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Post-operative pain following manual and mechanical glide path: a randomized clinical trial.

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Abstract

Introduction: this prospective randomized clinical trial evaluated the incidence of post-operative pain following glide path performed with PathFile™ (PF) versus stainless-steel K-file (KF).

Methods: in 149 subjects mechanical glide path was performed with Nickel-Titanium (NiTi) rotary PF; in 146 subjects manual glide path was performed with stainless steel KFs. Post-operative pain, analgesics consumption and 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 ($p < 0.05$). Student's t-test for continuous variables normally distributed, non parametric Mann-Whitney U-test for the non-normally distributed variables and chi-square test for dichotomous variables were utilised ($p < 0.05$). Although homogeneous baseline conditions at diagnosis, tooth type, pain prevalence and scores, the post-operative pain prevalence curves in PF group evidenced a more favorable trend in terms of time to pain resolution compared to KF group ($p = 0.004$). The difference was also evident in the model adjusted for analgesics consumption in both groups ($p = 0.012$). The mean analgesics intake per subject was significantly higher in KF group (3.7 ± 2.2) compared to PF group (2 ± 1.7) ($p < 0.001$). Mean pain stop values were also significantly higher in KF group (2.7) compared to PF group (1.7) ($p = 0.001$).

Conclusion: glide path with NiTi rotary PF leads to less post-operative pain and faster symptom resolution.

Keywords: post-operative pain, glide path, PathFile, NiTi rotary instruments; K-files.

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). Pre-treatment pain has a prevalence of 81% both for VAS and category studies. However, data available from the existing literature may be overestimated due to the fact that even slight discomfort may be categorized as pain in some VAS studies. Pre-treatment pain severity is reported to be mild with 54% value normalized to a 100 point-scale. Although the pre-treatment 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 one week. The prevalence and severity substantially decrease within the first two days. Root canal treatment clearly reduces pain prevalence and severity, although immediate post-treatment pain severity may sometimes slightly exceed the pre-treatment severity levels. This may be caused by ongoing inflammatory processes or apical instrumentation especially with pre-existing periradicular inflammation (3). An inter-appointment 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 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 a possible cause (6). Post-treatment pain may be due to apical extrusion of infected debris during chemo-mechanical 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) thank to their rotary

action that, combined with abundant irrigation, has the potential to reduce the risk of post-operative discomfort (10).

When using NiTi rotary instrumentation, both the clinician and the technique utilized 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 KFs, independently from the clinician's expertise (16). The system consists of three instruments, with 21-25-31 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; 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 full working length (WL), and then #2 and #3 are used at WL. It is hypothesized that creation of the glide path with NiTi rotary PF is probably less subjected to apical extrusion of debris compared to hand instrumentation.

The primary objective of this study was to evaluate the incidence of post-operative pain following glide path performed with PF versus stainless-steel KFs. The secondary objective was to evaluate the frequency of post-operative 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 genders presented at Turin University Dental School Department of Endodontics, between September 2010 and December 2010, with diagnosis of asymptomatic irreversible pulpitis, symptomatic irreversible pulpitis or pulp necrosis with or without apical periodontitis (acute or chronic), scheduled for initial endodontic

treatment were enrolled. Patients with sinus tract, periapical abscess or facial cellulitis did not enter the study as they were considered as potential outliers in post-treatment pain score analysis.

Patients' medical and dental status and history, demographic data, and socio-economic information were collected before the dental examination. Intra-oral examinations and data collection were done by a single examiner using 3.5X Galilean loupes. The examiner was randomly selected among the clinical assistant professors at the Department of Endodontics, all standardised 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 Ill.) and PSP imaging plates and processed and archived by dedicated scanner and software interface (OpTime Soredex, Finland). Teeth were classified as having lesions of endodontic origin (LEO) when loss of lamina dura and periodontal ligament (PDL) enlargement of more than 2 mm were present. Clinical and radiological data were analyzed by three blind examiners, selected from the clinical assistant professors at the Endodontics Department. In case of non-unanimous 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 analysed by the Fleiss' K score, until inter-examiner reliability ($k > 0.70$) 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 one of the two treatment arms for the creation of the glide path. Root canal treatment was completed one 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 nickel-titanium rotary instruments PF 1, 2 and 3 (Dentsply Maillefer, Baillagues, Switzerland), taper 0.02, tip size respectively ISO 13, 16 and 19, by using an endodontic engine (X-Smart, Dentsply Maillefer, Baillagues, Switzerland) with 16:1 contra angle, at the suggested setting (300 rpm on display, 5 Ncm), at electronic WL. 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 KF control group, the manual glide path was carried out by using Glyde™ (Dentsply Maillefer, Ballaigues, Switzerland) as a lubricating agent, with stainless-steel KF colorinox #08-10-12-15-17-20 (Dentsply Maillefer, Baillagues, Switzerland), used with “feed it in and pull” motion accordingly to Ruddle’s technique at 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 WL for each file of the sequence. 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 (Nicolor 5, OGNA, Muggiò, Italy) was performed with a 30 gauge needle syringe for a total of 10 ml. Root canals were dried with sterile paper points, then a cotton pellet and a temporary filling (Cavit, 3M ESPE, MN) were placed. Patients were then dismissed and received post-operative instructions and prescription for optional analgesics. They also received a 5-level pain scale form for post-operative pain severity evaluation (Table 1). The evaluation was done bi-daily (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 groups comparison) was used to compare the variation of pain-scale values reported in each of the 7 days in the two groups. To avoid an excessive β error, no correction for multiple comparisons was applied to the significance levels presented. Student's t-test was used for continuous variables normally distributed (analgesics intake, pain stop values), and the non parametric Mann-Whitney U-test for the non-normally distributed variables (pain scores at baseline); chi-square test was used for dichotomous variables (diagnostic variables, prevalence of pain and analgesics use). 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).

Results

Three hundred and fifty-nine subjects were enrolled in this study. Overall, 16.3% of patients in the PF arm and 19.3% in the KF arm were lost to follow-up: 10 patients in the PF group and 15 in the KF control group did not present at the second visit; 12 subjects in PF arm and 7 in the KF arm had incomplete data; 7/156 subjects in the PF group (4.5%) and 13/159 subjects (8.2%) in the KF group experienced post-operative flare-up, with no statistical differences between groups ($p = 0.18$). These patients required an unscheduled re-intervention during the observation period and were excluded from data analysis. Data analysis was performed on 295 subjects (mean age 42, range 16-70 years). Patients' characteristics were evenly distributed between the two arms. One hundred and forty-nine patients were assigned to the PF group: 24.8% presented with diagnosis of asymptomatic irreversible pulpitis, 32.8% with symptomatic irreversible pulpitis, and 42.4% had pulp necrosis (46.1% being symptomatic and positive to percussion test with a mean pain score value of 2.5; 73.2% having a LEO). One hundred and forty-six patients were allocated to the KF group: 23.4% presented with diagnosis of asymptomatic irreversible pulpitis, 29.4% with symptomatic

irreversible pulpitis, and 47.2% had pulp necrosis (55.1% being symptomatic and positive to percussion test with a mean pain score value of 2.1; 56.5% having a LEO). The statistical analysis did not show significant differences between groups in the prevalence of asymptomatic irreversible pulpitis ($p=0.86$), symptomatic irreversible pulpitis ($p=0.6$), and pulp necrosis ($p=0.45$), even when comparing symptomatic cases only ($p=0.39$). The PF group showed a higher prevalence of LEO compared with the KF group ($p=0.005$). In the PF group, 81.2% of teeth were multi-rooted and 18.8% were single-rooted. The respective figures in the KF group were 78.1% and 21.9%. The prevalence of pain at baseline was 57% in the PF arm and 61% in the KF arm ($p=0.55$). The mean pain score at baseline was 2.5 ± 1.53 in the PF group and 2.31 ± 1.35 in the KF group ($p=0.12$).

Post-operative pain, analgesics intake and pain stop values

Post-operative pain prevalence curves (Fig 1) showed a more favorable time-trend in the PF group compared to the KF group ($p=0.004$). The more marked steepness of PF curve evidenced a faster resolution of the pain symptoms, when present, after treatment. The difference between the two arms was more evident in the first four days. It attenuated in the following days until an overlap of 95% C.I. became evident, with no significant differences between groups at 1 week, as showedt in Fig. 1.

In both groups, time to pain resolution adjusted for analgesics consumption was significantly different ($p=0.012$). Forty-five subjects in the PF arm and 52 in the KF arm used analgesics ($p=0.3$). The mean analgesics intake per subject was significantly higher in the KF group (3.7 ± 2.2) compared to the PF group (2 ± 1.7) ($p<0.001$). Overall, pain stop value (in days) was also significantly larger in the KF group (2.7) compared to PF group (1.7) ($p=0.001$). This difference was still evident in the subgroup analysis excluding subjects with no pain at baseline ($p=0.009$).

Discussion

The primary aim of this study was to investigate the influence of manual versus mechanical glide path on the incidence of post-operative pain. Outcomes were improved in the group where the glide-path was created with NiTi Rotary PF

Although inter-appointment flare-up is uncommon, post-operative pain is relatively frequent also when the treatment is appropriately performed, and patients should be informed about this risk (4). Previous studies reported different post-operative pain incidences, ranging from 1.4 to 16%, and showed that age, gender, tooth type, pulpal status, presence of a sinus tract stoma, allergies and preoperative pain play a fundamental role (18). In a recent systematic review, post-operative pain prevalence at 24 h was 40% and markedly decreased during the first 2 days after treatment, dropping to 10% or less after 7 days (3). The same trend was observed in our study; however the NiTi Rotary PF technique led to significantly better outcomes. Despite the homogeneous baseline conditions at diagnosis, tooth type, pain prevalence and severity, the post-operative pain curves and pain stop values in the PF group showed a more favorable trend in terms of time to pain resolution compared with the KF group. No differences were found between the two groups in the prevalence of subjects assuming analgesics during the post-treatment period. However, patients in the KF group, where the glide path was performed with hand files, showed a significantly higher analgesic tablets consumption per individual.

Mechanical, chemical, or microbial injuries to the periradicular tissues are frequent causes of pain complication (19). Indeed, most cases of post-operative pain are caused by acute periradicular inflammation, such as acute periodontitis or acute periradicular abscess secondary to intracanal procedure (20). Periapical chronic inflammation may be adapted to the irritant and may exist without pain or swelling. However, new irritants, such as infected debris from the root canal system, may induce acute inflammatory response known as alteration of the local adaptation syndrome of the tissues to applied irritants (21,22). In this study, both groups were substantially homogeneous at diagnosis and had similar preoperative clinical conditions. The PF group showed a significantly higher prevalence of pre-operative chronic apical periodontitis. Despite this

unfavorable pre-operative prognostic factor, the post-treatment time to pain resolution trend of this group was better than the one of the KF group. This suggests a positive impact of the NiTi Rotary instrumentation for the creation of the glide path even in presence of LEOs.

The great elasticity of the NiTi alloy has permitted the increasing use of mechanical instruments for root canal shaping (23). NiTi tools enable a more centered canal preparation with less transportation and incidence of canal aberrations (24). Instrumentation techniques involving a sort of rotational action usually cause less extrusion of debris than manual techniques with a linear filing movement (25). It has been demonstrated that the amount of debris from the apical foramen produced with step-back technique instrumentation (2.58 mg) was greater than debris produced with other instrumentations, such as NiTi rotary instrumentation (less than 0.50 mg) (26). Moreover, ProTaper rotary instrumentation removes dentinal debris better than hand step-back technique (27). In our study glide path with hand stainless-steel KF was performed with “feed it in and pull” motion accordingly to Ruddle’s technique (17) at electronic WL. Compared to push and pull filing motion, which is known to maximize the extrusion of debris, this technique appears to facilitate the suspension of the debris in the irrigating solution (17) and therefore to minimize the risk of post-treatment pain (17). However PF technique is performed with only three NiTi rotary files that quickly reach WL. Compared to manual glide path, the number of files reaching the apical foramen and the time of apical instrumentation are dramatically increased. This may be attributed to the less favorable pain-related outcomes of the manual technique.

Canal scouting and pre-flaring are the first phases of canal instrumentation. They are fundamental for safer use of NiTi rotary instrumentation since they ensure a root canal smoothed path with a larger or at least equal diameter compared to non-cutting NiTi instruments’ tip size (28). In the pre-flaring phase, procedural difficulties or errors are more frequent, and the amount of extrusion of debris is also higher (29). NiTi rotary PFs have been recently introduced by Dentsply Maillefer for mechanical pre-flaring. The approach with NiTi rotary PFs showed to be less invasive and less technique-sensitive. In simulated canals, it has been demonstrated that clinicians’ expertise seemed

not to play a significant role on shaping outcomes, since both endodontic experts as well as inexperienced clinicians achieved similar results (16).

Furthermore, the amount of debris from apical foramen depends on the mechanical instrumentation's properties (30). The use of these tools may also reduce the frequency and intensity of post-operative complications, such as pain or flare-ups.

In this study, prevalence and severity of post-operative pain were measured through a multi-level pain scale. This method may have some limits in terms of objectivity considering the heterogeneity of personal character. However, previous studies argued that this method can be considered adequately reliable (31). In conclusion, within the limits of this study, our findings suggest that performing glide path with hand instrumentation may have a significant impact on individual quality of life in terms of post-operative pain, and the use of NiTi rotary instrumentation may be rather beneficial.

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Table/figure legends

Table 1 Five-level pain scale to evaluate pain severity: reference values given to patients.

Figure 1 Comparison between post-operative pain curves (mean values and 95% C.I.). The difference between groups is more evident in the first four days. It attenuates in the following days until an overlap of 95% C.I. became evident, with no significant differences between groups at 1 week.

Table 1 – Five-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 or 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

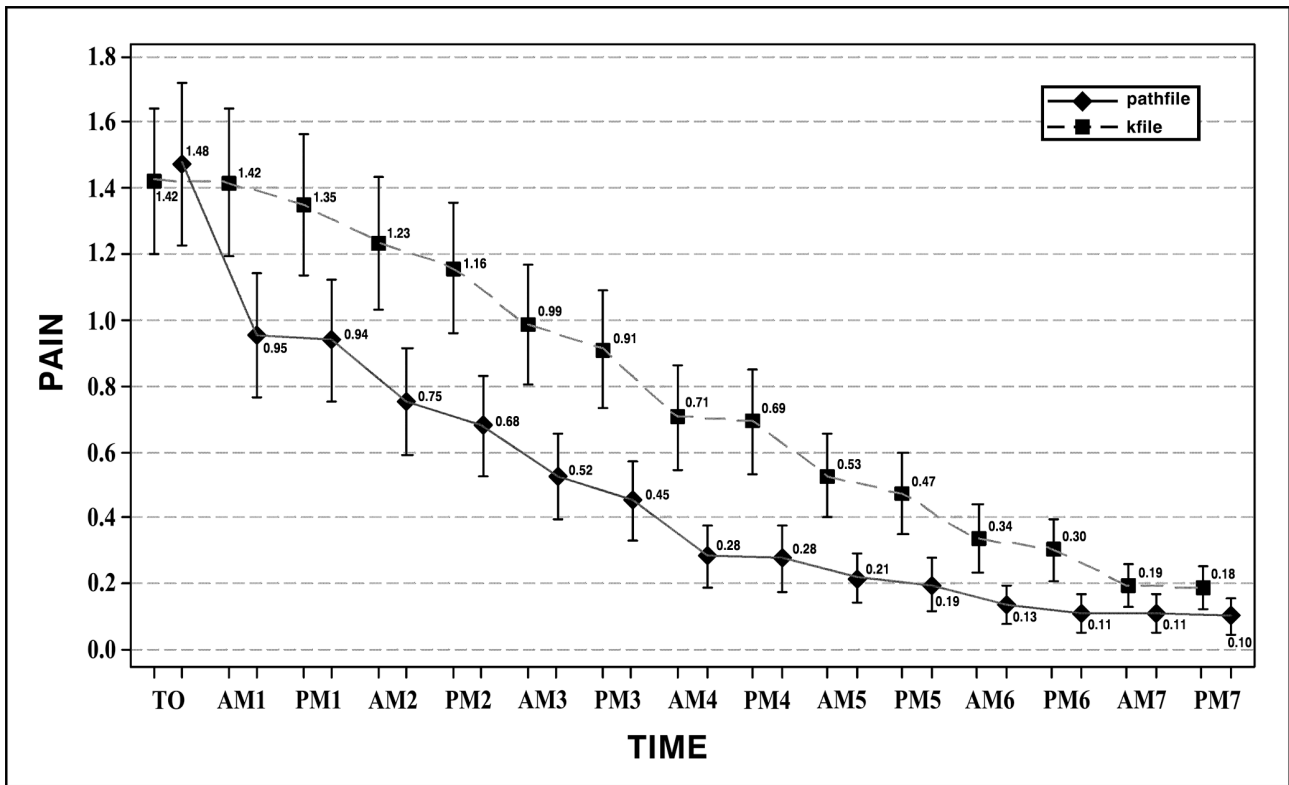


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