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Evaluate the efficacy of NiTi rotary pedo file systems versus manual instrumentation to reduce bacterial count in primary molars- a randomised clinical trial

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Abstract

Background: The main reason for endodontic failure is the presence of some species of bacteria inside the root canal system such as E. faecalis. E. faecalis was selected because it has the ability to tolerate harsh conditions.

Aim: The aim of present study was to evaluate the effectiveness of K File, Kedo SG Blue and Pro AF Baby gold in reducing E. faecalis within the root canals of primary molars.

Method: Total 60 canals (20 teeth) were divided into 3 groups- Group1- K file, Group2- Kedo SG Blue, Group3- Pro AF Baby Gold. Before and after instrumentations samples were collected with paper points. Samples were transferred to laboratory in BHI broth. All samples were inoculated into Arabinose sugar agar plate and keep it into Incubator at 37°C for 48 hours. The colony of E. faecalis was counted with digital colony counter.

Result: The result showed that E. faecalis were found from 36 (60%) canals. All the file system effectively reduced the E. faecalis count However Kedo SG Blue performed better when compared with Pro AF Baby Gold and K file.

Conclusion: All the three instrumentation systems for root canal debridement effectively reduced E. faecalis counts, but there were no significant differences between them. Kedo SG Blue showed greater percentage reduction of E. faecalis.

Keywords: Arabinose agar media, E. faecalis, Kedo SG Blue, Pro AF Baby Gold.

Introduction

Early primary tooth loss can create a variety of issues; hence primary dentition should be preserved in the dental arch. The primary goal of chemical and mechanical biomechanical preparation treatments is to eliminate bacteria, their by-products, and their substrates during endodontic therapy by disturbing and eliminating the microbial environment.[1] Several studies showed that E. faecalis was found 25 % cases of failed endodontic treatment in primary teeth.[2] It is a gram positive facultative anaerobic type, has ability to tolerate harsh conditions, remain viable in treated root canals for a long time.[3] The success of pulpectomy to quite an extent depends upon the elimination of irritants by cleaning and shaping of root canals.[4] According to Finn, primary tooth dentin is softer but less thick than permanent tooth dentin, and roots more divergent, shorter, and thinner, with more auxiliary and tortuous ribbon-like canals and frequently undetected root tip resorption.[5] Since a primary molar has complex root canal anatomy, it was difficult to remove all the bacteria from the *canals*, *thus* newer advances in the pediatric rotary file system were introduced to reduce the chairside time and effectively remove the bacteria from the root canals. Recent advance in pediatric endodontics includes Kedo SG Blue, Pro AF Baby Gold and other file systems to name a few. Kedo SG Blue file system has three Ni-Ti rotary files D1, E1, and U1 and the total length of files is 16 mm. (Fig 1) All the files are heat- treated and have controlled memory (CM). The ideal rotational speed is 250 - 300 RPM and the torque required is 2.2 - 2.4 N.[6] Pro AF Baby Gold file consists of 5 files B1, B2, B3, B4, B5 and the total length of file is 17mm to improve the shaping of canals with a sequential combination of 4% and 6% taper files. (Fig 2) All the files are heat-treated and made up of NiTi controlled memory (CM) wire.[6] There are very *few* in-vivo studies conducted to assess the efficiency of rotary NiTi files in the removal of bacterial *load* from root canals of the primary molars. Therefore this study was undertaken to assess and compare the efficacy of three file systems Kedo SG Blue, Pro AF Baby Gold and K file.

Method

The current investigation was a randomised clinical trial conducted in the Department of Pedodontics and Preventive Dentistry and Department of Microbiology. The ethical approval for the study was obtained from the K D Dental College Mathura (U.P.). The sample size was calculated with expected prevalence of 50% and absolute precision of 10%. The final sample size was estimated to be a minimum of 42 canals. Thus, the final sample size of present study was 60 canals (20 mandibular molars) and equally distributed into 3 groups. All the patients requiring pulpectomy procedure between the age group of 4–12 years visiting in the Department of Pedodontics and Preventive Dentistry were included in the study. The informed consent was obtained from parents or caretaker by providing them with detailed written information that was duly signed by them thereby permitting the participation of their children. The privacy and confidentiality of all subjects were maintained. All necrotic posterior teeth with minimum of 2/3rd root structure remaining, sufficient crown structure for rubber dam, and crown placement were included in the study. Patients who did not provide informed consent, root resorption more than 1/3 rd of the actual root length, non-restorable tooth, pathological mobility, Patients who received antibiotic therapy in the preceding 3 months, patient with systemic illness were excluded from the study. This research study is single

blinded. Participants were not aware about their groups and the treatment protocol. Using a clinical and radiographical examination, pulpectomy indicated cases were chosen for the study. After following proper sterilization, the procedure was started following administration of Local anesthesia. Rubber dam isolation was done for better accessibility. Access opening was done after initial caries removal followed by coronal and radicular pulp removal, an approximate working length was derived by superimposing the file over a periapical radiograph, terminating approximately 1 mm short from the root apex using ingle's method. Before instrumentation initial sample for the bacterial count was taken from each canal of molars by placing sterile 15 no. paper point and allow saturated for 30 seconds and place into a sterile vial containing 4.5 ml of BHI broth. The 60 canals (20 mandibular primary molars) were systematically assigned to three groups 20 canals in each. Group A- K file- 20 canals, Group B- Kedo SG Blue- 20 canals, Group C- Pro AF Baby Gold- 20 canals. All the file systems were used in mesiobuccal, mesiolingual, and distal canal in a systematic manner. Every first tooth was assigned to group A for mesiobuccal canal, group B for mesiolingual canal, and group C for distal canal. Every second tooth was assigned to group A for mesiolingual canal, group B for distal canal, and group C for mesiobuccal canal. Every third tooth was assigned to group A for distal canal, group B for mesiobuccal, and group C for mesiolingual canal. Irrigation between the instrumentation was done with the saline. *Second sample was* taken with sterile paper points to evaluate the reduction in *the bacterial count* and place into a *sterile vial* containing 4.5 ml of BHI broth. Thus total of 6 Samples were taken from 3 canals (3 samples prior to instrumentation and 3 after instrumentation). These samples were transferred to the laboratory in BHI broth within 30mins to 2 hours after collection.(Fig 3)

Laboratory Procedure

Arabinose agar was prepared by adding 27.05 grams of Arabinose agar base into 500 ml of distilled water and heated to dissolve the medium completely. After cooling it to 45-50 ^{o}C, rehydrate one vial of E. faecium selective supplement with 5 ml sterile distilled water and added to 500ml of Arabinose agar base. After proper mixing, it was poured onto sterile petriplates and used for inoculation of the samples.

Collection and processing of samples

All 6 samples with sterile paper points collected in 4.5ml BHI broth were homogenized in a vortex mixer for 3 minutes. Following homogenization, six-fold dilutions in sterile BHI broth were prepared and divided into 3 aliquots. Each aliquot was homogenized for 30 seconds in a vortex mixer and inoculated into an Arabinose agar plate with the help of a micropipette and incubated aerobically at 37 ^{o}C for 48 hours. The total count of viable E. faecalis was counted with the digital colony counter after 48 hours. In an Arabinose agar media, E. faecalis appears as colourless pink colonies.(Fig 4)

The obtained data was subjected to statistical analysis using statistical package for social sciences version (SPSS) Master 26.0 software. The power of the study was taken to be 80%. The test was performed at 95% confidence level with level of significance set P=0.05 (95%). $p< 0.05$ was significant and $p> 0.05$ was insignificant. To check the differences between groups paired t-test was used. The mean of pre-operative E. faecalis count was compared between all three file systems by using the one way anova test. The inter-

group comparison of mean post-treatment E. faecalis count was done using the Post-hoc bonferroni test.

Result

E. faecalis count was found to be positive among 36 (60.0%) canals out of 60 canals.(Table 1) The mean E. faecalis count decreased significantly from pre to post treatment in the all groups. (Graph 1) A highly significant difference (P= 0.001) were found among all three file systems after the instrumentation. (Table 2,3,4) There was no significant difference in mean of pre-operative and post operative E. faecalis count between K-file, KEDO SG BLUE and PRO AF BABY GOLD FILE. (Table 5,6) There was no difference in mean post-treatment E. faecalis count was found for the inter-group comparisons.(Table 7) There was no significant difference in mean percentage difference in E. faecalis count from pre to post-treatment between K-file, KEDO SG BLUE and PRO AF BABY GOLD FILE (Graph 2)

Discussion

Endodontic infections in a deciduous root canal are associated with a wide diversity of microorganisms. The main reason for endodontic failure is the presence of some species of bacteria inside the root canal system such as Enterococcus faecalis.[7] Cogulu et al,[8] Cancio et al,[2] Gomes et al,[9] Oncag et al,[10] Wang et al,[11] Dutta et al,[12] Mitrakul et al,[13] reported that the 14-83% of E. faecalis were found in the infected root canals of primary teeth. Similarly, in the present study, E. faecalis was found in 60% (36) of canals out of 60 canals. In this study, mandibular molars were used because they are easy to access. Studies by Machado et al,[14,15] Demiryurek et al [16] and Ramazani et al [17] done in context with the present study was limited to just to one root canal of primary molars. However, the efficiency of files should be checked for all the canals. In the present study, instrumentation was done for all the canals with different file systems in a systematic manner.

Barakat et al [18] observed saline has least antibacterial efficacy, while comparing the antibacterial effect of 0.5% metronidazole, 2% chlorhexidine, and normal saline irrigant solutions against E. faecalis bacteria. It is a known fact that other chemical irrigants give bias result, thus in the present study saline was used as an irrigating solution which has no antibacterial action. Therefore, result of bacterial elimination depends only on the mechanical action of instruments.

The methodology adopted for the collection of sample was in resemblance with the studies conducted by Pinheiro et al[19] and Subramaniam et al [20] where samples were collected using paper points and placed into their choice of transport media. Whereas, our choice of transport media is BHI broth similar to Seelan et al [21] and Pinheiro et al [22] since BHI broth supports good growth of many fastidious and non-fastidious anaerobic bacteria isolated from clinical specimens. There are many methods for the detection of E. faecalis from the root canals such as polymerase chain reaction (PCR), DNA extraction, and culture. Ford et al [23] reported Cephalexin-aztreonam-arabinose agar (CAA) is better to identify E. faecium from other enterococci species.

Rotary instrumentation in primary teeth has several drawbacks, such as the high cost of NiTi instruments, the need to discard the files regularly, and the need for operator training. Conversely, rotary systems require shorter instrumentation time than manual techniques. This is important in paediatric dentistry because it enables for faster procedures while maintaining quality and safety, as well as Minimising patient and professional tiredness.[19] Thus, the efficiency of the NiTi file systems in reducing in bacterial count was checked.

When Pinheiro et al[19] compared the cleaning performance of manual, hybrid, and NiTi rotary instrumentation techniques in primary teeth, they found no significant differences. A similar result was observed in the present study, which showed a significant reduction in *E. faecalis* count after instrumentation. However, no much difference was observed between Kedo SG Blue, Pro AF Baby Gold, and Hand K file. The results are similar to Neto et al [24] who compare protaper and manual K file. The mean percentage of reduction in E. faecalis count after instrumentation with K file, Kedo SG Blue, Pro AF Baby Gold was 47.17%, 54.81%, 50.51% respectively. Even though no much difference but when compared Kedo SG Blue showed a greater percentage in the reduction of E. faecalis count. Kedo SG Blue showed better results because it is a single file system hence it reduced instrumentation time, influencing the behaviour and co-operation of the child in the dental chair and thereby reduces fatigue caused in the operator due to shorter working hours, resulting in faster delivery of treatment.[25] Since only 36 canals (60%) were positive with E. faecalis count, therefore more elaborated sample size may achieve variation from results as reported in a literature.

Conclusion

Good instrumentation, whether manually or rotary can achieve mechanical disinfection. Rotary NiTi files were as efficient as manual K file instruments in reducing the root canal micro flora. But percentage wise Kedo SG Blue gave better performance than Pro AF Baby Gold and manual K file. Single file systems show better acceptance and performance. Emphasising the fact that, NiTi rotary files is an option for root canal instrumentation in primary teeth. However, mechanical instrumentation alone is insufficient to eliminate root canal infection, the use of complementary combination of antibacterial agents such as Sodium hypochlorite (NaOCL), Ethylenediaminetetraacetic acid (EDTA) and Chlorhexidine (CHX) is necessary.

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Legends of Figures

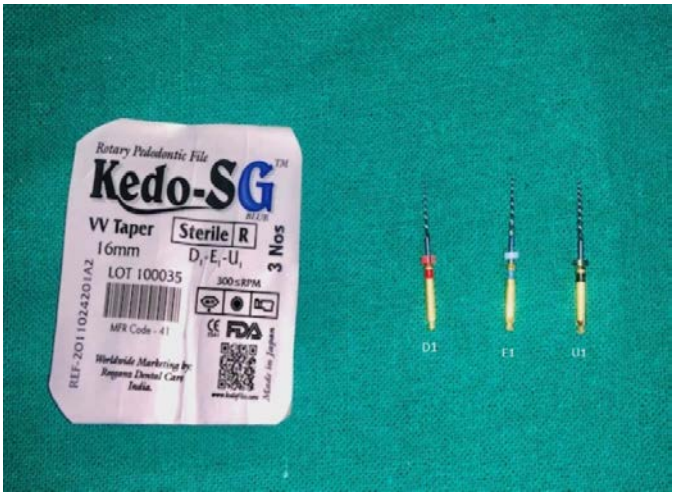


Fig. 1: Kedo SG Blue

Fig. 2: Pro AF Baby Gold

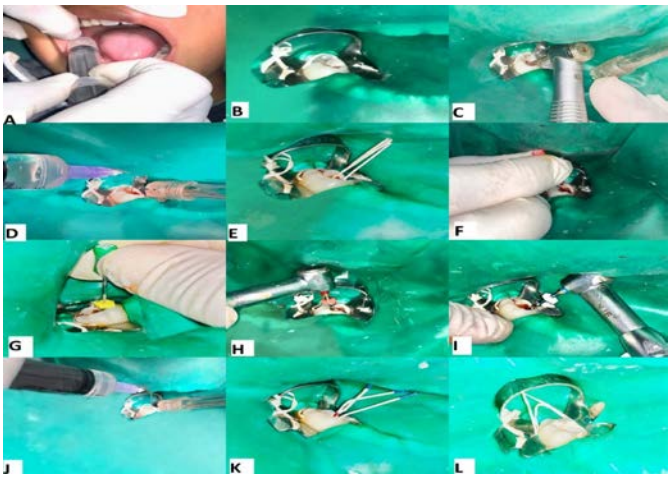
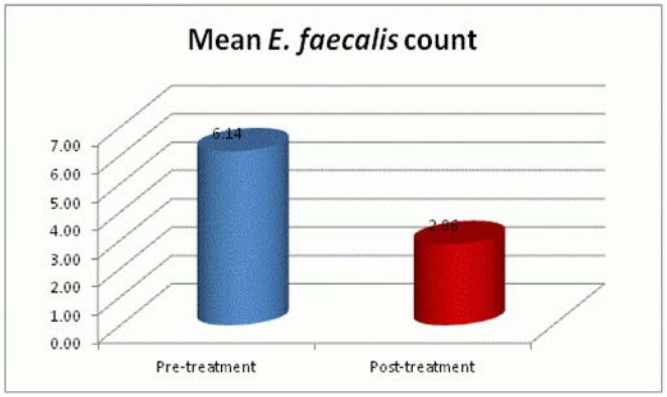


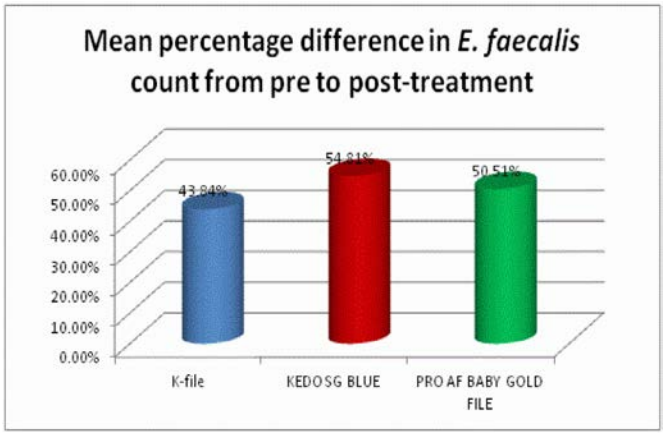
Fig. 3: Clinical procedure of pulpectomy using manual, rotary files systems and sample collection : (A) L A administration (B) Rubber dam isolation (C) Acess opening irt 85 (D) Irrigation with saline (E) Initial sample collection (F) Prepared all canals till 25 no. (G) prepation of distal canal with K File (H) Preparation of mesiobuccal canal with Kedo SG Blue (I) preparation of mesiolingual canal with Pro AF Baby Gold (J) irrigation with saline (K) 2nd sample collection (L) temparary restoration done.

Fig 4: Laboratory procedure**:** (A) Collected sample (B) Homogenization of sample for 3 mins (C) Incubated

aerobically at 37 ^{o}C for 48 hours (D) After 48 hours colonies of E. faecalis was counted with the digital colony counter.



Graph 1: Compare the reduction of E. faecalis count between pre and post treatment among all groups.



Graph 2: Mean percentage difference in E. faecalis count from pre to post-treatment among all groups.