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Comparative Evaluation of the Efficiency of "Obturagun" (Novel Obturating Device) and the Premixed Syringe as a Root Canal Obturating Device for Primary Teeth: Protocol for a Randomized Controlled Trial.

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Abstract:Background: Endodontics success of primary teeth depends on quality of obturation. Currently used pre-mixed syringe technique is being the most popular technique to obturate the root canal of primary teeth. But this technique is beyond the control of operator leading to over obturation , wastage of obturating material, contamination of obturating material, syringe phobia, increased obturation time, ultimately compromising the quality of obturation.To overcome these problems of current obturation device/techniques a novel device has been designed "Obturagun". It consists of two parts: volume based ampule and gun toy.

Objective:a) calculation of average pulp cavity volume of primary teeth, b) designing and developing of volume based ampule and obturagun, c) in-vitro evaluation of the effectiveness of obturagun on extracted tooth, d) evaluating the quality of root canal obturation of primary teeth usingobturagun and premixed syringe device

Methodology: This is a single blinded, randomized controlled trial. The study will be planned in four phases. In phase I average pulp cavity volume will be calculated using cone beam computed tomography of children in the age of 5-9 years.In phase II volume based ampule and obturagun will be designed and developed using CAD CAM software. In phase III randomized controlled trial will be conducted on 62 primary mandibular second molar ofusing obturagun andpremixed syringe device. In phase IV quality of obturation in both the groups will be assessed.

Expected result: Calculation of average pulp cavity volume will be start in January 2020 andis expected to complete by November 2020. Designing and developing of volume based ampule and obturagunwill be starting in December 2020 and will be completed by September 2021. First patient for clinical trial will be enrolled in November 2021; completion of clinical trial within 6 months.

Conclusion: Obturagun could become an alternative to primary root canal obturating device than can overcome the problem Premixed syringe device.
Trial Registration: ClinicalTrial.gov https://clinicaltrials.gov/ct2/show/NCT03798288

Key words: Obturagun, obturation, primary teeth, pre-mixed syringe, pulp cavity volume,

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INTRODUCTION:

Success of endodontics treatment of primary teeth depends on obturation material and obturating technique. Various obturating material have been used to obdurate the root canalsof primary teeth.[1] Zinc oxide eugenol although time tasted obturating material, it is antigenic in nature, irritant to periapical region and had slower rate of resorption than dentin.[1] Calcium hydroxide in pure form had good antibacterial properties but is not radio-opaque. Combination of calcium hydroxide and iodoform (vitapex, metapex) is the most popular commercial available obturating agent because of its good antibacterial property, non-irritating to periapical region and faster rate of resorption than dentin and cementum.[2-4] Therefore in the current study vitapex was used to obdurate the root canals of primary teeth.
Technique of obturation also contributes to the success of endodontics treatment in primary teeth. Ideally good obturating technique should fill the root canal optimally. Under obturation or over-obturation of root canal can lead to the failure of endodontics treatment.

Till date, various obturation techniques have been used to obturate the root canals of primary teeth such as pressure technique, lentulospiral, syringe method (premixed obturating syringe, endodontic pressure syringe, tuberculin syringe, insulin syringe etc).[5, 6] Pressure technique and lentulo-spiral have limitation of over-obturation, under-obturation, increase in obturation time and increased wastage of obturating material.[7] To overcome their disadvantage premixed syringe method has been developed (Vitapex) [5-8]. Although, premixed syringe method being the most popular method of root canal obturation among Pedodontist, but its use incites syringe phobia, increased wastage and contamination of obturating material, ultimately leading to behaviour problem and compromised the quality of obturation.
To overcome these problems during obturation of primary teeth we designed a new device called “obturagun”.
Obturagun consists of two parts:
Volume based ampule
Toy gun

Volume based ampule is based on the concept of pulp cavity of a volume of a single tooth. It will reduce the wastage and contamination of obturating material. Cone beam computed tomography (CBCT) dicom images of children in the age group of 5-9 will be used to calculate the average pulp cavity volume. Toy gun will act as a camouflage device to reduce syringe phobia.
Over all obturagun will not only reduce wastage and contamination of obturating material but also contribute in overcoming syringe phobia problem in children, thereby improving obturating time and quality of obturation. Thus the current study is planned to evaluate and compare the efficiency of “premixed syringe device with novel obturating device “Obturagun” for obturation of root canals in primary teeth.

METHODOLOGY:

Study Setting:

The study will be conducted in the department of Pediatric and Preventive Dentistry, SharadPawar Dental College, Sawangi (M) Wardha over a period of 27 months in four phases as described in **table 1**.

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Eligibility criteria:

Participants:

For phase I cone beam computed tomography (CBCT) dicom images of children in the age group of 5-9 years is analysed using Planmeca Romexis 5.2.0. R software. Primary mandibular second molar without any periapical pathology, internal and external resorption are included in study for pulp cavity volume calculation. For phase III (clinical trial) children in the age group of 5-9 years with inclusion and exclusion criteria for pulpectomy as described in **table 2** will be eligible to enrol in the study.

Requirement and screening:

Requirement of patient will be performed in the department of Pediatric and Preventive Dentistry, SharadPawar Dental College, Sawangi (M) Wardha, India. Children reporting to the department will be screened according to the inclusion and exclusion criteria of pulpectomy**(texbox 2)**. Requirement will be done by Pediatric Dentist, interested parent and cooperative children (Frankl's Behaviour rating scale IV) will be considered in the study. Based on inclusion and exclusion criteria for pulpectomy 60 children requiring pulpectomy will be selected and divided into two groups of 30 each**(Figure 1).**

Sample size:

For Phase I- Evaluation of average pulp cavity volume.

Literature search revealed lack of data on average pulp cavity volume, therefore pilot study was done to calculate sample size. Pilot study was done on five children. Already exposed CBCT dicom images were taken and pulp cavity volume of primary mandibular second molar and canine was calculated. Epi info online sample size calculator was used to calculate sample size of 62 teeth. So accordingly 62 teeth will be allotted to primary second molar (posterior teeth) and equal numbers of teeth will also be allotted to primary canines (anterior teeth). Further distribution of teeth jaw wise is described in Figure 2.

Phase III: Root canal obturation using novel obturagun device and premixed syringe device using calcium hydroxide (Vitapex/metapex).

Sample size was calculated using Epi info sample size online calculator using following formula (Mallayya C[11]). Sample size calculated was 54 patients,considering 10% loss, 60 samples will be taken which will be divided into two groups of 30 each.

METHOD:

Randomization:

Simple randomization - computer-generated randomized sequence list will be used to randomly allocate patients in two groups (group I- obturagun device and group II- pre-mixed syringe device). Only one tooth per child will be included in the study. In case the patient had more than one tooth meeting the inclusion criteria, tooth with a more severe complaint will be included.

Blinding:

It is single blinded study, participants and operator will not be blinded to the study. Assessors will be blinded to the group allocation and technique of obturation.

Data collection, management, and analysis methods:

Study objective and outcome:

The study aims to evaluate the efficacy of obturagun to obturate the root canals of primary teeth. The primary objectives are to evaluate the average pulp cavity volume of primary

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teeth, designing and developing of obturagun, to evaluate and compare the quality of obturation of obturagunwith premixed syringe device and to evaluate the acceptability of obturagun by pediatric patients.

The primary outcome of the study is to assess the quality of obturation done by Obturagun using Coll and Sadrian criteria.[9, 10].

Score

- Under filling (score 1) – Canal filled more than 2 mm short of the apex
- Optimal filling (score 2) – Canal filling ending at the radiographic apex or up to 2 mm short of apex
- Overfilling (score 3) – Any canal showing filling outside the root apex.

Mesiolingual canal was not considered in assessment because in majority of cases radiographicaly this canal is superimposed over mesiobuccal canal. The obturation was assessed by two investigators who will be blinded to the group allocation and technique of obturation. In cases of disagreement, the radiograph will be re-evaluated, and a diagnostic consensus will be reached.

Device:

Obturagun (Figure 3) consists of two parts: Volume based ampule and toy gun. Volume based ampule is based on the concept of pulp cavity of single tooth, which is designed to reduce wastage and prevent contamination of obturating material (Figure 3). Toy gun helps to lock the volume based ampule, which act as an camouflage device to reduce syringe phobia (Figure 3).

Intervention:

Children in the age group of 5-9 years who were already exposed to CBCT or children in need of CBCT for other purposes are included in study for calculation of average pulp cavity volume. Primary teeth without periapical pathology and root resorption are considered for pulp cavity volume calculation. The volume will be measured in cm^3. Primary canines are the tooth with largest pulp canal space in anterior region representing pulp canal space for individual primary anterior teeth. Whereas primary second molars are the tooth with largest pulp canal space in posterior region representing pulp canal space for individual primary posterior teeth. Therefore, these teeth will be selected to calculate the average pulp cavity volume.

Planmeca Romexis 5.2.0. R software will be used to calculate average pulp cavity volume using manual segmentation tool. Mid-sagital section will be divided into 3x3 sections of 0.4 mm thickness for obtaining accurate measurement (primary molars). Considering the average pulp cavity space, volume based ampule will be developed. Based on volume based ampule, obturagun will be designed and developed. Creo CAD CAM will be used for designing and 3D printing of volume based ampule and obturagun. Acrylonitrile Butadiene Styrene (ABS) plastics will be used for 3D printing of volume based ampule and Obturagun.

Based on technique of obturation, two groups will be made.

Group I - Novel obturagun device (ampule loaded with vitapex/metapex paste)

Group II- Premixed obturating syringe (Vitapex/metapex paste)

Vitapex/ Metapex paste – It is a commercially available paste (calcium hydroxide, iodoform & silicone oil) in ready to use syringe form for obturating primary teeth. This paste will be used in Obturagun for obturation of primary teeth.

To evaluate the efficiency of “Obturagun” invitropilot study will be conducted on extracted primary first/second molar using obturagun and premixed syringe, thereafter clinical trial will be conducted.

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The randomized clinical trial will be conducted on children in the age group of 5-9 yearswith no relevant medical history. Primary mandibular/maxillary second molar indicating for pulpectomy will be included in the study as per inclusion and exclusion criteria. Participation in the study will be voluntary and prior written consent will be obtained from the parents or guardians.

Clinical trial: Pre-operative intraoral radiograph will be taken using standard procedure ensuring presence of all the roots and apices. All the patients will be treated by single operator. The tooth will be anesthetized and isolated with rubber dam. Before gaining access, all caries will be excavated by a large round bur. The pulp chamber's roof will be removed with a no. 330 carbide bur (Dentsply Professional) in a high-speed handpiece. A tentative length will be obtained by measuring the tooth on the preoperative radiograph. A diagnostic radiograph with a K-file placed in each canal will be taken to ascertain the length of the root canal. The working lengths were established radiographically and kept 1 mm short of the radiographic apex. Standard hand files will be used to enlarge the root canals to size 40. Irrigation of the canals will be done using saline. Canals will be dried with absorbent paper points (Diadent) and obturation was done using assigned techniques.
A postoperative radiograph will be taken immediately after obturation. Each radiograph will be mounted in a slide frame and projected onto a screen. Two canals (mesiobuccal and distal) will be considered for radiographic evaluation (quality of obturation). The quality of obturation will be assessed based on the modification of the criteria put forth by Coll and Sadrian.[9, 10] Mesiolingual canal will not be considered in the assessment because in majority of cases radiographicaly this canal is superimposed over mesiobuccal canal. The obturation was assessed by two investigators who will be blinded to the group allocation and technique of obturation. In cases of disagreement, the radiograph will be re-evaluated, and a diagnostic consensus will be reached.

Statistical analysis:
SPSS version 16 will be used for data analysis, mean and standard deviation will be estimated for continuous data. Independent t test will be used to compare mean root canal volume between group I and group II. Mann Whitney U test will be was used to compare proportion of quality of obturation and voids between group I and group II. Z test was used compare proportion of voids at middle and apical third between the groups I and II. Statistical significance was kept at $p \leq .05$.

Ethical Consideration:
No adverse affect are expected through this clinical trial on children. Investigators ensure that the children and their parents are explained regarding purpose, potential risk and any others issues related to clinical trial in which parent volunteer their children for participation. Written informed consent will be obtained from the parents prior to participation of their ward in clinical trial. Detail of the clinical procedure and number of visits required will be explained to children and their parents for behaviour management of children and parental cooperation during clinical trial. Children parents will have the right to opt out of this clinical trial at any time without giving any reason for doing so. The trial is approved by the Institutional Ethical committee of SharadPawar Dental College, Sawangi (M) Wardha**.**

Patient Confidentiality and Involvement and data access:
Treatment involved in the clinical trial is the routine indicated endodontic treatment done using recommended and time tasted obturating material; the only difference is the technique of obturation. Children parent or children are not involved in designing or conceptualization

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of research. Children parents will have access to the data collected but won't have any right to change or modify the data at any point of clinical trial. Directly involved persons such as researchers will have access to data and would be able to modify.

Expected Result:

In vitro part of the study i.e calculation of average pulp cavity volume will be starting in January 2020 and is expected to complete by November 2020. Designing and developing of volume based ampule and obturagun will be starting in December 2020 and will be completed by September 2021.Recrument of first patient for clinical trial will be enrolled in November 2021 and is expected to complete within 6 months. Data collection is expected to complete by June 2022 and result of the clinical trial is expected to be ready for publication by October 2022.

DISCUSSION:

Current study is the first clinical trial in which root canal of primary teeth will be obturated using the concept of pulp cavity volume. Pulp cavity volume of primary teeth justify the amount of obturating material required to obdurate the root canal of single primary tooth thereby prevent wastage of obturating material. Premixed syringe device (Vitapex) is currently the most popular obturating device/ technique because of its better handling and easy dispense of obturating material from the syringe under pressure.[11-13] Other factor that contributes to its popularity is the premixed obturating material (Vitapex- mixture of calcium hydroxide and iodoform) in the syringe which has good antibacterial property, non-irritant to periapical region and faster rate of resorption than dentin and cementum.[14, 15] It has not been documented but clinical practise demonstrate that wastage, contamination of obturation material and syringe phobia are the main disadvantages of this device. To overcome these problems there was a need to change the obturating device/technique while using same obturating material[16].

Obturagun is a novel device based on the concept of pulp cavity volume and syringe camouflaging. Obturagun consists of volume based ampule and toy gun. Using the concept of pulp cavity volume, volume based ampule will be designed that will contain specific grams of obturating material sufficient to obdurate the root canal of single primary tooth thus preventing contamination and wastage of obturating material. Toy gun will act as a camouflage device to reduce syringe phobia during obturation. Obturagun is expected to improve quality of obturation and obturation time. Further it will reduce the anxiety and help in gaining cooperative behaviour during treatment. If the results are positive randomized clinical trials will be carried out comparing obturagun with other root canal obturating technique for primary teeth.

Expected Conclusion:

Obturagun is expected to reduce wastage and contamination of obturation material. It will also reduce phobia associated with syringe for obturating device, thereby improves quality of obturation and obturation time.

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Authors' Contributions:

Manuscript drafting and protocol writing was done by RK. Scientific background, methodology and design of the study protocol were the responsibility of RK and SB. RK and SB are responsible for conception of idea and design of device.

Conflict of interest:

No conflict of interest

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Table 1: Phases of the study

Phase I	Evaluation of average pulp cavity volume
Phase II	Designing and developing of volume based ampule, gun toy (Obturagun device)
Phase III	Root canal obturation using novel Obturagun device and premixed syringe device using calcium hydroxide (Vitapex/metapex). A) First in-vitro study, B) Clinical Trial.
Phase IV	Evaluating and comparing the efficiency of Obturagun device

Table 2: Inclusion and exclusion criteria for pulpectomy

Criteria		**Observations**
Inclusion	Clinical	Caries involving pulp/ grossly carious teeth

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criteria	examination	Presence or absence of sign of pulpal degeneration such as sinus, pain on percussion, periapical abscess
	Radiographical examination (IOPA)	Periapical radiograph showing signs of pulpal degeneration such as furcation involvement, internal resorption,
Exclusion criteria	Clinical examination	Un-restorable carious teeth
	Radiographical examination (IOPA)	Periapical pathology involving crypt of permanent successor External root resorption Periapical cyst , periapicalgranulaoma Calcification in canals

Figure 1: Requirement and screening of patient for the study

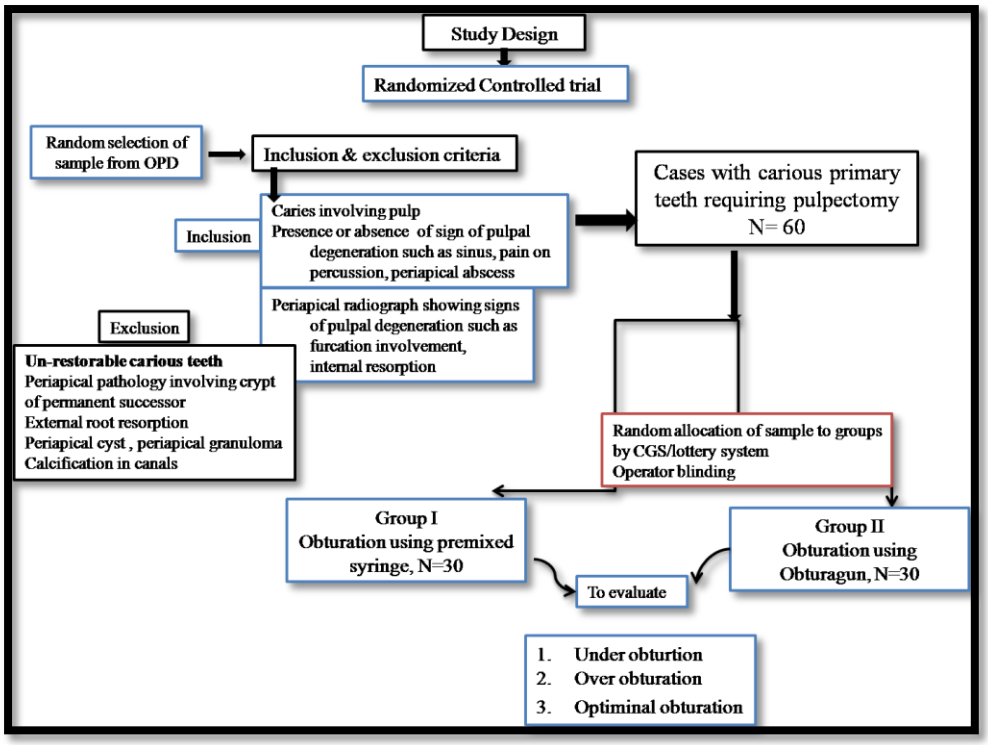

Figure 2: Distribution of sample size for calculation of average pulp cavity of primary teeth

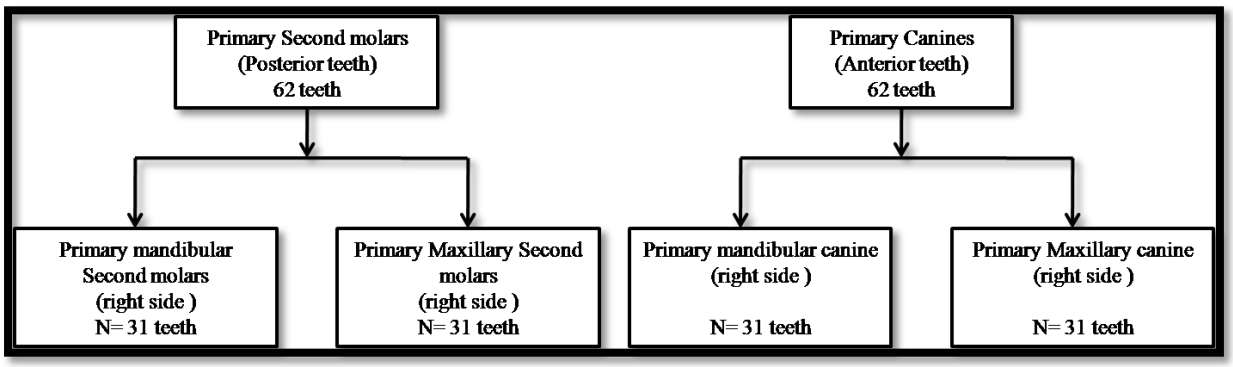

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Figure 3: Obturagun