle and with 5% NaOCl (Niclor 5, OGNA, Muggiò, Italy) and 10% EDTA (Tubuliclean, OGNA), for a total of 20 mL each solution. Root canals were dried with sterile paper points.

Root canal filling was completed at the same session with gutta-percha points and sealer (Pulp Canal Sealer EWT, Kerr Endodontics, Orange, CA, USA) using the continuous wave of condensation technique (Buchanan 1998). The access cavity was sealed with temporary filling (IRM, Dentsply International Inc., York, PA, USA), and patients were scheduled for subsequent post-endodontic restoration. No occlusal adjustment was performed. Patients were dismissed with postoperative instructions and a prescription for optional analgesics.

Outcomes

Primary outcomes:

POQoL was evaluated with an *ad hoc* prepared questionnaire immediately following treatment completion. The questionnaire evaluated difficulty in chewing, speaking, sleeping, carrying out daily functions, social relations and overall QoL with a Likert-like scale ranging from 0 (none) to 10 (very much).

Postoperative pain (mean and maximum pain) was assessed through a visual analogue scale (VAS) made of a 10 cm line, where 0 = no pain and 10 = unbearable pain.

Both parameters were evaluated by self-assessment for 7 days.

Secondary outcomes:

Days to complete pain resolution after treatment.

Analgesic intake, evaluated by the number of analgesic tablets taken in the postoperative period.

The questionnaires were progressively code numbered and were returned anonymously in a collecting box. Only the principal investigator was aware of the correspondence between codes and patients and was excluded from data analysis.

Sample size

To detect a 'conservative' between-group difference of 5% (change of 0.5 points on the visual scale) in postoperative pain (Pasqualini *et al.* 2012) and considering an alpha-error = 0.05 to reach a power (1 - beta) of 80%, the required sample size was 23 patients per group. Assuming a 10% loss to follow-up, 26 patients were enrolled in the study.

Randomization

The randomized sequence was obtained using computer-generated tables. The following parameters were considered for randomization, in order to obtain comparable groups and to control for potential confounders: prevalence of pain before treatment, mean pain before treatment and clinical diagnosis.

An operator, who was not performing the clinical treatment, prepared blinded envelopes containing the randomized allocation for each patient. The same operator communicated the allocation to the clinician after initial patient assessment and before root canal instrumentation.

Blinding

The operating clinician was not blinded to the allocation group as each instrument required a specific technique. Randomization, allocation and statistical analysis were performed by blinded operators.

Statistical methods

Patients were considered the statistical unit of analysis. The Kolmogorov–Smirnov test for normality was used to analyse data distribution. A suitable analysis of variance model for repeated measures (two groups of comparison) was used to compare the variation of indicator-scale values reported by each group in the 7 days post-treatment. The Student *t*-test was used for analgesic intake, pain stop values. The Mann–Whitney *U*-test was used to analyse indicators' scores at baseline. The chi-squared test was used for diagnostic and clinical variables, prevalence of pain.

A multivariate logistic regression model analysed the impact of each variable on POQoL. A mean pain score of 0 on day 4 was considered the cut-off between positive and negative outcome in the regression model. Estimates are represented as odds ratios (OR) and relative 95% confidence intervals (95% CI), reciprocally adjusted for age, gender, clinical factors and difficulty of the case, according to AAE (http://www.aae.org/uploadedfiles/publications_and_research/guidelines_and_position_statements/2006casedifficultyassessmentformb_edited2010.pdf). The level of statistical significance was set at $P < 0.05$. All statistical analyses were performed using the SPSS for Windows 17.0 software package (SPSS, Inc., Chicago, IL, USA).

Results

A total of 90 subjects were initially selected for potential inclusion, and 52 patients were finally enrolled and randomized between the rotary ($n = 26$) and reciprocating ($n = 26$) groups. Distribution of occupations and education between the two groups was relatively uniform, with a similar socio-economic middle-class background. Two patients in the rotary group and one in the reciprocating group were lost to follow-up due to nonattendance at the second visit. One patient in each group required an unscheduled re-intervention during the observation period, due to a postoperative flare-up, and were excluded from the analysis. Patient flow is shown in Fig. 1. Data analysis was performed on 47 subjects; 23 in the rotary group and 24 in the reciprocating group (50% male; 25% 16–30 years, 33% 31–45 years, 42% 46–60 years). Baseline patient characteristics are reported in Table 1.

Postoperative pain, analgesic intake and pain stop values

Pain score at baseline was lower in the reciprocating group (mean pain value, $P = 0.12$; maximum pain value, $P = 0.045$). Postoperative pain prevalence curves (Fig. 2–3) demonstrated a more favourable time-trend in the rotary group compared to the reciprocating group, for mean ($F = 2.64$; df = 1.98; $P = 0.077$) and maximum ($F = 3.97$; df = 2.48; $P = 0.015$) pain values. The steeper curve of the rotary group evidenced a more favourable resolution of pain after treatment. The difference between the groups was most evident in the first 4 days, both for mean and maximum pain score values. Mean pain stop value (in days), adjusted for analgesic consumption, and excluding subjects with no pain at baseline, was 4.4 ± 2.1 (95% CI 3.5–5.3) in rotary group and 5.1 ± 1.8 (95% CI 4.3–5.8) in the reciprocating group. However, this difference was not

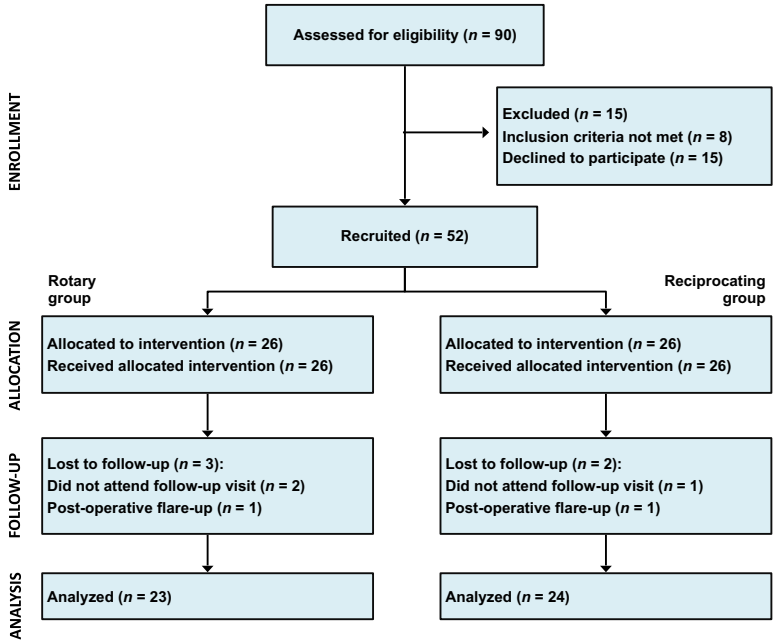

Figure 1 Diagram of patient flow.

Table 1 Sample baseline characteristics in rotary and reciprocating groups

Preoperative status	Group 1 (n = 23) Rotary	Group 2 (n = 24) Reciprocating	P
AAE difficulty (minimal/moderate/high) (n)	4/17/2	8/15/1	NS
Single/multirooted tooth (n)	9/14	14/10	0.03
Asymptomatic irreversible pulpitis (%)	21.7	16.7	NS
Symptomatic irreversible pulpitis (%)	47.9	50	NS
Pulp necrosis (%)	30.4	33.3	NS
Symptomatic apical periodontitis (%)	60.8	54.2	NS
LEO prevalence (%)	30.4	25	NS
Pain prevalence (%)	91.3	83.3	NS
Mean pain score	3.52	2.46	NS
Maximum pain score	5.04	3.46	0.045
Quality of life	2.52	1.42	NS

NS, not statistically significant difference (P-value >0.05).
LEO, lesion of endodontic origin with periradicular radiolucency >2 mm.

significant (P = 0.28). The mean analgesic intake per subject during the observation period was 4.1 ± 3.2 (95% CI 2.7–5.6) in the rotary group and 4.0 ± 2.6 (95% CI 2.9–5.1) in the reciprocating group (P = 0.89).

Postoperative quality of life indicators and regression analysis

Patient perception of the impact of root canal treatment on POQoL in general is shown in the relative 7 days curve (Fig. 4). This exhibits a similar trend to the pain curves, with a more favourable postoperative period in the rotary group (F = 4.88; df = 2.38; P = 0.006). Patients also reported increased difficulty eating in the reciprocating group compared with the rotary group (F = 3.67; df = 2.74; P = 0.017), as well as in performing daily activities (F = 4.28; df = 1.67; P = 0.023), sleeping (F = 3.89; df = 2.14; P = 0.021) and social relations (F = 3.54; df = 1.78; P = 0.039), whilst no differences were found in speaking.

Multivariate analysis, reciprocally adjusted for age, gender, clinical variables and clinical complexity, showed a significantly positive association between multirooted tooth type and a less favourable postoperative pain trend. This association was stronger in the rotary group (OR = 20.3, 95% CI 1.32–313.50). Pulp status at baseline significantly affected the incidence of postoperative pain in the reciprocating group (OR = 11.28, 95% CI 1.38–92.59). The presence of pre-existing periradicular inflammation (symptomatic apical periodontitis with percussion positive) showed a positive association with a less

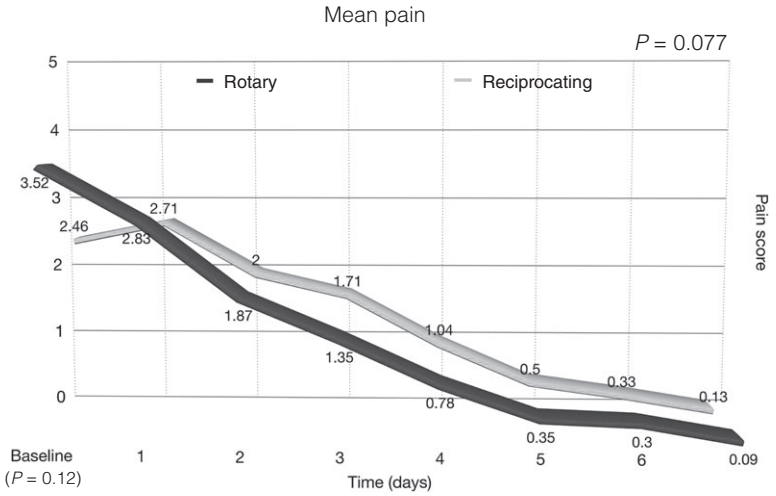

Figure 2 Average postoperative pain score curves.

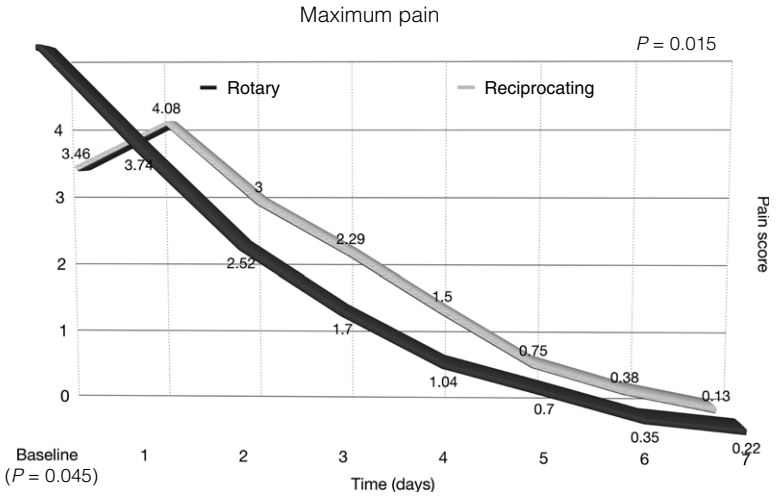

Figure 3 Maximum postoperative pain score curves.

favourable postoperative trend (OR = 3.75, 95% CI 0.6–23 in the rotary group and OR = 3.08, 95% CI 0.42–22.5 in the reciprocating group); however, this was not conclusive.

Discussion

The efficacy of different root canal treatment techniques has been widely discussed in terms of clinical outcomes and tooth retention. However, the evaluation of clinical outcomes does not consider the patient's perspective (Torabinejad *et al.* 2007, Hamasha & Hatiwsh 2013). Although patient-reported outcomes in endodontics have traditionally focused on perioperative pain, there is growing interest in the implications for POQoL (Dugas *et al.* 2002, Tsesis *et al.* 2005, Gatten *et al.* 2011), highlighting the importance of standardized outcome assessment methods (Del Fabbro *et al.* 2009, McGrath *et al.* 2012).

In this study, the impact of single-visit root canal treatment performed by rotary versus reciprocating shaping techniques on POQoL was evaluated by examining systematic postoperative surveys. Pain experience appeared to be less acute in the rotary group, where pain values decreased more rapidly

Figure 4 Postoperative quality of life score curves.

compared with the reciprocating group. Interestingly, time-trend curves of POQoL indicators in the reciprocating group demonstrated a temporary recurrence of symptoms in the first 24 h after treatment, before definitely decreasing at 48 h. This trend was not evidenced in the rotary group, where a constant decrease occurred immediately after treatment.

Studies have reported 40% post-treatment pain prevalence at 24 h, substantially decreasing within the first 2 days to 11% at 1 week (Pak & White 2011, Pasqualini *et al.* 2012). Other studies, using a VAS from 0 to 10, reported a reduction in pain prevalence after root canal treatment from 72% to 39% in 6 days (DiRenzo *et al.* 2002) with a substantial decrease in severe post-treatment pain within the first 2 days (Pak & White 2011). The prevalence of pain after endodontic procedures 4 days postoperatively is low, irrespective of the type of technique or medication utilized (Torabinejad *et al.* 1994, Pak & White 2011, Pasqualini *et al.* 2012). However, the difficulty of standardizing patient reports of pain following treatment due to the complexity of the individual response and the variety of measures used to quantify the painful experience must be appreciated (Dugas *et al.* 2002, Fillingim 2005, Iqbal & Kim 2008, Gatten *et al.* 2011).

Host factors, idiopathic factors and aspects related to chemomechanical root canal debridement are considered as the main contributors to postoperative pain (Siqueira *et al.* 2002). Predictive models demonstrated that postoperative pain depended on occlusal contacts, preoperative pain prevalence, periapical radiolucency, tooth type and previous emergency root canal treatment; the intensity of postoperative pain was related to tooth type and patient's age, while pain duration to age, gender and pre-existing periapical radiolucency (Arias *et al.* 2013). It is noteworthy that the extrusion of infected debris, medicaments and filling materials may result in an acute periapical inflammation and delayed healing (Tanalp & Güngör 2014).

The reciprocating motion applied to NiTi instruments relieves cyclic fatigue stress, while preserving the original canal anatomy (Varela-Patiño *et al.* 2010). However, a previous laboratory study reported a greater extent of debris extrusion using the reciprocating single-file system compared with full-sequence rotary NiTi instruments (Bürklein & Schäfer 2012). The reciprocal motion may enhance debris transportation beyond the apex during the counter-clockwise phase of movement (Roane *et al.* 1985). These laboratory data should be considered in the clinical context as the presence of periapical resistance and the use of irrigants may influence debris extrusion (Nair *et al.* 2005, Torabinejad *et al.* 2005). A recent systematic review and meta-analysis investigated the influence of the number of files (full-sequence rotary file versus reciprocating single-file systems) utilized during root canal preparation, on the apical extrusion of debris and its relationship with symptomatic apical periodontitis (Caviedes-Bucheli *et al.* 2015). Laboratory studies have revealed greater extrusion of debris with single-file techniques compared with multiple-file systems. *In vivo* studies have demonstrated that

instrument design has a greater impact than the number of instruments on neuropeptide expression in the periodontal ligament (Caviedes-Bucheli *et al.* 2010, 2013). Both rotary and reciprocating single-file systems generate apical extrusion of debris in laboratory studies, or expression of neuropeptides *in vivo*, supporting the hypothesis that the inflammatory reaction is not influenced by the number of files but the type of movement and instrument design. Therefore, implementation of reciprocating instruments design may lead to a more favourable postoperative progress.

In this study, some indicators of POQoL were more significantly affected by reciprocating instrumentation than rotary instrumentation. However, the additional analgesic intake reported was not different between groups.

In this study treatments were performed by expert operators. Previous studies reported no significant differences in postoperative pain experience after treatment performed by endodontists versus generalists (Dugas *et al.* 2002, Hamasha & Hatiwsh 2013). Improvements in postoperative quality of life indicators after root canal treatment were not different amongst patients treated by endodontists, graduate students or undergraduate students. However, patients' general satisfaction was higher after treatment by specialists (Hamasha & Hatiwsh 2013). As pre-treatment apprehension influences postoperative pain occurrence (Dugas *et al.* 2002, Gatten *et al.* 2011), a positive impact of an expert operator may emerge from shorter operating time and more efficacious communication when dealing with patient stress (Dugas *et al.* 2002, Hamasha & Hatiwsh 2013). Moreover, a significantly higher number of pecking motions needed by an inexpert operator to reach full WL may increase debris formation and risk of irritant extrusion (Tanalp & Güngör 2014).

A randomized controlled trial compared the incidence and intensity of postoperative pain following root canal treatment over single or multiple visits, and no significant differences were observed between groups (Wang *et al.* 2010). However, a systematic review reported a slightly higher frequency of pain and analgesic use in patients who had undergone single-visit treatment (Figini *et al.* 2008). This outcome was related to the immediate filling of the root canal system and the prolonged working time of a single-visit approach (Figini *et al.* 2008, Pak & White 2011).

Another recent study reported data in the 72 h that followed two appointments of root canal treatment (Nekoofar *et al.* 2015): a significantly higher pain experience and analgesics consumption in patients treated with reciprocating instruments were found. A similar trend was found in this study based on a single-visit approach, where the postoperative discomfort was significantly more evident in the reciprocating group compared with the rotary group. A beneficial effect on postoperative discomfort has been demonstrated when the instrumentation was a combination of continuous and reciprocating motion in relation to the instrument resistance encountered during shaping (Gambarini *et al.* 2013).

This study is limited by the differences between groups in terms of tooth type and maximum pain at baseline. The differences, although being in favour of the reciprocating group, could have slightly influenced the trend of pain decrease after treatment. Finally, the subjectivity of patient perception could not be comprehensively evaluated through a questionnaire.

Conclusion

Reciprocating motion had an impact on immediate postoperative discomfort, when performed in a single visit and when pre-existing periradicular inflammation was present, thereby negatively influencing patients' QoL.

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