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ORIGINAL RESEARCH

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Comparative evaluation of volumetric changes between two pediatric rotary files (Kedo-S plus, Kedo-SG blue) and manual files (hand K-files) during canal preparation of primary mandibular molars: an *in-vitro* nano-CT analysis

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Abstract

Pediatric endodontics has become popular due to advancements in cleaning, shaping and irrigation systems, resulting in faster and effective removal of infected pulp, saving time, and creating a pathogen-free environment. The patented rotary file system, Kedo-S, designed for primary teeth, introduced a single file generation for efficient pulp therapy. However, there are currently no studies assessing canal preparation in primary mandibular molars using nano-CT (computed Tomography). To evaluate the volumetric changes of two recently introduced pediatric rotary file systems in comparison with conventional hand file systems in primary mandibular molar using an ultra-high resolution nano-CT. This *in-vitro* study was performed in extracted primary mandibular molar based on certain inclusion and exclusion criteria. Samples were prepared and working length was determined before the pre-operative scan using a high resolution nano-CT device (SkyScan 2214, Bruker, Kontich, Belgium). A single well-experienced pediatric dentist prepared the canals using three file systems: Kedo-S plus, Kedo-SG blue and Hand K-files. A post-operative scan was performed similar to pre-operative scan. Image reconstruction was performed with NRecon software for 3D volumetric visualization and analysis of the root canals. Kedo-SG blue file systems had the highest mean difference in the canal volume (8.85%). Hand K-files had the least difference at (1.24%) of canal volume. Kedo-S plus file system had a mean canal volume difference (6.14%) which is closer to hand K-files. Rotary file systems resulted in a significant enlargement of canals compared to hand files.

Keywords

Volumetric change; Pediatric endodontics; Mandibular molars; Nano-CT; Kedo-S plus; Kedo-SG blue; K-files

1. Introduction

Dental caries is the most common disease that occurs worldwide even with a good preventive care system. Awareness should be created to pregnant mothers about the need to maintain the oral health of primary dentition as good as permanent dentition [1]. The pediatric dentist plays a pivotal role in providing awareness, prevention and treatment to those affected by dental caries [2, 3].

The treatment sequelae of dental caries in primary dentition varies from preventive resin restoration to pulpectomy, depending on the extent of dental caries. Pulpectomy is considered to be an invasive procedure in the pediatric population as it includes various steps such as: local anesthesia application, isolation of the tooth, removal of caries, access opening, obtaining patency of the canal, working length determination, cleaning and shaping, obturating and giving a suitable coronal seal [2, 4].

Cleaning and shaping is the step where constant update is done by the researchers [5, 6], conventionally the instruments were made of stainless steel metallurgy which is more stiffer that makes it difficult to access the curved canals. Later with the introduction of Nickel Titanium made instruments which are more flexible which drastically reduce procedural errors [7, 8].

Hand filing instruments, if not used cautiously, leads to ledging of the canal and apical blockage by dentinal shaving. It is also time consuming and not ergonomic for the operator. The engine driven filing system is a major boon in the field of endodontics [9]. The engine driven files are made by various

manufacturers around the world with the different metallurgies, length, diameters, cross section. The operators select their files depending on the anatomy of the canal, length of the canal, which are completely different in primary dentition [10, 11].

There are no specific rotary files available for pediatric endodontics until 2017. First rotary file system designed to specially suit the anatomy of the canals of primary dentition was Kedo-S [12]. There are various generations of files introduced by this specific manufacturer with different metallurgies, cross sections and diameters. Kedo-SG blue is a third generation Kedo rotary file system which has a heat treated titanium coated metallurgy. It is a two-file system for use in molars. The fifth and the latest generation is Kedo-S plus, a single file system with a combination of two metallurgies. Newer generations of file systems with dynamic innovative technologies ascertain periodic evaluations for their efficiency by laboratory and clinical means.

The constant evolution of imaging techniques from simple two dimensional images to three dimensional imaging systems that is from simple radiographs, cone beam computed tomography images, micro-computed tomography images. The micro-computed tomography images are non-destructive and three dimensionally reconstructable which helped to assess the various files and filing techniques [13–15].

Around 40 years ago, x-ray micro-computed tomography (micro-CT) was introduced as a non-destructive and reproducible three-dimensional technique for assessment [16]. Over the past two decades, micro-computed tomography technology has revolutionized the development and evaluation of rotary file systems in dentistry and endodontics [17, 18]. Recently, nano-computed tomography devices with incredibly high spatial resolution with a nano-focal spot source of less than 400 nm have been launched, which have been widely used in the medical field to visualize bone cells, cartilage, and vascular networks [19]. These nano-computed tomography devices, with their state-of-the-art precision rotational unit, flat panel detector, and excellent contrasting features, have been proposed to be superior to micro-computed tomography devices. Although nano-computed tomography has been used in dental research for implants and restorative dentistry, there are currently no studies on its use for assessing canal preparation in primary teeth. Therefore, this study aims to evaluate the volumetric changes of two recently introduced rotary files for primary dentition in comparison with traditional hand file systems in primary mandibular second molar using ultra-high resolution nano-computed tomography.

2. Materials and methods

2.1 Study design and ethical clearance

The design of this study is *in-vitro*. The study was done in the department of pediatric and preventive dentistry of a dental college and hospital. The sample size was computed using the G power algorithm. This was performed from the data obtained from the results of the previously published research conducted with a similar methodology at 95% power with a significance level of 0.05 [17, 20]. The calculated sample consisted of 60 primary mandibular second molars across three groups (twenty teeth per group).

2.2 Study sample

The samples used in the study were primary mandibular second molars. The teeth were extracted due to retained primary teeth (orthodontic treatment) and symptomatic decayed teeth in which the parents were not willing for pulp therapy for their child. The parents or guardian were informed that the extracted teeth would be used for research purposes and a consent form was signed by the parents or the guardian. The extracted teeth were rinsed under tap water. The soft and hard tissue debris were removed using ultrasonic scaler tips. Disinfection was done using 10% formalin solution in which the teeth were kept for one minute and the samples were transferred to specimen containers filled with distilled water till the initiation of the study [21]. All the teeth were subjected to visual and radiographic examination to assess theory suitability in the present study. An intra oral periapical radiograph was taken for the extracted teeth in two different angulations: perpendicular to the long axis of the tooth and slightly mesial or distal to the previous angulation. Primary mandibular second molars with presence of four canals (two mesial canals: mesiobuccal, mesiolingual and two distal canals: distobuccal, distolingual) were included in the present study. The teeth were excluded if external/physiologic resorption was noticed by visual examination; if internal resorption was noticed in any one of the canals; presence of pulp stones in any one of the canals; presence of calcified root canals; presence of any aberrant canal anatomy; and presence of only two or three canals.

2.3 Teeth sample preparation

A well experienced pediatric dentist who is regularly doing pulpectomy procedures using both hand and rotary file systems was selected to do the preparations for all three groups which also eliminates potential bias related to inter operator variability. Caries excavation was performed, and an access cavity was created using a high-speed air-rotor with a no.6 round bur from Mani Inc., Japan. The access cavity was refined until all the canals became clearly visible. To clear and flush any debris from the pulp chambers, 0.9% normal saline solution was used for irrigation, utilizing a side vented needle (30 gauge and 21 mm). Presence of four root canals was visually confirmed during this step. Any presence of an extra canal led to exclusion of the sample. To ensure patency, a size 10/0.02 taper K-file (Mani Inc., Tochigi, Japan), was introduced into the canal. The working length, determined visually using a brand new 15/0.02 taper K-file (Mani Inc., Tochigi, Japan), was noted for each sample, with the working length being set 1 mm short of the anatomical foramen. The average working length of the samples were kept approximately between 12 to 14 mm for maintaining uniformity during the preparation of the canal space.

2.4 Pre operative scan

All the prepared samples were numbered before subjecting to scanning procedure. After the initial preparation of the

samples, they were subjected to initial scanning using a high resolution nano-CT (SkyScan 2214, Bruker, Kontich, Belgium). A total of twenty putty ($3 \times 20 = 60$ teeth) index was made and three teeth were mounted to each putty index as the scanner allows only three samples to be scanned at a time. The putty index was also numbered as they will be used again during post operative scan. The samples were scanned 360° around the vertical axis in specific rotation steps of 0.3 degrees. The voltage for the x-ray source is set at 80 kv and current of 110 μA with voxel size of 1.58 μm. During the imaging process, each degree of rotation was maintained for 1200 ms, using a detector consisting of 1280×1280 pixels. This detector was selected to ensure the highest level of image accuracy. The scanning procedure of the samples approximately took 4 hours per putty index used. To guarantee the precision of the imaging outcomes, adherence to the manufacturer's instructions was observed concerning beam hardening correction and the establishment of optimal contrast limits. These adjustments were made based on initial scanning and reconstruction tests. After the initial scan the samples are randomly allocated to three groups (*i.e.*, 20 mandibular molars in each of the group) using block randomization method.

2.5 Root canal preparation

All the four canals were prepared using the following instrumentation protocol. The initial preparation involved the use of a new size 15/0.02 taper K-file (Mani. Inc., Tochigi, Japan) according to the manufacturer's recommendation, before introducing rotary files into the canal. Throughout the preparation process, a lubricant called 15% ethylene-diamine-tetra-acetic acid (RC Help, Prime Dental Products Pvt Ltd, Thane, India) was used in all sample groups. When changing the file sequence in all groups, irrigation was performed using saline solution. In this study, brand new files were employed to prepare each tooth sample; *i.e.*, one pack of files were used to prepare one tooth sample with four canals. The canal preparation was performed using three different file systems as described below (Fig. 1).

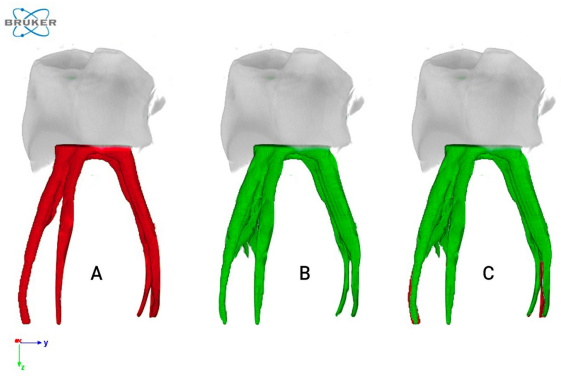

FIGURE 1. Three dimensional processed image of the tooth model prepared using the file system Kedo-S plus. (A) Preoperative image; (B) Postoperative image; (C) Superimposed image of pre and post operative images. Note the middle and apical thirds of the canal space had untouched regions, while the coronal third showed complete preparation of the canal.

• In Group 1, the Kedo-S P1 Plus rotary file (Kedo Dental, India) was utilized according to the manufacturer's instructions. The file was operated at 300 rotations per minute (rpm) and 2 Newton-centimeters (Ncm) torque using an electronic endomotor (XSmart, DENTSPLY India Pvt. Ltd., Delhi, India). The canals were prepared using the crown-down technique, employing pecking motions directed towards the apex until reaching the working length. Once the working length was achieved, a brushing motion was performed twice in the buccal and lingual directions to eliminate any remaining debris in the canal.

• In Group 2, the Kedo-SG blue rotary files (Kedo Dental, India) were utilized in a specific sequence according to the manufacturer's instructions. The files were operated at 300 rotations per minute (rpm) and 2 Newton-centimeters (Ncm) torque using an electronic endo motor (XSmart, DENTSPLY India Pvt. Ltd., Delhi, India). The canal preparation began by using the Kedo-SG blue D1 file in a pecking motion directed towards the apex until the working length was reached. Saline irrigation was performed, followed by the use of the Kedo-SG blue E1 file in a similar pecking motion. Once the working length was achieved, a brushing motion was performed twice in the buccal and lingual directions to eliminate any remaining debris in the canal.

• In Group 3, hand K-files (Mani Inc., Japan) were used for biomechanical preparation. The quarter turn and pull motion was employed with stainless steel hand K-files. The instrumentation sequence included file sizes of 20/0.02 taper, 25/0.02 taper, 30/0.02 taper, and 35/0.02 taper, continuing until the predetermined working length was reached. Irrigation was performed after each increase in file size during canal preparation.

2.6 Post operative scan

After the completion of the root canal preparation, the samples were carefully placed back into their respective putty indices. Subsequently, the samples underwent nano-CT scanning, following a similar protocol as the pre-operative scan analysis described earlier. During the scanning process, the volume of each canal in all the samples was calculated, starting from the canal orifice and extending 1 mm short of the apical foramen. This volumetric analysis allowed for a quantitative assessment of the changes in canal volume resulting from the root canal preparation procedure.

2.7 Imaging reconstruction and processing

For image reconstruction, NRecon software (ver. 2.1.0.2, SkyScan, Kontich, Belgium) was utilized. This software employed a specific algorithm to generate two-dimensional, 1000×1000 pixel axial images. During the reconstruction process, the settings for ring artifact correction and smoothing were kept at zero, ensuring minimal alteration of the original image data. The resulting images provided a clear visualization of the root canal anatomy in three dimensions.

Following image reconstruction, CTAn software (ver. 1.21.2.0, Skyscan, Aartselaar, Belgium) was employed for the 3D volumetric visualization and analysis of the root canals. This software facilitated the examination and measurement of

the canal volumes, allowing for a comprehensive analysis of the changes in canal morphology resulting from the root canal preparation procedures. The combination of NRecon and CTAn software enabled accurate and detailed visualization and analysis of the root canal structures in a three-dimensional format.

2.8 Data collection and statistical analysis

The volumetric data obtained from the prepared root canals were collected and organized in a Microsoft Excel spreadsheet. The preoperative and postoperative root canal volumes were recorded, and the difference in canal volume for each sample was calculated. The collected data were analyzed, and the results were presented as mean values along with standard deviations. The statistical analysis was conducted using Statistical Package for Social Sciences software (SPSS version 17, SPSS Inc., Chicago, IL, USA). One-way ANOVA (analysis of variance) and *post-hoc* tests were employed to assess the statistical significance when comparing within-group and between-group differences. A p-value of less than 0.05 was considered statistically significant, indicating a significant difference between the compared groups or conditions.

3. Results

The mean working length of the teeth samples were 13 $\pm$ 0.6 mm. Upon comparing the pre-volumetric and post-volumetric changes in all the samples across the different groups, it was observed that the Kedo-SG blue group exhibited the highest difference in canal volume, followed by the Kedo-S plus group, and then the hand K-files group. This difference was found to be statistically significant ($p < 0.001$). The Kedo-SG blue file system had the highest mean difference in canal volume, with an average change of 8.85%. On the other hand, the hand K-file group showed the least difference, with a mean change of 1.24% of the canal volume. The Kedo-S plus group exhibited a mean canal volume difference of 6.14%. These findings are summarized in Table 1, providing a clear overview of the differences in canal volume changes among the different file systems used in the study.

The intergroup comparison between the three file systems revealed that the mean difference in canal volume was statistically significant ($p < 0.001$) among all the groups. This indicates that there were significant differences in canal preparation among the three file systems. Table 2 provides a detailed summary of the statistical comparisons. Figs. 1,2,3 displays the 3D processed image of the tooth model prepared using different file systems used in the present study.

4. Discussion

Chemomechanical preparation involves use of irrigating agents and the mechanical preparation that helps to remove the bacteria, tissue debris, infected dentinal regions, thereby ensuring a sterile canal space which is ready to receive suitable filling material [22–25]. For pediatric endodontics, the usage of rotary files used for permanent teeth has become very common. Previous published research on comparing

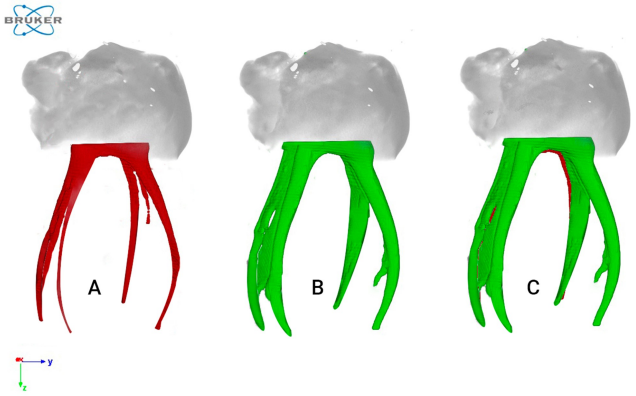

FIGURE 2. Three dimensional processed image of the tooth model prepared using the file system Kedo-SG Blue. (A) Preoperative image; (B) Postoperative image; (C) Superimposed image of pre and post operative images. Note the preparation appears more extensive and uniform along all the surfaces of the root canal.

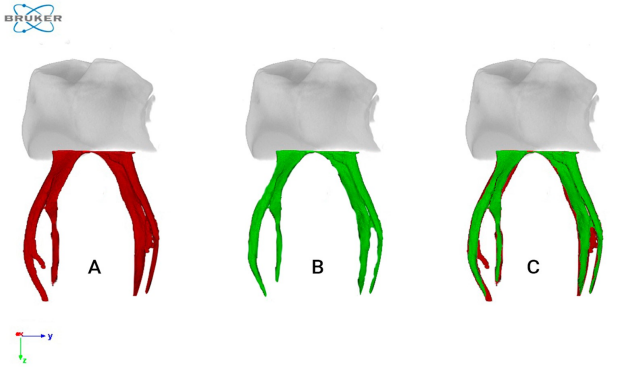

FIGURE 3. Three dimensional processed image of the tooth model prepared using the file hand K-file system. (A) Preoperative image; (B) Postoperative image; (C) Superimposed image of pre and post operative images. Note that there was minimal preparation and a greater number of untouched regions.

reciprocating file (Wave-One) with continuous rotation (MTwo) showed no significant difference in preparation of canal [26]. Another study based on stereomicroscopic analysis between two rotary files (MTwo and ProTaper) with hand K files showed significant difference in cleaning efficiency of the canal [25]. Other studies suggest coronal third preparation with rotary file (ProTaper) and apical preparation with hand file provide good results in cleaning and shaping of primary root canals [27–29]. All the results say neither reject or approve the usage of rotary files used for permanent teeth for pediatric endodontics.

The brand, Kedo-S, introduced the very first rotary file systems designed to effectively clean the canals that are complicated and ribbon-shaped root canal spaces of deciduous teeth. These rotary files were crafted with specific flute designs, cutting lengths, and cross-sections to cater to the unique requirements of cleaning and shaping primary teeth. In comparison to ProTaper and K files, Kedo-S demonstrated superior

TABLE 1. Comparison of pre- and post-volumetric changes within groups.

Group	Mean Pre-op canal volume ± SD (mm^3)	Mean Post-op canal volume ± SD (mm^3)	Mean difference in canal volume ± SD (mm^3)	Percentage of change in canal volume (%)	*p*-value
Group 1 (Kedo-S plus)	1779.21 ± 0.12	1892.09 ± 0.59	112.87 ± 0.47	6.14%	<0.001
Group 2 (Kedo-SG blue)	2296.73 ± 0.34	2509.60 ± 0.69	212.87 ± 0.35	8.85%	
Group 3 (Hand K-file)	3772.64 ± 0.41	3819.80 ± 0.84	47.15 ± 0.43	1.24%	

$p < 0.05$. SD: Standard deviation.

TABLE 2. Intergroup comparison of pre- and post-volumetric changes between groups.

Group	Mean difference (I-J)	*p*-value
Group 1 (Kedo S-plus)	Group 2 (Kedo SG blue)	<0.001
	Group 3 (Hand K-file)	<0.001
Group 2 (Kedo S-plus)	Group 1 (Kedo S-plus)	<0.001
	Group 3 (Hand K-file)	<0.001
Group 3 (Hand K-file)	Group 1 (Kedo S-plus)	<0.001
	Group 2 (Kedo SG blue)	<0.001

cleaning and shaping capabilities in the coronal and middle thirds of the root canals [30]. Computed tomography (CT) analysis revealed that Kedo-S had a comparable amount of dentin removal to Mtwo but demonstrated minimal perforation ability and faster canal preparation [31]. In the present study, the researchers utilized the third and fifth generation rotary Kedo Files for their investigation. These files include Kedo-SG blue and Kedo-S plus, both of which are 17 mm in length and made of NiTi (Nickel Titanium). They have undergone heat treatment and possess a variably-variable taper. Kedo-SG blue consists of two files for primary molars: D1, designed for slender canals; and E1, intended for wider canals. These files are coated with titanium oxide, enhancing their flexibility and fracture resistance. On the other hand, Kedo-S plus consists of a single file: P1 plus, employed for primary molars. These files have a dual metallurgy design, whereby the coronal half of the file undergoes heat treatment, while the apical half undergoes heat treatment along with an additional titanium oxide coating.

Hülsmann *et al.* [32] proposed several parameters for assessing the cleaning and shaping ability of endodontic instruments, such as canal transportation, untouched surface area, and working time. In this particular study, the change in volume of the canal was chosen as the parameter, as it is completely dependent on the design of the file being used [32]. The findings of the study can be solely attributed to the design of the file system used since all the preparations were performed by a single operator. Primary mandibular molars were selected in order to assess the files' performance in preparing narrow and tortuous canals, thus enabling the evaluation of the file designs' ability in canal preparation. Nano-CT is an emerging radiographic technology that provides highly defined voxels and more accurate imaging compared to micro-CT. With advancements in ultra-high spatial resolution, nano-CT offers a more detailed visualization of cellular structures.

In the present study, both hand files and rotary files demonstrated significant and predictable canal shaping. The mean difference in volume was found to be higher for Kedo-SG blue compared to Kedo-S plus. This can be attributed to the bulky core design of Kedo-SG blue, which facilitates uniform canal preparation in all dimensions. On the other hand, the Kedo-S plus group showed a mean difference in canal volume, closely resembling hand K-files. The higher volumetric change observed in the coronal third of the canal can be attributed to the dual metallurgy design of Kedo-S plus files. The coronal half of the file is stiffer and less flexible compared to the apical half, which consequently leads to more preparation in the coronal third of the canal. Surprisingly, the hand K-file group exhibited the least percentage of volumetric change, contradicting the results of previous studies where more dentin removal was observed in the coronal and middle thirds.

A well-prepared canal is defined as a canal that does not have any untouched areas of the rotary or hand file and maintains the original canal configuration and taper. However, the findings of our investigation demonstrated the presence of untouched regions in canals prepared using both rotary files and hand files. This finding aligns with the results of a previous study that also reported similar outcomes. In the Kedo-S plus group, untouched areas were observed at the middle and apical thirds of the root canals, specifically on the mesial or distal surfaces. This may be attributed to the brushing motion performed in the bucco-lingual direction during canal preparation, which resulted in effective preparation in that specific direction. However, the coronal third of the canals in the Kedo-S plus group did not exhibit any unprepared surfaces. On the other hand, the Kedo-SG blue group showed uniform preparation along all surfaces, which can be attributed to the wider design and cross-section of the Kedo-SG blue files

compared to Kedo-S plus. Canals prepared using hand K-files displayed a greater number of untouched regions, indicating under-preparation of the canals when conventional hand files were used. This finding is consistent with the results reported by Metzger *et al.* [33] and Zhao *et al.* [34]. One possible explanation for this observation is the structural nature of the primary mandibular molars used in our study. Since primary molars tend to have narrower and tortuous canals (compared to single rooted primary teeth), hand filing may not adequately prepare the canal walls three dimensionally and tend to under-prepare the canal space.

In this study, we have employed nano-CT to analyze the volumetric changes in canal preparation in primary molars. The results of our study revealed that rotary files resulted in a significant increase in volume compared to hand files. The narrow mesiodistal dimensions of the ribbon-shaped canals in primary teeth limit the extent of gross enlargement to avoid potential lateral perforations. Therefore, using a file system that minimally prepares the canal while efficiently removing infected debris can be a suitable option [35]. However, there are certain limitations to our study, such as the relatively small sample size and the use of teeth with wider canals. Analyzing the preparation of canals in narrower roots, such as primary molars, would provide a broader perspective on the effectiveness of the preparation. It is important to note that although this *in-vitro* nano-CT analysis favored the use of the Kedo-S plus pediatric rotary file system, further *in-vivo* analysis is required to assess postoperative pain, obturation quality, and the incidence of file fractures.

5. Conclusions

Considering the limitations of the present study, it was found that rotary file systems resulted in a significant enlargement of canals compared to hand files. Kedo-SG blue demonstrated a uniform preparation of the canal, while Kedo-S plus files exhibited more coronal preparation with minimal apical preparation. However, it is important to note that further clinical assessments are necessary to better comprehend how these results might be used in clinical practice.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

BS, GJ, VR, SV and PCM—designed the research study; wrote the manuscript; supervised all steps of the research. BS—performed the research. GJ, SV and VR—provided help and advice for the research. VR, AAS, AHHJ, TD—analyzed the data. AAS, AHHJ and TD—reviewed and edited the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board (or Ethics Committee) of Saveetha Dental College IHEC/SDC/PEDO-2103/22/133. Consent to participate is not available for this study.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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