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Comparative Evaluation of Quality of Obturation using Endoflas and Endoflas Powder with Aloevera Gel as Obturating Materials in Primary Mandibular Molars: A Double Blinded Randomized Controlled Trial

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Abstract

Paediatric endodontics is an evolving stream in paediatric dentistry and so is the materials used as obturating agents in primary teeth. A paradigm-shift change has been witnessed in the genre of obturating agents where more of natural plant products are preferred to be used as obturating materials in primary teeth due to its enriched biological and biocompatible properties.The aim of the present study is to comparatively evaluate the quality of obturation using Endoflas and Endoflas powder with Aloevera gel as an obturating material in primary mandibular molars.A double-blinded randomized clinical trial was conducted for recruiting participants in an age group of 4-9 years old requiring endodontic treatment (i.e; pulpectomy) in primary mandibular molars. Post-treatment, an immediate intra-oral periapical radiograph (IOPAR) was taken for assessment of the quality of obturation. Obturation quality was assessed using the modified Coll and Sadrian's criteria. Highest percentage of optimal fillings were observed in endoflas group (15/75%) followed by endoflas powder with aloe vera gel group (10/50%) while increased percentage of overfilling was found in endoflas powder mixed with aloe vera gel (7/35%) followed by endoflas group (4/20%). In case of underfilling quality of obturation, more of underfilled cases were found in endoflas powder mixed with aloe vera gel (3/15%) while only one underfilled case was seen in endoflas group. The difference in the quality of obturation was found to be statistically significant (p= 0.019). Endoflas powder with aloe vera gel can be used as an alternative and suitable obturating agent in primary teeth due to its wide repertoire of medicinal properties which are highly beneficial in alleviating the persistent periapical infection in primary teeth.

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INTRODUCTION

The primary objective of performing pulpal therapy in primary teeth is to maintain the integrity and preserve the health of oral tissues [1]. Pulpectomy aids in the retention of primary teeth in the dental arch diagnosed with irreversible pulpal pathosis and inflammation in a symptom-free state [2]. It is highly essential to maintain a successful root canal treated primary teeth in the oral arch as preserving a natural tooth in itself serves as the best possible space maintainer [3]. Preserving a natural tooth in the dental arch helps maintain the arch space and circumference while preventing untoward consequences on phonation, mastication and proper

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eruption of the underlying succedaneous tooth bud thereby maintaining the functional quality of life in children [4, 5].

Endodontic treatment in primary teeth is perceived to be highly tedious due to the complex anatomical diversification configured in its root canal system coupled with difficulty in paediatric behavioural management [6]. Despite of efficient chemomechanical preparation and thorough copious irrigation of the root canals, there are still chances of failure in pulp therapy due to entrapped microbes in the fins and isthumus of the tortuous, narrow and ribbon shaped root canals of primary teeth [7-9]. Thus owing to the difficulties perceived in complete debridement of the root canal system related to the complex morphology and closer proximity to the succedaneous tooth bud, there has been an emergence of obturating materials with advanced and additional antimicrobial properties to be used in primary teeth [10].

An ideal obturating material to be used in primary teeth should be biocompatible, able to eliminate residual pathogens and neutralize their toxic products and most importantly have a resorption pattern synchronous to the physiological resorption rate of primary roots to prevent formation of hollow tubes due to premature resorption of root filling substance and canal reinfection in order to create a favourable environment for the healing process [7,11]. However no definitive consensus exists as to the preferred root filling material and technique in primary teeth [12,13]. The role of obturation and achieving a good quality of obturation is of paramount importance as it seals the vestiges of contaminants in the root canal system which cannot be merely removed on debridement and better quality of obturation also minimizes the potential role of apical percolation and coronal leakage [14]. Therefore the success of endodontic therapy in primary teeth depends mainly on the reduction or elimination of bacteria from the root canals by using appropriate obturating materials having good antibacterial properties, which has thus led to the search of an effective root filling material for primary teeth which can overcome all the anatomical complexities and instrumentation obstacles encountered, thereby leading to successful treatment outcomes [15-17].

Herbal medicines (Botanical medicine, Phytomedicine, or Phytotherapy) refer to herbs, herbal materials, herbal preparations, and finished herbal products that contains parts of plants or other materials as active ingredients. In the present era, there has been an immense popularity of using herbal or natural products in various fields of science due to their high antimicrobial activity, biocompatibility, anti-inflammatory and anti-oxidant properties. One such ancient herb which has received enormous scientific attention is the "Aloevera" (Aloe barbadensis) which is a succulent plant that belongs to "Liliaceae" family and consists of two different parts, each of which producing substances with completely different composition and therapeutic properties [18]. The inner portion of the Aloe leaves is made up of parenchymatous tissues which produces *Aloe vera* gel (or mucilage), a clear, thin, tasteless, jelly-like material while the other part of the plant consists of a group of specialized cells known as the pericyclic tubules, which occurs just beneath the outer green ring of the leaf and produces an exudate that consists of bitter yellow latex with powerful laxative like actions [19]. More than 75 active ingredients have been identified from the inner gel including vitamins, minerals, enzymes, sugars, anthraquinones or phenolic compounds, lignin, saponins, sterols, amino acids and salicylic acid, while the active ingredients of Aloevera leaf pulp and exudates comprises of all the above mentioned essential products including organic and inorganic compounds, lipids, chromones, essential and non-esential amino acids which makes the herb highly beneficial for medicinal use [20]. Aloevera gel possesses innumerable biological and pharmacological actions such as wound healing, anti-inflammatory, anti-bacterial, anti-fungal, anti-viral, immunomodulating and anti-oxidant properties which makes the herb to be effectively employed for oral treatment [21]. One of the in-vitro study conducted to evaluate the anti-microbial efficacy of Aloevera against Zinc oxide eugenol (ZOE), Calcium hydroxide [$Ca(OH)_{2]}$ and $Ca(OH)_2$ + Iodoform (Metapex) in different combinations concluded that Aloevera + sterile water was found to have superior anti-microbial properties against most of the oral microbes found in the infected root canals of the primary molar teeth [22]. Several studies using Aloevera have demonstrated its anti-microbial efficacy, anti-fungal activity and its ability to form mineralized barrier in pulp capping [23]. Till date only two clinical trials have been conducted in primary teeth using a mixture of ZOE and Aloevera gel which have demonstrated a considerably good clinical as well as radiographical success and can be used as a suitable alternative obturating material against the conventional ZOE [3,24].

Endoflas-FS is an another newer material used as an obturating agent in primary teeth, which was first introduced in South America and is commercially available in powder and liquid form. The powder comprises of tri iodomethane, ZOE, $Ca(OH)_2$, barium sulphate, iodine dibutylorthocresol while the liquid

component contains eugenol and parachlorophenol. Endoflas encompasses the desirable properties of ZOE, $Ca(OH)_2$ and iodoform and has broad antibacterial efficacy, hydrophilic in nature which can be used in humid root canals, firmly adheres to the surface of root canal walls and disinfect the dentinal tubules [25,26]. The components of endoflas are biocompatible and can be removed by phagocytosis thus making the material resorbable which accounts for one of its most important property to be used as an obturating material in primary teeth. Endoflas has an advantage of having the resorption limited to excess material extruded beyond the apex and resorption does not occur within the canal, hence it is neither resistant to resorption nor it results in hollow tube effect [3,11].

There have been several studies conducted so far in the literature to assess the role of obturation and its quality in primary teeth, however there has been no study conducted till date to evaluate the obturation quality of this newer novel medicament Endoflas powder with Aloevera gel compared to Endoflas as an obturating agent in primary teeth. Hence the present study aims to comparatively evaluate the quality of obturation using Endoflas and Endoflas powder with Aloe vera gel for pulpectomy in primary mandibular molars.

MATERIALS AND METHODS

Study design and ethical consideration

The present study was designed as a double-blinded randomized controlled trial, conducted in the Department of Paediatric and Preventive Dentistry, India from September, 2019 to January, 2020. The trial was approved by the Institutional Scientific Review Board (SRB/MDS/PEDO/19-20/0052) and Ethical Committee (SDC/MDS/19-20/0185) in accordance to the ethical standards laid down in the 1964 declaration of Helsinki and its later amendments. Prior written informed consent was obtained from the parents/ accompanying guardian of the recruited children. CONSORT guidelines was followed for planning and reporting of the present trial at its various stages [27]. (Figure 1)

Sample size estimation and recruitment of study participants

A total sample of 40 children in an age group of 4-9 years with chief complaint of pain and indicated for pulpectomy in primary mandibular molars were recruited. Prior to the main study, a pilot study was conducted with 5 participants in each group and the results followed a normal distribution with a post-hoc power of 95% and an estimated sample size to be 20 participants each in two groups. Preset inclusion and exclusion criteria were followed for recruitment of participants. The intern posted recruited healthy children with complaint of pain in pulpally involved primary mandibular molars having a minimum of $2/3^{rd}$ of remaining root length and restorable tooth structure to be included into the trial whereas children with special healthcare needs or systemic diseases, non-restorable teeth with internal or external root resorption exceeding 2/3rds of root length with increased mobility other than physiological mobility were excluded. A postgraduate performed computer-generated randomization technique with allocation concealment using sequentially numbered, sealed, opaque envelopes to assign each recruited participant into either of the two groups as group I: Endoflas-FS(20/control) and group II: Endoflas powder with Aloevera gel (20/experimental).

Clinical procedure

All the treatment procedures were performed by a single trained paediatric dentist. On clinical and radiographic confirmation of the diagnosis (i.e; irreversible pulpitis), local anaesthesia (LA) using 2% lignocaine with 1:200,000 adrenaline (LOX* 2% ADRENALINE, Neon Laboratories limited, India) was administered to the tooth indicated for pulpectomy. On both subjective and objective confirmation of the effects of LA, the tooth was isolated using rubber dam (GDC Marketing, India). Under aseptic condition, a No.330 pear-shaped carbide bur (Mani, Inc, Tochigi, Japan) in a high-speed handpiece (NSK PANA AIR PA-SU B2) was used for removal of superficial caries and gaining endodontic access. Coronal pulp amputation was done with a sharp spoon excavator (Hu-Friedy Mfg. Co. LLC) followed by the use of a DG 16 endodontic explorer (Hu-Friedy Mfg. Co. LLC) to locate the canals in the dentinal map. A No.10 size K-file (Dentsply Maillefer, OK, USA) was used to determine the patency of the root canals followed by a No.15 size K-file for initial enlargement of the root canal space prior to using the rotary files. Working length (WL) was determined using ProPex Pixi electronic apex locator (Dentsply Maillefer, OK, USA). A No.15 size K-file was used to record the working length of each root canal with 1mm shorter than the '0.0' mark in the ProPex Pixi apex locator.

Instrumentation of all the teeth was done using the advanced paediatric rotary file system Kedo-SG Blue. It consists of three files namely D_1, E_1 and U_1 having a variably variable (VV) taper, titanium coated, with a total length of 16 mm and a working area of 12 mm. The D_1 and E_1 files are used for instrumentation in the posterior canals while U_1 file is used for instrumentation in anterior teeth [28]. The narrower

mesial canals were instrumented using a D_1 file (red colour coded, tip diameter of 0.25mm) while the wider distal canals were instrumented first by D_1 file followed by E_1 file (blue colour coded, tip diameter of 0.30 mm) in a bucco-lingual swiping motion for 1-2 times in each root canal resulting in smooth, tapered and conical preparation. All the rotary files were used in an X-Smart endodontic motor (Dentsply Maillefer, OK, USA) at 300 rpm and 2.4 N/cm torque. 17% EDTA gel (RC Help, Prime dental products, Pvt. Ltd. India) was used for lubrication of files during instrumentation. Each file was used upto seven teeth as per the manufacturer's instruction and also to maintain uniformity in the treatment among all the samples. The root canals were frequently irrigated after use of each file, alternatively with 0.9% normal saline (Fresenius Kabi India, Pvt. Ltd) and 2% chlorhexidine (Asep- RC, STEDMAN PHARMACEUTICALS PVT. LTD, India.) while final rinsing was done with normal saline. Finally the root canals were dried using No.15 size sterile paper points (Pearl Dent Co, Ltd., Vietnam) and obturation was done according to the intervention groups. In group I: Endoflas-FS (SANLOR LABORATORIES, COLOMBIA, USA) was used in a 2:1 powder:liquid ratio to achieve the desired medium consistency to be used as an obturating material in primary molars. Powder was dispensed onto the glass slab using a measuring scoop and was slowly incorporated into the liquid eugenol incrementally using an agate spatula by folding technique (manipulation method) to get the desired medium consistency. The prepared material was then carried into the dried root canals in an incremental pattern using a No. 20 size hand reamer (MANI, INC. Japan). Final compaction of the material into the root canals was achieved by compressing the material into the canals using wet cotton pellets technique.

In group II: obturation was carried using Endoflas powder with Aloevera gel. The gel prepared indigenously in the pharmacology lab was procured and only a small portion of the gel was used during obturation while the remaining portion was refrigerated. A 2:1 powder:gel ratio was followed to get a mix of desired medium consistency for using as an obturating material in primary molars. Two leveled scoops of endoflas powder and one scoop of Aloevera gel was dispensed on to the glass slab and powder was slowly incorporated into the gel incrementally using an agate spatula in a folding technique to get the desired medium consistency. The prepared material was then carried into the root canals incrementally using a No.20 size hand reamer while final compaction of the material into the root canals was achieved by compressing the material into the canals using wet cotton pellets technique.

On completion of the obturation, the access cavity was restored using type II Glass Ionomer Cement (Shofu, Shofuinc. Japan) and an immediate post-operative intraoral periapical radiograph (IOPAR) was obtained for assessment of the quality of obturation. Final coronal restoration of the tooth was achieved using a preformed SSC (3M ESPE) luted with type I Glass Ionomer Cement (Shofu, Shofuinc. Japan) either in same sitting or in subsequent appointment.

Assessment of quality of obturation

Quality of obturation was assessed using the criteria laid down by Coll and Sadrian (1996) as underfilled, optimal filled or overfilled by two trained paediatric dentists who were blinded to the study groups (Figure 2)[29]. Kappa statistics was performed to assess the consistency and reliability of the inter and intra-rater examination which reported a Cronbach's alpha value of 0.685 (moderate level of agreement) between the two examiners.

STATISTICAL ANALYSIS

The statistical analysis was performed using IBM.SPSS statistics software version 23.0. For descriptive data (i.e; age, gender and tooth type) frequency and percentage analysis was done followed by One-way ANOVA and Pearson's Chi-square test to find the level of significance between the two groups. Pearson's Chi-square test was used to compare the quality of obturation and the significance level between the two groups. A significance level of $p<0.05$ was set for the present study.

RESULTS

A total of 40 children (23 females and 17 males) in an age group of 4-9 years were recruited with a mean age of 5.62 $\pm$ 1.148 years. The distribution of the participants according to age, gender and tooth type distribution is tabulated in (Table 1). An intergroup comparison using One-way ANOVA and Chi-square analysis reflected an equal distribution of the participants in both the groups with respect to age ($p = 0.288$), gender ($p = 0.255$) and distribution of tooth type ($p = 0.875$) to eliminate any selection bias.

With regard to the quality of obturation in both the groups, 75% (n = 15) of children obturated with Endoflas and 50%(n = 10) of children obturated with Endoflas powder mixed with Aloevera gel had optimal fillings. Chi-square analysis between the two groups showed a statistically significant level of difference in their quality of obturation ($p = 0.019$) (Table 2, Figure 3).

Table 1: Demographic variables depicting sample size, age, gender, tooth type distribution, pre-operative cause of pain and post-operative analgesics consumed in each group with over-all p-value

Treatment Groups	ENDOFLAS (Control group) [N = 20]	ENDOFLAS POWDER + ALOEVERA GEL (Experimental group) [N = 20]	Total [N = 40]	Over-all p - value
Age (Years) Mean ± Standard Deviation	5.25 ± 1.344	5.77 ± 1.264	5.62 ± 1.148	0.288
Females N(%)	11 (55.0%)	12 (60.0%)	23 (57.5%)	0.255
Males N(%)	9 (45.0%)	8 (40.0%)	17 (42.5%)	
Tooth type distribution N(%)	Tooth 74 2 (10.0%) Tooth 75 8 (40.0%) Tooth 84 5 (25.0%) Tooth 85 5 (25.0%)	Tooth 74 3 (15.0%) Tooth 75 6 (30.0%) Tooth 84 4 (20.0%) Tooth 85 7 (35.0%)	Tooth 74 5 (12.5%) Tooth 75 14 (35.0%) Tooth 84 9 (22.5%) Tooth 85 12 (30.0%)	0.875

Chi – square test, p < 0.05 [a]Statistically significant values

Table 2: Depicting different Quality of obturation in each group with over-all p-value

Treatment Groups / Quality of obturation	ENDOFLAS (Control group) [N = 20]	ENDOFLAS POWDER + ALOEVERA GEL (Experimental group) [N = 20]	Total [N = 40]	Over-all p - value
Underfilling N(%)	1 (5%)	3 (15%)	4 (10%)	P = 0.019 (Sig)*
Optimalfilling N(%)	15 (75%)	10 (50%)	25 (62.5%)	
Overfilling N(%)	4 (20%)	7 (35%)	11 (27.5%)	
Total N(%)	20 (100%)	20 (100%)	40 (100%)	

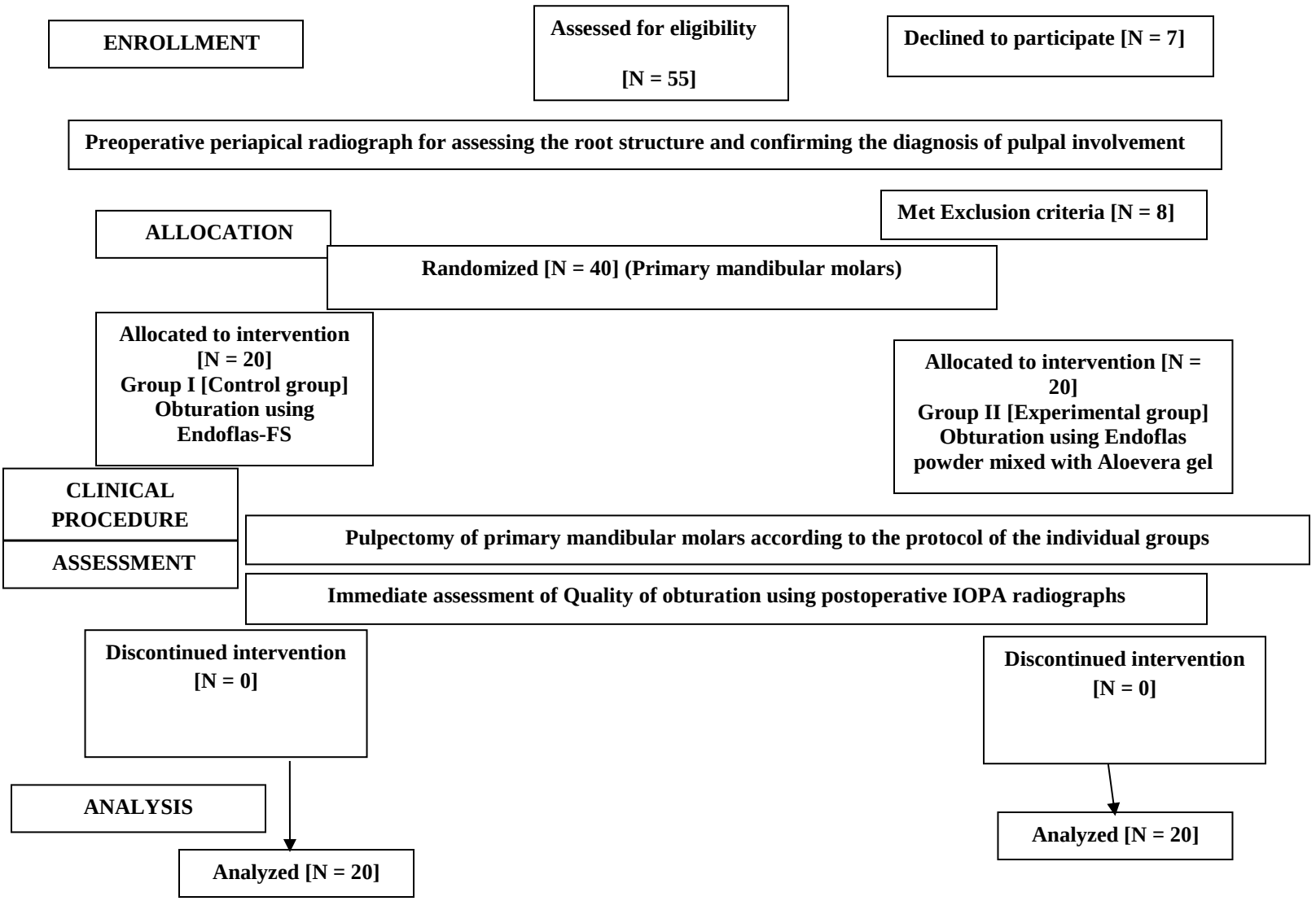

Fig. 1: CONSORT flowchart depicting the different stages followed during the double-blinded randomized controlled trial

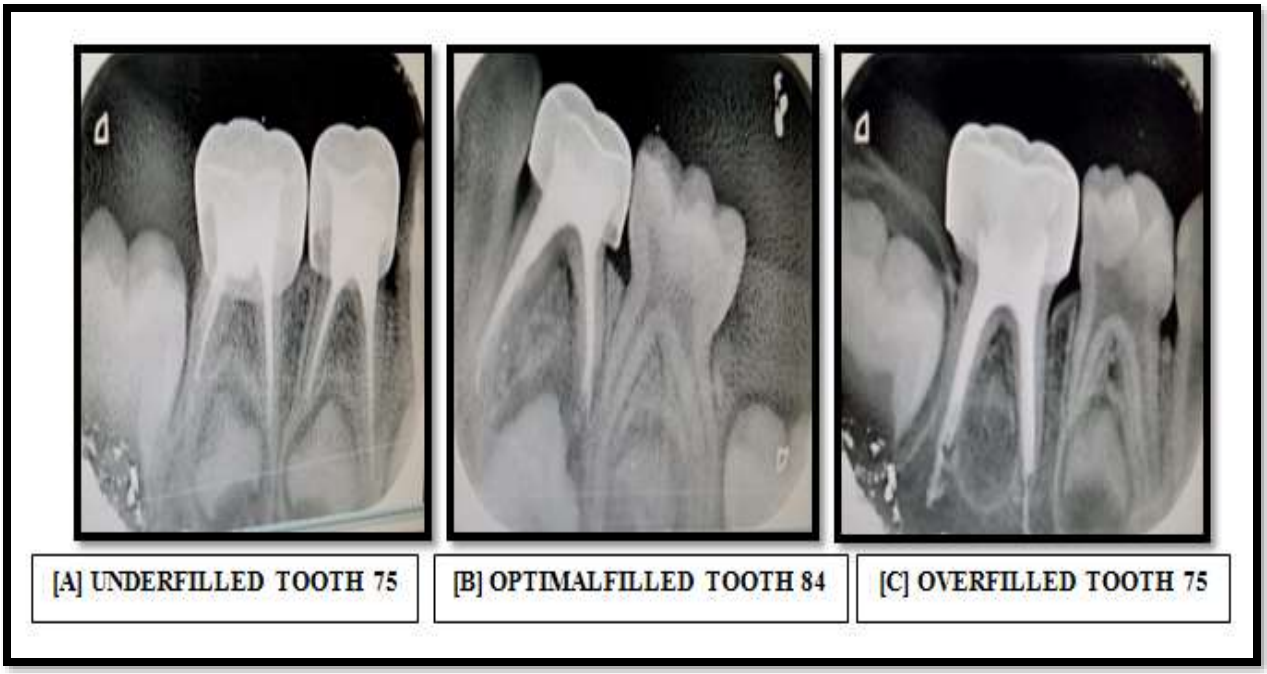

Fig 2: Immediate post-operative IOPA radiograph depicting different levels of quality of obturation according to Coll and Sadrian criteria (1996). [A] Underfilling [B] Optimal filling [C] Overfilling

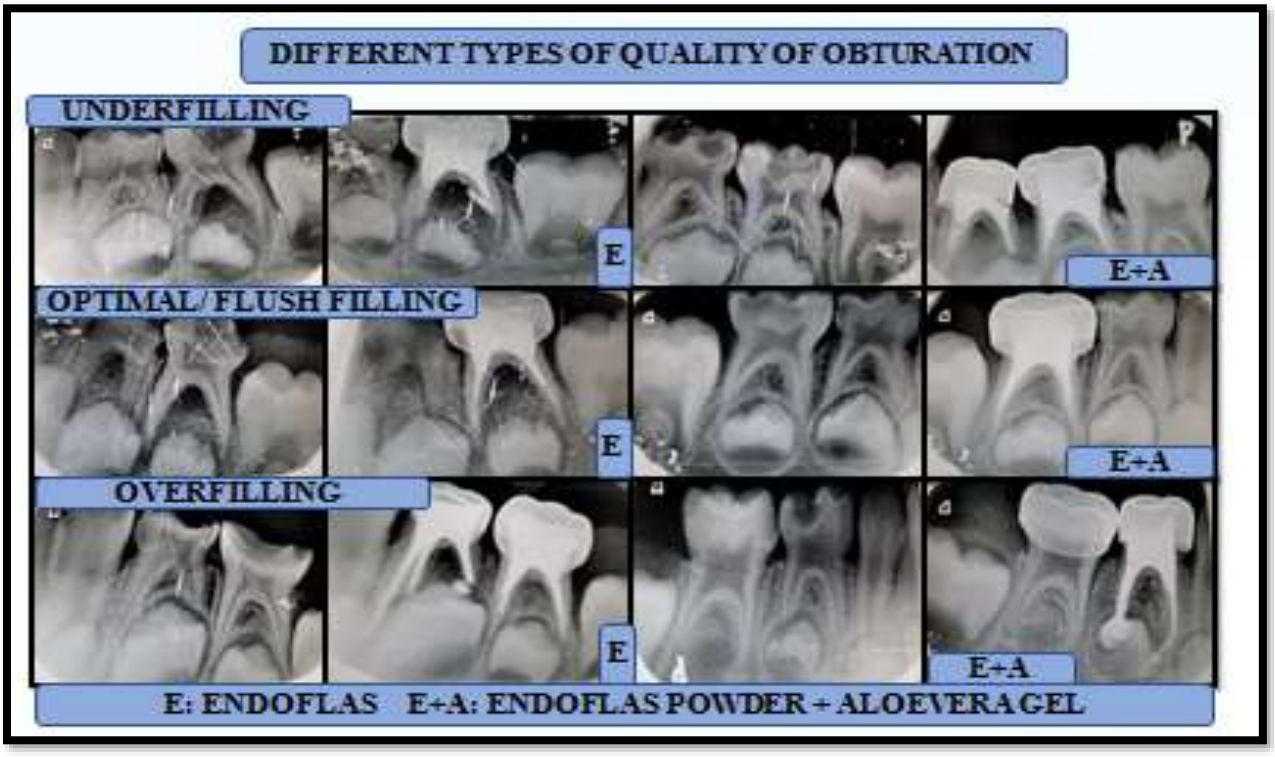

Fig 3: Immediate postoperative IOPA radiograph depicting different levels of quality of obturation according to Coll and Sadrian criteria (1996) in both the groups

DISCUSSION

Efficient cleaning and shaping of root canals is highly pivotal, however it cannot negate the importance of obturation in achieving successful root canal treatment [30]. Proper obturation of root canals aids in obtaining a hermetic seal which seals all channels of contaminants and preventing apical percolation leading to successful endodontic therapy [14]. Success of an endodontic therapy is primarily dependent on achieving a proper access opening with thorough debridement of the inflamed, infected, degenerated or necrotic pulp tissue coupled with frequent copious irrigation followed by drying of root canals and optimal obturation. Similar scenario of successful endodontic therapy holds true in case of paediatric endodontics as well, however endodontics in primary teeth is more of chemomechanical in practice rather than majorly centered on mechanical debridement since the intricate root canal system in primary teeth donot easily permit for thorough debridement of its multiple accessory canals to eliminate the residing microbes and therefore use of appropriate obturating materials with advanced properties is highly quintessential to overcome all the anatomical hurdles in order to achieve successful treatment outcomes [31-37]. Hence quality of obturating agents plays an important role in determining the prognosis of endodontic treatment in primary teeth [38,39].

The commonly used root filling materials for primary teeth includes ZOE, iodoform based pastes and Ca(OH)2, however the noted disadvantages in each of the material discourages its wide spread use in primary teeth [1,40]. ZOE is known as the traditional root filling material in primary teeth but the material is known to be highly irritating to the periapical tissues causes necrosis of bone and cementum [41, 42], asynchronous resorption pattern of material compared to the physiological rate of resorption in primary roots, resist resorption causing deflection in the eruption pathway of succedaneous tooth with enamel defects [10,29,43], limited antibacterial properties [29,41,44-46] and allergic reaction towards eugenol exhibiting cyto and neuro- toxicity [29] are the various shortcomings encountered in ZOE pulpectomized teeth. Similarly iodoform paste has been found to be irritating to the periapical tissues, causes cemental necrosis, discolouration of teeth and results in faster intra-radicular rate of resorption compared to the physiological resorption rate of primary roots [41,48-50]. Allergic reactions to iodine and occurrence of encephalopathy in some individuals are also the noted disadvantages of iodoform [1,48]. The most noted disadvantages of $Ca(OH)_2$ is formation of "hollow tube effect" [3,11,26], inflammatory root resorption [10,51], inadequate seal against microbes, dissolution under liquid (tissue fluid), lack of adhesion to hard tissues, weak antimicrobial properties, aggressive internal root resorption and its use in primary teeth has been greatly curtailed due to occurrence of extensive internal root resorption [11]. The noted disadvantages of the most commonly used obturating materials such as ZOE, Iodoform pastes and $Ca(OH)_2$ have led to the evolution of more suitable and innovative obturating materials for primary teeth. One such most promising material recently in use for obturating in primary teeth is Endoflas-FS. Endoflas powder comprises of a major and balanced combination of ZOE, Iodoform pastes and $Ca(OH)_2$ which compensates the disadvantages of one component with the advantages of the other and balances the properties of endoflas [3]. One of the major advantage of endoflas which makes it the most suitable obturating material in primary teeth is its property of neither being resistant to resorption nor does it results in the hollow-tube effect. Endoflas results only in resorption of the extruded obturating material beyond the periapex and don't cause any intra-radicular resorption of obturating material hence prevents reinfection of the root canals [26]. Another major breakthrough in the field of paediatric endodontic is the use of herbal plant products in combination with the existing obturating materials in primary teeth because of their advanced biocompatible and biological properties.

Herbs are known to possess high anti-microbial, anti-inflammatory and anti-oxidant properties due to the presence of a wide variety of active phytochemicals, including flavonoids, terpenoids, lignans, sulfides, polyphenolics, carotenoids, coumarins, saponins, plant sterols, curcumins, phthalides and biocompatible properties making their use in dentistry more extensive [20,21]. Aloe vera is a succulent plant that belongs to Liliaceae family. The word "Aloe" derive its name from an Arabic word "Alloeh" meaning shining bitter substance while "vera" in Latin terminology means true. Globally over 300 species of Aloe vera plants has been found but the Aloe barbadensis species has been shown to exhibit an enriched and best medicinal properties. The plant mainly flourishes in the dry areas of Africa, Asia, Europe, and America [18]. Aloe vera has a wide variety of applications in dentistry due to its advanced anti-microbial, anti-bacterial, anti-viral, anti-fungal, anti-inflammatory and analgesic properties. Aloe vera can be used suitably as an obturating material in combination with other materials in primary teeth and its high anti-microbial

action helps in eliminating the periapical infection resulting in successful treatment outcomes [21].

In the present clinical trial, highest percentage of optimal fillings were observed in endoflas group (15/75%) followed by endoflas powder with aloe vera gel group (10/50%) while increased percentage of overfilling was found in endoflas powder mixed with aloe vera gel (7/35%) followed by endoflas group (4/20%). In case of underfilling quality of obturation, more of underfilled cases were found in endoflas powder mixed with aloe vera gel (3/15%) while only one underfilled case was seen in endoflas group. The most important parameter for determining the highest percentage of optimal fillings in endoflas group is due to the well-defined and determined manipulative technique with a suitable powder: liquid ratio to give a well desired consistency of the material to be used as an obturating material in primary teeth that aids in performing a quality obtuaration in primary teeth while in case of endoflas powder with aloe vera gel, even thougha determined powder: gel ratio is used for better clinical convenience but despite that incorporating a definite amount of aloe vera gel into the endoflas powder to get a desired medium consistency is often very difficult to achieve resulting in a much inconsistent flowable obturating material that poses substantial difficulty in appropriate condensation and packing of the material into the primary root canals. The same reason can also be held responsible for underfilling of root canals using endoflas powder with aloe vera gel and in an attempt to obdurate the entire root canal length, generally the material after placement into the root canals is pushed deeper resulting in eventual overfilled root canals due to the inconsistent nature of the material. However besides this noted disadvantage of endoflas powder with aloe vera gel, the material encompasses excellent healing properties due to its high anti-microbial action resulting in successful treatment outcomes. Till date no clinical trial has been conducted to compare this novel medicament of endoflas powder with aloe vera gel and endoflas as obturatin g material in primary teeth. The present trial is the first study to experiment this novel medicament endoflas powder with aloevera gel as an obturating material in primary teeth. The existing literature have used aloe vera in combination with ZOE as an obturtaing material in primary teeth and have demonstrated successful treatment outcomes due to the advanced biological properties of aloe vera gel [3,24]. In the present study use of two-dimensional imaging technique (IOPAR) to evaluate the quality of obturation can be considered as a potential limitation of the study.

CONCLUSIONS

Endoflas is one of the promising obturating agent in primary teeth, however endoflas powder with aloe vera gel despite its inconsistent nature can be suitably used as an obturating material in primary teeth. More of large sample clinical trials are needed to be carried out to substantiate and support the fingings of the present study.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest

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REFERENCES

1. Fuks AB, Eidelman E, Pauker N. Root fillings with Endoflas in primary teeth: a retrospective study. Journal of Clinical Pediatric Dentistry 2002; 27: 41–45.
2. Barcelos R, Santos MP, Primo LG, Luiz RR, Maia LC. ZOE paste pulpectomies outcome in primary teeth: a systematic review. Journal of Clinical Pediatric Dentistry 2011; 35: 241–248.
3. Goel H, Mathur S, Sachdev V. Clinical and radiographic evaluation of four different zinc-oxide integrated root canal obturating materials used in primary teeth, Pediatric Dental Journal 2018; 28: 1-14.
4. Dummett Co Jr, Kopel HM. Pediatric endodontics. In:Ingle JI, Bakland LK, editors. Endodontics. 5th ed.Hamilton: BC Decker Inc.; 2002. P. 861-902.
5. Ounsi HF, Debaybo D, Salameh Z, Chebaro A, Bassam H. Endodontic considerations in pediatric dentistry: A clinical perspective. Int Dent South Afr 2009; 11: 40 -50.
6. Garcia-Godoy F. Evaluation of an iodoform paste in root canal therapy for infected primary teeth. ASDC J Dent Child 1987; 54: 30-34.
7. Pinky C, Shashibhushan KK, Subbareddy VV. Endodontic treatment of necrosed primary teeth using two different combinations of antibacterial drugs: an *in vivo* study. J Indian Soc Pedod Prev Dent. 2011; 29: 121-127.
8. American Academy of Pediatric Dentistry. Guideline on pulp therapy for primary and young permanent teeth. *Pediatr Dent*. 2009; 31(6): 179–86.

9. Bodrumlu E, Semiz M. Antibacterial activity of a new endodontic sealer against Entercoccus faecalis. *J Can Dent Assoc*. 2006; 72: 637.
10. Rajsheker S, Mallineni S K, Nuvvula S. Obturating Materials Used for Pulpectomy in Primary Teeth-A Mini Review. J Dent Craniofac Res. 2018; 3(1:3).
11. Goldman M, Pearson AH. A preliminary investigation of the Hollow Tube theory in endodontics . J Oral Therap Pharmacol 1965; 6: 618–626.
12. Rabinowitch BZ. Pulp management in primary teeth. Oral Surg OralMed Oral Pathol. 1953; 6:(542–50), 671–676.
13. American Academy of Paediatric Dentistry. Guideline on pulp therapy for primary and young permanent teeth. Reference manual 2006–07. Pediatr Dent. 2007; 28: l44–8.
14. Gutmann JL, Dumsha T. Cleaning and shaping the root canal system. In Cohen S, Burns RC, editors: Pathways of the pulp, ed 4, St Louis, 1987, Mosby.
15. Kopel HM. Root canal therapy for primary teeth. J Mich State Dent Assoc.1970;52(2):28-33
16. Rifkin A. A simple, effective, safe technique for the root canal treatment of abscessed primary teeth. ASDC J Dent Child 1980; 47(6): 435–441.
17. Tronstad L. Recent development in endodontic research. Scand J Dent Res.1985;16:161–71.
18. Surjushe A, Vasani R, Saple DG. *Aloe vera*: A short review. Indian J Dermatol 2008; 53: 163-166.
19. V. E. Tyler, The Honest Herbal: A Sensible Guide to the Use of Herbs and Related Remedies, Pharmaceutical Products Press, New York, NY, USA, 3rd edition, 1993.
20. J. H. Hamman, "Composition and applications of Aloe vera leaf gel". Molecules, 2008; 13(8): 1599–1616.
21. Sajjad A and Sajjad Subhani S. Aloe vera: An ancient herb for modern dentistry- A literature review. Journal of Dental Surgery, 2014; 1-6.
22. Kriplani R, Thosar N, Baliga MS, Kulkarni P, Shah N, Yeluri R. Comparative evaluation of antimicrobial efficacy of various root canal filling materials along with aloevera used in primary teeth: A microbiological study. J Clin Pediatr Dent 2013;37:257-262.
23. Batista VE, Olian DD, Mori GG. Diffusion of hydroxyl ions from calcium hydroxide and aloe vera pastes. Braz Dent J 2014; 25(3): 212-216.
24. Khairwa A, Bhat M, Sharma R, Satish V, Maganur P, Goyal AK. Clinical and radiographic evaluation of zinc oxide with aloe vera as an obturating material in pulpectomy: an in vivo study. J Indian Soc Pedod Prev Dent 2014; 32(1): 33-38.
25. Fuks AB, Eidelman E, Pauker N. Root fillings with Endoflas in primary teeth: a retrospective study. Journal of Clinical Pediatric Dentistry 2002; 27: 41–45.
26. Rewal N, Thakur A, Sachdev V, Mahajan N. Comparison of endoflas and zinc oxide eugenol as root canal filling materials in primary dentition. J Indian Soc Pedod Prev Dent 2014; 32(4): 317-321.
27. Altman D, Schulz K, Moher D, et al. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. Ann Intern Med. 2001; 134: 663–694.
28. Priyadarshini P, Jeevanandan G, Govindaraju L, Subramanian EMG. Clinical evaluation of instrumentation time and quality of obturation using paediatric hand and rotary file systems with conventional hand K-files for pulpectomy in primary mandibular molars: a double-blinded randomized controlled trial. Eur Arch Paediatr Dent 2020.
29. Coll JA, Sadrian R. Predicting pulpectomy success and its relationship to exfoliation and succedaneous dentition. Pediatr Dentistry 1996; 18, 57–63.
30. Fuchs C, Friedlander C, Rosenberg E et al: Statistical models for evaluating the penetrating ability of endodontic instruments. J Dent Res 1990;69:1617-1621.
31. McDonald R and Avery R: Dentistry For The Child And Adolescent, 9th ed. St. Louis, CVMosby 2011;388-411.
32. Faria G, Nelson-Filho P, Freitas AC, Assed S, Ito IY. Antibacterial effect of root canal preparation and calcium hydroxide paste (Calen) intracanal dressing in primary teeth with apical periodontitis. J Appl Oral Sci 2005;13:351-5.
33. Ito IY, Junior FM, Paula-Silva FW, Da Silva LA, Leonardo MR, Nelson-Filho P. Microbial culture and checkerboard DNA-DNA hybridization assessment of bacteria in root canals of primary teeth pre- and post-endodontic therapy with a calcium hydroxide/ chlorhexidine paste. Int J Paediatr Dent 2011;21:353-60.
34. Mathewson RJ, Primosch RE. Fundamentals of Paediatric Dentistry, 3rd edn. Chicago IL: Quintessence Publishing, 1995: 257-280.
35. Spedding RH. Root canal treatment for primary teeth. Dent Clin North Am 1973;17:105-124.
36. Andlaw RT, Rock WP. A manual of Paediatric Dentistry, 4th edn, Edinburgh: Churchill Livingstone, 1996, 107-116.
37. Gould JM. Root canal therapy for infected primary molar teeth-A preliminary report. J Dent Child, 1972; 39: 269–273.
38. Mass E, Zilberman UL. Endodontic treatment of infected primary teeth, using Maisto's paste. ASDC J Dent Child 1989;56(2):117-20.

39. Barker BCW, Parsons KC, William GL, Mills PR. Anatomy of root canals in deciduous teeth. Aust Dent J 1975;20:101-106.
40. Fuks AB. Pulp therapy for the primary and young permanent dentitions. Dental Clinics of North America 2000; 44: 571–596.
41. Erausquin J, Muruzabal M. Root canal fillings with zinc oxide eugenol cements in the rat molar. Oral Surg Oral Med Oral Pathol 1967; 24(4): 547–558.
42. Holland R, Souza V, Filho SA. Root canal treatment with calcium hydroxide. Effects of overfilling and refilling. Oral Surg Oral Med Oral Pathol 1979; 47: 87 –92.
43. Sadrian R, Coll JA. A long-term follow up on the retention rate of zinc oxide eugenol filler after primary tooth pulpectomy. Pediatric Dentistry 1993; 15: 249 –53.
44. Fidalgo F, Rebeiro M, Oliviera M. A systemic review of root canal filling materials for deciduous teeth: is there analternative for zinc oxide-eugenol? ISRN Dent 2011: 1-7.
45. Mortazavi M, Mesbahi M. Comparison of zinc oxide and eugenol , and Vitapex for root canal treatment of necrotic primary teeth. International Journal of Paediatric Dentistry 2004; 14:417–24.
46. Ramar K, Mungara J. Clinical and radiographic evaluation of pulpectomies using three root canal filling materials: an in-vivo study. Journal of Indian Society of Pedodontics and Prevent ive Dentistry 2010; 28: 25 –9.
47. Chawla HS, Setia S, Gupta N, Gauba K, Goyal A. Evaluation of a mixture of zinc oxide, calcium hyd roxide and sodium fluoride as a new root canal filling material for primary teeth. J Indian Soc Pedod Prev Dent 2008; 26(2) : 53-58.
48. Rotstien I. Tooth discoloration and bleaching. In: Ingle JI, Bakland LK, editors. Endodontic. 5th ed. BC Decker Inc; 2002.
49. Erausquin J, Muruzabal M. Tissue reaction to root canal filling with absorbable pastes. Oral Surg Oral Med Oral Pathol 1969; 28: 567-78.
50. Nurko C, Ranly DM, Garcia -Godoy F, Lakshmyya KN. Resorption of a calcium hydroxide/iodoform paste (Vitapex) in root canal therapy for primary teeth: A case report. Pediatr Dent. 2000; 22: 517–520.