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Post-operative pain following glide path preparation using Neoniti GPS file and manual K-files in non-vital lower molars: A randomized controlled trial

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Abstract
A glide path file may contribute to extruding contaminated debris during the first treatment phase. Using rotary techniques rather than manually operated instruments is thought to decrease the amount of extruded debris and hence post-operative pain levels.
Aim: To compare the effect of using Neoniti GPS rotating glide path file in comparison to manual stainless-steel K-files on post-operative pain, in asymptomatic nonvital mandibular molars.
Methods: Thirty nonvital asymptomatic mandibular permanent molars were randomly allocated into two equal groups (n=15). In the control group, glide path preparation was achieved using manual stainless-steel K-files (#10, 15). In the experimental group, a glide path was created using Neoniti GPS path file. Standardized cleaning and shaping procedures were performed in both groups.
Results: Neoniti GPS for glide path preparation resulted in significantly less post-operative pain incidence at 6 h (p= 0.039) and was associated with significantly lower post-operative pain levels at 12 h (p=0.047). No other significant difference was found between the two groups at 24, 48 and 72 h.
Conclusions: Glide path preparation using Neoniti GPS rotary file decreased post-operative pain incidence after 6 h and reduced pain intensity after 12 h compared to manual glide path preparation.

Keywords: Necrotic teeth, rotary glide path, post-endodontic pain, asymptomatic teeth

Introduction

Apical debris extrusion is one of the key factors affecting post-operative pain. Bacteria and foreign materials forced into the periapical tissues have been associated with increased levels of inflammation, post-operative pain, and flare-up incidence [1, 2].

Rotary instrumentation techniques have been shown to extrude less debris in laboratory studies [3-5], and to reduce post-treatment pain levels relative to manual techniques [6-8]. In a similar manner, glide path kinematics are thought to influence post-endodontic pain [9-11].

The extrusion of bacteria in a necrotic tooth can cause a degree of inflammatory response according to the amount extruded and the bacterial virulence especially in asymptomatic cases [2, 3]. The initially extruded debris can be more harmful to the periapical tissues since the canals are yet to be cleaned and the number of the present micro-organisms is at its highest [12, 13].

Recently, a lot of dedicated NiTi rotary glide path instruments with improved shaping abilities have been introduced aiming to simplify the procedure and decrease the risk of canal aberrations. When compared with manual K-files, the use of engine-driven glide path instruments has resulted in a lower amount of extruded debris [4, 16, 17], lower post-obturation pain levels [9-11], and shorter preparation times [18]. Although several in-vitro studies have compared apically extruded debris/bacteria after using different types of glide path files [10, 16-18]. Only three studies assessed the effect of different glide path kinematics on post-operative pain [9-11].

The present study was conducted to expand the available evidence on the influence of glide path kinematics (Rotary Neoniti GPS vs. manual K-files) on post-operative pain in patients with nonvital asymptomatic permanent lower molars. The null hypothesis tested was that there would be no difference in post-operative pain between manual and rotary glide path techniques.

Materials and Methods

This randomised clinical trial has been written according to Preferred Reporting Items for Randomised Trials in Endodontics (PRIRATE) 2020 guidelines and was previously registered on www.clinicaltrials.gov (ClinicalTrials.gov ID: NCT04559438). Prior to clinical trial registration, the study protocol was accepted by the Ethics Committee/Institutional review board, Faculty of Dentistry, Cairo University (Approval number: 61020). The study was performed between January 2021 and October 2021. Participants included in this study were recruited from the outpatient clinic of the Endodontic Department at the Faculty of Dentistry, Cairo University, Egypt.

Eligibility criteria

Participants included were healthy patients aged between 18-45 years old with nonvital first or second mandibular permanent molars. Only asymptomatic patients were included with no pain on percussion with or without periapical lesions. Patients with history of intolerance to non-steroidal anti-inflammatory drugs or those who have consumed pre-operative medication (anti-inflammatory drugs/antibiotics) 7 days before treatment were excluded. Other exclusion criteria comprised patients with two or more adjacent teeth requiring endodontic treatment, acute peri-apical abscess or acute exacerbation of a chronic abscess, teeth that show association with acute periapical abscess/swelling, mobility Grade II or III or a pocket depth larger than 5 mm, previous root canal therapy, or non-restorability.

Sample size calculation

Based on a previous study by Adıgüzel *et al*., [11], the sample size was calculated using P.S. software version 3.1.6. Using independent t-test, a type I error of 0.05 and a power of 0.8; a sample of 26 subjects (13 for each group) was required to detect a significant difference between the two groups regarding postoperative pain at 72 h, where mean control was equal 2.19, and SD control was equal 1.33. Mean difference estimated was equal 1.5. The sample size was then increased to compensate for a possible dropout rate of approximately 15% making the total sample size 30 participants (n=15).

Randomization, allocation concealment and blinding

A sequence of numbers from 1-30 was randomly arranged by the assistant supervisor using computer software (http://www.random.org/) into two columns. The randomized sequence was kept with the assistant supervisor only; hence the operator was not aware of which group the patient will be enrolled into. Following local anaesthesia administration and access cavity opening, the clinician confirmed the diagnosis of a nonvital tooth by the absence of bleeding in the access cavity. The operator contacted the assistant supervisor over the phone to reveal which group this number was assigned to. The patients were unaware of the assigned treatment.

Diagnosis

The diagnosis of asymptomatic nonvital mandibular molars was based on the following criteria:

- History of chief complaint reported no pain with hot or cold stimulus.
- Extraoral examination precluded the presence of a swelling.
- Clinical examination showing no pain on percussion.
- The tooth gave a negative response to cold pulp testing, ethyl chloride spray (WALTER RITTER GmbH + Co. - PHARMACEUTICA, Germany).
- Radiographic examination revealing lower permanent molar teeth with or without periapical periodontitis.

Endodontic procedures

The selected tooth was anaesthetized and isolated. A standard access cavity was performed. The canals were explored using #8 hand stainless steel K files. Working length was determined using an apex locator (Root ZX; J. Morita USA, Irvine, CA, USA).

Glide path preparation

Glide path was performed according to the assigned group. In the experimental group, glide path was achieved using rotary Neoniti GPS file (15/.03). The file was introduced inside the canal in continuous rotation at a speed of 300 rpm and torque of 1.5 N/cm. If resistance was encountered, the file was removed, cleaned and the procedure was repeated until the file reached the full working length [10].

In the control group, glide path was performed using hand stainless-steel K-files #10 and #15. Instruments were introduced in a "feed it in and pull motion" according to Ruddle's technique where the file was inserted in a watch-winding/reciprocation motion (1/4 turns), [9, 19]. Additionally, if the operator sensed resistance to advancement, the file was removed, cleaned from debris, and the canal was flushed with NaOCl 5.25% (Clorox, 10th of Ramadan, Egypt). The procedure was repeated until the file gradually advanced apically and the working length was reached.

After glide path preparation, the rest of the preparation was standardized in the 2 groups. ProTaper Next file system (Dentsply, Tulsa Dental Specialties, USA) was used in both groups, following the manufacturer's instructions, at a speed of 300 rpm and a torque of 2 N/cm. Shaping of the canals was done using X1 (17/.04) and X2 (25/.06). If a single distal canal was present, this canal was further instrumented using X3 (30/.07). Engine-driven instruments were operated using a gear reduction torque-controlled motor (X-Smart; Dentsply Tulsa Dental Specialties).

No lubricant/EDTA gel was used during instrument introduction inside the canal neither in glide path preparation nor mechanical preparation. The canals were thoroughly irrigated using 3 ml 5.25% NaOCl [10, 20, 21]. A side vented 30-gauge needle (CERKAMED, Stalowa Wola, Poland) was used. Canals were then irrigated using 1 mL EDTA 17% (PREVEST DenPro, India) for 1 minute [22]. Following EDTA, canals were irrigated using 3 mL 5.25% NaOCl followed by saline. Canals were dried using sterile paper points and filled with ProTaper Next gutta percha cones (X2 or X3) and sealed with a resin-based sealer (Adseal; META BIOMED Co., LTD., Chungbuuk, Korea). A modified single cone technique was used. The access cavity was then sealed with a temporary restoration (Cavit, 3M ESPE, Germany).

Assessment of post-endodontic pain

Patients were asked to rate their pain levels on a VAS chart 6, 12, 24, 48, and 72 h after treatment. Patients were advised to call the operator in cases of severe or persistent pain or swelling. If needed, the operator prescribed a suitable analgesic (Ibuprofen 400 mg) and instructed the patients to record the number of tablets taken in another provided chart.

Statistical Analysis

Categorical data were analysed using Fisher's exact test. Ordinal data were analysed using Mann-Whitney U test for intergroup comparisons and Friedman's test followed by

Nemenyi post hoc test for intragroup comparisons.

Numerical data were presented as mean and standard deviation (SD) values. They were explored for normality by checking the data distribution and using Shapiro-Wilk test. Non-parametric data (modified VAS scores) were analysed using Mann-Whitney U test for intergroup comparisons and Friedman's test followed by Nemenyi post hoc test for intragroup comparisons. Parametric data (Age) were analysed using independent t-test. The significance level was set at $p<0.05$ for all tests. Statistical analysis was performed using R statistical analysis software version 4.1.3 for Windows (R Core Team (2022). R: A language and environment for statistical computing. R

Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/.)

Results

The Neoniti group showed lower mean pain scores at all time intervals with a statistically significant difference after 12 h (P=0.047) as presented in Table (2). Analysis within the Neoniti group showed values measured at 6 h to be significantly higher than 72 h value (p<0.001). The highest values were measured at 6 h (1.87±2.00), followed by 12 h (0.80±1.21), 24 h (0.40±0.74), and 48 h (0.07±0.26), and 72 h (0.00±0.00). In the control group, there was a significant difference between pain scores measured at different intervals ($p<0.001$). The highest value was measured at 6 h (3.00±1.65), followed by 12 h (1.93±1.67), 24 h (1.00±1.46), and 48 h (0.47±0.92), and 72 h (0.13±0.35). Post hoc pairwise comparisons showed values measured after 6 h to be significantly higher than values at other intervals ($p<0.001$) except for 12 h. In addition, they showed values measured after 12 h to be significantly higher than after 72 h ($p<0.001$). Incidence of pain categories (None-mild-moderate-severe) among the two groups were compared and presented in Table (3). No patient reported severe pain or flare-up occurrence at all time intervals in both study groups. No patient in either group reported analgesic intake.

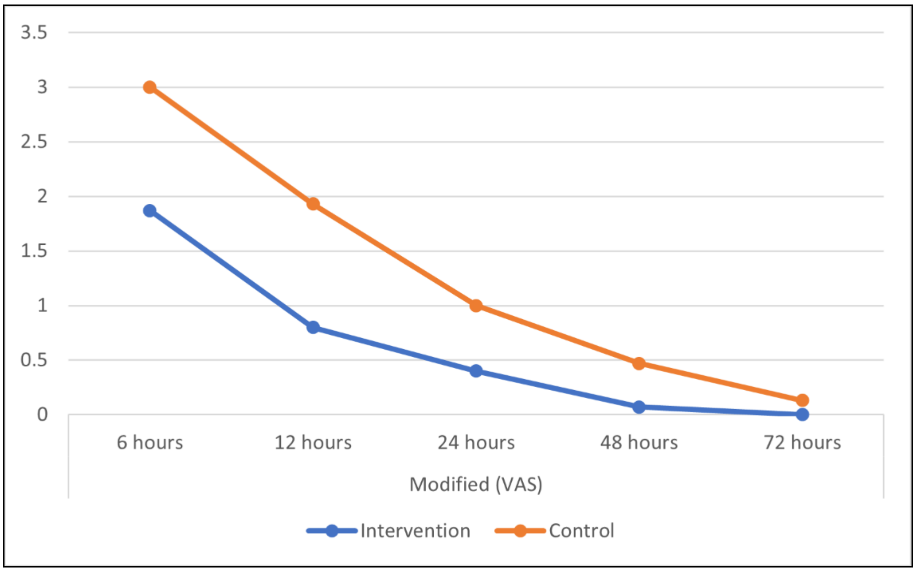

Fig 1: Line chart showing average modified (VAS) scores at different intervals.

Discussion

Preliminary scouting of the canals followed by preparation of a glide path are the first instrumentation steps and two of the most critical steps of endodontic treatment. A successful nonsurgical root canal treatment is dependent on the creation of a reproducible glide path that allows ridding the canals of vital or necrotic pulp tissues, intracanal bacteria and smear layer [23].

A "glide path" was described by West (2010) as a smooth tunnel from the orifice of the canal to its apical constriction that secures the original canal pathway (24). Several authors have recommended using hand stainless steel K-files for preparing the glide path [25-28]. According to a survey of the American Association of Endodontists by West (2010), more than 50% of dentists prefer preparing the glide path to a size #15 K-file or larger; whereas, West recommended a very loose size #10 K-file [24]. Manual files offer the advantage of tactile sensation which makes them irreplaceable in challenging cases. Besides, they are less likely to separate during use and are able to replicate the canal shape when a small file is used, which helps the clinician to better visualize the hidden anatomy [27]. The problem with the typically available stainless-steel k-files used for obtaining a glide path is the major difference between their tip diameters. When transitioning from a K-file #10 to #15, there is a 50% increase in tip diameter. This leap in size, combined with the inherent stiffness of stainless-steel can considerably increase the risk of iatrogenic errors [28, 29]. According to West (2011), K-file size #15 is a potentially unsafe file due to its inability to easily follow the glide path created by size #10 file [29]. West (2011) suggested two methods to solve this problem, either to proceed with a size #15 manual file following the use of size 10 but use a balanced force technique, or to use narrow rotary NiTi glide path instruments [29]. Other shortcomings of using hand instruments for glide path preparation include operator fatigue [30] and increased preparation time [31, 32]. In spite of their disadvantages, manual stainless-steel K-files are still considered a valid and a reliable option for glide path preparation [26, 33-35].

Over the last decade, various types of automated glide path files have surfaced. Automated glide path files include conventional NiTi files and heat-treated files, Glide path management using engine-driven instruments can be considered a simpler alternative to manual stainless-steel files. Yet, the use of rotary instruments is accompanied by an increased risk of fracture due to torsional failure or cyclic fatigue failure [36, 37].

The mechanism behind post-endodontic pain has been

explained by the occurrence of acute inflammation in the periapical tissues due to a mechanical, chemical, or microbial injury [1]. Apical debris extrusion is believed to be one of the main factors affecting post-operative pain [2].
The extrusion of bacteria in a necrotic tooth can cause a degree of inflammatory response according to the amount extruded and the bacterial virulence [2, 3].
Eligible participants in this study were asymptomatic to limit the variables affecting post-operative pain since pre-operative pain was found to be the most dominant variable affecting post-operative pain levels [1, 10]. Because of the high number of micro-organisms initially present before cleaning and instrumentation [12, 13], the amount of extruded debris during preliminary canal enlargement; though smaller in amount, can carry more toxicity to the periapical tissues than those extruded during the shaping procedures [3]. Nonetheless, the effect of this small amount of debris might be masked after complete instrumentation [10, 17]. Choosing an instrument that extrudes less apical debris is believed to affect post-operative pain. Likewise, choosing a glide path file that extrudes less debris may affect pain incidence or severity [9].
In this study, canals were first explored using #8 K-files only to confirm patency. Randomization was done after checking patency and working length determination to make sure that uncontrolled variables were similarly allocated among the two groups of the study. In an aim to standardize the final glide path preparation size, an apical size of #15 was chosen for the two study groups. Ruddle *et al.* [38], recommended enlarging the glide path to at least 0.15mm [19]. Moreover, the final apical size of the glide path is thought to affect the total amount of extruded debris [17]. Plotino *et al*. reasoned that if a rotary glide path file needs the prior use of a manual file size #10 or larger, it should be named a pre-flaring file because it only enlarges the already established glide path [39]. In our study, Neoniti GPS advanced to the full working length without the need for recapitulation using manual files or the prior use of size #10 K-files.
Findings of our study revealed that rotary glide path techniques using Neoniti GPS file resulted in significantly less post-operative pain incidence at 6 h and significantly less post-operative pain intensity at 12 h compared to manual glide path techniques. This finding is in accordance with two similar previous studies by. and Keskin *et al*., [10]. and Both studies revealed a considerable advantage of using rotary glide path instruments instead of manual K-files in reducing post-operative pain. No patient reported flare-ups or analgesic intake in this study which also agrees with Keskin *et al*. [10]. In addition, a logistic regression analysis by the same study revealed that nonvital teeth had significantly less post-operative pain than vital teeth at 12, 18, 24, and 72 h [10]. This might explain the overall low pain severity observed in this study.
Although rotary Neoniti GPS file resulted in less post-operative mean pain scores than manual K-files at all time intervals, there was no statistically significant difference at 24, 48 and 72 h. This result is partially in line with Adıgüzel *et al*., [11]. In their study, no significant difference between engine-driven glide path and the control group were found at 48 and 72 h regarding post-operative pain levels. However, at 24 h engine-driven glide path techniques produced significantly less post-operative pain severity than the control group, which according to the authors was named "without glide path group" but was preliminary scouted using #10 or #15 K-files. It should be noted that Adıgüzel *et al*., [11], didn't assess pain levels before the 24-h period, so no comparison with our study could be made at this time duration.
The lower post-operative pain associated with rotary glide path techniques is thought to be ascribed to the different file kinematics. This could be explained by the effect of the push and pull motion used with K-files which has a tendency of forcing debris into the periapical tissues [17, 40]. Reddy and Hicks concluded that rotational movement whether with manual or engine-driven instruments produced significantly less debris than vertical motion [40]. A number of in-vitro studies have also shown that manual glide path files were associated with a statistically larger amount of extruded debris than rotary glide path files [4, 16, 18].
The anatomy of root canals often carries a degree of complexity, for this reason heat-treated files could be beneficial in the preliminary enlargement of curved or narrow canals, decreasing the incidence of procedural mishaps. Thermomechanically treated files do not tend to fully straighten during use [41]. Neoniti rotary system demonstrated a stable martensitic phase during clinical use [42]. This file system also has a soft tip and is made of controlled memory wire using the electric discharge machining technology [43]. Conversely, the relatively stiff stainless steel files may contribute to the occurrence of procedural errors such as apical transportation [31]. This can inadvertently enlarge the apical constriction, resulting in more apical debris extrusion, compromised canal sealing and increased post-operative pain [1, 10]. Glide path preparation using Neoniti GPS (15/.03), Scout-RaCe (10,15/.02), OneG (14/.03), and Path Files (13,16/.02) resulted in significantly less apical and middle canal transportation compared with size #15 stainless steel K-file in artificial double-curved canals [44]. On the other hand, when performance of manual files and rotary glide path files were compared by Alves *et al*. none of the groups caused procedural errors or changes in canal curvature [35]; however, manual K-files used in this study were operated using a balanced force technique, which may have guarded against the occurrence of canal deviations [29]. A systematic review by Plotino *et al*. assessed the difference between manual and engine driven files in terms of canal transportation [39]. Results of their meta-analyses revealed significantly less transportation with engine-driven glide path files in the apical third, in studies utilizing 2D-imaging, and in the apical and middle thirds in studies using 3D-imaging/micro-CT evaluation. Furthermore, quantitative analysis of studies using the same subsequent shaping system showed that automated glide path instrumentation significantly reduced canal transportation than hand files at the apical and coronal thirds [39].
In addition to the effect of glide path file kinematics and metallurgy, the instrument's size and taper can potentially impact the amount of apically extruded debris. In the present study, the two glide path instruments used had the same apical size with a slightly different taper (15/.02 and 15/.03). The slightly larger taper of Neoniti GPS file may have facilitated coronal debris removal [18]. A study by Pawar *et al*. compared the effect of glide path file taper on debris extrusion and concluded that using a rotary file size (20/.04) caused less debris extrusion than a hand file of the same apical size (20/.02) [45]. Nevertheless, these results may be confounded by the different instrumentation kinematics. Another study evaluating the amount of extruded bacteria after glide path preparation found a statistically significant difference between manual K-files and engine-driven files while no difference was found among rotating glide path files with different tapers [16]. Gunes and Yeter reported no significant difference

in apical debris extrusion among rotary glide path files with different tapers, where the only detected significant difference was between manual K-files (#10 and 15) and OneG file (14/.03), which has a very similar apical size and taper to the GPS file used in our study (15/.03) [17]. To provide a more detailed understanding on the impact of different tapers on debris extrusion, instruments compared should have the same design, apical size and should be operated by the same kinematics, which might be difficult to execute.

The instruments' cross-sectional design that could have also affected the instruments' debris removal capability. Neoniti GPS file has a variable rectangular cross-section [43, 46] compared to a squared cross-section of K-files [47]. Having a thinner core is believed to provide an increased clearance space facilitating coronal transportation of debris [33].

Table 1: Summary of statistics of demographic data

Parameter			Intervention	Control	*P*-value
Sex	Male	n	4	7	0.449ns
		%	26.7%	46.7%	
	Female	n	11	8	
		%	73.3%	53.3%	
Age	Mean± SD		27.27±10.24	27.93±9.99	0.858ns

ns: non-significant (p>0.05)

Table (2): Mean and standard deviation (SD) values of modified Visual Analogue Scale (VAS) scores for different groups.

Interval	VAS scores (mean±SD)		P-value
	Intervention	Control	
6 hours	1.87±2.00	3.00±1.65	0.111ns
12 hours	0.80±1.21	1.93±1.67	0.047*
24 hours	0.40±0.74	1.00±1.46	0.309ns
48 hours	0.07±0.26	0.47±0.92	0.141ns
72 hours	0.00±0.00	0.13±0.35	0.164ns

*; significant ($p \leq 0.05$) ns; non-significant (p>0.05)

Table (3): Frequency (n) and percentage (%) values for modified (VAS) categories (None-mild-moderate-severe) in different groups.

Interval		Intervention	Control	*P*-value
6 hours	None	7(46.7%)	1(6.7%)	0.038*
	Mild	4(26.7%)	9 (60.0%)	
	Moderate	4 (26.7%)	5 (33.3%)	
	Severe	0 (0.0%)	0 (0.0%)	
12 hours	None	10 (66.7%)	5 (33.3%)	0.056ns
	Mild	5 (33.3%)	6 (40.0%)	
	Moderate	0 (0.0%)	4 (26.7%)	
	Severe	0 (0.0%)	0 (0.0%)	
24 hours	None	11 (73.3%)	9 (60.0%)	0.333ns
	Mild	4 (26.7%)	4 (26.7%)	
	Moderate	0 (0.0%)	2 (13.3%)	
	Severe	0 (0.0%)	0 (0.0%)	
48 hours	None	14 (93.3%)	11 (73.3%)	0.327ns
	Mild	1 (6.7%)	4 (26.7%)	
	Moderate	0 (0.0%)	0 (0.0%)	
	Severe	0 (0.0%)	0 (0.0%)	
72 hours	None	15 (100.0%)	13 (86.7%)	0.464ns
	Mild	0 (0.0%)	2 (13.3%)	
	Moderate	0 (0.0%)	0 (0.0%)	
	Severe	0 (0.0%)	0 (0.0%)	

*; significant ($p \leq 0.05$) ns; non-significant (p>0.05)

Conclusions and recommendations

The use of an automated glide path file in continuous rotation (Neoniti GPS) rather than manual stainless-steel K-files (#10, #15) significantly decreased post-obturation pain incidence after 6 h and caused significantly lower pain levels after 12 h in patients with asymptomatic nonvital mandibular molars. No statistically significant difference regarding pain incidence or severity was observed between the two groups at 24, 48 and 72 h. No severe pain or analgesic intake was reported for both automated and manual glide path techniques. Though there is no solid evidence to prove the superiority of rotary glide path files in reducing post-operative pain levels, available evidence suggests encouraging results. More randomized clinical trials with larger sample sizes are needed to corroborate these findings.

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