Postoperative Pain after Manual and Mechanical Glide Path: A Randomized Clinical Trial

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Abstract

Introduction: This prospective randomized clinical trial evaluated the incidence of postoperative pain after glide path performed with PathFile (PF) (Dentsply Maillefer, Ballaigues, Switzerland) versus stainless-steel K-file (KF). **Methods:** In 149 subjects, the mechanical glide path was performed with nickel-titanium (NiTi) rotary PF; in 146 subjects, the manual glide path was performed with stainless-steel KFs. Postoperative pain, analgesics consumption, and the number of days to complete pain resolution were evaluated in the following 7 days. An analysis of variance model for repeated measures was used to compare the variation of pain-scale values ($P < .05$). The Student's t test for continuous variables normally distributed, the nonparametric Mann-Whitney U test for the nonnormally distributed variables, and the chi-square test for dichotomous variables were used ($P < .05$). Despite homogeneous baseline conditions at diagnosis, tooth type, pain prevalence, and scores, the postoperative pain prevalence curves in PF group evidenced a more favorable trend in terms of time to pain resolution compared with the KF group ($P = .004$). The difference was also evident in the model adjusted for analgesics consumption in both groups ($P = .012$). The mean analgesics intake per subject was significantly higher in the KF group (3.7 ± 2.2) compared with the PF group (2 ± 1.7) ($P < .001$). Mean pain stop values were also significantly higher in the KF group (2.7) compared with the PF group (1.7) ($P = .001$). **Conclusions:** The glide path with NiTi Rotary PF leads to less postoperative pain and faster symptom resolution. *(J Endod 2012;38:32–36)*

Key Words

Glide path, K-files, nickel-titanium rotary instruments, PathFile, postoperative pain

Pain is a frequent complication associated with endodontic treatment (1), and it has a great impact on the quality of life (2). Treatment-associated pain has been widely discussed in a recent systematic review (3). Pretreatment pain has a prevalence of 81% both for Visual Analog Scale (VAS) and category studies. However, data available from the existing literature may be overestimated because of the fact that even slight discomfort may be categorized as pain in some VAS studies. Pretreatment pain severity is reported to be mild with 54% value normalized to a 100-point scale. Although the pretreatment values vary across the studies, all the studies reported a steady decline in pain prevalence over time after treatment. Post-treatment pain prevalence at 24 hours is 40% decreasing to 11% at 1 week. The prevalence and severity substantially decrease within the first 2 days. Root canal treatment clearly reduces pain prevalence and severity although immediate post-treatment pain severity may sometimes slightly exceed the pretreatment severity levels. This may be caused by ongoing inflammatory processes or apical instrumentation especially with preexisting periradicular inflammation (3). An interappointment flare-up is slightly more unusual (4). Studies have reported varying frequencies of flare-ups, ranging between 1.4% and 16% (4). Flare-up is defined as an acute exacerbation of a pulpal or periradicular pathosis with a subsequent development of pain and swelling after the initiation or continuation of the root canal treatment (5). Pain usually starts within a few hours or days after root canal procedures and frequently requires unscheduled visits (5). Although the reasons for such exacerbations are not always clear, changes in periapical tissue pressure, in number or virulence of endodontic microbiota, or in environmental conditions may be possible causes (6). Post-treatment pain may be caused by the apical extrusion of infected debris during chemomechanical instrumentation, which may generate an acute inflammatory response (7, 8). Although all instrumentation techniques produce apical extrusion of debris even when the preparation is maintained at the apical terminus, the difference lies in the ability of some techniques to extrude less debris than others (9). Most of the recent nickel-titanium (NiTi) engine-driven instruments extrude less debris than the stainless-steel hand K-files (KFs) thanks to their rotary action that, combined with abundant irrigation, has the potential to reduce the risk of postoperative discomfort (10).

When using NiTi rotary instrumentation, both the clinician and the technique used play a significant role in preventing torsional stresses, which may increase the frequency of instrument separation to a great extent (11). This risk may be reduced by performing coronal enlargement (12, 13) and by creating a glide path, either manual (14, 15) or mechanical (16), before using NiTi rotary instrumentation. The new NiTi Rotary PathFile (PF) leads to significantly less modifications in coronal and apical canal curvature and to fewer canal aberrations compared with manual glide path with stainless-steel

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KFs, independently from the clinician's expertise (16). The system consists of 3 instruments, with a 21-, 25-, and 31-mm length and 0.02 taper; they have square section. The PF #1 (purple) has an ISO 13 tip size, the PF #2 (white) has an ISO 16 tip size, and the PF #3 (yellow) has an ISO 19 tip size. The manufacturer suggests using the first PF immediately after a #10 hand KF has been used to scout the root canal to the full working length (WL), and then #2 and #3 are used at the WL. It is hypothesized that the creation of the glide path with the NiTi rotary PF is probably less subjected to apical extrusion of debris compared with hand instrumentation. The primary objective of this study was to evaluate the incidence of postoperative pain after glide path performed with PF versus stainless-steel KFs. The secondary objective was to evaluate the frequency of postoperative analgesics intake in both groups of patients.

Materials and Methods

In this prospective randomized controlled clinical trial, a sample size of 280 patients (140 per group) was required to set the study power at 80%. The first consecutive informed and cooperating healthy subjects of both sexes who presented at Turin University Dental School Department of Endodontics between September 2010 and December 2010 with a diagnosis of asymptomatic irreversible pulpitis, symptomatic irreversible pulpitis, or pulp necrosis with or without apical periodontitis (acute or chronic) and were scheduled for initial endodontic treatment were enrolled. Patients with sinus tract, periapical abscess, or facial cellulitis did not enter the study because they were considered as potential outliers in post-treatment pain score analysis.

Patients' medical and dental status and history, demographic data, and socioeconomic information were collected before the dental examination. Intraoral examinations and data collection were performed by a single examiner using 3.5× Galilean loupes. The examiner was randomly selected among the clinical assistant professors at the Department of Endodontics, all standardized through a case-series presentation.

For each patient, pulpal and periradicular status was assessed through vitality thermal and electric pulp tests (Diagnostic Unit; Sybron, Orange, CA), palpation, and percussion. Periodontal charting was also recorded. Periapical radiographic examination was performed (Planmeca Intra, Helsinki, Finland) using Rinn XCP devices (Rinn Corp, Elgin, IL) and PSP imaging plates and processed and archived by a dedicated scanner and software interface (OpTime, Soredex, Finland). Teeth were classified as having lesions of endodontic origin (LEO) when a loss of lamina dura and a periodontal ligament enlargement of more than 2 mm were present. Clinical and radiologic data were analyzed by 3 blind examiners selected from the clinical assistant professors at the Department of Endodontics. In case of nonunanimous opinion, the majority opinion was accepted. The examiners were previously calibrated on the evaluation criteria through a case series presentation, and the concordance among examiners was analyzed by the Fleiss' K score, until interexaminer reliability ($\kappa > 0.70$) was expected.

The subjects were then assigned to a different operator randomly selected among the assistant professors at the Department of Endodontics. Twenty-one expert operators were involved. After local anesthesia with 2% mepivacaine with adrenaline 1:100,000 and isolation of the tooth with the rubber dam, the access cavity was performed. Afterwards, patients were randomly allocated to the 1 of the 2 treatment arms for the creation of the glide path. Root canal treatment was completed 1 week later.

In the PF test group, the mechanical glide path was performed by using Glyde (Dentsply Maillefer, Ballaigues, Switzerland) as a lubricating agent, with Ni-Ti rotary instruments PF 1, 2, and 3 (Dentsply Maillefer), taper 0.02, tip size, respectively, ISO 13, 16, and 19, by using an endodontic engine (X-Smart, Dentsply Maillefer) with 16:1 contra angle at the suggested setting (300 rpm on display, 5 Ncm) at the electronic WL. The electronic WL was recorded with an apex locator (Diagnostic Unit, Sybron, Orange CA) and checked twice during the treatment. The initial WL was recorded with a #10 stainless-steel KF colorinox (Dentsply Maillefer, Baillagues, Switzerland) during canal scouting, before glide path. A second WL was recorded before using the PF 3 with a #17 KF.

In the KF control group, the manual glide path was performed by using Glyde as a lubricating agent, with stainless-steel KF colorinox #08-10-12-15-17-20 (Dentsply Maillefer, Baillagues, Switzerland), used with a "feed it in and pull" motion according to Ruddle's technique at the electronic WL (17). In this hand instrumentation technique, the file proceeds apically with a −1/4 +1/4 motion to the point of resistance and then is gently pulled out for the debris removal. The procedure is repeated until reaching the WL for each file of the sequence. The electronic WL was recorded as previously described and checked twice during the treatment. The initial WL was recorded with a #10 KF during canal scouting before glide path. A second WL was recorded at the #17 KF stage.

During treatment, irrigation with 5% NaOCl (Niclor 5, OGNA, Muggiò, Italy) was performed with a 30-G needle syringe for a total of 10 mL. Root canals were dried with sterile paper points, and then a cotton pellet and a temporary filling (Cavit; 3M ESPE, St Paul, MN) were placed. Patients were then dismissed and received postoperative instructions and a prescription for optional analgesics. They also received a 5-level pain scale form for postoperative pain severity evaluation (Table 1). The evaluation was done bidaily (AM and PM) for 1 week, and patients were required to keep record of their analgesics intake. The time (in days) necessary to achieve a complete pain resolution (pain stop value) was also assessed.

A statistical analysis was performed on the data collected. The Kolmogorov-Smirnov test for normality was used to analyze data distribution. A suitable analysis of variance model for repeated measures (2-group comparison) was used to compare the variation of pain-scale values reported in each of the 7 days in the 2 groups. To avoid an excessive β error, no correction for multiple comparisons was applied to the significance levels presented. The Student's t test was used for continuous variables normally distributed (ie, analgesics intake and pain stop values) and the nonparametric Mann-Whitney U test for the nonnormally distributed variables (pain scores at

TABLE 1. 5-Level Pain Scale to Evaluate Pain Severity: Reference Values Given to Patients

0	No pain	The patient feels well
1	Slight pain	If the patient is distracted, he/she does not feel the pain
2	Mild pain	The patient feels moderate pain, even while concentrating on some other activity
3	Severe pain	The patient feels very unwell but nevertheless can continue with ordinary activities of daily life
4	Very severe pain	The patient is forced to give up ordinary activities of daily life
5	Extremely severe pain	The patient is no longer able to perform any type of activity and needs to lie down and rest