Comparison of Quality of Obturation and Post-Operative Pain Using Manual vs Rotary Files in Primary Teeth - A Randomised Clinical Trial

Abstract

Introduction: Cleaning and shaping plays a very important role in success of root canal procedures. There are various instrumentation techniques available for root canal preparation. Recently, an exclusive rotary file for root canal preparation of primary teeth has been introduced.

Aim of the Study: The aim of this in vivo study was to compare the quality of obturation and intensity, and duration of post-operative pain between two rotary file systems with manual files during the pulpectomy of primary molars. Materials and Methods: Forty five primary mandibular molars were included in this study, which was randomly allocated into one of the three experimental groups (n = 15). Group A: Instrumentation was done using Hand K-file; Group B: Instrumentation was done using Kedo-S rotary file system; and Group C: Instrumentation was done using K3 rotary file system. The quality of obturation was recorded as optimal, underfilled, or overfilled using standardized intraoral periapical radiographs. This study also evaluated the intensity and duration of postoperative pain at different time intervals: 6, 12, 24, 48, and 72 hours following the pulpectomy.

Results: With respect to quality of obturation, less underfilling was noticed in Kedo-S rotary files (16.7%) followed by using K3 rotary files (33.3%) and hand K files (43.3%). Kedo-S file showed the least underfilled canals (16.7%) and comparatively more overfilled canals (26.6%) and it was statistically significant (P value of 0.001 and 0.002 respectively). On comparing the intensity and duration of postoperative pain among the three groups, there was no statistically significant difference between these groups (P > 0.05). Conclusion: Kedo-S pediatric rotary file system shows considerably better quality of obturation when compared to that of K3 rotary and hand K file systems without much of any significant difference in relevance to the post-operative pain.

Keywords: Hand files, pediatric rotary files, pulpectomy

Introduction

Successful pulp therapy (SPT) requires absolute aseptic condition of the root canals by adequately cleaning and shaping the root canal.[1] Convoluted pulpal canals often make the biomechanical preparation a challenging process in primary teeth.[2] Ideal obturation should provide fluid impervious seal for successful pulp therapy.[3] There are numerous factors which are responsible for achieving the ideal quality of obturation such as adequate filling of the obturating material till the apex and the presence of three-dimensional seal.[4] One of the main complications faced by children following pulp therapy is the presence of postoperative pain which in turn may affect the child's behavior and quality of life.[5] Postoperative pain is due to the apical extrusion of the debris during instrumentation producing inflammatory reaction.[6] The use of hand instruments is very time consuming and produces unwanted complications like apical transportation and ledge formation.[7] Adequately tapered preparations are required to seal the root canals till the apex with the obturating material.[8]

Barr et al., introduced the Ni-Ti rotary file system rotary file system for primary teeth.[9] K3 rotary file system is a third generation Ni-Ti rotary file system, which is asymmetric in cross section and has a positive rake angle and varied pitch that effectively removes the dentinal shavings from the canals.[10] The safe end tip of the K3 files prevents the risk of perforation during canal instrumentation.[11] The in vitro study by Elmsallati et al. using K3 rotary file system, revealed that there was minimal preparation of root canal space during instrumentation.[12] Francinne et al. compared the clinical instrumentation...
time and apical displacement by using hand K files and K3 rotary file and found that K3 file system required less instrumentation time when compared to hand K files.[13] Topcuoglu et al. evaluated postoperative pain after root canal instrumentation in primary maxillary molars and found that the pain was more intense when hand files were used for instrumentation.[14] Recently, exclusive rotary files for primary teeth are available for root canal instrumentation. However, there is a lacuna of literature comparing the quality of obturation, as well as postoperative pain using two different rotary file systems with hand files in primary teeth. Hence, the aim of this current study was to evaluate the quality of obturation and intensity and duration of pain following pulp therapy using Hand K file, kedo-S and K3 rotary file system in mandibular primary molars.

**Materials and Methods**

The randomized controlled trial was carried out in the Department of Paedodontics and Preventive Dentistry in a private dental college. The study was approved by the Institutional Review Board (STP/SDMDS2015PED4d). A total of 86 children between the age group of 6-8 years requiring pulpectomy in any one of the primary mandibular molars were examined and 45 children were selected for this randomized clinical trial. Randomization was done based on computer generated randomization method. The sample size was determined with the previous clinical study with 95% power using G Power analysis.[14] The children were randomly assigned to one of the three experimental groups: Group 1: Instrumentation was with Hand K files, Group 2: with Kedo-S Rotary Ni-Ti files and Group 3: with K3 Rotary Ni-Ti files (0.25 tip, 0.04 taper) [Figure 1].

The primary mandibular molars with asymptomatic irreversible pulpitis and children with no history of analgesic usage within 12 hours prior to the procedure were included in this study. Children with systemic illness, badly broken down teeth, presence of radiographic evidence of internal or external root resorption or calcification metamorphosis were excluded from the study. An unweighted kappa test was carried out in an independent manner to assess the consistency and reliability for the diagnosis and results evaluator, which resulted in a score of 0.90 (excellent) pulpectomy procedure of all the 45 subjects which was carried out by a single operator. Preoperative intraoral periapical radiographs (IOPA) were taken before the procedure. Topical anaesthetic gel was applied followed by administration of local anaesthesia containing 2% lignocaine in 1:200,000 adrenaline. The teeth requiring pulpectomy was isolated with rubber dam and access was gained using No 330 Pear shaped bur (Mani, Tochigi, Japan). The working length was determined by using No. 15 K-file (Mani, Tochigi, Japan) with 1 mm short of apex using radiographic method. The canal preparation was done using:

![Figure 1: Flow chart of randomization of the participants and the variables assessed](image)

Group A: Using Hand K-files (15-35 size) (Mani, Tochigi, Japan) in quarter pull turn method till the predetermined working length.

Group B: After initial filling with No 15 Size K- files, Kedo-S pediatric rotary Ni-Ti files (Reeganz Dental Care Pvt. Ltd.) were used. Mesio buccal and mesiolingual canals were instrumented with D1 (0.25 tip, 0.04 to 0.08 taper) rotary file and distal canal was prepared with E1 (0.30 tip, 0.04 to 0.08 taper) rotary file till the working length using X-Smart (Dentsply India Pvt. Ltd., Delhi, India).

Group C: After initial filling with No 15 K files followed by K3 rotary Ni-Ti files (0.25 tip, 0.04 taper) (Sybron Dental, Westcollins, CA, USA) in back and forth motion till the predetermined working length using X-Smart (Dentsply India Pvt. Ltd., Delhi, India).

During root canal preparation, the canals were irrigated with one mL of 3% sodium hypochlorite (NaOCl) between each file using a 29-gauge double side port NaviTip irrigation needle (Ultradent, South Jordan, Utah, USA). Saline was used as final irrigant after the canal preparation to remove the remnants of NaOCl. The canals were dried with appropriate sized sterile absorbent paper points (Pearl Dent Co, Ltd., Vietnam) and obturation was done with Metapex (Meta Biomed Co. Ltd. Chungbuk, S. Korea) by inserting the Metapex tip inside the canal and filling the obturating material from the apex to the canal orifice. Postoperative IOPA was taken to evaluate the quality of obturation. The coronal space was covered with glass ionomer (Vitrebond, 3M ESPE, St Paul, MN, USA), which was lightly cured for 40 seconds. The outcome assessment was done by two pediatric dentists, who were blinded to the files used for preparing the canals. Quality of obturation was recorded as underfill, optimal fill, and overfill using post-operative radiograph.
The intensity and duration of postoperative pain was measured following the pulpectomy at 6, 12, 24, 48, and 72 hours using facial pain intensity rating scale [Figure 2]. Parents were trained by the dental surgeon who checked for the quality of treatment, on how to use the pain scale. A telephone call was made to the parent/care-taker on 6, 12, 24, 48 and 72 hour period and the pain scale value was obtained. Patient was instructed to take analgesics in case of pain within this period of time. Intensity of pain was scored from zero to three according to four-point facial pain intensity rating scale, which is as follows:

(a) zero-no pain;
(b) one-slight pain
(c) two-moderate pain
(d) three-severe pain

The statistical analysis was done using SPSS software version 17.0. (Chicago, SPSS Inc). Chi-square test was used to analyse the quality of obturation among the groups. Chi-square test was used to evaluate the post-operative pain among groups. Statistical significance was set at \( P < 0.05 \).

### Results

A total of 45 children who required pulpectomy of mandibular primary molar were included in the study. Among them 27 (60%) were male and 18 (40%) were female. The demographic distribution of the participants is given in Table 1. Among the 3 file groups used, Kedo-S file showed the least under-filled canals (16.7%), and comparatively more over-filled canals (26.6%) and it was statistically significant (\( P \) value of 0.001 and 0.002 respectively). Kedo-S also had the highest optimal fill (56.7%) but was not statistically significant (\( P \) value of 0.881) [Table 2].

The intensity and duration of post-operative pain related to root canal preparation using the three groups at multiple time intervals, after 6 hours, 12 hours, 24 hours, 48 hours, and 72 hours are shown in Table 3. At 6, 12, 24, and 48 hours, the intensity and duration of pain was similar in all the groups and there was no significant statistical difference between the groups and within the groups studied, regardless of the quality of obturation (\( P > 0.05 \)). At 72 hours, children reported with no pain in any of the groups investigated. In all these three groups, the severity and duration of post-operative pain were found to be less over the period of time.

![Figure 2: Four-point facial pain intensity rating scale used in this study](image)

### Discussion

The primary and the ultimate objective of pulpectomy is to prevent further destruction of the teeth, thus preventing the early loss of primary teeth.\([15]\) A successful root canal therapy depends on complete hermetic seal preventing the ingress of bacteria into the root canal space. Chemico-mechanical preparation and adequate obturation of the root canals remains a crucial factor in clinical success of pulpectomy.\([16]\) The manual instrumentation using K-files were used in root canal preparation of primary teeth for...
many years. Due to its inefficiency in cleaning the root canals, many rotary files were introduced and are being used recently for pulp therapy, which produces uniform taper throughout the root canals. Primary molars have bizarre root canal anatomy with narrow ribbon shaped canals which makes root canal preparation cumbersome. Ni-Ti rotary instruments show greater resistance to fracture as it is flexible and also minimizes transportation. The instrumentation using rotary file system is proved to be time efficient with less flare ups when used in curved root canals. Barr et al. reported that the use of rotary file system in primary teeth which showed consistent obturation throughout the root canal. In the literature there are various in vitro and in vivo studies comparing the quality of obturation with different rotary instrumentation.

In our study, we compared the quality of obturation between instrumentation done using hand K-file, Kedo-S and K3 file which showed statistically significant difference with Kedo-S in relation to less under-filled canals and comparatively more over-filled canals. In the present study, K3 files were used as it has less screw in effect in an asymmetrical cross section thereby reducing instrument binding and fracture. An in vitro study comparing the cutting efficacy of K3 files concluded that K3 rotary file system has adequately maintained original root canal curvature compared to manual instrumentation.

Kedo-S file has shorter length and variable taper resulting in adequate enlargement of the root canal at the coronal and apical third. These properties of Kedo-S rotary system aids in minimal over filling of root canal space during pulpectomy. In a study done by Romero et al., comparing manual instrumentation with K3 rotary files, they found a significant difference in the quality of obturation with rotary instrumentation.

In vitro study done by Pathak S et al., compared the cleaning efficacy of manual instrumentation and two rotary systems and found that rotary file system showed better cleaning efficiency in coronal and middle one-third of the root canals compared to other preparations.

In vitro study by Deshpande AN et al., showed complete filling of the root canals with rotary instrumentation whereas, in hand file group the quality of obturation was found to be unsatisfactory.

In this present study, there was no significant difference in the quality of obturation of the primary teeth using two types of rotary files and hand K files. This is in accordance with the study comparing K3 rotary files with hand K file, which reported that there is no significant difference seen between the groups.

Postoperative pain evaluation and management is an important aspect of root canal treatment as it may influence the positive behavior of the child. Single visit pulpectomy was carried out throughout this study to ensure standardization. Single visit pulpectomy was also found to exhibit less intensity of pain compared to multi-visit pulpectomy. Root canal preparation using rotary Ni-Ti files promotes more uniform obturation of the root canals and the crown down technique used reduces the extrusion of debris into the peri-apical area thereby reducing inflammation. The most important factor which is responsible for postoperative pain and swelling is the extrusion of debris into the periapical region. Therefore, this study also compared the intensity and duration of postoperative pain followed by three different types of root canal preparation and obturation in mandibular primary molars. The intensity of postoperative pain after pulpectomy were similar in both manual and rotary instrumentation groups. There was no statistical significant difference seen between the groups. In contrary, in a study done by Topcuoglu et al., 2017 showed significantly higher intensity of postoperative pain with manual root canal preparation compared to rotary files. While evaluating the duration of pain, highest number of children reported greatest pain at six hours after treatment which gradually decreased over time. The limitation of the study includes, distinguishing the source of pain caused during rubber dam isolation during postoperative pain evaluation. Only two-dimensional evaluation of the quality of obturation was performed in the current study using intraoral periapical radiograph. Long term follow up is required to assess the clinical and radiographic success of the pulpectomy procedure performed.

**Conclusion**

Within the limitations of the present study, the quality of obturation was better with Kedo-S pediatric rotary files compared to hand K-files and K3 rotary files, as it showed significant difference in relation to less underfilled canals and comparatively more overfilled canals. Based on post-operative pain, there was no significant difference observed among the groups.

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**Conflicts of interest**

There are no conflicts of interest.

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