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Comparative Evaluation of Quality of Obturation using Three Different Obturation Techniques in Primary Mandibular Teeth using Endoflas as Obturating Material - A Randomized Controlled Trial

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ABSTRACT

Background

Pulpectomy is the treatment of choice for primary teeth with inflamed pulp resulting from caries or trauma. The clinical success of pulpectomy procedure is determined by the aseptic root canal preparation and hermetic seal of the root canal system. The success is also influenced by appropriate case selection, mixing of the obturation material and usage of proper technique for obturation.

Aim

To compare the quality of obturation using three different obturation techniques in primary mandibular molars using Endoflas as obturating material.

Materials and Method

The present study is a single blinded randomized clinical study conducted in 90 children between the age group of 4 and 8 years of age requiring pulpectomy in primary mandibular molars. In group 1 obturation was done using Engine driven lentulospiral in 30 teeth, in group 2, obturation was done using hand held lentulospiral in 30 teeth and in group 3, obturation was done using reamer with Endoflas as obturation material. Post-operative radiograph was taken and evaluated for the quality of obturation in terms of length of obturation, presence of voids and time taken for obturation was recorded. Independent t test and Chi square test was performed.

Results

A total of 90 children (46 females and 44 males) participated in the study. An equal distribution of the participants with respect to the age (P = 0.217), gender (P = 0.561), and teeth (P = 0.117) was observed between the groups. There is no significant difference between the three experimental groups in terms of level of canal obturation and voids (p>0.05).

Conclusion

The present study concludes that there is no difference in the quality of obturation among the three different groups when Kedo SG Blue was used for biomechanical preparation but it is preferable to use Engine driven lentulospiral as it saves chair side time.

INTRODUCTION

The primary goal of Pediatric Dentistry is the

preservation of primary teeth in a healthy state with normal function and to retain it as a natural space maintainer till their exfoliation [1,2] . Primary teeth are important not only for the normal development of the jawbone and musculature, but also for the guidance of eruption of succedaneous permanent teeth and for phonation, mastication and esthetics [3,4]. Early loss of primary teeth can lead to alteration in the eruption path of permanent teeth, development of aberrant habits, altered phonation, etc [5,6].

Pulpectomy is the treatment of choice for primary teeth with inflamed pulp resulting from caries or trauma [7]. The treatment consists of extirpation of the infected pulp tissue along with debris from the canal by thorough chemo mechanical preparation of the root canal. It is then followed by obturation of the root canal with an antibacterial, resorbable filling material to create a three-dimensional (3D) seal to prevent recurrence of bacterial infection [8,9].

The root canal morphology of the primary teeth is complex. Deposition of secondary dentin and physiological root resorption influences the anatomical forms and tortuosity of the root canal system. The complex morphology includes thin ribbon-shaped and lateral branching canals, apical ramifications, and connecting fibrils [10]. The clinical success of pulpectomy procedure is determined by the aseptic root canal preparation and hermetic seal of the root canal system[11,12]. The success is also influenced by appropriate case selection, mixing of the obturation material and usage of proper technique for obturation[8,13].

The objectives of the root canal fillings are to seal the obturation material to the root canal walls, fill the root canal completely throughout its length without voids and without extrusion of the material. The three dimensional fluid-tight seal of the root canal system is important. It hinders the micro leakage between the root canal and the periapical tissues thereby cutting off the nutrient supply to any surviving micro organism. This also prevents toxic bacterial products entering the periapical tissues. The 3D hermetic seal is necessary to prevent recurrence of infection [14].

Different obturation materials and obturation techniques are available to obtain a proper apical seal with fewer voids[15,16] . The commonly used obturating materials in primary teeth include zinc oxide eugenol paste (ZOE), calcium hydroxide [Ca(OH)2] paste, iodoform, and/or combination of these.

Endoflas is an obturating material, which is a combination of zinc oxide eugenol (ZOE), iodoform, and calcium hydroxide, introduced by Sanlor Laboratories in Colombia, South Africa. The hydrophilic property of this material can produce a perfect hermetic seal [17,18]. It showed significantly greater antimicrobial activity and the long-term substantivity of this material was found to be superior when compared to other obturating materials such as ZOE and Metapex[19]. The resorption pattern coincides with physiological root resorption. If the material is extruded beyond apex, the resorption limits only to the excess material outside the canal [20].

Various obturating techniques available include endodontic pressure syringe, lentulospiral (hand and rotary), mechanical syringe, incremental filling technique using endodontic finger or hand plugger, jiffy tube, tuberculin syringe, reamer technique, insulin syringe technique, PastInject, cotton pellet, paper point, small amalgam plugger or condenser, disposable injection technique and NaviTips[8,21,22].

The purpose of the present study was to assess the quality of obturation in mandibular primary molar teeth using hand held lentulospiral, engine driven lentulospiral and reamer with Endoflas as obturation material.

MATERIALS AND METHOD

The present clinical study was a single blinded randomized clinical trial undertaken in the Department of Paediatric and Preventive Dentistry, private dental college in Tamil Nadu, India. Ethical approval was obtained from the Institutional Ethical Committee prior to the start of the study. (SRB/SDMDS04/18/PEDO/11)**.** Sample size was calculated from a previous study by R. Singh et al. 2015 with 90% power and alpha error set at 5% using G power. Sample size was calculated to be 81(27 per group).

The study population consisted of 90 children (4-8 years) who required pulpectomy for one of the mandibular primary molars. After recording a detailed case history and full mouth dental examination, standardized intra oral periapical radiographs were taken using PSP plates showing the entire root with root apices. The complete study protocol was explained to the parents/caretakers of the study participants and a written informed consent was obtained before the start of the study. Participation of their children into the study was voluntary.

The following provides the inclusion and exclusion criteria of the study protocol.

Inclusion Criteria

- Healthy cooperative children
- Primary mandibular molars with signs of chronic irreversible pulpitis and pulp necrosis o History of spontaneous pain o Presence of inter radicular or peri apical radiolucency o Absence of internal or external pathologic root resorption o Teeth with adequate coronal tooth structure to receive preformed metal crown.

Exclusion Criteria

- Teeth with internal resorption o Teeth with more than one third of the root resorbed o Teeth which were unrestorable
- Patients with underlying systemic conditions, special health-care needs and who were uncooperative for the treatment procedure
- Parents/caretakers who were not willing to participate and those who refused to sign the informed consent

The participants were equally distributed and randomly assigned into three groups. Randomization was done according to a computer generated sequence of random numbers. The sequence was numbered in advance and was sealed in an envelope to ensure adequate concealment. As the participant was recruited into the trial, the investigator opened the sequentially arranged envelopes to determine the type of obturation technique that has to be used in that particular participant.

- Group I: Obturation using Engine driven Lentulospiral (Control) (n = 30 teeth)
- Group II: Obturation using Hand held Lentulospiral (n = 30 teeth)

- Group III: Obturation using Reamer (n = 30 teeth)

Pulpectomy Procedure

Single visit pulpectomy was performed by a single operator, who could not be blinded. Armamentarium and materials used in the study are shown in Figure 2. Topical anaesthesia was applied and Inferior alveolar nerve block was given using 2% lignocaine with 1:200,000 adrenaline (LOX* 2% ADRENALINE, Neon Laboratories limited, India) with a 2 ml syringe with needle measuring 20mm 25 gauge (UNOLOCK single use syringe, Hindustan Ltd., Chennai, India)(Figure 3). The subjective and objective signs of local anesthesia were verified before the continuation of the treatment. The procedure was carried under rubber dam isolation (GDC Marketing, Hoshiarpur, Punjab, India). All the instruments, and burs used were sterilised/disinfected. Using a number 4 round carbide bur (Dentsply Maillefer, OK, USA) in a high-speed handpiece, the superficial caries was removed. Access to the pulp chamber was gained using No. 330 high speed bur (Figure 4). Roof of the access cavity was removed using a safe ended diamond tapered fissure. Coronal pulp amputation was done with a spoon excavator. The initial orifice was located using a DG-16 explorer (Hu- Friedy, IL, USA) . No. 15 size K-file (Dentsply Maillefer, OK, USA) was used to determine the patency of the canals and the working length was determined using Ingle's radiographic method and kept 1 mm short of the apex. Biomechanical preparation was done using Kedo- SG Blue rotary files. In all the canals, instrumentation was done with D1 followed by E1. (Reeganz Dental Care Pvt., Ltd., India) aided with copious irrigation with 2.5% Sodium Hypochlorite (Novodent Equipment and Materials Ltd., Bombay, India). Final irrigation was done using normal saline (Fresenius Kabi India Pvt. Ltd., Goa, India). No. 30 sterile absorbent paper points (Dentsply Maillefer, OK, USA) were used to dry the canals.

A homogeneous mixture of Endoflas (Sanlor & Cia. S.en C.S., Colombia) was used for the obturation of the root canals. Based on the requisite and physical limitations of different delivery systems, the powder-liquid ratio was adjusted to suit the intended technique.

After the mixing of Endoflas to the correct consistency, an assistant recorded the time consumed to complete the root canal obturation with the three different obturation techniques using a stopwatch.

- Group I: Engine driven lentulospiral

A 21mm lentulospiral of size 25 mounted in a slow speed contra-angle handpiece (1,000 rpm) was used to deliver the creamy mixture of Endoflas into root canals. A rubber stopper was adjusted at the predetermined working length. The lentulospiral was smeared with cement, inserted into the canal and rotated in clockwise direction and withdrawn from the canal while still rotating. The process was repeated until the canal orifice appeared to be filled with the obturation material. A wet cotton pellet dipped in saline was used to slightly press the material.

- Group II: Hand held lentulospiral

  A 21 mm handheld lentulospiral of size 25 was held by hand. A rubber stopper was adjusted at the predetermined working length. The lentulospiral was inserted into the canal with clockwise rotation, accompanied by a vibratory motion to allow the material to reach the apex, and then withdrawn from the canal, while simultaneously continuing the clockwise rotating motion. A wet cotton pellet dipped in saline was used to slightly press the material.

- Group III: Reamer

  A 21 mm reamer of size 25 was used to deliver Endoflas into root canals. A rubber stopper was adjusted to the predetermined working length. The reamer was smeared with a fresh mix of Endoflas, inserted into the canal and rotated in counter clockwise direction accompanied by a vibratory motion. Then it was pumped up and down, with a wiping motion against the walls of the root canals. It was then withdrawn from the canal. This process was repeated until the canal orifice appeared to be filled with the obturation material. A wet cotton pellet dipped in saline was used to slightly press the material.

The stopwatch was started after the mixing of the Endoflas and stopped after compressing the material with moist cotton pellets. After the completion of root canal obturation, the access cavity was sealed with Type 2 glass ionomer cement (Shofu, Shofuinc. Japan) . The teeth were restored with stainless steel crowns (3M ESPE, Germany)

Radiographic Evaluation

A postoperative radiograph was taken immediately using Photo stimulated Phosphor plate system and Vista scan (Durr dental, Germany). The PSP plates were exposed to an X-ray source set at 70kVp, 10mA, and 0.20 s exposure time. The quality of obturation was assessed based on modified Coll and Sadrian criteria [23] [Table 1]. The obturation was assessed by two investigators who were blinded to the group allocation and technique of obturation. In case of disagreement, the lower score was selected. Evaluation of voids was based on their presence/absence in each third of the root canal.

After the completion of root canal obturation, the access cavity was sealed with Type 2 glass ionomer cement (Shofu, Shofuinc. Japan). The teeth were restored with stainless steel crowns (3M ESPE, Germany)

Statistical Analysis

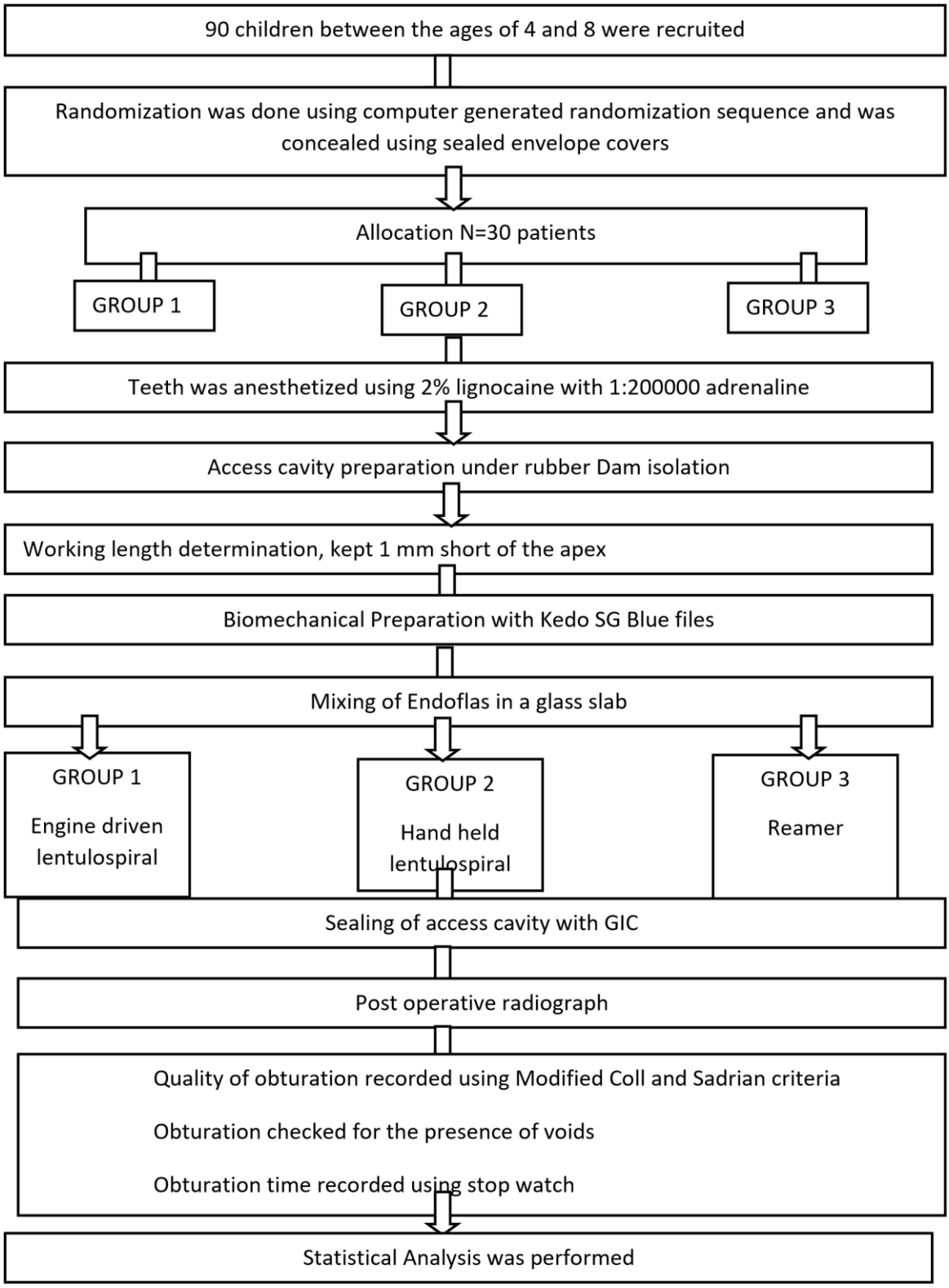
The statistical analysis was done using SPSS software version 17.0 (SPSS Inc., Chicago, IL, USA) with statistical significance set at $p<0.05$. Independent t test and chi square test were used to compare the distribution of the participants with respect to age, sex and distribution of teeth between the groups. The mean values of the study groups were compared using ANOVA and Chi-square test. Pearson's Chi-square test was used to compare the quality of obturation between the groups. ANOVA and Tukey Post Hoc test was performed to compare the time consumed with each obturation technique.

Table 1: Modified Coll and Sadrian Criteria

Grade 1	Underfill	Canals filled more than 2mm short of the apex

Grade 2	Optimal fill	canals having obturating material ending at the radiographic apex or upto 2mm short of the apex
Grade 3	Overfill	Canals showing obturating material beyond the root apex

METHODOLOGY FLOWCHART



RESULTS

General Characteristics

A total of 90 children (46 females and 44 males) participated in the study. Of 90 primary mandibular molars, 21(23.3%) were mandibular left primary second molars, 23(25.6%) were mandibular left primary first molar, 21(23.3%) were mandibular right primary second molar and 25(27.8%) were mandibular right primary first molar. An intergroup comparison was done with respect to the age, gender, and distribution of the teeth using Chi-square test. No statistically significant difference was noted between the groups with respect to the age (P = 0.217), gender (P = 0.561), and distribution of teeth (P = 0.117) indicating that there was an equal distribution of the participants and the teeth between all the three groups eliminating the chances of bias.

Level of canal obturation

The results show that there is no significant difference between the three experimental groups to obturate the root canals using Endoflas. In mesial canals, Hand held lentulospiral (56.7% optimal fill), and Engine driven lentulospiral (50% optimal fill) showed best and acceptable results compared to Reamer(46.7% optimal fill). In distal canals, Hand held lentulospiral (50% optimal fill), and Reamer (50% optimal fill) showed best and acceptable results compared to Engine driven lentulospiral (46.7% optimal fill).These results are not statistically significant($p>0.05$)[Table 2]

Voids

All the three experimental groups produced voids. Hand held lentulospiral produced a maximum number of voids in the upper third, middle third and lower third of the mesial canals (43.3%, 53.3%, and 50.5% respectively). Engine driven lentulospiral produced least voids in the upper and lower third of the mesial canals (66.7% and 66.6% respectively). Reamer produced least voids in the middle third of the mesial canal (63.3%).

In the upper third of the distal canal, both reamer and engine driven lentulospiral produced a maximum number of voids (43.3% and 43.35 respectively). In the middle third of the distal canal, engine driven lentulospiral (36.7%) and in the lower third of the distal canal, reamer (43.3%) produced the maximum number of voids. Hand held lentulospiral produced the least number of

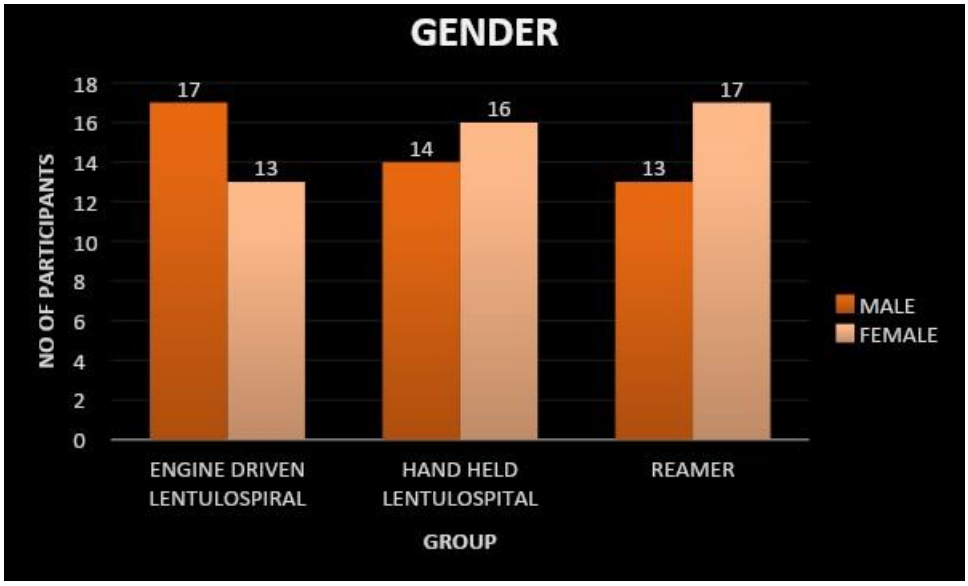
voids in the upper, middle and lower third of the distal canal (60.0%, 70% and 66.7% respectively). These results are not statistically significant ($p>0.05$) [Table 3]

Time

Time taken for obturation of the canal was recorded and intergroup comparison was made. Obturation with Engine driven lentulospiral consumed least time (mean =5.82) followed by handheld lentulospiral and obturation time was maximum with Reamer (mean = 8.67). These results are highly statistically significant ($p<0.05$) [Table 4]

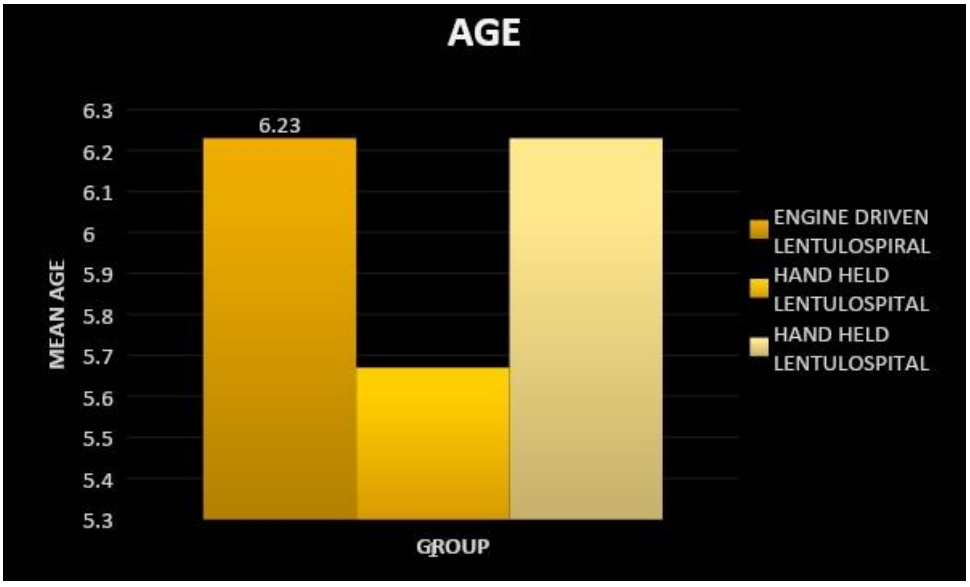
Graph 1: General Characteristics of the Participants-

Distribution of Participants according to Gender



Graph 2: General Characteristics of the Participants-

Distribution of Participants according to Age



Graph 3: General Characteristics of the Participants-

Distribution of Teeth between the Groups

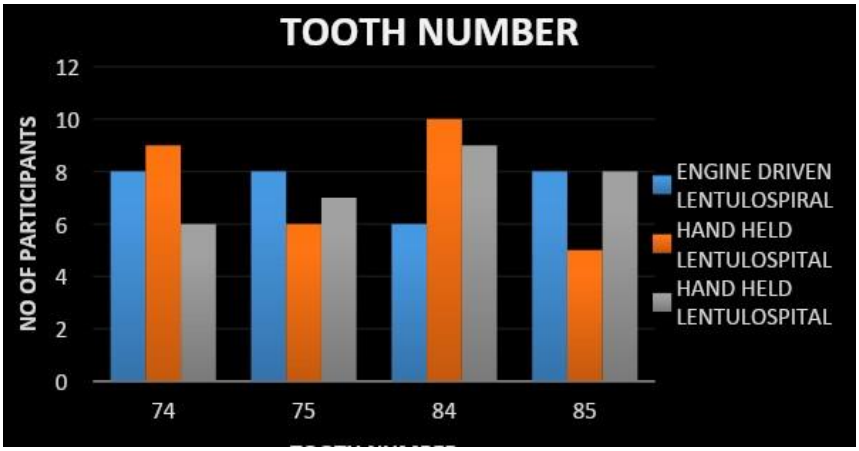


Table 2: General characteristics of the Participants and teeth

PARAMETERS	ENGINE DRIVEN LENTULOSPIRAL	HAND HELD LENTULOSPIRAL	REAMER	P VALUE
AGE	6.23±1.524	5.67±1.373	6.23±1.445	0.217
SEX				
MALE	56.7% (n=17)	46.7% (n=14)	43.3% (n=13)	0.561
FEMALE	43.3% (n=13)	53.3% (n=16)	56.7% (n=17)	
TEETH				
74	26.7% (n=8)	30.0% (n=9)	20.0% (n=6)	
75	26.7% (n=8)	20.0% (n=6)	23.3% (n=7)	0.117

84	20.0% (n=6)	33.3% (n=10)	30.0% (n=9)	
85	26.7% (n=8)	16.7% (n=5)	26.7% (n=8)	

Graph 4: Comparison of level of obturation with three different techniques

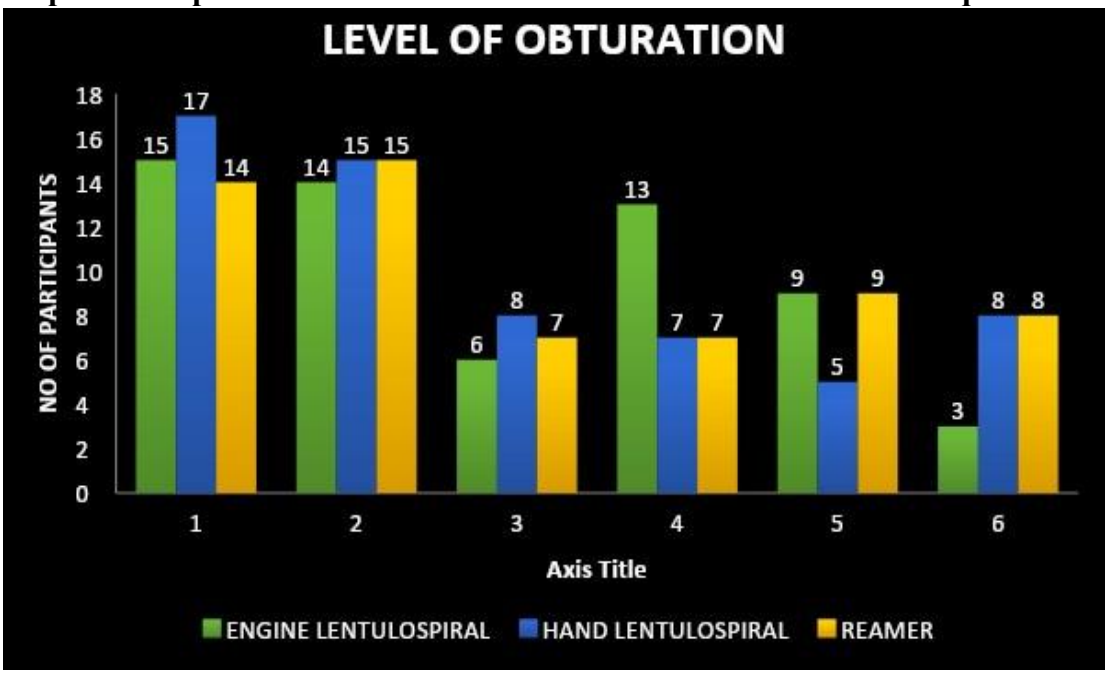


Table 3: Comparison of level of obturation with three different techniques

GROUP	MESIAL			DISTAL		
	UNDER FILL	OPTIMAL FILL	OVER FILL	UNDER FILL	OPTIMAL FILL	OVER FILL
ENGINE DRIVEN LENTULOSPIRAL	30.0% (n=9)	50.0% (n=15)	20.0% (n=6)	10.0% (n=3)	46.7% (n=14)	43.3% (n=13)
HAND HELD LENTULOSPIRAL	16.7% (n=5)	56.7% (n=17)	26.7% (n=8)	26.7% (n=8)	50.0% (n=15)	23.3% (n=7)
REAMER	30.0% (n=9)	46.7% (n=14)	23.3% (n=7)	26.7% (n=8)	50.0% (n=15)	23.3% (n=7)

p value	0.739	0.254

Table 4: Comparison of voids with three different techniques

GROUP	MESIAL			DISTAL		
	CORONAL THIRD	MIDDLE THIRD	APICAL THIRD	CORONAL THIRD	MIDDLE THIRD	APICAL THIRD
ENGINE DRIVEN LENTULOSPIRAL	33.3% (n=10)	50.0% (n=15)	33.3% (n=10)	43.3% (n=13)	36.7% (n=11)	36.7% (n=11)
HAND HELD LENTULOSPIRAL	43.3% (n=13)	53.3% (n=16)	50.0% (n=15)	40.0% (n=12)	30.0% (n=9)	33.3% (n=10)
REAMER	30.0% (n=9)	36.7% (n=11)	36.7% (n=11)	43.3% (n=13)	33.3% (n=10)	43.3% (n=13)
p value	0.532	0.392	0.378	0.955	0.861	0.718

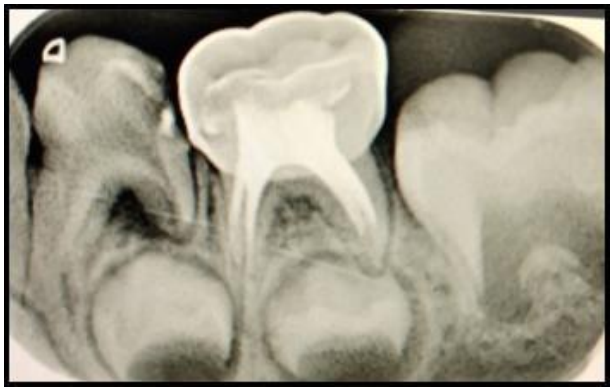
Table 5: Comparison of time with three different techniques

GROUP	MEAN(mins)	SD	P VALUE
ENGINE DRIVEN LENTULOSPIRAL	5.8243	.43119	

HAND HELD LENTULOSPIRAL	7.0377	.54135	0.000
REAMER	8.6733	.62803	

Radiographs showing underfilled, optimally filled and overfilled canals

Underfilled canals



Optimally filled canals

Over filled canals

DISCUSSION

A good and accepted obturation technique is one which shows optimal obturation with least voids [24]. An ideal obturation is the main essence of an ideal pulpectomy [25,26]. Various techniques are being employed to establish the best method to obturate root canals.

There are various studies in the literature which evaluate the techniques of obturation in primary teeth using zinc oxide eugenol as obturating material[27,28]. But the studies providing evidence of obturation using Endoflas as obturation material is limited.

Mandibular molars alone were included in the study in order to maintain uniformity and also for the ease of access. Children between the ages of 4 and 8 were included and the study population was equally distributed among the three groups with respect to age, therefore not contributing to the risk of bias. Also, there was an equal distribution of the teeth and the participants with respect to gender.

Single visit pulpectomy was first reported by Gould JM in 1972. Coll JA,1996 reported 77.8% success rate with single visit pulpectomy at the end of 90.8 months follow up [23]. Bharuka SP , 2016 reported that there is no statistically significant difference in the clinical and radiographic success rates at the end of 6 months between single visit and two- visit pulpectomy in teeth with apical periodontitis [29,30]. Therefore in the present study single visit pulpectomy was done. All the pulpectomy procedures were done by a single operator. Therefore, the operative bias is not a consideration in the present study.

The quality of obturation can be assessed with various modalities like radiographs, fluid filtration, bacterial leakage, radioisotopes, dye penetration, microscopic analysis, clearing techniques and micro computerized tomography. Among these methods, the most conservative method is the radiographic assessment of the obturation. Both conventional and digital imaging techniques are used for this purpose. In spite of the fact that radiographs are two dimensional, they are accurate for voids smaller than 300µm [31,32].

Photo stimulated phosphor imaging plate (PSP) radiography is one type of digital imaging technique where the image is captured on a phosphor plate as analog information and later

converted to digital format . Computerized enhancements of the digitalized image can be done by altering the contrast, measuring the distance of the root canal filling materials from the apex and

detection of voids . Therefore, in the present study, PSP was used to compare the root canal filling techniques.

Bawazir and Salama reported the use of lentulospiral 2 sizes smaller than the previously used file size [33]. The tip dimension of Kedo SG Blue E1 file is 0.30mm. Hence in this study 25 size lentulospiral was used.

In the present study, all three obturation techniques equally produced optimal obturation. Bawazir and Salama evaluated engine driven lentulospiral and hand-held lentulospiral in primary teeth and concluded that there was no statistically significant difference between the two techniques of obturation in terms of quality of the root canal filling. This is consistent with the results of the present study.

Memarpour compared anesthetic syringe, NaviTips, pressure syringe, tuberculin syringe, lentulospiral, plugger and concluded that lentulospiral produced best results in terms of length of obturation [8].

In the present study, overfilling was most commonly encountered in the group obturated with engine driven lentulospiral. This result is similar to the result of the study by Memarpour et al. This could be due to displacement of rubber stopper [8].

In the present study, all the three techniques used for obturation of the canals produced voids. This is consistent with the results of the previous studies [33]. The location and size of the voids depends on various factors such as type, consistency and viscosity of the obturation material, method used to deliver the material, operator skills and experience [34]. Presence of voids can lead to microbial regrowth, reinfection and increased risk of post-treatment disease [34,35].

In the present study, statistically significant difference was observed in the time consumed with each obturation technique. Obturation time was more with reamer. This could be due to the fact that, with reamer the incremental filling of the canal is done 5-7 times till the canal orifice gets filled with Endoflas [36].

There is no previous study available in the literature which evaluates the quality of obturation using reamer, hand held lentulospiral, engine driven lentulospiral as obturation technique when Kedo SG Blue rotary file is used for biomechanical preparation

The disadvantage of this study is that, radiograph can only give a two dimensional view of the obturation and that the exact size and number of voids cannot be determined. Also, the quality of obturation with each technique depends on the operator skills and experience

CONCLUSION

The results of the present study draw to the following conclusions

- There was no difference in the quality of obturation using engine driven lentulospiral, hand held lentulospiral and reamer using Endoflas as obturating material when biomechanical preparation was done with Kedo SG Blue rotary files
- Time taken for obturation using Engine driven lentulospiral was the least compared to the other two techniques.
- It is preferable to use Engine driven lentulospiral to obturate the root canals of the primary teeth as it saves chair side time.

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