COMPARATIVE EVALUATION BETWEEN MANUAL K-FILE AND HYBRID ROTARY PROTAPER NEXT TECHNIQUES FOR PRIMARY MOLAR PULPECTOMY: A CLINICAL STUDY

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LIST OF ABBREVIATIONS

Sr. No.	Short Form	Full Form
1	PTU	ProTaper Universal
2	PTN	ProTaper Next
3	H file	Hedstrom File
4	K file	Kerr File
5	G-G Drills	Gates Glidden Drills
6	GIC	Glass Ionomer Cement
7	CDE	Continuing Dental Education
8	RWL	Radiographic Working Length
9	IOPA	Intraoral Peri-apical Radiograph
10	LA	Local Anesthesia
11	Ni-Ti	Nickel- Titanium
12	SS	Stainless Steel
13	NaOCl	Sodium Hypochlorite
14	EDTA	EthyleneDiamineTetracetic Acid
15	SSC	Stainless Steel Crown
16	ZOE	Zinc Oxide Eugenol
17	$Ca(OH)_2$	Calcium Hydroxide
18	CBCT	Cone Beam Computed Tomography
19	HF	HyFlex Files
20	TF	Twisted Files
21	NCF	Number of Cycles to Failure

INTRODUCTION

Maintenance of primary teeth in the dental arch until their physiologic exfoliation is of great concern in pediatric dentistry. The primary teeth contribute to mastication, phonation, and esthetic appearance. They provide a mold for the growth of jaws and space for adequate alignment of permanent teeth. Pulpectomy should be considered as a treatment of choice for primary teeth with evidence of chronic irreversible pulpitis or pulp necrosis with or without periapical involvement.[1] Various characteristics of primary molars such as the presence of narrow, slender, tortuous and divergent roots with accessory canals present mostly in the furcation area are to be taken into consideration while performing pulpectomy, as they complicate the treatment procedure. The long chair side time associated with this procedure, especially in children with behavior management issues further complicate the procedure. To successfully perform pulpectomy on primary teeth, an intimate knowledge of the internal and external morphology of each primary tooth is

required.[2] A practical pulpectomy technique for the primary dentition should include the following features:

1. Fast and simple procedures, with short treatment times and a minimal number of appointments;
2. Effective debridement of the root canals without weakening the tooth structure or endangering the underlying permanent teeth;
3. Few procedural complications; and
4. Maintaining tooth function until it is naturally shed.[3]

As in permanent teeth endodontic therapy, the main objective of biomechanical preparation of the primary teeth is debridement of the canals.[4] Root canal instrumentation has been performed with files, reamers, burs, sonic instruments, mechanical apparatus and since the last few years using rotary instruments.[5]

For almost the last 100 years, hand instruments have been in clinical use and they still are an integral part of cleaning and shaping procedures. Because of the thin root walls, sonic and ultrasonic cleaning devices should not be used to prepare the canals in primary teeth.[4]

Initially, carbon steel was used to manufacture root canal instruments. In 1960, it was replaced by SS alloys. To avoid the undesirable shaping effects and excessive removal of dentin from the inner aspect of curved canals by the conventional stainless steel files, they were modified by the manufacturers to increase their flexibility. Even these flexible SS instruments with noncutting tips were unable to enlarge the severely curved canals. In order to overcome this problem, instruments made of new alloy Ni-Ti were manufactured.[6]

Ni-Ti was developed by W. F. Buehler in early 1960, which is a root magnetic, salt resisting and water-proof alloy.[6] The alloy was named Nitinol, an acronym for the elements from which the material was composed; Ni for Nickel, Ti for Titanium and Nol from the Naval Ordnance Laboratory. In **1988, Walia HM et al.**[7] introduced the use of nickel titanium alloy for the manufacturing of root canal files. These alloys consist of 55% (w/w) nickel and 45% (w/w) titanium. Ni-Ti files have 2-3 times higher elastic flexibility in bending and torsion as well as superior resistance to corrosion compared to SS files.

Earlier the use of rotary instruments in primary teeth was contraindicated by some, suggesting that during instrumentation the curves increase the chance of perforation of the apical portion of the root or the coronal one-third of the canal into the furcation. Hence, precurving of all instruments was recommended to reduce the possibility of perforation.[8] But now, the more flexible Ni-Ti instruments are recommended rather than SS instruments. Hand or rotary techniques are ideal for primary teeth.[4]

There are no clear guidelines on the use of the rotary system for instrumentation in primary teeth. After the successful use of the rotary system for pediatric endodontics initiated by **Barr ES et al. (2000)**[9], many in-vitro [5,6,10-18] and few in-vivo studies [3,19-23] have been carried out in primary teeth using various rotary systems and have shown to reduce the chair side time, produce less procedural errors with better quality of obturation. The different Ni-Ti rotary systems that have been studied in primary teeth include the Profiles[5,6,9,11], ProTaper[3,11-13,20,23], Mtwo[14,16,17,23,25], FlexMaster[10,21], Hero Shaper[11,24], Twisted Files[12], Wave One[13,15], One Shape[15], Reciproc[17], V taper[18], K3[19], Revo-S[25] and ProTaper Next[25].

The ProTaper rotary file system (Dentsply Maillefer, Ballaigues, Switzerland) developed in 2001, is one of the most commonly and successfully used rotary system for

instrumentation in primary teeth. Advances in the designing features of the ProTaper files lead to the development of ProTaper Next rotary file system (Dentsply Maillefer, Ballaigues, Switzerland) in 2013. It is a 5-file system, numbered X1, X2, X3, X4 and X5 with each having a tip size of .017, .025, .030, .040 and .050 and taper of 4%, 6%, 7%, 6% and 6% at 1mm from tip respectively. Its characteristic design features such as an off-centered rectangular cross-section leading to a swaggering and unique asymmetric rotary motion and its manufacturing from M-wire technology lead to its greater flexibility, reduced risk of fracture and increased resistance to cyclic fracture.[26] These characteristics help shape the root canal to a more conical shape and thus enhance the quality of root canal filling. Little is known about the impact of these design modifications on the instrumentation time and quality of obturation for primary teeth pulpectomy. Very few in-vivo studies[3,9,19-23] have been carried out to assess the effectiveness of rotary instrumentation in primary teeth. Due to the advanced features of ProTaper Next rotary system, various studies showing its effectiveness in permanent teeth[27-33] have been carried out. Search of literature reveals none such study being undertaken in primary teeth.

Hence, study was planned to compare the instrumentation time and quality of obturation following the use of Manual K files and hybrid rotary ProTaper Next technique for pulpectomy in primary molars.

AIM AND OBJECTIVES

Aim of the study:

To evaluate and compare the instrumentation time and quality of obturation using manual K file and hybrid rotary ProTaper Next techniques for primary molar pulpectomy.

Objectives:

1. To evaluate the instrumentation time and quality of obturation in primary molars using manual K-files.

2. To evaluate the instrumentation time and quality of obturation in primary molars using hybrid rotary ProTaper Next technique.

3. To compare the instrumentation time and quality of obturation in primary molars between the manual K-File and hybrid rotary ProTaper Next techniques.

REVIEW OF LITERATURE

Coll JA, Sadrian R (1996)[34] reviewed 65 children with 81 pulpectomies in primary teeth for long-term success. They gave various clinical and radiographic criteria to evaluate the success of pulpectomy procedure. Clinical criteria included were: 1.No gingival swelling or sinus tract 6 months or more post-operatively. 2. No purulent exudate expressed from gingival margin. 3. No abnormal mobility other than that of normal exfoliation and 4.No pain on post-operative check-up. The radiographic criteria were: 1.No pathologic signs of external or continued root resorption if any was present pre-operatively.2.A bifurcation radiolucency resolved 6-12 months postoperatively and 3.No periapical radiolucency formation postoperatively. Adequacy of the endodontic fill was recorded. For molars, a short fill meant all the canals were filled 1mm or more short of the apex, a complete fill had one or more of the canals having ZOE ending at the radiographic apex, and a long fill meant any canal showing ZOE outside the root.

Following the tooth loss, the alveolar area was examined radiographically for signs of retained ZOE. They observed a success rate of 77.7% after a follow-up of 90.8 months. Enamel defects were observed in 18.7% of the succedaneous teeth. They also observed that teeth without any or minimal preoperative root resorption and those filled short of or completely to the apex had a significantly greater success rate than long fills.

Barr ES, Kleier DJ, Barr NV (2000)[9] performed pulpectomy on a primary central incisor and mandibular second molar using rotary Profiles 0.04 taper for instrumentation. They suggested that the same principles of canal debridement and dentin shaping using Ni-Ti that are applied to permanent teeth must be used for primary teeth. The canals were cleansed and shaped with sequentially larger files until the last file bound. They suggested that it is not necessary to use a "crown down" instrumentation technique in primary teeth since the dentin cuts more easily than in permanent teeth. Also, care must be taken not to over-instrument as perforations can readily occur in thin dentinal walls. After irrigation, the canals were dried and filled with a stiff paste of USP ZOE. They considered this technique as a more effective way to debride the uneven walls of primary teeth. The authors suggested that the novice clinician should begin by using the .04 rotary tapers since they are efficient without undue aggressiveness. The study concluded that the use of Ni-Ti files allow easy access to all canals with faster and easier removal of tissue and debris compared to hand files. It also results in a funnel-shaped preparation facilitating a consistently dense uniform fill with some disadvantages like the cost of Ni-Ti files, low-speed constant - torque handpiece and the need to learn the technique.

Silva LA, Leonardo MR, Nelson-Filho P, Tanomaru JM (2004)[5] compared the cleaning capacity and instrumentation time in 17 deciduous molars with 33 mesial and distal canals using the manual and rotary instrumentation techniques. Coronal access was

performed and working length was obtained. The root canals were injected with India ink. Teeth were divided into 3 groups: Group I— Manual instrumentation with K files upto no.35 file and stepped back to no.50 file; group II—Instrumentation using rotary Profile .04 upto no.35 file and stepped back with no.40, no.45 and no.50 files activated by an Endo Plus motor at 250 rpm; Group III—Control group where root canals were not instrumented. The instrumentation time was recorded using chronometer and the cleaning capacity of techniques was measured after the clearing process by analyzing the removal of India ink from the cervical, middle and apical third of the canals with a stereoscopic magnifying glass. The results showed no significant difference for cleaning capacity between manual and rotary techniques in the 3 root thirds, but it was different from control group. Time needed for rotary instrumentation (3.46 minutes) was significantly less than with the manual technique (9.06 minutes).The Ni-Ti files do not need to be precurved due to elastic memory and the root canal preparation is quicker because they are activated by a motor. However, the operator needs training because of loss of tactile sensitivity. The study concluded that although no differences in cleaning capacity were observed, the reduced instrumentation time with the rotary technique was a relevant clinical factor.

Kuo CI, Wang YL, Chang HH, Huang GF, Lin CP, Guo MK et al (2006)[3] developed a modified protocol for root canal instrumentation using Pro Taper rotary files in 51 primary molars requiring pulpectomy in 22 children, aged between 3.2 -7.7 years. It involved the use of No.10 K-file to explore the canals followed by SX file to about 3 mm beyond the canal orifice for coronal enlargement and obtaining straight-line access and then S2 file upto the working length. A dry cotton pellet moistened with one-fifth-diluted Buckley's formocresol solution was placed over the canal orifices and the tooth was sealed with an intermediate restorative material. 5 to 7 days later, No.25 or 30 H-file

were used because most of the primary molar root canals are ribbon-shaped and the Ni-Ti files are designed mostly for conical root canals. The root canals were filled with Vitapex. Clinical signs and symptoms and radiographic appearance were assessed based on the Coll and Sadrian criteria at 3-month intervals for 12 months. The clinical evaluation was carried out by the operator. The radiographic evaluation was performed by two senior pediatric dentists. The entire first visit was generally completed within 30 minutes. With regard to canal filling quality, 28 cases (55%) were flush-filled, 8 cases (16%) were under-filled, and 15 cases (29%) were over-filled. Ledges, over-instrumentation, instrument separation, and lateral perforation were not encountered. They obtained a success rate of 95% at the 12-month follow-up. The study concluded that using the modified protocol, it took only 4-5 minutes to prepare all of the root canals of a primary molar, resulting in a consistently dense fill.

Nagaratna PJ, Shashikiran ND, Subbareddy VV (2006)[6] compared the efficacy of Profiles and K files in 20 permanent and 20 primary molars which were divided equally into two groups. In group I: K files till no.25 and in group II: Profile 0.04 taper 29 series from size 2 to 7 were used. Internal 3D shapes of the canals were determined by intracanal impressions made using light and heavy bodied vinyl poly siloxane impression materials. The impressions were viewed within 24 hrs under a stereomicroscope to assess the flow, taper, and smoothness of walls. The time taken for NiTi files was shorter than K-files in primary teeth than permanent teeth that may be due to the shorter root length. NiTi reduces the patient fatigue. The fracture was seen more in NiTi, though K files showed more deformities. This was due to the tendency of instruments to bind with the canals, with results that continued rotation of hand piece resulted in wearing of the cutting blades. The failure of larger instruments was due to the lack of initial orifice enlargement, a reflection of increased taper of instruments with

results that they bind more at the orifice. The study concluded that Profile series 29 rotary instruments prepared canal rapidly with good taper and smoothness but the fracture was noted more. Canal preparation with K-files is time-consuming with poor taper and smoothness but instrument fracture is less and it is more cost effective. NiTi rotary use would be more advantageous in the child patient as the chair-side time is significantly reduced.

Crespo S, Cortes O, Garcia C, Perez L (2008)[35] divided 60 single rooted primary teeth into two groups and compared the efficiency, preparation time and root canal shape using Profile rotary system and K-Files. Profile is not aggressive and cuts less than other systems. In the conventional group, K-files with quarter turn-pull technique were used. In Ni-Ti rotary group, Profile 0.04 taper instruments starting with the one that better approximated the canal upto the WL and then 4 sequentially larger taper files were used. The rotary files were used with a X-smart motor at 250 rpm and slow torque and the preparation time was noted. Intracanal impressions were made using light and heavy bodied vinyl siloxane materials and observed within 24 hrs. The rotary system showed statistically less instrumentation time compared to conventional system compensating for the higher expense of the rotary files. It is due to the fact that less number of files are used with rotary systems as well as they are engine powered, hence faster. It can positively influence treatment as the patient cooperation is not lost due to tiredness. However, this system can generate more anxiety in a child due to its noise and vibration, potentially hindering cooperation. Also, passing the working length should be avoided as it will enlarge the apical orifice leading to overfilling. Profiles have twice the taper of K files resulting in more conical canals. The study concluded that the higher conicity seen with rotary files allows easier insertion of the material and facilitates condensation, favoring a higher quality of filling and increasing clinical success.

Kummer TR, Calvo MC, Cordeiro MM, de Sousa Vieira R, de Carvalho Rocha MJ (2008)[36] evaluated ex-vivo the instrumentation time, risk of perforation and dentin removal by manual and rotary instrumentation in 80 primary teeth embedded in resin and sectioned for evaluation before and after instrumentation. In group I: 40 teeth were instrumented using K files from sizes 15 to 40 with "watch-winding" manipulation; group II: 40 teeth were instrumented using Hero 642 files with taper 0.04, size 30, 2 mm short of the WL; taper 0.02, size 35 and 40, up to the WL that were introduced into the canal with a gentle push-pull motion and a reducing 50:1 handpiece. The results showed no instrument fracture and removal of a larger amount of dentin at the coronal and middle thirds by manual instrumentation. This may be explained by the tendency of the operator to perform more intensive instrumentation at the side opposite to the most favorable support. Root perforations coincided with areas showing largest resorption, primarily affecting the middle thirds and lingual root canals of the maxillary and mandibular molars as the dentin walls in these areas are thin. The study concluded that the use of rotary technique leads to more regular canals and shorter instrumentation time. This factor is clinically relevant in pediatric dentistry as it allows faster procedures with the maintenance of quality and security, as well as reducing the patients and professionals fatigue. However, previous training of the operator in rotary instrumentation is important to control the working length because there is a reduction in tactile sensitivity during apical preparation compared with manual filing.

Nazari Moghaddam K, Mehran M, Farajian Zadeh H (2009)[10] conducted a study on 23 extracted primary molars to compare the cleaning efficacy and instrumentation time using K files and Flex Master files. In group I: 30 canals were instrumented manually using K files upto size 25 and step back upto size 35; group II: 30 canals were coronally enlarged with the Orifice Shaper "Introfile" followed by crown-

down preparation using Flex Master files 25/04 and 25/02; group III: 8 canals as control group. Teeth were cleared for analysis of cleaning efficacy as stated by Silva et al. The advantages of NiTi rotary files include their ability to create smooth, predetermined funnel-form shapes with minimal risk of ledging and transportation, no need of precurving, reduced probability of canal deformation due to their elastic memory and radial land that keeps the file in center of root canal. But, the basic dilemma is that all rotary instruments are centered in root canals during rotation and leave the unclean and potentially infected tissue in fins and isthmuses. There are no clear guidelines for their use in primary teeth. Little is known about the impact of these design modifications on deciduous teeth pulpectomy. Hence, this study was carried out. There were no statistical differences between the three-thirds of the roots prepared by rotary instruments, coronal thirds of roots prepared with hand instruments were significantly different from other two sections. This may be due to the operator's tendency to place hand instruments further coronally; while rotary preparation path is not affected by the operator. The study concluded that the canals which were prepared by rotary files required less instrumentation time and produced a conical pathway allowing effortless entrance of obturating paste and less overfilling. Clinically, time efficacy in primary molar endodontics, especially with the unpredictability and difficulty of canal morphology is invaluable.

Madan N, Rathnam A, Shigli AL, Indushekar KR (2011)[37] compared the cleaning capacity and instrumentation time with manual K-files and rotary ProFiles in-vitro in 75 primary molar root canals. The teeth were decalcified, dehydrated, cleared, and analyzed for the presence of dye remaining on the root canal walls. The results showed a significant difference in cleaning capacity of the root canals with ProFiles and K-files in apical and coronal thirds of the root canal. ProFiles were found to be more

efficient in cleaning the coronal thirds and K-files in cleaning the apical thirds of the root canals. They also suggested that the recently recommended technique for use of rotary NiTi instruments employs the use of "Hybrid Instrumentation technique." It employs the combination of tapered instruments for crown-down technique and apical enlargement with flexible instruments. This combination is ideal to instrument root canals in permanent teeth but no literature is available for its use in primary teeth. Both the techniques were equally effective in cleaning the middle thirds of the canals. The time taken during the cleaning of the root canals appeared to be statistically shorter for K-files than Profiles.

Ochoa-Romero T, Mendez-Gonzalez V, Flores-Reyes H, Pozos-Guillen AJ (2011)[19] conducted a double-blinded, randomised, clinical trial comparing the instrumentation and obturation times and quality of root canal filling between rotary and manual instrumentation techniques in 40 necrotic primary teeth in children aged 5-9 years. For manual technique, K files were used with quarter-turn-pull technique. For rotary technique, K3 files with 0.06 taper were used. The canals were cleaned and shaped with 3 progressively larger tapered files, using "crown down" technique. Canals were filled with iodoform paste, coronal space was covered with GIC and a preformed metallic crown was placed. Instrumentation and obturation time elicited in the rotary group (mean- 13.3 min and 1.5 min) was significantly less than the manual group (mean- 17.7 min and 2.1 min). It correlates with less chair time, creating a positive impact on child cooperation by diminishing fatigue. For the manual and rotary technique, 50% and 80 % canals were optimally filled, 40% and 10% were underfilled and 10% each were overfilled respectively. Rotary NiTi instrumentation allows greater apical enlargement, reducing apical transportation and improving canal shape. Thus, promoting a higher filling quality and increasing clinical success. Also, they have 2-3 times greater flexibility compared to

stainless steel owing to their very low modulus of elasticity and superior resistance to torsional fracture due to their ductility, facilitating their use in curved canals with minimum transportation and fracture. The study concluded that the use of rotary instruments in the pulpectomy of primary molars represents a promising technique as chair time is significantly reduced.

Pinheiro SL, Araujo G, Bincelli I, Cunha R, Bueno C (2012)[38] conducted a study to compare the cleaning ability and instrumentation time between manual and rotary technique for pulpectomy in 15 extracted deciduous molars. After access opening and working length determination, canals were filled with India ink. After 48 hours, teeth were divided into three groups: G1 – manual instrumentation with K files utilizing initial instrument with better fit and then two sequential instruments, G2 – Instrumentation using rotary Endowave files No.15 to 30 at 300 rpm speed and 3 N/cm torque, G3 – Instrumentation using rotary ProTaper files S1, S2, F1and F2 using an electronic motor X smart at 300 rpm speed and 3 N/cm torque. Both the rotary files were used with anti-curvature filing motion. The teeth were sectioned buccolingually and three blinded examiners evaluated the canal cleaning and noted the instrumentation time. ProTaper system presented shorter instrumentation time compared to manual technique. The shorter time required is probably related to the reduced number of instruments and greater efficacy of dentin cutting, reducing patient fatigue. No statistically significant difference was seen between the groups regarding cleaning ability. The present methodology employed an increasing sequence of first series rotary instruments to allow anatomical compatibility between the instrument and root canal of deciduous molars. The literature presents no specific operative sequence for deciduous teeth, therefore protocols for permanent teeth are adapted for this purpose. The various advantages of using NiTi files include their flexibility in curved and irregular canals, allow easy access to all canals,

maintain original canal shape with a reduced tendency of apical flaring and iatrogenic errors. Considering the benefits and cost, their utilization in Pediatric dentistry is well indicated, especially in children with behavior management problems. The study concluded that ProTaper system was more effective for instrumentation in deciduous teeth presenting shorter instrumentation time and similar cleaning ability compared to other techniques.

Mhatre SH, Bijle MNA, Patil SG (2012)[39] presented a case report of a 5-year-old child requiring pulpectomy with 75 wherein Sx ProTaper rotary file was used for instrumentation using the crown down technique. ZOE was used as the obturating material and the cavity was sealed with GIC. This pulpectomy procedure was completed in a single visit. They suggested that one visit endodontic treatment is faster, more convenient and prevents the recontamination of root canals between appointments. However, inability to dry canals completely, insufficient time for the procedure, long appointments induced stress on patients, operator skill, root canal anatomy and instrument availability all should be considered while deciding upon single visit treatment. The result of this case report demonstrated a successful response to single visit pulpectomy using single file ProTaper system and 5.25% NaOCl irrigation. This provides a satisfactory treatment modality minimizing the requirement for patient reappointment and therapeutic duration. Although further studies with larger samples are required to confirm the findings demonstrated by this report.

Musale PK (2013)[40] gave a review on rotary instrumentation in primary teeth. He pointed out that that there are two major concerns of hand instrumentation in primary teeth. One is the increased preparation time, especially for young children with limited cooperation and the other being inconsistency of quality tapered preparation leading to further problems in obturation. Rotary instrumentation represents a significant evolution

in endodontics which results in a faster, safer and better quality preparation. Its use in permanent teeth has been very successful. Primary root canals are flattened, narrow, curved and ribbon-shaped with myriad anatomic variations and the impact of these design modifications on their preparation is not clearly known. Many authors have reported clinical success in primary molars with a modified protocol using Profiles, ProTaper, Hero Shaper and K3 rotary files. He highlighted important points which are to be taken into consideration when using rotary in primary teeth. Application of protocols for permanent teeth to primary teeth may lead to lateral perforation of the inner root surface, especially in curved molar roots. The abrupt cervical constriction, with a shelf of dentin overlying the canal orifice results in an acutely curved root canal orifice in primary molars which should be removed to improve straight-line access and reduce the risk of instrument separation. Orifice enlargement files may be used only for early coronal enlargement and to facilitate straight-line access. Each rotary file should be inspected for unwinding or distortion before introducing into the canal. Only light pressure should be applied during preparation while using torque controlled Endo-motors. The number of times each file is used should be an operator's decision depending on various factors. He concluded that modified rotary instrumentation protocol is the time efficient way to do root canal preparation of primary teeth in pediatric dentistry.

Kathariya MD, Patil S, Patil A, Jadav RH, Mandlik J, Sharma AS (2013)[41] conducted a cross-sectional study among 182 postgraduate students to assess the usage of different advanced endodontic instruments in the specialty of pedodontics from different dental institutes in India using a structured questionnaire. Response to the use of surgical microscope, ethyl chloride, loop for magnification, digital radiography, apex locator, Ni-Ti rotary file and electric motor was assessed. Introduction of these new technologies has made endodontic treatment easier, faster and most importantly, better.

The use of new techniques was more commonly seen by males and seniors as compared to juniors. They observed that the highest positive response to the usage of advanced endodontic instruments was related to Ni-Ti rotary files with the highest number seen among 3rd-year students. Also, it was found that instead of availability newly advanced endodontic instruments and techniques, their use and acceptance by postgraduate students of pediatric dentistry is not at an acceptable level and there is a need for more training and comprehensive education regarding new techniques and methods.

Vieyra JP, Enriquez FJJ (2014)[20] compared the instrumentation time and efficiency of rotary and hand instrumentation on 45 vital and necrotic human primary teeth in children aged 4-7 years. Root canals were instrumented in Group I: K-files and "step back technique" up to size #35; Group II: Rotary Light Speed LSX instruments upto size #50 for anterior teeth and #40 for molars; Group III: Pro Taper files-SX, S1 to F2. Because many pulpal ramifications cannot be reached mechanically, copious irrigation was carried out with 0.5% NaOCl and final irrigation with distilled water using EndoVac irrigation system. Teeth were obturated using Vitapex. The entire first visit, including local anesthesia, rubber dam placement, root canal preparations was completed within 18-20 minutes. Of which, canal preparation using rotary instruments took 8-12 minutes. Mean instrumentation time for the three groups was GI: 20.10 ± 7.86 minutes, GII: 9.37 ± 2.19 minutes and GIII: 10.45 ± 4.77 minutes. With regard to canal filling quality, 29 cases were flush-filled, 5 cases were under-filled and 11 cases were over-filled. Children were recalled for examination based on criteria of Coll and Sadrian at 6-month intervals for 2 years. The over-filled Vitapex was gradually resorbed within 9 months with no clinical symptoms or signs. Clinical and radiographic success rates were 95% at 12 to 24 months follow-up. They suggested that although their protocol recommended instrumentation up to size 40, use of the combined techniques is recommended to allow more effective

instrumentation. However, the produced dentin removal must be evaluated to establish the file size that may provide higher security to dental tissues and avoid excessive dentin removal, increasing the fragility of tooth structure. Instrumentation by both techniques is safe to the deciduous tooth and permanent tooth bud provided that all steps are strictly followed, allowing disinfection and contributing to the repair of infectious and inflammatory processes. The study concluded that time efficacy in primary molar endodontics, especially with the unpredictability and difficulty of canal morphology, is invaluable. The use of rotary files in primary teeth result in a) Decreased working time that helps maintain patient cooperation by diminishing the potential for tiredness. b) A more conical shape of canal favoring a higher quality of filling and increasing clinical success.

Ahmed HM (2014)[42] gave an overview of the procedure of pulpectomy in primary molar teeth and also discussed the current updates and recommended guidelines that should be followed for this procedure. The unpredictable outcomes of nonvital pulpotomy and high failure rate of early extraction followed by space maintainers leaves no viable substitute than total pulpectomy for treating nonvital teeth. The primary molars show peculiar characteristics such as aberrant internal anatomy due to secondary dentine formation and physiologic root resorption and complex pulp and periodontal inter-relationship. For pulpectomy in primary teeth, application of rubber dam or equally effective isolation technique is mandatory. Accurate determination of working length using radiographs and electronic apex locators is recommended. For manual instrumentation, stainless steel files not larger than no.30, should be used carefully to prevent the occasion of broken segments. The use of rotary NiTi files reduce instrumentation time and has become popular. Intermediate solutions such as saline or sterile distilled water followed by careful drying can prevent the formation of toxic

interactions. ZOE, $Ca(OH)_2$, Iodoform based pastes such as KRI paste, Metapex, Vitapex, Endoflas are used for obturation. Following filling and resolution of all symptoms, the tooth should be restored with a suitable coronal restoration followed by stainless steel crown to prevent microleakage. He concluded that adequate knowledge of anatomic variations, radiographic limitations, instrumentation procedures, irrigants and root filing techniques are essential prior to commencing pulpectomy procedures in exfoliating or retained primary molars.

Makarem A, Ravandeh N, Ebrahimi M (2014)[21] conducted a study on 46 children aged 3-6 years with extensive caries and history of spontaneous pain in the primary second molars. They were equally divided into two groups which differed in their instrumentation technique. Periapical radiographs were taken using the paralleling technique. In group A. instrumentation was carried out using H files till #30. In group B rotary Flex Master files #20, #25 and #30 with 4% taper were used. Instrumentation time was recorded using a chronometer. Canals were filled with ZOE using a Lentulo spiral (#25). Final radiographs were taken by the same operator and two other pediatric dentists, blinded to the assignment, evaluated the radiographs to record the mean distance from apex to fill level in mesial and distal roots, obturation form, and presence of perforation. The difference noted in terms of instrumentation time was statistically significant, with group A having mean instrumentation time of 18.73±3.15 minutes and in group B was 10.1±1.71 minutes. No differences in terms of canal obturation time were obtained. There were significantly more superior mesial canals in group B than in group A which might be due to the better canal instrumentation. However, in the distal canals, the difference was not significant. Regarding obturation form, 73.9% in rotary and 47.8% in conventional group were acceptable suggesting that canal forms were more closely followed with the rotary method. Significantly less number of voids were seen in rotary

group compared to the manual group. No canal perforations were noted. The study concluded that pulpectomy procedure with rotary method reduces chair time and provides a more acceptable obturation quality than the conventional method.

Dhingra A, Banerjee S, Aggarwal N, Yadav V(2014)[27] carried out an ex-vivo study on 50 mandibular first molars to evaluate root canal curvature, canal transportation, centric ability and working time of ProTaper Next rotary file system using CBCT. Teeth were sectioned through the furcation and mounted on the acrylic block. Only mesiobuccal roots were considered. Working length was determined and seven small grooves filled with composite acted as reference points from the apex of the tooth at levels 0, 1, 2, 3. 5 and 7 mm, for the superimposition of CBCT images obtained before and after instrumentation. The speed was set at 350 rpm with a torque of 2.5 N/cm. Meantime taken to prepare root canals with PTN upto X2 was 183 s and 245 s upto X5.The high cutting efficiency of PTN and need of two files, i.e. X1 and X2 in most cases reduces working time as compared to many other rotary systems giving the operator more time for proper irrigation and recapitulation. The canal transportation using PTN was negligible and more in mesial direction apically and in distal direction coronally. Centric ratio was nearer to one exhibiting centered preparations. Also, PTN created a negligible or slight change in the angle of curvature showing that it produces less straightening and preserves the canal curvature. It is made up of M wire Ni-Ti technology that is formed by the characteristic thermomechanical processing. It is flexible and has an increased resistance to cyclic fatigue. The taper varies, therefore, contact between dentin and file is reduced, reducing the taper lock. In the study, one set of instrument was used to prepare 4-5 canals with no incidence of instrument breakage. Results of the study proved that there are very fewer chances of instrument separation. The cross-section is rectangular in shape resulting in an asymmetric motion, where only two edges contact with canal wall at a time leading to

an efficient canal preparation. The rotation of the off-centered cross-section creates an enlarged space for debris removal, optimizes the canal tracking and reduces binding. It has a small shaft size, providing better access to posterior teeth. They concluded that PTN is one of the few rotary systems that provides quick and safe endodontic treatment and is successful in preserving root canal anatomy with less incidence of instrument separation.

Dhingra A, Banerjee S, Yadav V, Aggarwal N (2014)[28] compared the canal shaping with PTN and the PTU using CBCT in mesiobuccal canals of 100 mandibular first molars. He sectioned the teeth through the furcation and performed access opening of the mesiobuccal canals. Teeth were divided into two instrumentation groups: Canals were prepared in Group I: with PTN rotary file system and in Group II: with the PTU rotary file system. The pre-instrumentation and post instrumentation scans were superimposed to calculate canal transportation and the centric ability of the instrument and cross-sectional area of the root canal. ProTaper Next has been recently introduced in the market by Dentsply Maillefer. The system consists of 5 files from X1 to X5. The instrument is available in various sizes. Various features that make PTN better than PTU include its rectangular cross section with only two edges in contact with the canal wall at one time producing characteristic asymmetric motion thus maintaining anatomy of the canal. The PTN files are manufactured using M-wire technology. M–Wire has been developed through a proprietary thermomechanical processing procedure. It contains the 3 crystalline phases, including deformed and micro twinned martensite, R-phase, and austenite. Fracture of rotary NiTi instruments is because of cyclic fatigue which usually occurs near the apical third of a root canal with the highest curvature without any warning. The microstructure of NiTi materials plays an important role on their mechanical behavior and root canal preparation, especially regarding strength and fatigue resistance. Hence, the PTN files have greater resistance to cyclic fatigue and increased flexibility.

The shaft size of PTN is 13 mm as compared to 15 mm of PTU allowing better access to posterior teeth by PTN compared to PTU. The study concluded that PTN exhibited less canal transportation, less canal straightening, removed less dentin, gave a more centered preparation, and had reduced instrumentation time compared to PTU owing to its designed features.

Dhingra A, Gupta R, Singh A (2014)[29] conducted a study comparing the centric ability of ProTaper Next, Wave One & ProTaper using Cone Beam Computed Tomography of 90 mandibular molars. The canal centering ability of the instrument depends on the alloys used for manufacturing it, the instrument design, cross section, taper and tip. The ability to enlarge the canal without canal deviation, apical transportation or instrument separation is a primary objective in endodontics. So it is important to compare the efficacy of instruments during preparation of curved root canals with respect to ability of instruments to maintain original canal curvature, centering ability of the instrument during canal preparation and its ability to preserve dentin thickness. The molars were divided into three groups. In group I ProTaper Next was used for instrumentation in the sequence ProTaper Universal SX then ProTaper Next X1, X2, X3, and X4 at a speed of 300 rpm and 200 g/cm torque in a rotational motion. In group II Wave one primary file was used as per manufacturer's recommendations. In group III ProTaper files were used in the sequence Sx, SX, S1, S2, F1, F2, F3, and F4. As Ni-Ti instruments require less stress to bend, they exert less force and being nonaggressive by nature, do not lead to excess cutting on either side. Stainless steel, however, has a tendency to cut more in one wall than the other. ProTaper Next is designed with a rectangular cross section for greater strength. The patented design's axis of rotation differs from the center of mass. As a result, only two points of the rectangular cross-section touch the canal wall at a time. It is used with a unique asymmetric rotary motion

that further enhances its canal shaping efficiency. ProTaper Next is available in five instruments with diameter and taper (X1 0. 17/0. 04, X2 0. 25/0. 06, X3 0. 30/0. 07, X4 0. 40/0. 06, X5 0. 50/0. 06). These files are manufactured with M-Wire NiTi alloy for increased flexibility and resistance to cyclic fatigue.

Musale PK, Mujawar SA (2014)[11] conducted a study on 60 extracted primary mandibular second molars which were divided into 4 groups of 15 teeth each. Instrumentation was carried out in all the four groups by different methods. In group I: K files were used till No.30 group II: Profiles 0.04 were used till No.30, group III: Sx, S1, and S2 ProTaper Universal files were used with a modified protocol, group IV: Hero Shaper 0.04 file till no.30 was used. After instrumentation files were inspected for distortion and instrumentation time was measured. Internal three-dimensional root canal shapes after preparation were analyzed using CBCT. For an analysis of the cleaning efficacy, the teeth were cleaned as reported by Silva et al. Under the recommended protocols of the present study, it can be concluded that taper of the canal prepared with all rotary files was significantly better than K-files and the shaping ability was not significantly different amongst the rotary file groups. Cleaning efficacy of rotary files were significantly better than manual instrumentation with K-files and none of the rotary files were distorted/separated during this study. Thus, it was concluded that rotary files can be an acceptable alternative in primary teeth root canal preparation as instrumentation time is reduced and the prepared root canal is more conical which favors better obturation. Rotary files also facilitated better removal of intracanal tissue and debris. These positive results emphasize the need for further investigation.

Katge F, Patil D, Pimpale J, Wakpanjar M, Shivsharan P, Dalvi S (2014)[43] gave a review on application of rotary instrumentation in pulpectomy procedure for

primary teeth. Although the manual instrumentation is widely used in primary teeth, there are limitations regarding the effective cleaning of root canals, possible ledge formation, perforations, dentine compaction and instrument fracture. Various authors have reported clinical success in primary molars with a modified protocol using Profile, ProTaper, Mtwo, Flex master, Light Speed LSX, Hero 642 and K3 rotary files. From the various studies, they have concluded that use of Ni-Ti rotary files allows easy access to all canals, maintains original anatomy, does not need precurving, allows quicker preparation, reduce possibility of root canal deformation, increasing patient cooperation and results in a more predictable uniform fill of obturation paste. They also suggested various aspects to be taken into consideration when using the rotary file system like never instrument in a dry canal, frequent inspection of the file for distortion or fracture, need for training to learn the technique, cost of endomotor, handpiece, and Ni-Ti files. They concluded that the literature on rotary techniques is limited and not many studies are available for use in primary teeth hence conclusions are difficult to draw.

Capar ID, Arslan H, Akcay M, Uysal B (2014)[30] conducted a study on 100 extracted mandibular premolars to compare the crack formation in dentin using ProTaper Universal, ProTaper Next and HyFlex rotary system. 25 teeth were left unprepared and served as a negative control; another 25 teeth were instrumented with the ProTaper Universal system up to size F4 as a positive control, and the remaining 50 teeth were shaped with the following experimental groups with an apical size 40 file: ProTaper Next X4 and HyFlex 40/0.4. After root canal preparation, all of the roots were sectioned perpendicular to the long axis at 2, 4, 6, and 8 mm from the apex, and the sections were then observed under a stereomicroscope to evaluate the absence/presence of cracks. They observed that the ProTaper Next and HyFlex instruments caused fewer dentinal cracks

compared to the ProTaper Universal instrument. However, there were no significant differences in crack formation between the ProTaper Next and HyFlex groups.

Gomes GB, Bonow ML, Carlotto D, de Castilho Jacinto R (2014)[44] compared the time required for root canal instrumentation and obturation of necrosed mandibular deciduous molars in eight children from 6 to 8 years, either using rotary or manual techniques. In the first visit, coronal access was performed with #02 carbide bur and the teeth were sealed with a formocresol-soaked cotton pellet and temporary restorative material. In the second visit, root canals were enlarged with a #15 K file and divided into two groups. In Group I: Manual instrumentation involved 21 mm K-files no.20 to no.30 used sequentially with a half-turn clockwise motion followed by a similar counter-clockwise motion and file removal.; Group II: Rotary instrumentation involved the use of 3 ProTaper NiTi files i.e.S2, F1 and F2 introduced with a push-pull motion and the root canals were shaped using S2. Root canal filling was performed with iodoform-based paste. There was no significant statistical difference between manual and rotary techniques as to the duration of instrumentation and obturation. The likely explanation for not obtaining a difference could be that the rotary system used was not developed specifically for deciduous teeth. Therefore, access to the oral cavity, child mouth aperture, and instrument size may have interfered in the in vivo rotary instrumentation dynamics. MB canal showed the highest average instrumentation time for both techniques due to the difficulty of access to this canal. The study concluded that root canal instrumentation with rotary can be an alternative to manual instrumentation in pediatric dentistry. However, it does not reduce total service, root canal preparation or filling times.

Capar ID, Arslan H, Akcay M, Ertas H (2014)[31] conducted a study on 60 extracted mandibular premolars to compare the instrumentation time and apically

extruded debris using different rotary file systems. Specimens were distributed equally across 4 groups according to the rotary files used for instrumentation. In group I: ProTaper Universal files were used in the sequence Sx, S1, S2, F1 and F2; group II: HyFlex files were used in the sequence of 25.08 and 25.06; group III: Twisted file adaptive files were used in the sequence SM1 and SM2; group IV: ProTaper Next X1 and X2 were used at 300 rpm speed and 200g/cm torque. A common design feature of ProTaper Universal and ProTaper Next is the presence of progressive and regressive percentage of taper on a single file. However, ProTaper Universal F2 instrument has a 0.08 taper and ProTaper Next has a 0.06 taper at apical 3mm. ProTaper Next has an off-centered, rectangular design that generates traveling waves of motion along the active part of the file and enhances augering debris out of the canal compared with a file with a centered mass and axis of rotation. The superior performance of this file may be attributed to the swaggering motion, variable taper that decreases the screw-in effect and dangerous taper lock by minimizing contact between the file and dentin. The study concluded that the Twisted File Adaptive and ProTaper Next systems extruded significantly less debris and the instrumentation time with ProTaper Universal system was significantly longer than all the other instruments.

Elnaghy AM (2014)[32] compared the cyclic fatigue resistance of Pro-Taper Next (PTN) with Twisted Files (TF), HyFlex CM (HF) and Pro-Taper Universal (PT). Cyclic fatigue occurs as the file is subjected to continual cycles of tension and compression that result in the structural breakdown of metal due to the concentration of stress at the propagating crack front and eventually fracture. Geometric designs, structural characteristics, and surface texture have a significant influence on the susceptibility of NiTi instruments to fracture mechanically. PTN files are available in five sizes: X1 (tip size 17 with a taper of .04), X2 (tip size 25 with a taper of .06), X3 (tip size 30 with a

taper of .07), X4 (tip size 40 with a taper of .06) and X5 (tip size 50 with a taper of .06), manufactured using M-Wire technology. M-Wire (Dentsply Tulsa Dental Specialties) is formed by utilizing a series of heat treatments to NiTi wire blanks. The M-Wire technology offers greater flexibility and resistance to cyclic fatigue than those instruments made of regular super-elastic wire. To compare cyclic fatigue resistance they used PTN X2, TF, HF and PT F1 size 20, .07 taper. 20 files from each system were rotated in artificial canals made of tempered steel with 5 mm radius and 45° angle of curvature until fracture occurred. The number of cycles to failure (NCF) was recorded to evaluate their cyclic fatigue resistance. The study concluded that cyclic fatigue resistance of PTN files was significantly greater than PT files, similar to HF files and significantly less than TF files. This can be attributed to manufacturing process including M-wire technology, off-centered rectangular cross-section, and asymmetric rotation to enhance strength. Also, the non-uniform and reduced contact points between the instrument and root canal wall could have enhanced the fracture resistance.

Nerkar R, Yadav S, Mehta V, Joshi P (2015)[45] gave a review on the use of root canal preparation in primary teeth with NiTi rotary files. Owing to the wide use of NiTi rotary instruments in adult endodontics which has proved as an efficient and effective technique, their use in pediatric endodontics has been carried out. Same principles of canal debridement and dentin shaping can be applied to primary teeth. Superior characteristics of the NiTi alloys are shape memory, high elasticity, higher strength and low modulus of elasticity compared to stainless steel. Advantages of NiTi rotary files include their flexibility and instrument design that allows the files to closely follow the original root canal path, no need of precurving, removal of tissue and debris more easily and quickly, reduced working time, the minimal likelihood of instrument fracture and ideal obturation form. These instruments are driven by a low-speed constant torque

handpiece at a rotational speed of 150-300 rpm. Different types of handpiece can be used such as rotary contra-angled, reciprocating and vertical stroke. When using rotary in primary teeth care must be taken not to over instrument as lateral perforations can readily occur in thin dentinal walls, apical overextension of NiTi can result in enlarged apical foramen and cause overfill of pulpectomy paste. Use of NiTi has various disadvantages such as the cost of the handpiece, endo motor and Ni-Ti files, susceptibility to fracture, need to learn the technique and cyclic fatigue of endodontic instruments. However, they concluded that rotary preparation for primary teeth is faster than hand preparation and this is very important to shorten the chair time in pediatric dentistry. Rotary systems also show better cleaning efficacy when compared to manual instrumentation especially, in coronal and middle one third.

Kocak MM, Cicek E, Kocak S, Saglam BC, Yılmaz N (2015)[33] conducted a study to access the apical extrusion of debris using ProTaper Universal and ProTaper Next rotary systems. 40 extracted mandibular premolars were selected. Coronal access was prepared and working length was established. An experimental model described by Myers and Montgomery was used to determine the amount of extruded debris. The specimens were divided into two groups: Group I: PTU files were used in the following sequence- SX at two-thirds of the WL, S1, and S2 at WL –1 mm and F1, F2 and F3 at the WL. Group 2: PTN files were used in the sequence PU SX, PN X1, X2, and X3.Both the files were used in a gentle brushing motion with an electric and torque-controlled endodontic motor. For PTN a rotational speed of 300 rpm and 200 g cm torque was used. PTU group had a significantly greater amount of extruded debris than the PTN group. PTU instruments are composed of conventional NiTi alloy and have a convex triangular cross-sectional design, non–cutting safety tip and a flute design that combines multiple tapers within the shaft allowing it to cut dentine more effectively. PTN files are made of

M–Wire to increase flexibility and improve cyclic fatigue. The study concluded that less extrusion of apical debris with PTN files could be related to the design of apical portion and an off-centered rectangular cross-section which provides the non-uniform and reduced contact points between the instrument and root canal wall. This plus the lower taper could lead to the removal of more debris in the coronal direction and result in less debris extrusion.

George S, Anandaraj S, Issac JS, John SA, Harris A (2016)[46] gave a review on the use of NiTi rotary instruments in primary teeth. The negotiation and through instrumentation of bizarre and tortuous canals encased in roots programmed for physiological resorption are the main challenges for pulpectomy in primary teeth. Hand preparation techniques are time-consuming and can lead to iatrogenic errors. Hence, much attention is directed to the use of Ni-Ti rotary instruments. Different NiTi rotary systems such as K3, Profiles, ProTaper, Mtwo, Flex-Master, Hero Shaper, Wave One, Reciproc and ProTaper Next have their characteristic advantages due to their variable design, taper, blades, grooves, and tips. Instrumentation using these systems has been compared with manual techniques by many authors and have shown significantly shorter clinical time, better cleaning efficacy and a more predictable uniform filing. Thus, reducing patient's and professional's fatigue. Also, their application is more appropriate in children with behavior management problems. Disadvantages in using rotary systems include the requirement of training the operator, cost of NiTi rotary systems and need to use an additional H-file system as root canals of primary teeth are ribbon-shaped and rotary instruments many leave unclean areas and infected tissue in the fins and isthmuses. Also, application of protocols for permanent teeth to primary teeth may lead to lateral perforation on the inner root surface, especially in curved molar roots. They concluded that the goals of instrumentation can be achieved with both manual and rotary techniques

but considering the preparation time as an important clinical factor in pediatric dentistry, use of rotary instruments in primary teeth pulpectomies is recommended.

Dey B, Jana S, Chakraborty A, Ghosh C, Roy D (2016)[47] gave a review comparing the use of Ni-Ti rotary and hand files instrumentation in primary teeth. In modern endodontic practice, hand-driven instruments are replaced by rotary cutting instruments due to the change in their metallurgy, instrument taper and their rotational motion in the root canals. Ni-Ti files have greater elastic flexibility in bending and torsion and greater resistance to torsion fracture. Hand preparation techniques are time-consuming and lead to various iatrogenic errors although the use of NiTi rotary files is fairly limited to permanent teeth. No clear guidelines are available for the suitable preparation technique of primary teeth despite there being several advantages of rotary instrumentation and various studies performed on primary molars. Primary and permanent teeth work on the same principle. However, the major concerns when the protocols of permanent teeth are applied to primary teeth include the shorter, thinner, ribbon-shaped and more curved roots of primary molars with undetectable root tip resorption, leaving unclean areas in fins and isthmuses and the susceptibility to lateral perforation on the inner root surface of curved molar roots. All these factors hamper the application of NiTi rotary instruments in primary teeth. Literature suggests that .04 rotary tapers should be used to begin the preparation since they are efficient without undue aggressiveness with a low-speed i.e. 150-300 rpm and constant-torque handpiece. They concluded that the rotary instrumentation would increase patient comfort, improve working conditions, help in the application of obturation paste and minimize extrusion of material, thus increasing its benefits for utilization in deciduous teeth. Notwithstanding, this is a recent technique and studies are necessary to demonstrate its efficacy, especially in pediatric dentistry.

Topcuoglu G, Topcuoglu HS, Akpek F (2016)[25] carried out a study using 60 extracted primary first mandibular molars divided into four groups to assess the amount of debris extruded apically during root canal preparation using various nickel titanium instrumentation systems and hand files. Distal roots were selected.No.10 K-file was placed in the canal and working length was established. Hand instrumentation was carried out till No.30 K-file using step-back technique. Rotary groups included instrumentation using Mtwo file system till size 30, ProTaper Next system till X3 and Revo-S system till AS 30. Apically extruded debris during instrumentation was collected into pre-weighed Eppendorf tubes which were then stored in an incubator at 70°C for 5 days. Weight of dry extruded debris was established by subtracting the pre-instrumentation and post-instrumentation weight of the Eppendorf tubes for each group. He concluded that all instruments were associated with apical extrusion of debris but ProTaper Next files caused less debris extrusion, which may be due to its unique design: an offset center of mass and rotation which provides greater cross-sectional space for enhanced cutting, loading, and movement of debris toward the coronal area of canal compared with files having a centered mass and axis of rotation. Another reason may be the less number of instruments used in ProTaper Next group.

Jeevanandan G (2017)[22] presented two cases of pulpectomies on primary mandibular molars in 4 year old children using the Kedo-S NiTi rotary files for instrumentation. After application of anaesthesia, endodontic access opening with coronal pulp extirpation was carried out and working length was determined. Biomechanical preparation was performed using crown-down technique with Kedo-S Ni-Ti rotary system (Reeganz dental care Pvt. Ltd. India). RC help was used as a lubricating paste, normal saline as an irrigant and Metapex as the obturating material. On 6 month follow up, both the cases showed clinical as well as radiographic success. This Kedo-S

system consists of three Ni-Ti rotary files with total length of 16 mm and 12 mm working length. The files are named as D1, E1 and U1 respectively. D1 file has a tip diameter of 0.25 mm and can be used in primary molars with narrow canals (mesial canals in mandibular and distobuccal canals in maxillary molars). E1 file has a tip diameter of 0.30 mm and can be used in wider molar canals (distal canal in mandibular and palatal canal in maxillary molars). U1 has a tip diameter of 0.40 mm for use in primary incisors. This system must be used in a low speed constant- torque handpiece at 150-300 rpm. Its advantages include the gradual taper that aids in easy coronal enlargement and straight-line access. As these files have variable taper and are designed according to the diameter of primary teeth they aid in efficient canal preparation avoiding over instrumentation of the inner wall of root surface resulting in better quality of obturation. The clockwise motion of these files pulls the pulpal tissue and dentin out of the canal .The duration of canal preparation was approximately 2-3 minutes that helped reduce fatigue of the patient. The disadvantages include cost of the handpiece, Ni-Ti rotary files, technique sensitivity and requirement of proper training. The study concluded that considering the better root canal preparation and quality of obturation, the use of Kedo S paediatric rotary files is recommended for pulpectomy procedure in primary teeth.

Govindaraju L, Jeevanandan G, Subramanian E (2017)[48] conducted a survey to assess the level of knowledge and practice of Indian dentists in the use of rotary instrumentation in primary teeth. It was a questionnaire survey conducted from August to November 2016. The sample comprised of 100 dentists which included both, bachelors and masters in dental surgery, practicing in Chennai. A self-administrated 10-item questionnaire was prepared in English and validated by a group of 10 dentists who were asked to respond to the same questions twice, once on the 1st day and other after a week. The results obtained showed that 50% used rotary instrumentation in primary teeth of

which 32% were MDS, 11% had attended CDE programs regarding rotary instrumentation. ProTaper was the most commonly used rotary system (34%). Advantages of using the rotary system as observed by the participants included decreased working time (26%), better removal of pulp tissue (13%), uniform canal preparation (12%) and easy access to the canals. The disadvantages experienced by the practitioners were instrument separation (26%), cost of the system (25%), length of the existing file system (15%), length and taper of the existing system (27%). 76% of them were not aware of minimally invasive files and its use in primary teeth and 66% thought that there was a need for an exclusive rotary file for canal preparation in primary teeth. The study concluded that there is a need for more training and comprehensive education programs regarding the technique of using the rotary file system in primary teeth and both length and taper were the limitation in using existing rotary system in primary teeth and there is a necessity for developing an exclusive pediatric rotary file.

Mehta DN, Dave BH, Bargale SS, Poonacha KS, Mulchandani V, Thomas PS (2017)[49] conducted an online questionnaire-based survey to access the knowledge, attitude, and practice regarding the use of rotary instruments by pediatric dentists. It comprised a set of 12 validated questions sent to 596 student members of Indian Society of Paedodontics and Preventive Dentistry out of which 365 participants responded back. 85% favored the use of rotary instruments in pediatric practice due to their advantages including efficiency in both, preparation time and root canal shape, increased patient cooperation by diminishing potential for tiredness, favor a higher quality of filling and increase clinical success. 55% had attended a Continuing Dental Education or Workshop regarding rotary instruments. Knowledge regarding their use is mandatory to avoid procedural errors and patient discomfort. 67.2% were aware of the generations of rotary

instruments in pediatric practice from various sources. 43.2% were aware of minimally invasive files i.e. self-adjusting files. 38.1% were using rotary instruments in pediatric practice. 79.1% found the use of hand instruments more time-consuming. Reasons for not using rotary instruments were cost-effectiveness of instruments, fear of curved canals, concern regarding patient cooperation, cyclic fatigue, proneness to fracture and insufficient knowledge about the technique. 86.6% were in favor of the need for an exclusive pediatric rotary endodontic system which will eliminate the fear from practitioner's mind, encouraging more use and thus demystify the suspense cloud. The study concluded that advantages of rotary instruments have inclined postgraduate students towards the usage of rotary instruments in primary teeth and have a positive attitude regarding the same. However, a proper training and knowledge regarding the use are mandatory to procure good results. Hence, more training workshops should be held and their inclusion in the curriculum should be done to ensure proper use of rotary instruments and reduce errors as it is a technique-sensitive step in pulpectomy.

Govindraju L, Jeevanandan G, Subramanian EMG (2017)[23] conducted a study on 45 children, aged 4-8yrs requiring pulpectomy in any one of the primary mandibular molars. They randomly divided children into 3 groups. After administration of LA and rubber dam isolation, access opening was done and coronal pulp was amputated using spoon excavator. With No.10 K file, canal patency was established and working length was determined radiographically. In group 1: canals were instrumented using K files from No.15-30 in quarter turn method. In group 2: S2 ProTaper file and in group 3: Mtwo file of 0.04 taper and 0.25 tip was used. Instrumentation time was recorded using a stopwatch. Canals were dried and obturated with Metapex. A postoperative radiograph was taken and quality of obturation was assessed by another pediatric dentist blinded to the procedure. The post-obturation restoration was done with GIC and teeth

were restored using SS crowns. In Group 1: 60% mesial canals were optimally filled; 13.3% and 26.7% were under- and over-filled, respectively. 40% of distal canals were optimally filled, 26.7% and 33.3% were under- and overfilled. In Group 2: 73.3% of mesial canals were optimally filled; 13.3% and 13.4% were under- and over-filled respectively. 60% of distal canals were optimally filled; 20% were under- and over-filled each. In Group 3: 60% mesial canals were optimally filled; 33.3% and 6.7% were under- and over-filled. In distal canals, 53.3%, 26.7%, and 20% were optimal, under- and overfilled. Quality of obturation was superior in mesial than distal canals. Distal canals instrumented with rotary files were over obturated in a majority of cases. This could be due to the anatomy of root canals. Distal canals are usually straight and wide while mesial canals are curved and slender. A significantly reduced instrumentation time was observed with rotary instrumentation. This could positively influence the behavior of a child in the dental chair.

MATERIALS AND METHOD

This randomized controlled clinical study was carried out in the department of pediatric and preventive dentistry of the said dental college. Ethical clearance from the ethics committee of the concerned dental college was obtained prior to the commencement of the study. 42 primary molars in 31 children (16 boys and 15 girls) in the age range of 6 to 8 years were selected for the study based on the inclusion and exclusion criteria. Parents of the selected children were explained the purpose of the study and those who signed the informed consent only their children were included in the study **(Annexure 1, page no. i)**.

The total study sample consisted of 42 primary molars (2 maxillary first molars, 2 maxillary second molars, 11 mandibular first molars and 27 mandibular second molars).

INCLUSION CRITERIA:

1. Children of 6 to 8 years age having primary molars diagnosed with chronic irreversible pulpitis, pulp necrosis or acute or chronic abscess.[3]
2. Affected primary molars with at least 2/3rd of root remaining.[19]
3. Affected primary molars having sufficient coronal tooth structure to support a rubber dam[19], sustain restoration and would not fracture under masticatory force until its natural exfoliation time.

EXCLUSION CRITERIA:

1. Children having any systemic illness.
2. Primary molar with internal or external resorption.
3. Primary molar having pulpal perforation due to carious process.[19]

ARMAMENTARIUM:

For performing pulpectomy procedure

1. Sterile disposable gloves, mouth mask and head-cap **[Colour Plate I (1), page no.45]**
2. Diagnostic Instruments: Mouth Mirror, Probe, Explorer, Tweezer; Restorative instruments: Spoon excavator, cement carrier, condensers, burnisher, plastic filling instruments (API Ashoosons, India), Cotton holder, sterile cotton pellet, waste receiver, Airotor Hand Piece (Mini-head Hand piece, Dentmark. India), Round and safe ended tapered fissure bur (BR-31 and EX-24, Dia Burs, Mani Inc., Japan), Endoblock (Denstply /Maillefer, Ballaigues, Switzerland) **[Colour Plate I (2), page no.45]**

3. Disposable Syringes (Nirlife, Aculife Healthcare Pvt. Ltd), Lignocaine with 2% adrenaline (LOX 2% Adrenaline, Neon Laboratories Ltd, India), Sodium hypochlorite solution (Hyposept, UPS Hygienes Pvt. Ltd. India), Normal Saline (Infutec Healthcare Pvt. Ltd. India), RC Help and RC Cal (Prime Dental Products Pvt.Ltd. India), MD-Temp, Absorbent paper points and Metapex (METABIOMED Co, Ltd. Korea), Type I and Type II GIC (XtraLute and XtraCem, Medicept Dental India Pvt. Ltd.), Oil Impervious Mixing Pad, Agate Spatula and Petroleum Jelly **[Colour Plate I (3), page no.45]**
4. Rubber Dam Kit (Hygiene Dental Dam Kit, Coltene/Whaledent Inc) **[Colour Plate II (1), page no.46]**
5. K- files No.8- 40, H-files No.20-35 (MANI INC, Japan) **[Colour Plate II (2), page no.46]**
6. X-Smart ^{TM} Endo motor (Denstply /Maillefer, Ballaigues, Switzerland) **[Colour Plate II (3), page no.46]**
7. Rotary Sx ProTaper and Rotary X1 ProTaper Next file (Denstply /Maillefer, Ballaigues, Switzerland) **[Colour Plate II (4), page no.46]**
8. Stainless steel crowns (3M ESPE, USA), instruments and pliers for manipulation **[Colour Plate III (1), page no.47]**

For noting the instrumentation time

Digital stop watch **[Colour Plate III (2), page no.47]**

For processing and evaluation of radiographs

1. Size 0 (22× 35mm) intra-oral periapical radiograph (E-speed, Carestream Health Inc. USA), X-ray film positioning system (House Brand , Model: XCP X ray positioning FPS 3000 kit) **[Colour Plate III (3), page no.47]**
2. Dental X ray machine (Aditya Medical Systems Ltd, India Model no: AMS 6010)
3. Automatic X-Ray processor (XP05 Automatic Intraoral Film Processor, Dentomed Healthcare, India) **[Colour Plate IV (1), page no.48]**
4. X-Ray Viewer Box (Avishkar International Pvt. Ltd, India Model no: AVI-1811) **[Colour Plate IV (2), page no.48]**
5. Transparent plastic 1 mm grid **[Colour Plate IV (3), page no.48]**
6. Magnifying glass (Handheld 80mm 10X Magnifying Glass) **[Colour Plate IV (4), page no.48]**

The disinfection and sterilization of the various instruments, equipments and materials is given in a tabulated form below:

Sr. No	Instruments, equipments and materials	Disinfection and sterilization protocol followed
1	Diagnostic instruments including mouth mirror, probe, explorer, tweezer, Restorative instruments including spoon excavator, cement carrier, condensers, burnisher, plastic filling instruments (API Ashoosons, India), cotton holder,	a.Cleaning: Removal of gross debris by scrubbing them with water and soap b.Disinfection using Cidex (2.4% gluteraldehyde) for 20 minutes as per product manual. Burs were disinfected with 0.2% gluderaldehyde. c.Rinsing using distilled water

	waste receiver, round and safe ended tapered fissure bur (BR-31 and EX-24, Dia Burs, Mani Inc., Japan) and Endoblock (Denstply /Maillefer, Ballaigues, Switzerland), rubber dam clamps, instruments and pliers for manipulation of stainless steel crowns	d.Drying: The instruments were dried using autoclavable towel followed by inspection for cleanliness e.Packing: The instruments were then packed in autoclavable pouches for their sterilization f. Sterilization: By Autoclaving at 121° C at 15 psi pressure for 15 minutes. (burs were autoclaved for 20 minutes as per the product manual)
2	Cotton pellet	Autoclaved at 121° C at 15 psi pressure for 15 minutes.
3	Airotor handpiece (Mini-head Hand piece Dentmark, India)	Cleaned with a soft moistened cloth. b.Dried and lubricated using spray oil c.Autoclaved at 121° C at 15 psi pressure for 15 minutes
4	Metapex	Use of disposable tips for each tooth
5	Rubber dam sheets	Disposable
6	X-Smart TM Endo motor (Denstply /Maillefer, Ballaigues, Switzerland) contra-angle head	a.Cleaned with a cotton cloth moistened with rubbing alcohol and lubricated for 2-3 seconds after each use. b.The head was placed into an autoclavable pouch and autoclaved for 18 minutes at 134˚ C as per the product manual

7	X-Smart TM Endo motor (Denstply /Maillefer, Ballaigues Switzerland) motor section of the handpiece and control unit	Cleaned with a cotton moistened with rubbing alcohol as per the product manual
8	K- files No.8- 40 and H-files No.20-35 (MANI INC, Japan)	a.Scrubbed with brush and 0.2% gluteraldehyde b.Rinsed with distilled water and air dried c.Placed in an autoclavable endobox and then autoclaved at 121° C at 15 psi pressure for 20 minutes.
9	Rotary Sx ProTaper and Rotary X1 ProTaper Next file (Denstply /Maillefer, Ballaigues, Switzerland)	a.Scrubbed with soap and warm water followed by rinsing with distilled water. b. Air dried and placed in the autoclavable endobox for autoclaving at 136° C for 20 minutes.
10	X-ray film positioning system (House Brand, Model: XCP X ray positioning FPS 3000 kit)	a.The instruments were disassembled. b. Removal of debris with hot water and soap c.Components were placed in separate sterilization pouches and autoclaved at 121° C at 15 psi pressure for 20 minutes as per the product manual
11	Stainless steel crowns (3M ESPE, USA)	Wiping and immersion in Cidex (2.4% gluteraldehyde) solution for 10 min b.Ultrasonic cleaning for 15 min

		c.Autoclaving 121° C at 15 psi pressure for 20 minutes.

Examination of children was done and the findings were recorded in the case history proforma specially designed for the study **(Annexure 2, page no. v)**.

Of the 42 teeth selected for the study, 32 teeth were diagnosed with chronic irreversible pulpitis, 1 tooth with pulp necrosis and 9 teeth were having dentoalveolar abscess based on the clinical signs and symptoms and radiographic findings. The diagnosis was verified with a senior faculty member.

After the diagnosis was established the treatment was performed either in one or multiple visits. One-visit pulpectomy was performed in teeth showing large carious exposure with frank involvement of radicular pulp but without any periapical changes; teeth with inflammation extending beyond coronal pulp indicated by hemorrhage from the amputated radicular stumps that is dark red and uncontrollable and multiple-visit pulpectomy was performed in non-vital teeth; teeth with necrotic pulp and furcation and peri-radicular involvement; teeth associated with infection, abscess or presence of a sinus tract.[50]

The instrumentation technique was selected for each tooth by random allocation sequence using chit method.[51,52] For random allocation of 42 cases equally into two groups, 42 chits were prepared with “Rotary” (for the hybrid ProTaper Next rotary instrumentation group) written on 21 chits and “Manual” (for conventional/hand instrumentation group) on 21 chits. The child was allowed to take one chit from the bowl, per tooth and the chit was then discarded. Biomechanical preparation as per the chit was performed. In this study the participants and the evaluators were blind in regard to the technique group allocation. Because the rotary and manual techniques each have

recognizable characteristics, they could not be blinded to the operator.[19] Thus, the selected teeth were randomly divided into 2 groups of treatment with 21 primary molars per group.

Pulpectomy was performed on the selected molars using either of the following technique:

Group 1: Manual K-files instrumentation

Group 2: Hybrid rotary ProTaper Next instrumentation

All the intra-oral periapical radiographs were taken on size 0 films (22× 35mm) using the conventional paralleling technique.[21] The distance between the source and the tooth; the tooth and the film was standardized to achieve comparable before and after images using XCP, X-ray positioning device. To minimize errors, all the radiographs were obtained using the same X-ray machine under standardized kilovolts (60 kV), milliamperes (7 mA), and exposure time (0.5 sec) and also were similarly processed in the Automatic Intraoral X-ray processor according to the manufacturers guidelines.

The pulpectomy procedure was carried out in minor OT which was fumigated previous night of the date of appointment. Disposable gloves, mask, head cap was used by the operator and disposable head cap, paper towel and glass was provided to the patient. Under local anaesthesia and rubber dam isolation, the pulpectomy procedure was carried out following complete caries removal. A standard access opening was obtained using a round bur. A safe-ended tapered fissure bur was used for de-roofing and removal of the coronal pulp tissue was carried out using a spoon excavator until all canal orifices could be clearly identified **[Colour Plate V, page no.49]**. The patency of each canal was established using # 8, #10 and #15 K-file.

ESTABLISHMENT OF WORKING LENGTH:

Radiographic working length (RWL) was determined using Ingle's method.[53,54] Pre-operative radiograph was used to determine the RWL. A 15 size K-file with a length 1 mm less (safety allowance) than the length as measured on the pre-operative radiograph was inserted into the prepared root canal. This 1 mm was to allow for possible image magnification and distortion. Following this, another diagnostic radiograph was obtained using the paralleling technique. The distance between the tip of the file and the apical foramen was measured, and this was added or subtracted to the initial length determined on the pre-operative radiograph. Following this, 1 mm was subtracted (safety factor to conform to the apical termination of the root canal at the apical constriction) from this adjusted working length to yield the radiographic working length. **[Colour Plate VI, page no.50]**

BIO-MECHANICAL PREPARATION:

For the manual group, instrumentation of teeth was carried out using the conventional step-back technique with a quarter-turn pull motion using stainless steel K–files upto no.30 or 35 as per apical gauging. After use of each file, canals were copiously irrigated with 2.5% sodium hypochlorite and normal saline.[3] Final irrigation was done with normal saline. Recapitulation was carried out to maintain the patency of the canals.

For teeth in the rotary group, coronal enlargement was carried out with Sx ProTaper file to about 3 mm beyond the canal orifice before establishment of working length with a slight buccolingual brushing motion.[3] Then the working length was taken and X1 ProTaper Next rotary file was used up to the established working length to complete the apical preparation using brushing motion. Both these rotary files were used with an X-Smart Endo motor at the speed of 300 rpm and torque setting at 2.5 Ncm.

Then H-files No.25 and No.30 were used.[3] Irrigation was carried out with 2.5% sodium hypochlorite and normal saline after use of every file.[3] Final irrigation was done with normal saline. RC Help was used as a lubricant during instrumentation. Each file was discarded after being used in 5 primary molars.[3]

INSTRUMENTATION TIME:

The instrumentation time was noted in minutes from the start of instrumentation till the completion of cleaning and shaping of the canals using a digital stop watch.[23] The time interval for obtaining the working length was not included in the instrumentation time and the stop watch was stopped during that time interval and again restarted after the length was established. The time taken for irrigation, biomechanical preparation and exchange of files was included in the instrumentation time.[16]

OBTURATION:

For both groups, after final irrigation, the canals were dried with absorbent paper points and filled with resorbable root canal filling material- Metapex.[23] With Metapex, the filling material was transported to the canals directly from its pre-packed polypropylene syringe. The syringe was inserted into the canals, near the apex. The paste was pressed down into the canals and when the paste flowed back from the canals into the pulp chamber the syringe was then slowly withdrawn. The paste was not used to fill the pulp chamber.[55] A cotton pellet was placed in the pulp chamber and pressed, thus pushing the Metapex into the canals. The excess coronal filling material was removed and the coronal space was covered with Type II GIC. The pulpectomy treated teeth were restored with stainless steel crowns either on the same day or in the next appointment.[23]

[Colour Plate V, page no.49]

NUMBER OF VISITS:

In teeth indicated for multiple visits, pulpectomy was completed over two visits depending on the symptoms. The first visit comprised of rubber dam isolation, access opening, coronal pulp debridement, establishment of working length, biomechanical preparation and placement of intra-canal medicament followed by temporary restoration. On the second appointment, i.e. 5 to 7 days later, after resolution of the symptoms, following rubber dam isolation, obturation was carried out.[3,50]

ASSESSMENT OF QUALITY OF OBTURATION AND PRESENCE/ABSENCE OF VOIDS:

A postoperative radiograph was taken immediately following obturation using the XCP instrument with the same setting as the preoperative radiograph.[56] The radiographs were coded with a numerical identity number by a non-examiner in order to avoid bias during scoring of the radiographs. Two senior faculty members who were blind to the study interpreted the radiographs independently, using a magnifying glass (10X) and a viewer box with a transparent plastic 1 mm grid placed behind the radiograph. An assessment proforma was provided to these two evaluators wherein they noted the findings **(Annexure 3, page no. ix)**. The inter and intra-rater reliability of the two evaluators was assessed using Kappa coefficient and was found to be excellent.[57] **(Annexure 4, page no. xi)**

All measurements were made by counting the squares shown on each radiograph. The extent of obturation for each tooth and each canal was measured separately. All measurements were rounded to the nearest millimeter and were subtracted from the length of the respective root canals measured from the floor of the pulp chamber to the root apex.

The difference in the measurements was considered to determine the obturation form.[58]

The following parameters were recorded immediately following obturation of the teeth:

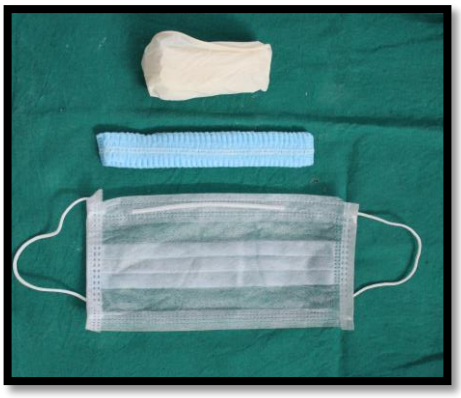
1. Quality of filling, based on the modified criteria of Coll JA and Sadrian R.[34,56] :

   Under-filled: All canals were filled more than 2 mm short of the apex.

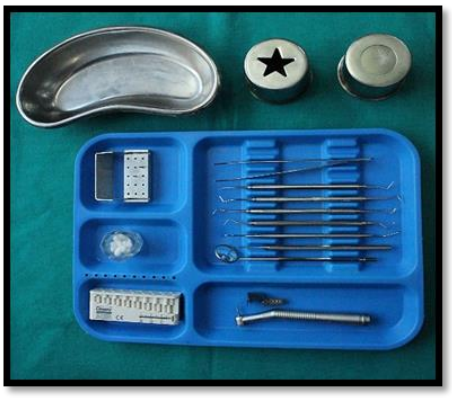
   Optimally-filled: One or more of the canals having obturating material ending at the radiographic apex or 2 mm short of apex.

   Over-filled: Any canal showing the obturating material outside the root.

2. Presence or absence of voids.[21,59]



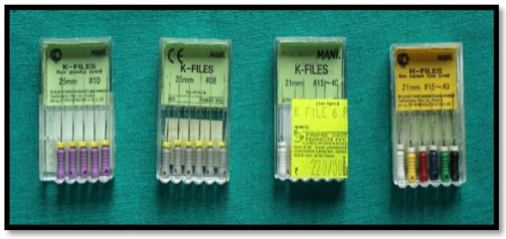
(1) Disposable gloves, head cap and facemask



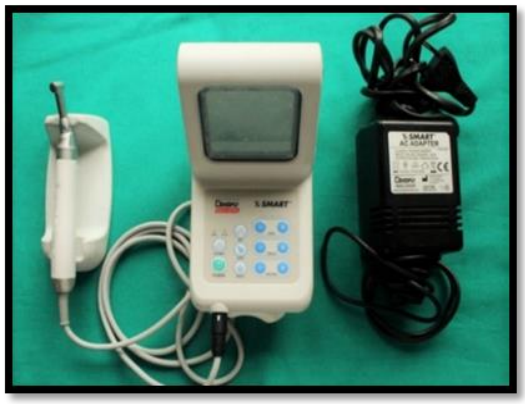
(2) Diagnostic and Restorative instruments

(3) Materials for pulpectomy procedure

(1) Rubber dam Kit

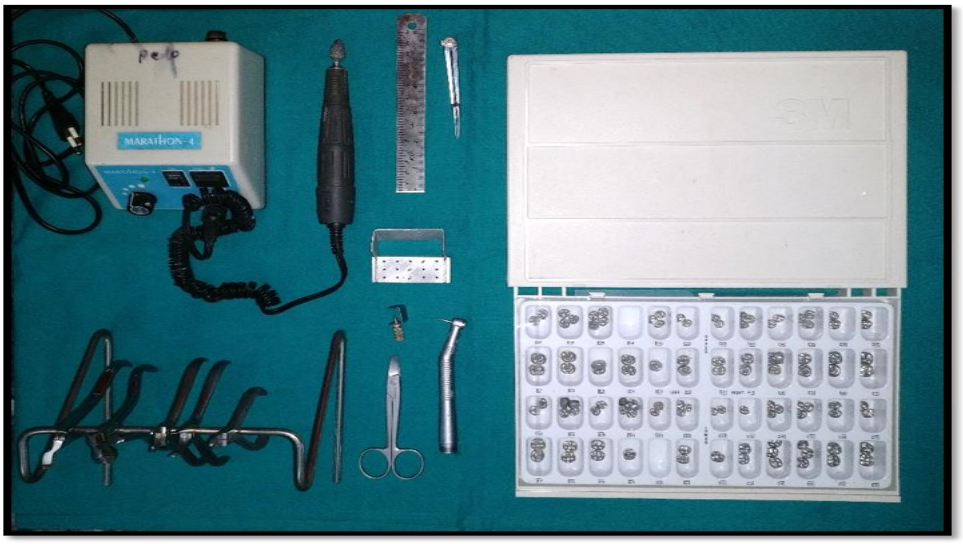


(2) K and H files (21mm)



(3) X-Smart ™ Endo motor

(4) Sx ProTaper and X1 ProTaper Next Rotary files



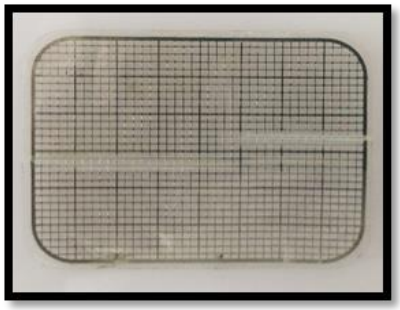
(1) Stainless steel crowns, instruments and pliers

(2) Digital Stopwatch

(3) Size 0 IOPA radiograph, X-ray film positioning system

(1)Automatic X-ray processor

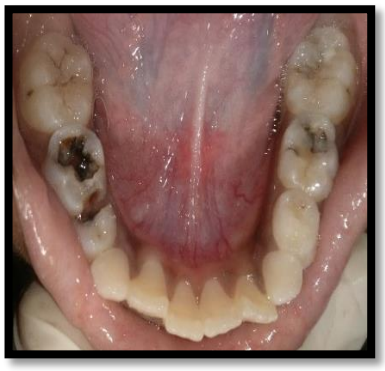
(2) X-ray Viewer Box



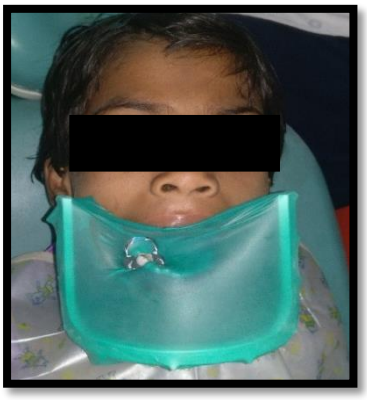
(3) Transparent plastic 1 mm grid

(4) Magnifying glass (10X)

CLINICAL PHOTOGRAPHS OF CASE NO: 4

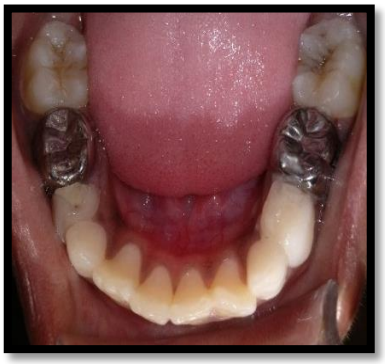


Deep carious lesions with 75 and 85 diagnosed with chronic irreversible pulpitis



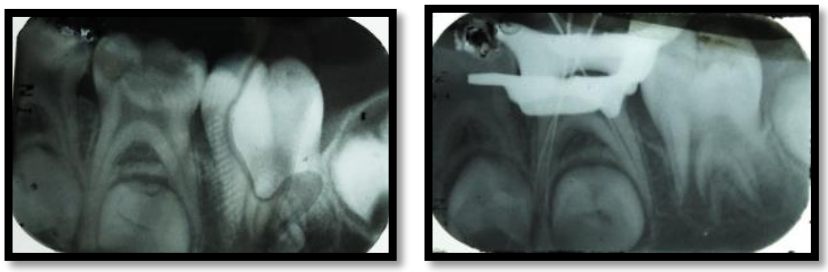
Rubber dam isolation with 85

Access opening with 85



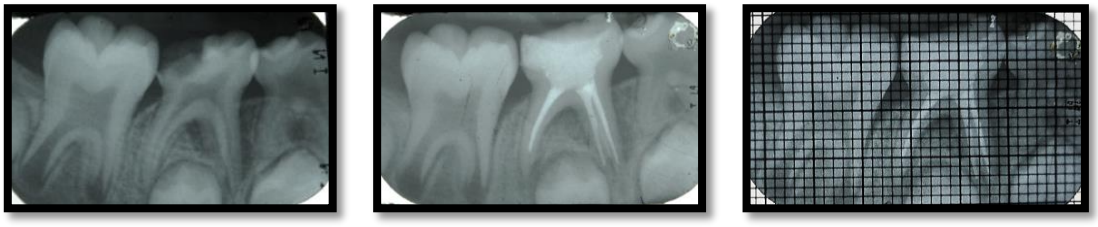
Stainless steel crowns with 75 and 85

RADIOGRAPHIC WORKING LENGTH DETERMINATION



(1)IOPA of 75- Case no.6 : (a) Pre-operative IOPA (b) 15 mm K file with a length 1 mm less than measured on pre-operative radiograph inserted into the canals. Estimated WL: 14 mm for the mesial canals and 13 mm for the distal canal. For the mesiobuccal and mesiolingual canal, the tip of the file was 1 mm beyond the apex and for the distal canal it was 2 mm short of the apex. Hence, the adjusted working length is 13 mm for the mesial canals and 15 mm for the distal canal.1 mm was subtracted from this adjusted working length. Thus, the resultant RWL is 12 mm for mesial canals and 14 mm for distal canal.

QUALITY OF OBTURATION- OPTIMAL FILLING OF TEETH IN BOTH THE GROUPS



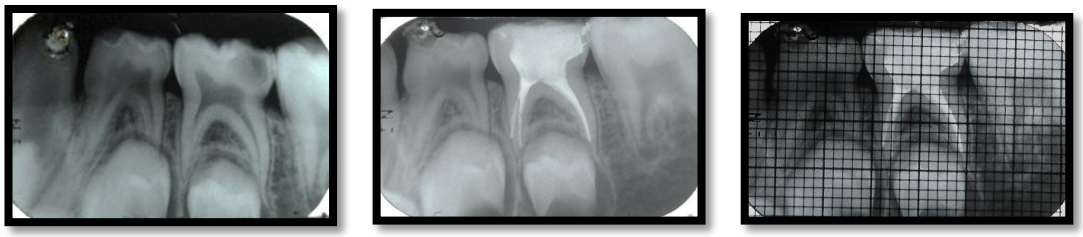
(1) (a) (b) (c)

(1) IOPA of 85- Case no.14: Manual technique:

(a) Pre-operative IOPA

(b) Post-obturation IOPA with optimally filled mesiobuccal, mesiolingual canals and underfilled distal canal. Hence, quality of obturation for the tooth is optimal

(c) Postoperative IOPA with 1mm Grid placed behind it



(2) (a) (b) (c)

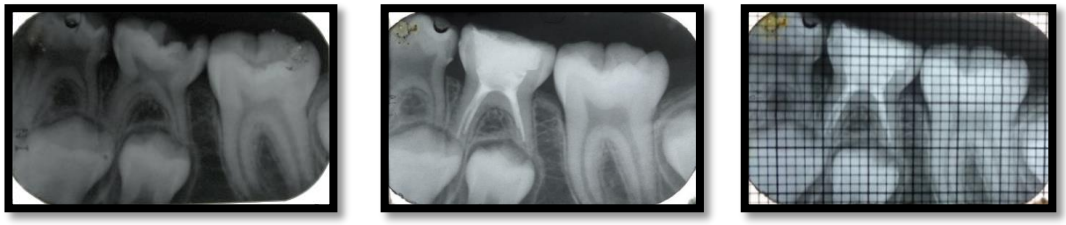
(2) IOPA of 75- Case no. 24: Rotary technique:

(a) Preoperative IOPA

(b) Post obturation IOPA showing optimally filled mesiobuccal, mesiolingual and distal canals. Hence, quality of obturation for the tooth is optimal

(c) Postoperative IOPA with 1mm Grid placed behind it

QUALITY OF OBTURATION- UNDER-FILLING AND OVERFILLING OF TEETH IN THE MANUAL GROUP



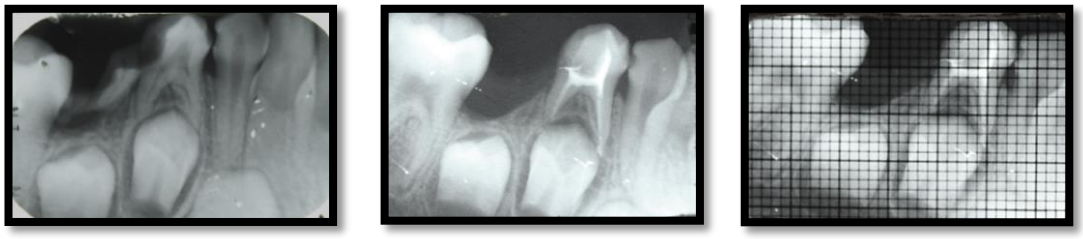
(1) **(a)** **(b)** **(c)**

(1) IOPA of 75- Case no. 40: Manual technique:

(a) Preoperative IOPA

(b) Post obturation IOPA showing underfilled mesiobuccal, mesiolingual and distal canals. Hence, quality of obturation for the tooth is under-filled

(c) Postoperative IOPA with 1mm Grid placed behind it



(2) **(a)** **(b)** **(c)**

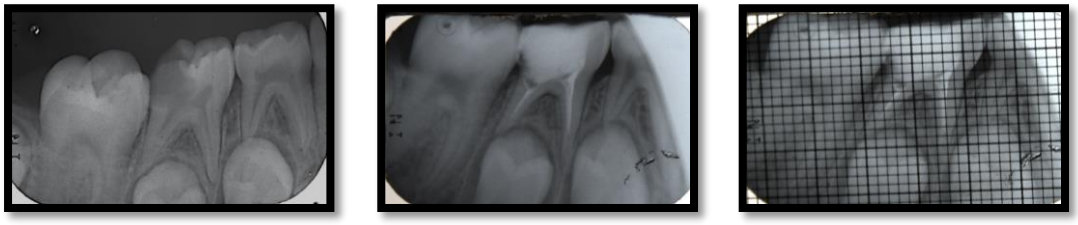
(2) IOPA of 84- Case no. 2: Manual technique:

(a) Preoperative IOPA

(b) Post obturation radiograph showing overfilled mesial canals and optimal filled distal canal. Hence, quality of obturation for the tooth is overfilled

(c) Postoperative IOPA with 1mm Grid placed behind it showing extrusion with 1 mm of vertical and horizontal extent

QUALITY OF OBTURATION- UNDER-FILLING AND OVERFILLING OF TEETH IN THE ROTARY GROUP



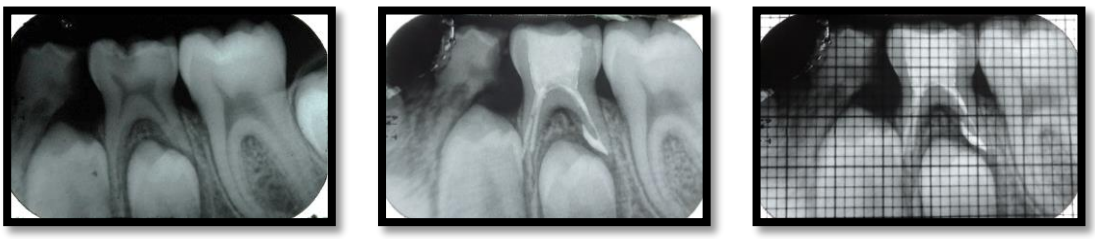
(1) (a) (b) (c)

(1) IOPA of 85- Case no. 10: Rotary technique:

(a) Preoperative IOPA

(b) Post obturation radiograph showing underfilled mesial and distal canals

(c) Postoperative IOPA with 1mm Grid placed behind it



(2) (a) (b) (c)

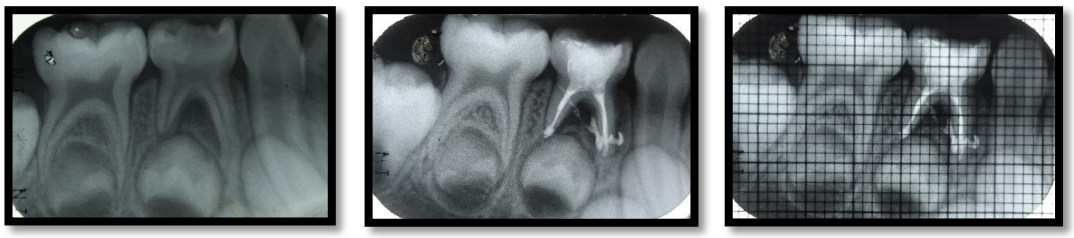
(2) IOPA of 75- Case no. 37: Rotary technique:

(a) Preoperative IOPA

(b) Post obturation IOPA with optimally filled mesial canals and over-filled distal canal. Hence, quality of obturation for the tooth is over-filled

(c) Postoperative IOPA with 1mm Grid placed behind it showing extrusion with 3mm of horizontal and vertical extent

QUALITY OF OBTURATION- OVERFILLING OF TOOTH IN THE ROTARY GROUP



(1) **(a)** **(b)** **(c)**

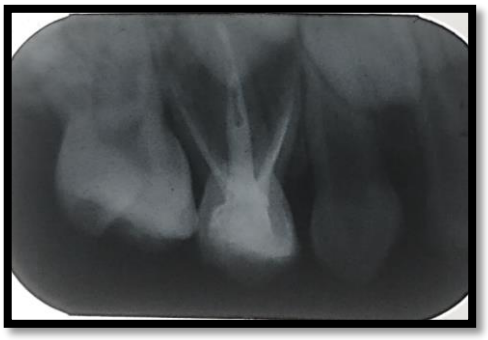
(1) IOPA of 84- Case no. 31: Rotary technique:

a) Preoperative IOPA

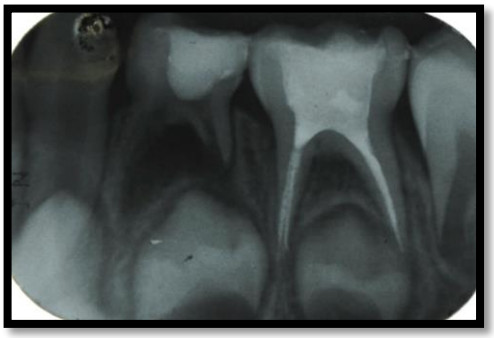
b) Post obturation radiograph showing overfilled mesial canals and optimally filled distal canal. Hence, quality of obturation for the tooth is over-filled

c) Postoperative IOPA with 1mm Grid placed behind it showing extrusion with 2mm of horizontal and 3 mm vertical extent

QUALITY OF OBTURATION - PRESENCE OF VOIDS

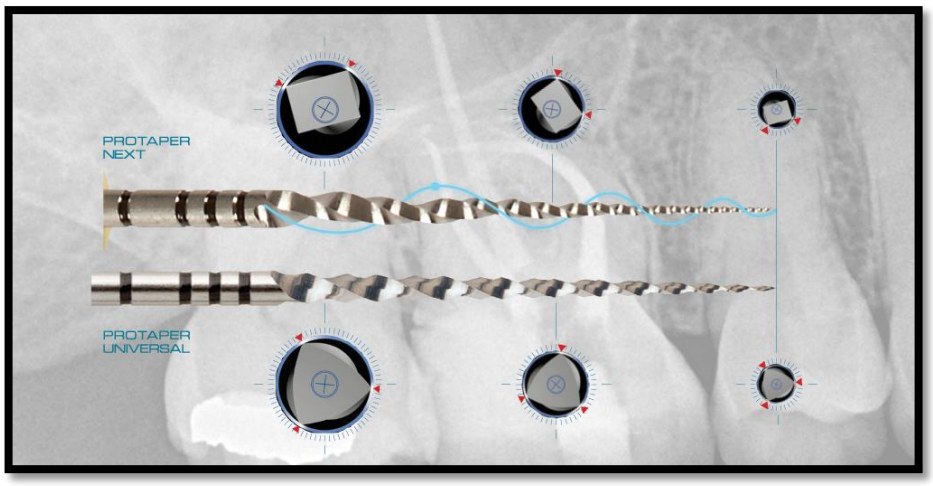


IOPA of 54- Case no. 42: Showing void in the palatal canal



IOPA of 75- Case no. 11: Showing voids seen in the mesial canals

CROSS-SECTION DESIGN COMPARISON OF THE PROTAPER UNIVERSAL AND PROTAPER NEXT FILES



Comparison of the cross section design of ProTaper Universal and ProTaper Next rotary file system

Courtesy: 2017 Dentsply Sirona(https://www.dentsplysirona.com/en ca/products /endodontics / glide-path-shaping/protaper-next-files-learn-more

RESULTS

Statistical methods:

The data on demographic characteristics of children were obtained and summarized as per the scale of measurement. The instrumentation time was expressed in minutes and seconds in terms of mean, standard deviation and median for two treatment groups. The comparison between the times was carried out using Mann-Whitney U test. The distribution of teeth and individual canals of each tooth in two groups was obtained according to the quality of obturation and was compared statistically using Fisher's exact test. The distribution of teeth as per voids was obtained and compared statistically using Pearson's chi-square test. The inter and intrarater agreement was obtained using Kappa statistics. All the analyses were performed using SPSS version 20.0 (IBM Corp.) and statistical significance was tested at 5% level.

The details of the methods used in the study are as below:

Sample mean for a set of observations is given by

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

Standard deviation for a set of observations in given by

$$s = \sqrt{\frac{1}{(n-1)}\sum_{i=1}^{n}(x_i - \bar{x})^2}$$

where x_i = observation on each object

n = number of objects

Median: It is the middle value of a set of values when arranged in the increasing order of magnitude.

Chi-square test

Let X and Y be two variables under study with r and s levels respectively; and the data on $r \times s$ levels be in the form of counts. Let the null hypothesis be that the two variables are independent. That is, knowing the levels of X does not help in predicting the levels of Y; against the alternative hypothesis that the two factors are not independent. That is, knowing the level of X can help in predicting levels of Y. To decide about the acceptance of hypothesis, the Chi-square test statistic is used which is defined as:

$$\chi^2 = \sum_{i=1}^{r}\sum_{j=1}^{s}\frac{(O_{ij} - E_{ij})^2}{E_{ij}}$$

where O_{ij} is the observed frequency count for i^{th} level of variable X and j^{th} level of variable Y. E_{ij} is the expected frequency count for same cell. The expected count is given by

$$E_{ij} = \frac{n_i \times n_j}{n}$$

where n_i and n_j are the total counts for i^{th} level of variable X and j^{th} level of variable Y; and n is the total count. The calculated Chi-square value is compared with the tabulated one for $(r\text{-}1)\times(s\text{-}1)$ degrees of freedom. If the corresponding p-value is smaller than the pre-decided significance level, say 0.05, then we reject the null hypothesis and accept the alternative one. If the p-value is more than 0.05, then we accept null hypothesis.

Fisher's exact test

Fisher's exact test is a statistical test to determine if there are any non-random associations between two categorical variables.

If X and Y are the two categorical variables with m and n observed states respectively, then a m x n matrix can be generated with a_{ij} as the number of observations for i^{th} state of X and j^{th} state of Y. Accordingly, the row and the column sums R_i and C_j are

$$N = \sum_i Ri = \sum_j Cj$$

The conditional probability of getting the actual matrix given the particular row and column sums is given by

$$P_{cutoff} = \frac{R_1!R_2!...R_m!)(C_1!C_2!...C_n!)}{N!\prod a_{ij}!}$$

This is a multivariate generalization of hypergeometric distribution. All possible matrices of non-negative integers consistent with rows and column sums are determined, and for each matrix the conditional probability using above expression is determined, such that the sum of probabilities is 1. To determine the P-value of the test, the tables need to be

ordered by some criterion that measures dependence, and those tables that represent equal or greater deviation from independence than the observed table are the ones whose probabilities are added together. In a typical 2 x 2 case, the P-value of the test is simply the sum of P-values of matrices that are less than P_{cutoff}.

Results:

31 children were selected as per the inclusion criteria (16 boys and 15 girls). Pulpectomy procedure was undertaken in 42 primary molars which were divided equally into two groups: manual/conventional and rotary group depending on the type of biomechanical preparation. The descriptive statistics for demographic characteristics of age and sex for the children in the two treatment groups i.e. Manual and rotary instrumentation technique is given in **Table 1 (page no. 92)** and **Graph 1 (page no. 95)**. The mean age of boys was 6.94 ± 0.90 years with a median of 6.33 years, while that of girls was 7.27 ± 1.03 years with a median of 7.25 years. The overall age was 7.10 ± 0.96 years with a median of 7.16 years. Total 22 teeth in boys and 20 teeth in girls were treated. In boys, 10 teeth were instrumented using rotary technique and the other 12 using manual technique. In girls, 11 teeth were instrumented using rotary technique and 9 using manual technique. The distribution of chosen teeth according to the groups is also given in Table 1. Of the selected 21 primary molars, the rotary group comprised of 1 maxillary first molar, 3 mandibular first molars and 17 mandibular second molars. The 21 primary molars in the manual group comprised of 1 maxillary first molar, 2 maxillary second molars, 8 mandibular first molars and 10 mandibular second molars.

The instrumentation time required using the two techniques is given in **Table 2 (page no. 92)**. In the Rotary group, the mean instrumentation time was 11.14 ± 1.97 min (median=10.45 min) while in the Manual group, the mean instrumentation time was 19.02

± 4.39 min (median=20.05 min). The intergroup comparison was done using Mann-Whitney U test and the difference obtained highly significant with p-value < 0.0001. A column chart representation of the data is shown in **Graph 2 (page no. 95).**

The inter and intra-rater reliability was assessed using Kappa coefficient as depicted in **Table 3 (page no. 92)**.The reliability of the two examiners was assessed in 10 cases each for the assessment of quality of obturation and voids as per the criteria**.** The inter-rater agreement between two examiners was 0.808 (0.0004) as regards to the assessment of quality of obturation and 1.000 (< 0.0001) for the assessment of voids. Thus, showing excellent agreement between two raters. Similarly, the same 10 radiographs were reassessed after a period of 1 week by both the examiners separately. The data of which is given in **Annexure 4 (page no. xi).**The intra-rater agreement for Examiner #1 as regards to the assessment of quality of obturation was 0.808 (0.0004) and for the assessment of voids was 1.000 (< 0.0001). Hence, showing excellent agreement. For Examiner #2, the agreement as regards to the assessment of quality of obturation was absolute, while for the assessment of voids was 0.737 (0.0157) which was good.

The distribution of teeth as per the quality of obturation i.e. underfilled, optimal and overfilled in the two treatment groups were compared using Fischer exact test as presented in **Table 4 (page no. 93)**. In the Rotary group, 14 (66.7%) teeth were optimally filled **[Colour Plate VII (2), page no. 51]**, 1 (4.8%) tooth was underfilled **[Colour Plate IX (1), page no. 53]** and 6 (28.5%) teeth were overfilled **[Colour Plate IX (2), page no. 53]**. In the Manual group, 16 (76.2%) teeth were optimally filled **[Colour Plate VII (1), page no. 51]**, 2(9.5%) teeth were underfilled **[Colour Plate VIII (1), page no. 52]** and 3 (14.3%) teeth were overfilled **[Colour Plate VIII (2), page no. 52]**. The difference in the proportion of teeth according to the quality of obturation in the two treatment groups was

statistically insignificant as indicated by the p-value of 0.578. A graphical representation is shown in **Graph 3 (page no. 95).**

The quality of obturation of the individual canal of each tooth was also assessed separately. The distribution of mesiobuccal canals as per the quality of obturation in the two treatment groups is given in **Table 5 (page no. 93)**. In the Rotary group, 15 (71.4%) mesiobuccal canals (maxillary and mandibular molars) were optimally filled **[Colour Plate VII (2), page no. 51]**, 2 (9.5%) were underfilled **[Colour Plate IX (1), page no. 53]** and 4 (19.1%) were overfilled **[Colour Plate X (1), page no. 54]**. In the Manual group, 14 (66.7%) mesiobuccal canals (maxillary and mandibular molars) were optimally filled **[Colour Plate VII (1), page no. 51]**, 5 (23.8%) were underfilled **[Colour Plate VIII (1), page no. 52]** and 2 (9.5%) were overfilled **[Colour Plate VIII (2), page no. 52]**. The difference in the distribution of the quality of obturation of the mesiobuccal root canals was statistically insignificant in the two treatment groups as indicated by the p-value of 0.409. A column chart representation of data is given in **Graph 4 (page no.96)**.

The distribution of mesiolingual canal of mandibular molars and distobuccal canal of maxillary molars as per the quality of obturation in the two treatment groups is presented in **Table 6 (page no. 93).** In the Rotary group, 14 (66.7%) canals were optimally filled **[Colour Plate VII (2), page no 51]**, 2 (9.5%) were underfilled **[Colour Plate IX (1), page no. 53]** and 5 (23.8%) were overfilled **[Colour Plate X (1), page no. 54]**. In the Manual group, 15 (71.4%) canals were optimally filled **[Colour Plate VII (1), page no. 51]**, 3 (14.3%) canals each were underfilled **[Colour Plate VIII (1), page no. 52]** and overfilled **[Colour Plate VIII (2), page no. 52]**. The difference in the distribution of quality of obturation by the two instrumentation techniques was statistically insignificant as indicated by the p-value of 0.798. A graphical representation of which is given in **Graph 5 (page no. 96)**.

The distribution of palatal canal of maxillary molars and distal canal of mandibular molars as per the quality of obturation in the two treatment groups is given in **Table 7 (page no. 94).** In the Rotary group, 16 (76.2%) canals were optimally filled **[Colour Plate VII (2), page no. 51]**, 1 (4.8%) was underfilled **[Colour Plate IX (1), page no. 53]** and 4 (19.0%) were overfilled **[Colour Plate IX (2), page no. 53]**. In the Manual group, 18 (85.7%) canals were optimally filled **[Colour Plate VII (1), page no. 51]**, 3 (14.3%) were underfilled **[Colour Plate VIII (1), page no. 52]** and none was overfilled. The difference in the distribution of quality of obturation by the two instrumentation techniques was statistically insignificant as indicated by the p-value of 0.119. A graphical representation of this distribution is shown in **Graph 6 (page no. 97).**

The presence or absence of voids in the two groups was compared using Chi-Square test and its distribution is given in **Table 8 (page no. 94)**. In the Rotary group, voids were present in 5 (23.8%) teeth, while in 16 (76.2%) teeth they were absent. Similar was the finding in the Manual group **[Colour Plate XI, page no. 55]**. The difference in the distribution of teeth as per the presence and absence of voids in the two treatment groups was statistically insignificant as indicated by the p-value of 0.999. A graphical representation of which is shown in **Graph 7 (page no. 97)**.

The distribution of overfilled teeth as per the extent of extrusion in the two groups is presented in **Table 9 (page no. 94)**. Extrusion of obturating material was observed in all total 9 teeth of which 6 (66.67%) were in rotary group and 3 (33.33%) were in manual group. There was no statistical difference between the two groups as regards to the extrusion of the material. The extrusion of the obturating material was measured using 1mm grid in vertical and horizontal direction. 2 and 3mm extrusion in vertical direction

was found in 3 teeth each in rotary group **[Color Plate IX (2), page no. 53 and X (1), page no. 54]**; whereas in manual group 1 and 2 mm extrusion was found in 2 and 1 teeth respectively**[Color Plate VIII (2), page no. 52].** The number of teeth with extrusion in rotary group were 6 (28.57%), while that in manual group were 3 (14.28%). The difference in the number of extruded teeth in two treatment groups was statistically insignificant as indicated by a p-value of 0.452.This is presented in **TABLE 9(A).**

As regards the extrusion of obturating material in horizontal direction is concerned, 2 teeth had 1mm, 3 teeth had 2 mm and 1 tooth had 3 mm extrusion in rotary group**[Color Plate IX (2), page no. 53 and X (1), page no. 54]**. In the manual group, 1 and 2 mm horizontal extrusion was found in 2 and 1 teeth respectively. **[Color Plate VIII (2), page no. 52].** A graphical representation of which is given in **Graph 8 and 9 (page no. 98)**.

DISCUSSION

Pulpectomy should be considered as a treatment modality for irreversibly inflamed and necrotic primary molars. Pulpectomy can be performed by various techniques depending on the confluence of various patient-related factors. The treatment options charted out maybe a single visit or a multi-visit pulpectomy. The ultimate goal of pulpectomy is to achieve good hermetic seal which depends on various factors such as good biomechanical preparation, types of obturating material used and achievement of minimum voids.[59]Cleaning and shaping of the root canals is an important step determining the success of this treatment. Since the inception of the concept of root canal therapy, stainless steel files have been extensively used for biomechanical preparation. Canal preparation using stainless steel hand files is time consuming, leads to iatrogenic errors like zipping, ledging, canal transportation and apical blockage.[22] These

disadvantages of stainless steel files lead to the development of Ni-Ti rotary files. The Ni-Ti rotary files have the properties of shape memory, super elasticity and high resistance to cyclic fatigue that allows quicker root canal preparation, help maintain patient cooperation by diminishing patient and operator's physical tiredness, eliminates the need of precurving the files and facilitates successful instrumentation of curved canals with minimum transportation.[4,5,9] Ni-Ti files have the ability to rotate around their own axis without risk or damage to the original anatomy of the tooth[5], owing to their low modulus of elasticity they are 2 to 3 times more flexible than stainless steel files and closely follow the original root canal path[7], show superior resistance to torsional fracture due to their ductility[7], substantial reduction in the incidence of several procedural errors such as ledges formation, transportation, perforation and over-instrumentation and effective for children who are less cooperative.[21] Since its advent, Ni-Ti files have been popularly used for biomechanical preparation in permanent teeth and have shown to decrease the instrumentation time in curved molar roots, increase patient comfort and lower the risk of flare-up.[60-62]

Considering these advantages, **Barr ES et al.**[9] in **2000** initiated the use of Ni-Ti rotary files for biomechanical preparation in primary teeth. Since the last two decades, various in-vitro [5,6,10-18,24,25,35,37,38,63-66] ,few ex-vivo[36] and in-vivo studies[3,9,19-23,44, 67] have been carried out to evaluate the effectiveness of rotary instrumentation in primary teeth. The Ni-Ti rotary instruments with their varied design characteristics, have gained immense popularity for their use in primary teeth. Of the various rotary systems that are available, ProTaper system (invented in 2001) has been used in many in-vivo studies in primary teeth [3,20,23,39,44,67] and have shown to be safe and efficient[3], lead to better quality of filling[20] and reduce the instrumentation time.[3,20,23,67] **Govindaraju L et al. (2017)**[48]

carried out a survey to evaluate the use of rotary instrumentation for pulpectomy in primary teeth and observed that (34%) practitioners used ProTaper followed by K3 (6%) and Mtwo (4%). ProTaper Next system invented in 2013 by Dentsply Malliferer, is an advanced version of the ProTaper rotary system with unique characteristics for better function. Many in-vitro studies have been carried out in permanent teeth using the ProTaper Next files and have found that these files have greater resistance to cyclic fatigue[32], better centering-ability[29], cause fewer dentinal cracks[30], less debris extrusion[31], less canal transportation and less instrumentation time[28] compared to ProTaper rotary files. **Topcuoglu G et al. (2016)**[25] compared the apical extrusion following instrumentation using Revo S, ProTaper Next, Mtwo, and K files in primary teeth and concluded that ProTaper Next files cause less debris extrusion compared to the other systems used. Considering all these advantages, ProTaper Next was chosen in the present study.

To the best of our knowledge, no in-vivo study comparing K files with ProTaper Next rotary file system in primary teeth has been reported in the literature. Hence, this randomized controlled trial was undertaken to evaluate the instrumentation time and quality of obturation using K-files and hybrid ProTaper Next rotary technique for pulpectomy in primary molars. The sample size was in accordance with the previous study[19] and was finalized after consultation with the statistician.

Despite various studies performed using the rotary files in primary molars, there are no clear guidelines or instructions for the suitable biomechanical preparation technique of these teeth. **Barr ES et al. (2000)**[9], **Ochoa-Romero T et al. (2011)**[19], **Vieyra JP et al. (2014)**[20] and **Makarem A et al. (2014)**[21] have used the same protocol for instrumentation in primary teeth as applied to the permanent teeth. Application of the

protocols for permanent teeth to primary molars may lead to lateral perforation on the inner root surface, especially in curved molar roots.[3] This is due to the softer and less dense root dentin, thinner and more curved roots with undetectable root tip resorption and ribbon-shaped root morphology of the primary teeth. Hence, **Kuo CI et al. (2006)**[3]**, Govindaraju L et al. (2017)**[23] modified the protocols for instrumentation in primary molars in their studies. **Kuo CI et al. (2006)**[3] used Sx and S2 ProTaper rotary files followed by No.25 and 30 H-files for instrumentation. **Govindraju L et al. (2017)**[23] used only S2 ProTaper file in one rotary group and Mtwo file of 0.04 taper and 0.25 tip in the other rotary group for instrumentation.

In the present study, modification of protocol suggested by **Kuo CI et al. (2006)**[3] was applied. The maximum possible caries was removed with excavator and the pulp chamber was opened using a BR 31 round bur. For complete de-roofing of the pulp chamber EX 24 safe ended tapered fissure bur was used. In order to get straight line access and reduce the risk of separation of instrument, the dentin overlying the abrupt cervical constriction at the canal orifice was removed with the help of Sx ProTaper file. It eliminates the internal triangles of dentin, avoiding lateral perforations or over-instrumentation of the inner root structure of the middle and apical third. Using G-G drills for removal of the thin dentin shelf might cause accidental perforation of the pulpal floor or excessive removal of inner root structures especially when treating primary molars with thinner pulpal floors. Hence, G-G drill was not used in this study. Sx has a gradually tapered design that can remove dentin selectively. It can replace the use of G-G drills and simplify the instrumentation procedures.[3] Then, the ProTaper Next X1 rotary file was used to the complete working length. Both these rotary files were used with an electric

motor at a speed of 300 rpm and torque of 2.5 Ncm as recommended by the manufacturers.

In this study, ProTaper Next X1 file was used, replacing the use of ProTaper S2 file as suggested by **Kuo CI et al. (2006)**[3] in his modified protocol. The ProTaper Next system comprises of 5 files available in different lengths namely X1, X2, X3, X4, and X5. In sequence, these files have yellow, red, blue, double black, and double yellow identification rings on their handles, corresponding to sizes 17/04, 25/06, 30/07, 40/06, and 50/06, respectively. In this study only ProTaper Next X1 rotary file was used in a brushing motion, away from external root concavities, to facilitate flute unloading and apical file progression with light apical pressure as recommended by the manufacturers.[26] The X1 has a tip diameter of 0.17 and a taper of 4% which approximates the root canal size of primary molars.

The ProTaper Next system possesses the following advantages:

1. Progressive taper on a single file that serves to minimize the contact between a file and dentin decreasing taper lock and screw effect, thus increasing efficiency.
2. Made from M-wire technology which has shown to improve resistance to cyclic fatigue by almost 400% compared to files of same tip diameter, taper, cross section, decrease potential for file separation and increases flexibility and passively follows the canal until the working length is achieved.
3. Off-centered, rectangular cross-section design for greater file strength unlike the convex triangle cross section and symmetric rotation with ProTaper Universal. The patented design's axis of rotation differs from the center of mass. Unique asymmetrical rotary motion at any given cross-section, as the file contacts the canal wall at 2 points only **[Colour Plate XII, page no. 56].**Thus, giving the file

a snake-like "swaggering" movement as it moves through the root canal. Clinically this provides the following significant advantages :

i. Reduced engagement with dentin, limiting the undesirable taper lock.

ii. Affords more cross-sectional space for enhanced cutting, loading, and augering debris

iii. Allows any file to cut a bigger envelope of motion compared to a similarly-sized file with symmetrical mass and axis of rotation.

4. Fewer files and only one torque and speed setting for all files result in a shorter clinical sequence. This, in turn, means that less time is spent changing instruments. The high cutting efficiency also reduces the shaping time. For the clinician, this is a valuable time that can be used for other procedures such as irrigation.

This modified sequence combined with its use in a torque-limited handpiece in the present study resulted in no instrument separation within the canals.

The Ni-Ti rotary files are designed mostly for conical root canal shapes. However, most of the primary molar root canals are ribbon-shaped. It is necessary to use an additional H-file (No. 25 or No. 30) combined with copious sodium hypochlorite irrigation to remove any loose pulp tissue with a brushing motion and to ensure that all of the root canals are cleaned and ready for filling.[3]

Silva LA et al. (2004) [5]**, Crespo S et al. (2008)**[35] have documented in-vitro studies that compared the cleaning efficiency of the rotary system with manual biomechanical preparation techniques and concluded that there was no much difference between the two systems in relation to this parameter. Moreover, studies done by them were in-vitro and evaluating the cleaning efficiency in-vivo in children is not feasible. Hence, the parameter

of cleaning efficiency has not been included in this study, and the statistical analysis only takes into account the criteria of time and quality of obturation, when studied in-vivo.

Several different products have been reported as successful filling materials for pulpectomies of primary teeth.[58] Zinc Oxide Eugenol, one of the most widely used obturating material for primary teeth, has been reported to be irritating to periapical tissues, cause necrosis of bone, cementum and alter the path of eruption of the succedaneous tooth when extruded beyond the apex.[68] Calcium hydroxide-iodoform paste gives excellent results when used as an obturating material in pulpectomy and is available premixed in polypropylene syringes (Vitapex, Metapex). The main ingredients of these calcium hydroxide–iodoform paste (Vitapex, Metapex) are calcium hydroxide 30.3%, iodoform 40.4%, silicone oil 22.4%, others 6.9 %. This mixture can be filled in the root canals using disposable tips, which are delivered with the material. The silicone oil, here, is thought to neutralize some of the alkalinity of the paste causing lesser injury to the periapical tissues which is short-lived. Metapex is less expensive than Vitapex (costing approximately 1/3rd the price of Vitapex) and is thus more commonly used from the economic point of view.[55] **Subramaniam P et al. (2011)**[55], **Gupta S et al. (2011)**[68] in their study showed a higher percentage of success with Metapex compared to ZOE when used for obturation in primary teeth. Metapex shows good resorbable properties, is radiopaque in nature, does not set to a hard mass, is easily inserted and removed from the canals, is harmless to the permanent tooth germs and gets resorbed within few weeks when extruded from the apex.[68] Considering these advantages, Metapex was chosen as the obturating material in the present study. Clinical guidelines of the American Academy of Pediatric Dentistry[69] recommends the tooth to be restored with a material that seals the

tooth from microleakage following pulpectomy. Hence, we restored each pulpectomy treated tooth with stainless steel crown.

The instrumentation time noted using the rotary technique was 11.14± 1.97 minutes (median=10.45 minutes) and that using the manual technique was 19.02±4.39 minutes (median=20.05 minutes). Thus, there is a highly significant reduction in biomechanical time with rotary technique compared to the manual technique. Various in-vitro studies undertaken with 0.04 Profiles[5,6,9,11,35], Hero 642[11,36], Flex Master[10], Mtwo[16], Wave One[13] and ProTaper[11,13,38] rotary systems have shown similar results compared to manual K files in primary teeth, of a statistically significant reduction in instrumentation time. Also, various in-vivo studies in primary teeth instrumented with rotary ProTaper files[3,20, 23,67], FlexMaster[21], K3 files[19] and Mtwo files[23] have reported significant reduction in instrumentation time compared to the manual instrumentation technique. Almost similar instrumentation time in rotary and manual preparation was observed in **Ochoa-Romero T et al (2011)**[19] study when compared to the present study. The shorter time required in the rotary instrumentation is probably related to the reduced number of instruments and greater efficacy of dentin cutting using rotary files as the rotary system is power-driven. Contrary to our study, in-vitro studies conducted by **Madan N et al. (2011)**[37] using K files and Profiles and **Katge F et al. (2016)**[70] using H files and Mtwo files reported reduced instrumentation time in the K and H file group respectively. This may be because **Madan N et al. (2011)**[37] used the full series of Profile system as used in permanent teeth and **Katge F et al. (2016)**[70] used the complete series of Mtwo system, thus requiring more time to change the files of complete series.[70] This may also be attributed to the operator's experience in performing the manual biomechanical preparation.[37] **Gomes GB et al. (2014)**[44] found no difference in the instrumentation and

obturation time when ProTaper and manual instrumentation was compared in 8 necrotic mandibular molars. However, this result should be cautiously interpreted, as the sample size was not big enough to avoid the influence of random sampling variability in statistical analysis.

In the present study, we used only Sx ProTaper and X1 ProTaper Next rotary files and X2-X5 files of the ProTaper Next series were not used. Hence, we observed less instrumentation time in the rotary group compared to the manual group.

In-vitro studies conducted by **Silva LA et al. (2004)**[5] and **Nazari Moghaddam K et al. (2009)**[10] have also reported much lesser time with rotary instrumentation (3.46 and 2.07 minutes, respectively) compared to the manual instrumentation (9.06 and 5.55 minutes, respectively). Compared to the above mentioned in-vitro studies, in-vivo studies, in general, have reported longer instrumentation time due to reasons of varying patient cooperation, frequent irrigation regimes, procedural difficulties encountered due to patient fatigue in mouth opening during the procedure and frequent changing of the rotary instruments.

Different laboratory approaches have been used to evaluate root canal filling quality in-vitro or in extracted teeth such as the penetration of dye, use of radioisotopes, clearing techniques following tooth sectioning, and radiographic assessment. Use of IOPA and digital radiography is the only clinical way to evaluate the quality of obturation. Most of the vivo studies[20,21,23,44,56,58,59,67,71] have assessed the quality of obturation using IOPA. Hence, we used this technique to compare the quality of obturation following the use of the two different instrumentation techniques.

Two faculty members evaluated the radiographs using a viewer box and magnifying glass with 10X magnification. A similar method of radiographic evaluation has been used by **Kuo CI et al. (2006)**[3] and **Makarem A et al. (2014)**[21]. **Reddy PVR et al. (2015)**[72] placed the post obturation IOPA's on a viewer with a graph sheet behind the radiographs. In order to standardize the measurements of obturation quality, transparent 1 mm grid was put behind the IOPA X-rays so that quantitatively maximum intra and inter-examiner reproducibility can be obtained. In the present study, we used standardized criteria for radiographic exposure and angulation of the tube using paralleling radiographic technique. Hence, obtaining the same projection of the grid and the X-ray, thus increasing the reproducibility and accuracy.

In this study, the quality of obturation was assessed for the teeth according to the modified Coll and Sadrian criteria.[34,56] The two faculty members from the department were asked to rate the 10 post-obturation radiographs separately. The same 10 radiographs were again evaluated by both the examiners separately after a period of 1 week. The inter and intra-examiner reliability kappa coefficient value for both the examiner was excellent **(Table no. 3, page no. 92).**

As regards the quality of obturation in the present study is concerned there was no statistically significant difference between optimal, underfilled and overfilled teeth in both the groups using the modified Coll and Sadrian criteria. Various studies[23,56,59,73,74] have used the same criteria for assessment of the quality of obturation. **Mortazavi M et al. (2006)**[67] reported similar findings to that of the present study using ProTaper and K-files for instrumentation, whereas **Ocheo Romero T et al. (2011)**[19] and **Makarem A et al. (2014)**[21] reported statistically significant better quality of filling with the rotary technique compared to the manual technique.

In the present study, both the rotary and manual groups were observed to have almost equal number of optimal obturation cases i.e. 14 (66.7%) and 16 (76.2%) teeth respectively. However, we observed double the number of cases with overfilling in rotary group (6 teeth-28.5%) compared to manual group (3 teeth-14.3%); though, the difference being statistically insignificant. It is also interesting to note that the underfilled teeth were double in manual group (2 teeth-9.5%) compared to rotary group (1 tooth-4.8%); again the difference being statistically insignificant. Therefore, with the rotary technique there are less underfilled and more overfilled teeth compared to manual technique. **Kuo CI et al (2006)**[3] reported 55% flush-filled, 16% under-filled and 29% over-filled cases using the modified ProTaper instrumentation protocol. In manual biomechanical preparation the apical constriction is felt and thus there is no tendency to extend beyond the determined working length. However, due to the lack of tactile sensitivity in the rotary files, there is a tendency for crossing beyond the working length and a chance of over-instrumentation. Thus, leading to extrusion of the obturating material in the periapical area.

A limitation of using this criteria for the assessment of quality of obturation is the judgement as to what constitutes a short fill (under-filling means all the canals were filled more than 2 mm short of the apex) vs an optimal fill (an optimal filling had 1 or more of the canals having obturation up to the radiographic apex or up to 2 mm short of the apex), in a tooth in which 1 canal was filled optimally and the others were very short of the apex.[56] In such cases, failure of the pulpectomy can be due to the underfilled canals in spite of the tooth being judged as optimally filled. Hence, we further assessed the quality of obturation for each canal separately.

Mesiobuccal and mesiolingual canals of the mandibular molars in most cases were seen and rated separately but sometimes the canals were observed to be overlapping. Hence, in such cases the mesiolingual canal was rated same as mesiobuccal canal. In the present study, the analysis of quality of obturation in individual canals of all the teeth between the two groups showed no statistically significant differences. **Govindaraju L et al. (2017)**[23] has also reported the similar findings of no statistical significant difference in the quality of obturation of mandibular canals using ProTaper, Mtwo and K files.

In the present study, 4 overfilled distal canals were observed in the rotary group as compared to none in the manual group. **Govindaraju L et al. (2017)**[23] too observed more overfilled mandibular distal canals instrumented with rotary files compared to the manual technique. The distal canals are usually wide and straight and the mesial canals being curved and slender with anastomosis at the apical third region, maybe the cause for more overfilled distal canals in the rotary group.

There were 4 overfilled mesiobuccal canals in the rotary group and 2 in the manual group. Also, there were 5 overfilled mesiolingual canals in the rotary group and 2 overfilled mesiolingual canal of mandibular molars and 1 distobuccal canal of maxillary molar in the manual group. Thus, there were more number of mesial canals showing overfilling in the rotary group compared to the manual group.

In the present study, optimal filling was observed in equal number of mesiobuccal and mesiolingual canals with the rotary technique (15+14) compared to the manual technique (14+15). This may be due to better biomechanical preparation using both the techniques. However, **Makarem A et al. (2014)**[21] observed a statistically higher proportion of optimum canal obturation of mesial canals using FlexMaster rotary

technique compared to the manual technique. It might be attributed to the better preparation of canals with the rotary method, leading to a better flow of the obturating material.

Presence of voids in the obturation is one of the factor which might provide pathways for leakage and the possibility of microorganism and toxin retention, leading to post-treatment failures. Various factors influencing the location and size of the voids include the type, viscosity, and consistency of the paste, the method used to apply the paste, and operator skill and experiences[58,59], which were same for both the instrumentation groups. The post-obturation IOPA was also assessed on the viewer box for the presence or absence of voids by using a 10X magnifying glass and the same number of voids (5 teeth each) were found in both the groups. Contrary to the present study, **Makarem A et al. (2014)**[21] observed significantly fewer voids in the rotary group.

We measured the extent of extrusion in all the overfilled teeth. The extrusion is in the three-dimensional periapical space which is measured in two-dimensions on radiographs. Hence, the extrusion can be both vertical and horizontal. The vertical extrusion may also be horizontally in the third dimension. In this study, we measured the extent of extrusion of the obturation material both vertically from the radiographic apex as well as horizontally mesio-distal extension from the apex. We found that the number of overfilled teeth as well the extent of extrusion was both greater in the rotary group. The lack of tactile sensitivity when using the rotary instruments could be a possible reason for this finding. The better biomechanical preparation in the rotary group leads to smooth flow of the obturating material and may thus lead to overfilling. To the best of our knowledge, no study comparing the rotary and manual instrumentation in primary teeth have measured the extent of extrusion.

A potential limitation of this study design would be that the outcome is due in part to a superior operator rather than a superior technique. Hence, the technique is operator sensitive.[59]

Intraoral periapical radiograph depicts only a two-dimensional view of the obturation.[71,73] This can be a lacunae in the assessment of the quality of obturation and voids from the technical point of view, which unfortunately is not under the control of the operator/ study. In a previous study by **Dandashi MB et al. (1993)**[75], voids were assessed using lateral and anterior/posterior radiographs; however, since it was an in vitro study, multiple views were taken. The present study being in-vivo, multiple such views are not possible.[58,74] However, three dimensional picture of obturation can be obtained with the use of CBCT to analyze both, the quality of obturation i.e. type of filling (under-filling, optimal and overfilling) and voids.

All the rotary files are designed for the permanent teeth and not for the primary teeth. Yet, considering the advantages of the rotary system, various studies have been carried out to assess the effectiveness of a modified protocol for instrumentation in primary teeth. In this study, rotary instrumentation showed a highly significant reduction in in-vivo instrumentation time to almost half that of the manual technique. This reduced instrumentation time is highly beneficial in pediatric patient as it allows fast, safe and quality procedures, thereby reducing the patient's and dentist's physical fatigue.[40] It is also advantageous in children who are less cooperative, patients whose dental treatment is carried out under general anesthesia, and children who cannot tolerate multiple appointments. It also decreases the working time for children having multiple teeth in need of pulpectomy.[21] In this study, both the rotary and manual instrumentation showed no statistically significant difference regarding the quality of obturation and presence of

voids. Therefore, it is recommended to conduct in vivo studies with large sample size and long-term follow-up to evaluate the clinical and radiographic success of the pulpectomy procedure using the rotary technique. It is also recommended to use digital radiography to eliminate the processing errors and improve the features of evaluation, like magnification and contrast. To accurately assess the quality of root canal obturation in three dimensions, this study may be designed with the use of CBCT.[59,73]

SUMMARY AND CONCLUSION

A randomized clinical controlled trial to evaluate and compare the instrumentation time and quality of obturation of hybrid ProTaper Next rotary and K file manual technique was conducted. 42 primary molars in 31 children of 6-8 years were included in the study.

Following findings were observed:

1. Significantly lower time of 11.14 minutes in the rotary group compared to 19.02 minutes in the manual group was required for the biomechanical preparation of primary molars. Thus, significantly reducing the clinical time with the rotary technique to half (7.88 minutes) of the manual method.
2. Statistically, no significant difference in the quality of obturation and presence of voids was observed amongst the two techniques.

3. Overfilled obturation was more in the rotary group compared to the manual group.

Significant reduction time in instrumentation of primary teeth by the rotary technique is of great clinical importance as more number of pulpectomies can be performed in reasonably cooperative children having nursing/ high risk/ rampant caries for improving the oral health status.

The recurring high cost of Ni-Ti files, expertise required in using the rotary technique are the factors limiting the application of rotary technique in pediatric endodontics. However, the reduced biomechanical preparation time helps in treating more number of cases thereby generating extra revenue thus compensating for the high cost of the rotary files.

It may be concluded that rotary technique can be recommended with know-how and expertise in pediatric endodontics.

ProTaper Next is a recent advancement in rotary endodontics and no in-vivo investigation evaluating its efficacy has been reported in primary teeth. Though both rotary and manual technique were found to have equal results qualitatively, a significant reduction in treatment time by rotary technique to half that of manual technique will certainly help successful treatment in more number of children.

The results of our study emphasize the need for further long-term research to recommend a protocol for use of the rotary technique in pediatric endodontics.

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Table 1: Descriptive statistics for age and number of teeth treated per group according to gender

Gender	Number of children	Age (in years) Mean ± SD / (median)	Number of teeth	Group	
				Rotary Teeth (FDI system) 55-54-64-65-75-74-84-85	Manual Teeth (FDI system) 55-54-64-65-75-74-84-85
Boys	16	6.94±0.90 (6.33)	22	10 0-1-0-0-4-0-3-2	12 1-1-0-0-4-3-2-1
Girls	15	7.27±1.03 (7.25)	20	11 0-0-0-0-5-0-0-6	9 0-0-0-1-1-2-1-4
Total	31	7.10±0.96 (7.16)	42	21 0-1-0-0-9-0-3-8	21 1-1-0-1-5-5-3-5

Table 2: Descriptive statistics for instrumentation time in the two groups

Group: Technique	N	Mean ± SD (min)	Median (range)	P-value*
Rotary	21	11.14 ±1.97	10.45 (8.40-15.43)	< **0.0001(HS)**
Manual	21	19.02 ±4.39	20.05 (9.07-25.43)	

*Obtained using *Mann-Whitney U test*; HS: Highly Significant

Table 3: Inter and intra rater reliability

		Kappa coefficient (P-value)	
		Assessment of obturation form	Assessment for the presence or absence of Voids
Inter-rater		0.808 (0.0004)	1.000 (< 0.0001)
Intra-rater	*Examiner #1*	0.808 (0.0004)	1.000 (< 0.0001)
	Examiner #2	1.000 (< 0.0001)	0.737 (0.0157)

Table 4: Distribution of teeth as per quality of obturation in the two treatment groups

Group: Technique	Optimal	Under filled	Overfilled	P-value*
Rotary (n=21)	14 (66.7%)	1 (4.8%)	6 (28.5%)	0.578 (NS)
Manual (n=21)	16 (76.2%)	2 (9.5%)	3 (14.3%)	
Total	30 (71.4%)	3 (7.2%)	9 (21.4%)	

*Obtained using *Fisher exact test*; NS: Not Significant

Table 5: Distribution of mesiobuccal canals as per quality of obturation in two groups

Group: Technique	Optimal	Under filled	Overfilled	P-value*
Rotary (n=21)	15 (71.4%)	2 (9.5%)	4 (19.1%)	0.409(NS)
Manual (n=21)	14 (66.7%)	5 (23.8%)	2 (9.5%)	
Total	29 (69%)	7 (16.7%)	6 (14.3%)	

*Obtained using *Fisher exact test*; NS: Not Significant

Table 6: Distribution of mesiolingual canal of the mandibular molars /distobuccal canal of the maxillary molars as per the quality of obturation in the two groups

Group: Technique	Optimal	Under filled	Overfilled	P-value*
Rotary (n=21)	14 (66.7%)	2 (9.5%)	5 (23.8%)	0.798(NS)
Manual (n=21)	15 (71.4%)	3 (14.3%)	3(14.3%)	
Total	29 (69%)	5 (12%)	8 (19%)	

*Obtained using *Fisher exact test*; NS: Not Significant

Table 7: Distribution of palatal canal of maxillary molars/distal canal of mandibular molars as per the quality of obturation in the two groups

Group: Technique	Optimal	Under filled	Overfilled	P-value*
Rotary (n=21)	16 (76.2%)	1(4.8%)	4 (19%)	0.119(NS)
Manual (n=21)	18 (85.7%)	3(14.3%)	0	
Total	34 (81%)	4 (9.5%)	4 (9.5%)	

*Obtained using *Fisher exact test*; NS: Not Significant

Table 8: Distribution of voids in the two groups

Group: Technique	Present	Absent	P-value*
Rotary (n=21)	5 (23.8%)	16 (76.2%)	0.999(NS)
Manual (n=21)	5 (23.8%)	16 (76.2%)	
Total	10 (23.8%)	32 (76.2%)	

*Obtained using *Chi Square test*; NS: Not Significant

Table 9: Distribution of overfilled teeth as per the extent of extrusion in the two groups

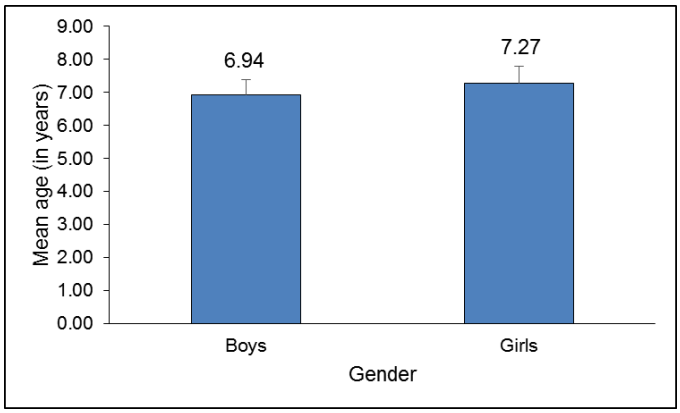
Groups	Horizontal (n=9)	Vertical (n=9)
Rotary technique		
1mm	2 (22.2%)	0
2mm	3 (33.3%)	3 (33.3%)
3mm	1 (11.1%)	3 (33.3%)
Manual technique		
1mm	2 (22.2%)	2 (22.2%)
2mm	1 (11.1%)	1 (11.1%)

Table 9A: Distribution of teeth as per the presence and absence of extrusion

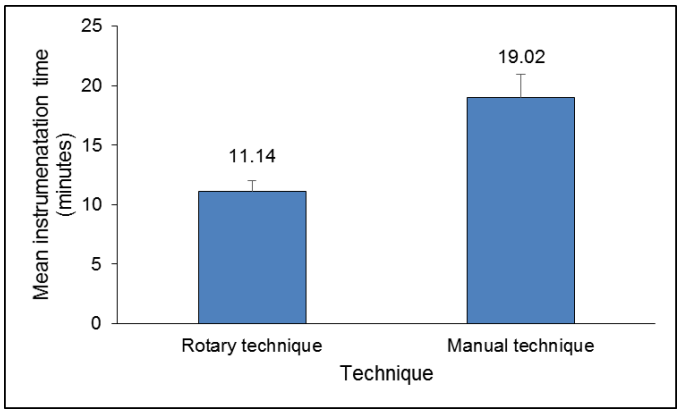
Groups	With extrusion	Without extrusion	P-value*
Rotary technique (n=21)	6 (28.57%)	15 (71.43%)	0.452 (NS)
Manual technique (n=21)	3 (14.28%)	18 (85.71%)	

*Obtained using Pearson's Chi-square test; NS: Not significant

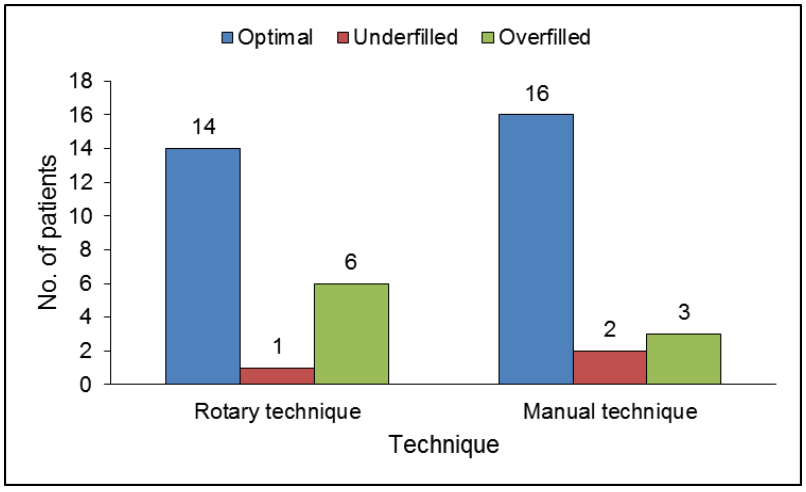
Graph 1: Column chart showing the mean age according to gender



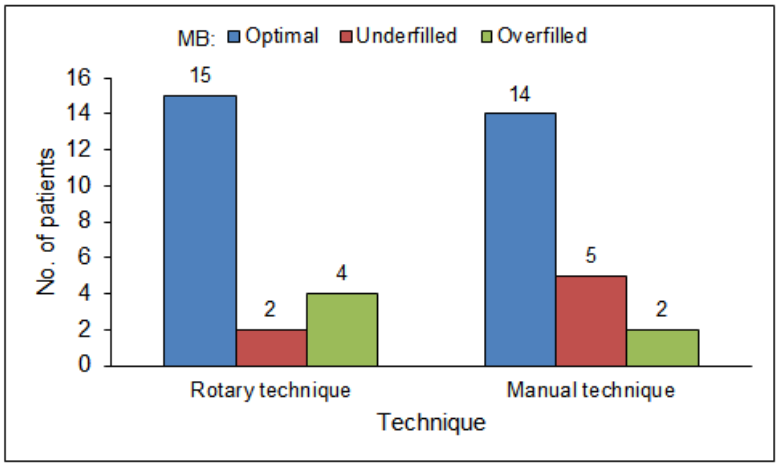
Graph 2: Column chart showing the mean instrumentation time in the two groups



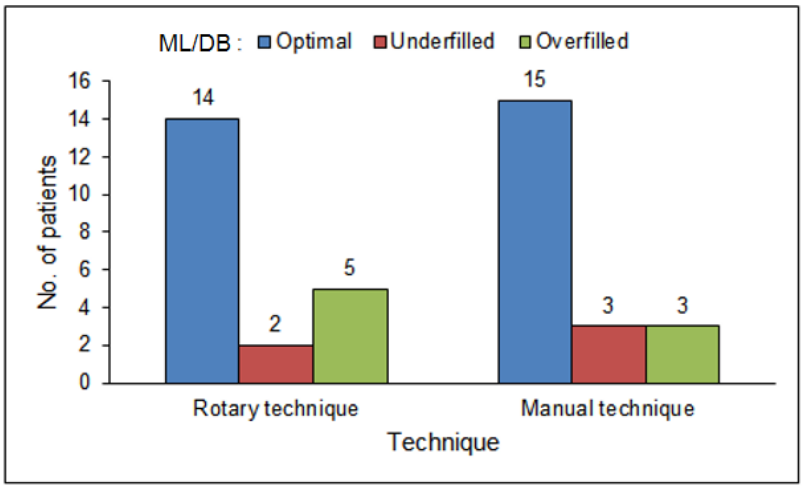
Graph 3: Column chart showing number of teeth according to the quality of obturation in the two groups



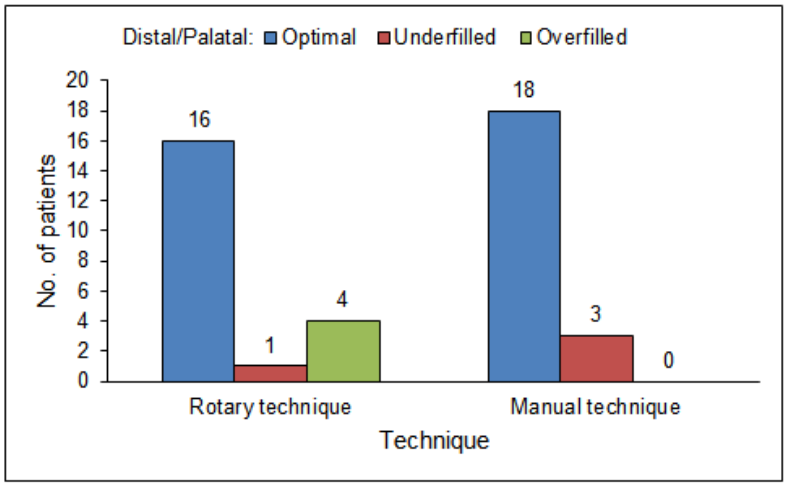
Graph 4: Column chart showing number of mesiobuccal canal according to the quality of obturation in the two groups



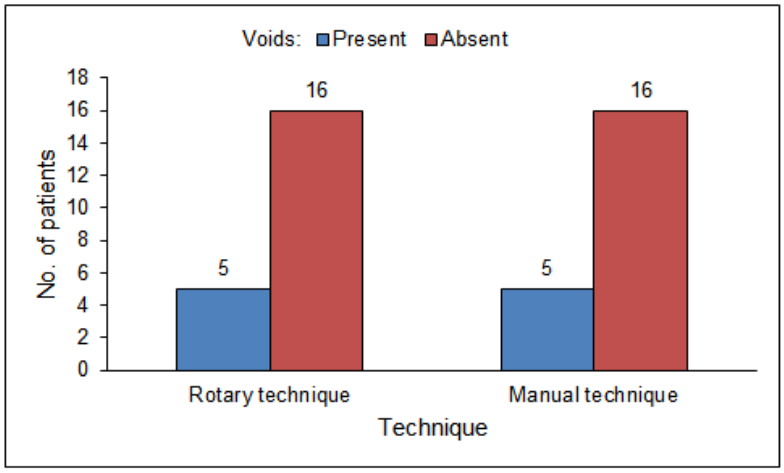
Graph 5: Column chart showing number of mesiolingual canal in mandibular molars/ distobuccal canal in maxillary molars according to the quality of obturation in the two groups



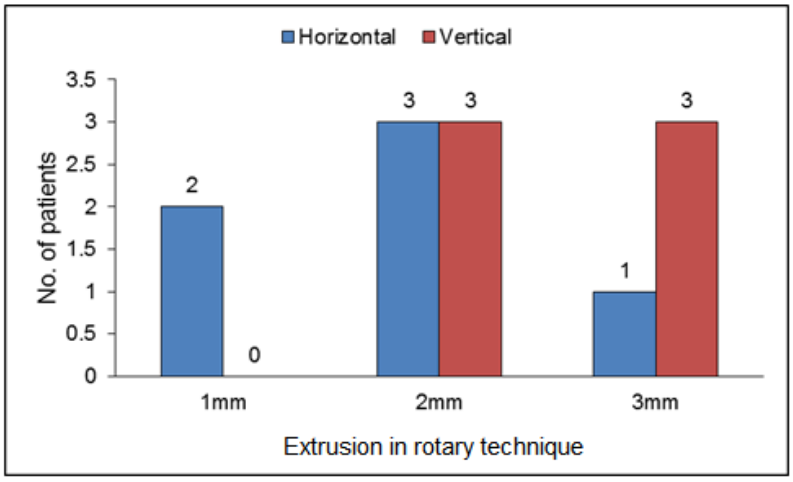
Graph 6: Column chart showing number of palatal canal in maxillary molars/ distal canal in mandibular molars according to the quality of obturation in the two groups



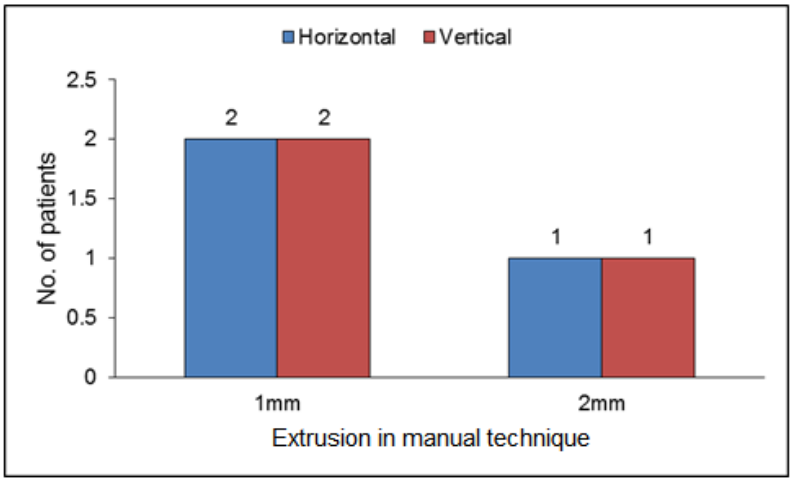
Graph 7: Column chart showing number of teeth with the presence and absence of voids in the two groups



Graph 8: Column chart showing number of overfilled teeth according to the extent of extrusion in the rotary group



Graph 9: Column chart showing number of overfilled teeth according to the extent of extrusion in manual group



ANNEXURE -1

Information Sheet for Patient/Parent

Introduction

I, a Post Graduate in the Department of Pediatric and Preventive Dentistry, in a dental college working on my thesis titled

"**Comparative evaluation between manual K file and hybrid rotary ProTaper Next techniques for primary molar pulpectomy: A clinical study"**

My study subjects will be children of 6-8 years old coming to the department of pediatric and preventive dentistry.

Purpose of the research

To compare the instrumentation time and the quality of obturation in primary molars between the manual K-File and hybrid rotary ProTaper Next techniques.

Voluntary Participation

Your participation in this research is entirely voluntary. You can withdraw from it any time you wish. This will no way adversely affect the subsequent outcome of the treatment or your relationship with the operating doctor on inclusion to the project. Any additional expense for the project will be borne by the project fund and will not be charged to you.

Confidentiality

The information that we collect from this research project will be kept confidential. Information about the patient that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about the patient will have a number on it instead of your name.

If illiterate, a literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness _____ Thumb print of participant

Signature of witness _____

Date _____

Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

I acknowledge the treatment planning, and also the doctor has informed me about this research project suitably and sufficiently to my satisfaction. I agree to let my child's treatment be taken as required. I agree to take part in this project. I shall co-operate with the doctors, in all respects. I permit to publishing the results of my participation in this study. I shall not be given any reimbursement or compensation. I have been informed of my right to opt out of this research project at any time without giving any reason for doing so. I hereby record my consent for participation in the said project.

....

Parent's/guardian's name Signature/thumbprint Date Time

.... ……

Investigator's name Signature Date

Time

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

"Comparative evaluation between manual K file and hybrid rotary ProTaper Next techniques for primary molar pulpectomy: A clinical study"

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

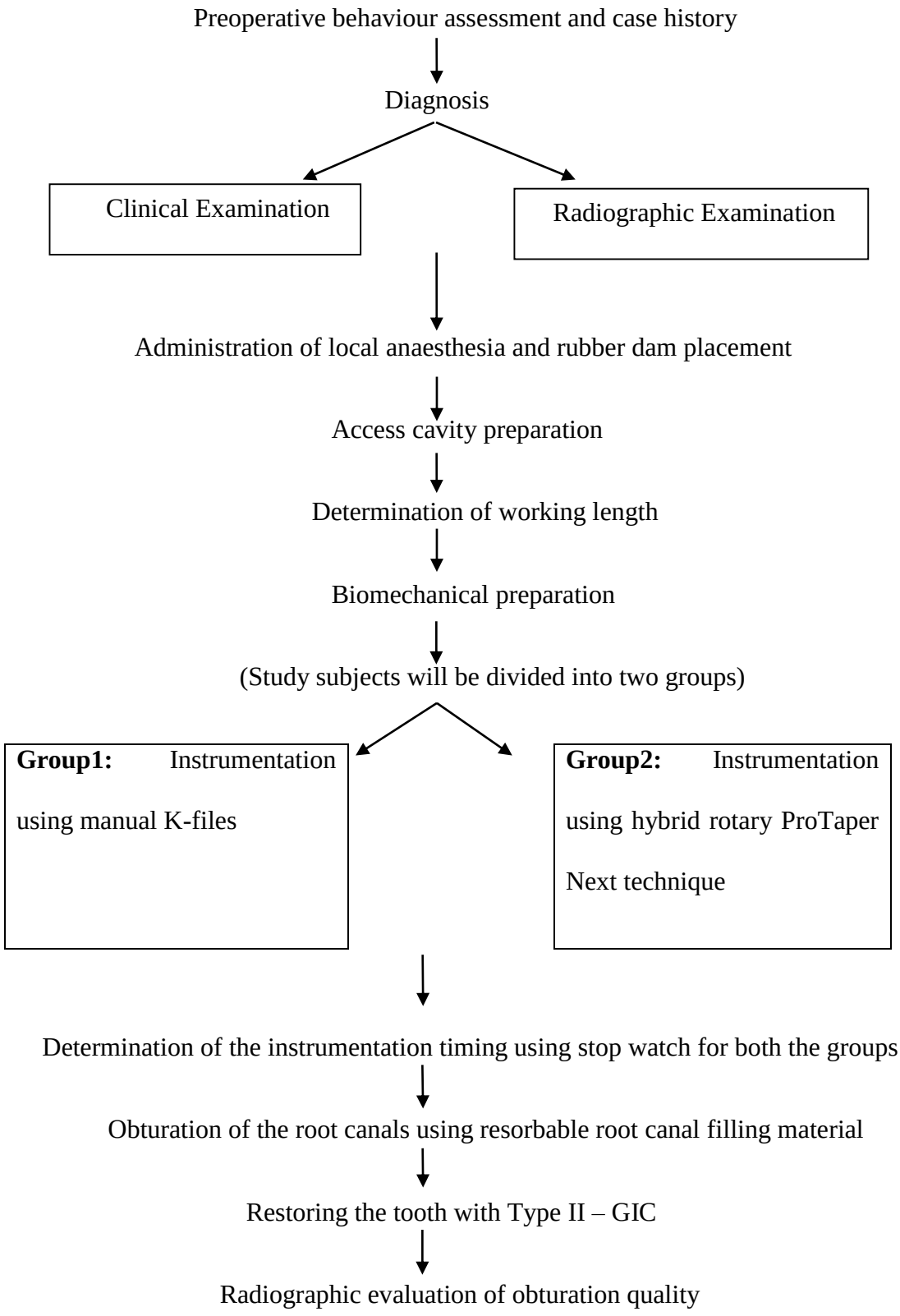
Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

Procedures and Protocol



ANNEXURE-2

Examination Proforma/ Case Record Form

Identification No. Day Month Year Examiner Orig /Dupl

☐☐ ☐☐|☐☐|☐☐☐☐ ☐|☐

1 2 3 4 5 6 7 8 9 10 11 12

GENERAL INFORMATION:

Name of child: _____

Day Month Year

Date of birth: ☐☐|☐☐|☐☐☐☐

13 14 15 16 17 18 19 20

Age: ☐ years (21)

Gender: ☐ M:1 ; F:2 (22)

Group: ☐ (23) 1: Manual instrumentation 2: Rotary instrumentation

Name and Address of parent: _____

_____

_____Contact No. of Parent: _____

Behavior Assessment as per Frankl behavior rating scale**:** ☐ (24)

Code 1: Definitely negative Code 2: Negative

Code 3: Positive Code 4: Definitely positive

Chief Complaint:

H/O Present illness:

Past Dental History:

Medical History:

I. Extra Oral Examination

- Facial Form
- Facial symmetry
- Facial profile
- Swelling on face and jaws
- Lymph nodes
- Mouth opening

II. Intra Oral Examination

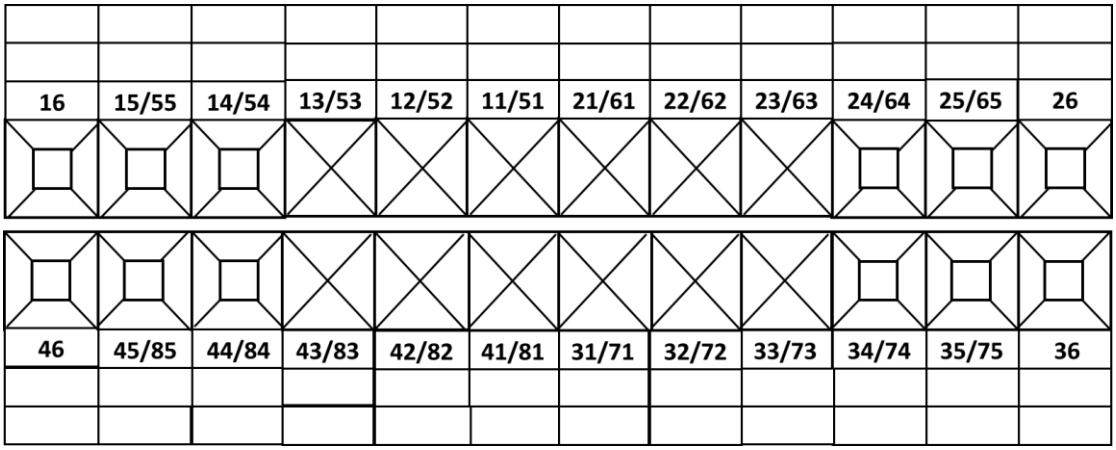
A. Examination of Soft tissues

- Gingiva
- Oral mucosa
- Palate
- Floor of mouth
- Tongue

B. Examination of Hard tissues:

- Teeth Present (FDI notation)
- Deep caries/carious exposure/restorations
- Tenderness
- Swelling location:
- Swelling: Hard/Soft/fluctuant:
- Sinus location:

Caries Status and Treatment Needs (WHO – Modified)



Primary Teeth (Pr) and Permanent Teeth (Pt) Status

Pr	Pt	STATUS
A	0	Sound
B	1	Decayed
C	2	Filled, with Decay
D	3	Filled, No Decay
E	4	Missing, as a Result of Caries
	5	Missing Any Other Reason
F	6	Fissure Sealant
G	**7**	Bridge Abutment Special Crown Or Veneer/Implant, Crown For Badly Carious Tooth/Endodontic Treated Tooth/Band(Or)Crown For Space Maintainer or regainer
	8	Un-erupted Tooth(Crown)/Unexposed Root
T	T	Trauma(Fracture)
	9	Not recorded

Treatment Code

CODE	STATUS
0	None
P	Preventive Caries-Arresting Care
F	Fissure Sealant
1	One Surface Filling
2	Two Or More Surface Fillings
3	Crown For Any Reason
4	Veneer Or Laminate
5	Pulp Care And Restoration
6	Extraction
7	Treatment For Need Or Nursing / Rampant/High Risk Caries
8	Indirect Pulp Capping/Indirect Pulp Therapy
9	Not Recorded

deft / defs score:

DMFT /DMFS score:

deft + DMFT/ defs + DMFS score:

III. Provisional diagnosis:

IV. Investigations:

Radiographic interpretation:

IV. Diagnosis:

V. Treatment Plan: Pulpectomy Procedure

a) Tooth number-

b) Determination of working length-

c) Instrumentation Protocol-

d) Instrumentation Time-

e) Obturation-

f) Post Obturation Radiographic Assessment-

ANNEXURE -3

Evaluation Form

Identification No. ☐ ☐ Examiner: ☐

IMMEDIATE POST OBTURATION RADIOGRAPHIC ASSESSMENT

OF LEVEL OF FILLING:

-UNDERFILLING- All the canals were filled more than 2 mm short of the apex.

-OPTIMAL FILLING: One or more of the canals having obturating material ending at the radiographic apex or upto 2 mm short of the apex.

-OVER FILLING: Any canal showing obturating material extending beyond the radiographic apex.

RADIOGRAPHIC ASSESSMENT (for the tooth)

Presence of voids		Level of filling		
Present	Absent	Under filled	Optimally Filled	Over filled

RADIOGRAPHIC ASSESSMENT (for each canal)

Root canal	Level of filling		
	Under filled	Optimally Filled	Over filled
Mesiobuccal			
Mesiolingual/distobuccal			
Distal/Palatal			

Assessment Of Extrusion Of The Filling Material

EXTRUSION:

Measurement (mm) of the largest dimension of any extruded material vertically and horizontally beyond the radiographic apex.

Vertical extent : ……mm

Horizontal extent: ……mm

ANNEXURE-4

Assessment Of Inter And Intra-Examiner Reliability

Examiner 1		Examiner 1: After 1 week		Examiner 2		Examiner 2: After 1 week	
Quality Of Obturation	Voids	Quality Of Obturation	Voids	Quality Of Obturation	Voids	Quality Of Obturation	Voids
Optimal	A	Optimal	A	Optimal	A	Optimal	A
Overfilled	P	Overfilled	P	Overfilled	P	Overfilled	P
Overfilled	A	Overfilled	A	Overfilled	A	Overfilled	A
Optimal	A	Optimal	A	Underfilled	A	Underfilled	A
Optimal	A	Optimal	A	Optimal	A	Optimal	A
Optimal	P	Underfilled	P	Optimal	P	Optimal	A
Optimal	A	Optimal	A	Optimal	A	Optimal	A
Optimal	P	Optimal	P	Optimal	P	Optimal	P
Optimal	A	Optimal	A	Optimal	A	Optimal	A
Underfilled	A	Underfilled	A	Underfilled	A	Underfilled	A

A: Absent

P: Present

Master Chart with instrumentation time, quality of obturation and extent of extrusion in the manual and rotary groups

Case. No	Age	Sex	Tooth No.	No. of visits	Instru-mentation technique	Instru-mentation time	Quality of obturation For tooth	Quality of obturation for canals			Voids	Horizontal Extrusion	Vertical Extrusion
								MB	ML/DB	Distal/Palatal			
1	7.25	M	74	1	manual	20.05	optimal	optimal	optimal	optimal	A		
2	6.08	M	84	1	manual	16.19	overfilled	overfilled	overfilled	optimal	P	1mm	1mm
3	8.17	F	65	1	manual	20.17	overfilled	overfilled	overfilled	optimal	A	2mm	2mm
4	7.25	F	85	1	manual	16.33	optimal	optimal	optimal	optimal	A		
5	6.25	M	74	1	manual	17.44	optimal	optimal	optimal	optimal	A		
6	6.25	M	75	2	manual	25.26	optimal	optimal	optimal	optimal	P		
7	6.33	F	74	1	manual	18.51	optimal	optimal	optimal	optimal	A		
8	6.33	F	85	1	manual	20.1	optimal	underfilled	underfilled	optimal	P		
9	6.25	M	75	1	manual	15.15	optimal	optimal	optimal	optimal	A		
10	8.08	F	85	1	rotary	14.45	underfilled	underfilled	underfilled	underfilled	A		
11	6.33	F	75	1	rotary	14.4	optimal	optimal	optimal	optimal	P		
12	6.42	F	74	2	manual	20.00	optimal	underfilled	optimal	optimal	A		
13	8.33	F	75	1	rotary	14.15	optimal	optimal	optimal	optimal	A		
14	6.33	M	85	1	manual	24.45	optimal	optimal	optimal	underfilled	A		
15	8.33	M	75	1	manual	25.05	optimal	optimal	optimal	optimal	A		
16	6.17	M	74	1	manual	15.43	underfilled	underfilled	underfilled	underfilled	A		
17	6.17	M	75	1	manual	22.41	optimal	optimal	optimal	optimal	A		
18	6.17	M	84	1	rotary	10.01	optimal	optimal	optimal	optimal	P		
19	6.17	M	85	2	rotary	11.47	optimal	optimal	optimal	optimal	A		
20	8.25	F	85	1	rotary	9.35	optimal	optimal	underfilled	optimal	A		
21	8.17	M	54	1	rotary	10.42	optimal	optimal	optimal	optimal	A		
22	7.17	F	84	1	manual	15.23	optimal	optimal	optimal	optimal	A		

Master Chart with instrumentation time, quality of obturation and extent of extrusion in the manual and rotary groups

23	7.17	F	85	2	manual	20.25	optimal	optimal	optimal	optimal	A		
24	8.17	M	75	1	rotary	12.5	optimal	optimal	optimal	optimal	A		
25	6.25	M	75	1	rotary	10.45	optimal	underfilled	optimal	optimal	P		
26	6.17	M	75	1	rotary	9.4	optimal	optimal	optimal	optimal	A		
27	6.17	M	85	1	rotary	11.07	optimal	optimal	optimal	optimal	P		
28	8.33	F	85	1	rotary	12.14	optimal	optimal	optimal	optimal	A		
29	7.17	M	55	1	manual	25.43	optimal	optimal	optimal	optimal	A		
30	8.25	F	85	1	rotary	10.21	optimal	optimal	optimal	optimal	A		
31	6.17	M	84	2	rotary	10.45	overfilled	overfilled	overfilled	optimal	A	2mm	3mm
32	8.17	M	75	1	rotary	10.2	overfilled	overfilled	overfilled	overfilled	P	1mm	3mm
33	6.08	F	85	1	rotary	9.42	overfilled	overfilled	overfilled	optimal	A	2mm	2mm
34	7.75	M	84	2	manual	21.07	optimal	optimal	optimal	optimal	A		
35	6.08	F	75	1	rotary	10.15	overfilled	overfilled	overfilled	overfilled	A	1mm	2mm
36	6.17	F	85	2	rotary	10.45	overfilled	optimal	overfilled	overfilled	A	2mm	2mm
37	6.17	F	75	2	rotary	9.43	overfilled	optimal	optimal	overfilled	A	3mm	3mm
38	6.33	M	84	2	rotary	8.4	optimal	optimal	optimal	optimal	A		
39	5.58	F	85	1	manual	11.42	overfilled	underfilled	overfilled	optimal	P	1mm	1mm
40	5.58	F	75	1	manual	20.43	underfilled	underfilled	underfilled	underfilled	A		
41	8.33	F	75	2	rotary	15.43	optimal	optimal	optimal	optimal	A		
42	8.33	M	54	1	manual	9.07	optimal	optimal	optimal	optimal	P		