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**COMPARATIVE EVALUATION OF POST-OPERATIVE PAIN  
AFTER SINGLE SITTING PULPECTOMY USING HAND  
AND ROTARY INSTRUMENTATION IN PRIMARY MOLARS  
OF CHILDREN – A RANDOMISED CONTROL STUDY.**

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**Dissertation**

*Submitted to KLE Academy of Higher Education and Research (KAHER), Belagavi  
In Partial Fulfillment of the Requirements for the Degree Of*

**MASTER OF DENTAL SURGERY**

**In**

**PEDIATRIC AND PREVENTIVE DENTISTRY  
(BRANCH - VIII)**

**Under the Guidance of**

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I hereby declare that this dissertation entitled “**Comparative evaluation of post-operative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children – A randomised control study.**” is a bonafide and genuine research work carried out by me under the guidance of **Dr. Shivayogi M. Hugar** M.D.S. Professor, Department of Pediatric and Preventive Dentistry; KAHER’S KLE Vishwanath Katti Institute of Dental Sciences, Nehru Nagar, Belagavi-590010.

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## **ACKNOWLEDGEMENT**

*No endeavor can start, continue and complete without the blessings of the **Almighty**. At the outset, I thank the almighty for always being by my side by bestowing strength and patience to complete the task entrusted.*

*I am highly beholden to **Dr. Alka Kale** M.D.S Principal, KLE VK Institute of Dental Sciences, Belagavi, for providing me the required facilities and infrastructure.*

*I am privileged to express my extreme gratefulness, deepest regards and indebtedness to my respected teacher and guide **Dr. Shivayogi M. Hugar** M.D.S, Professor & HOD, Department of Pediatric and Preventive Dentistry, K.L.E. VK Institute of Dental Sciences, Belagavi, for providing continuous guidance. He is a person with amicable and dissolution. I had a great opportunity to learn from a person with such caliber and research expertise. His guidance, everlasting inspiration, thought of perseverance, incessant encouragement and constructive criticism, with valuable suggestions for improvement without whom the completion of this dissertation would not have been possible.*

*I am appreciative and grateful to my teachers **Dr. Chandrashekhar Badakar, Dr. Niraj Gokhale, Dr. Vidyavathi Patil, Dr. Chaitanya Uppin and Dr. Shweta Kajjari**, Department of Pediatric and Preventive Dentistry, KLE VK Institute of Dental Sciences, Belagavi for their help and professional support all throughout my course.*

*I take this opportunity to thank my batch mate, good friend **Dr. Pooja K. Dialani** for her ceaseless support, kindness and constant help all throughout.*

*I would also like to convey my heartfelt gratitude to my dear colleagues **Dr. Krishna S. Kadam, Dr. Neha Kohli, Dr. Bhuvanesh N. Bhusari and Dr. Sanika U. Karmarkar** for their eagerness and willingness to help me during the course.*

*I would be failing in my duties if I do not thank my seniors **Dr. Sanjana Soneta, Dr. Riddhi Joshi, Dr. Rucha Davalbhakta and Dr. Gowtham A.** for their guidance, moral support and timely help throughout my course.*

*I am very much indebted to this department and extend my appreciation to all the **non-teaching staff** of the department for their able assistance.*

*I take pleasure to thank my friends **Kanika Gupta, Dr. Bhavya Nigam and Dr. Dhananjay Sharma** for their constant support during the study.*

*I sincerely acknowledge the help from **Mr. Anand and Mr. Arun** all the staff at Sri Vighneshwara Xerox centre, KLE Academy of Higher Education and Research without whom the task would have been left unaccomplished.*

*I gladly would like to express my love and gratitude to my sister **Miss. Aditi Saxena** who has given me immense strength, inspired me and stood by me through thick and thin. She has been a friend, a critic and role model.*

*Last but not the least I would like to thank my parents, my father **Dr. Rajeev K. Saxena**, for his inspiration, blessings and courage without whom this wouldn't be possible and I wouldn't be what I am today and my mother, **Dr. Ragini Saxena** whose unconditional love, immeasurable support, understanding, innumerable sacrifices and prayers which they constantly shower on me and all my family members for their love, unstinted help and support.*

**Dr. NIVEDITA SAXENA**

## **ABSTRACT**

**AIM:** The aim of the study is to evaluate and compare the post-operative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children.

**METHOD:** Sixty children of age 4-8 years were selected for the single sitting pulpectomy after fulfilling inclusion and exclusion criteria and all participants were equally divided into two groups. Single sitting pulpectomy procedure was carried out in both the groups. In control group K files and in experimental group Pro AF baby Gold pediatric rotary files were used followed by Obturation with zinc oxide eugenol (ZOE) cement. Evaluation of post operative pain was done using Modified Visual Analogue Scale (VAS) at 24 hrs, 48 hrs and 72 hrs. Furthermore, evaluation of instrumentation time and quality of obturation was done. Patient is recalled after seven days for the placement of stainless steel crown.

**RESULTS:** The results showed no statistically significant difference in the post-operative pain after single sitting pulpectomy using hand and rotary Instrumentation in primary molars of children. Additional analysis summaries no significant difference with quality of obturation in both the study groups. However, a significant difference has been observed in the instrumentation time while using rotary method of instrumentation as compared to hand instrumentation with independent 't' test value 19.797 and 'p' value 0.001.

**CONCLUSION:** Among both the materials there was no significant difference found in post operative pain and quality of obturation after single sitting pulpectomy in children. However, lesser instrumentation time was taken by rotary instrumentation as compared to conventional K file during single sitting pulpectomy in children.

**KEYWORDS:** Children, Hand instrumentation, Post operative pain, Pulpectomy, Rotary instrumentation.

## LIST OF ABBREVIATIONS

1.	3D	Three Dimensional
2.	AAPD	American Academy of Pediatric Dentistry
3.	BMP	Biomechanical Preparation
4.	cm	centimeters
5.	CM	Controlled memory
6.	CONSORT	CONsolidated Standards of Reporting Trials
7.	CTRI	Clinical Trials Registry of India
8.	d	Mean difference
9.	et al	et alia
10.	etc.	et cetera
11.	EDTA	Ethylene diamine tetra acetic acid
12.	FDI	Federation Dentaire Internationale
13.	GIC	Glass Ionomer Cement
14.	h/hrs	hours
15.	H file	Hedstrom file
16.	H <sub>2</sub> O <sub>2</sub>	Hydrogen peroxide
17.	i.e.	Id est
18.	IRB	Institutional Review Board
19.	IOPAR	Intraoral periapical radiograph
20.	K file	Kerr file
21.	LA	Local anesthesia
22.	mm	millimeters

23.	mL	milliliters
24.	min	minutes
25.	MID	Minimum Intervention Dentistry
26.	n	Sample Size
27.	N	Newton
28.	NaCl	Sodium Chloride
29.	NaOCl	Sodium Hypochlorite
30.	NiTi	Nickel-Titanium
31.	No.	Number
32.	NSAID	Non Steroidal Anti Inflammatory Drugs
33.	OPD	Outpatient Department
34.	PDL	Periodontal ligament
35.	PI	Principal Investigator
36.	rpm	Rotations per minute
37.	SPSS	Statistical package for the Social Sciences
38.	SD	Standard Deviation
39.	SE	Standard Error
40.	Sl.	Serial
41.	SOP	Standard Operating Protocol
42.	SSC	Stainless Steel Crown
43.	TiO <sub>2</sub>	Titanium dioxide
44.	VAS	Visual Analogue Scale
45.	WB FPRS	Wong Baker FACES Pain Rating Scale

46.	Z	Standard Score
47.	ZOE	Zinc oxide eugenol
48.	$\alpha$	Alpha
49.	$\beta$	Beta
50.	%	Percentage

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## **INTRODUCTION**

*“Learning and innovation go hand in hand. The arrogance of success is to think that what you did yesterday will suffice for tomorrow.”*

-William Pollard

Primary teeth act as a natural space maintainer which guides the eruption of permanent teeth to their optimal position in the dental arch. Preservation and retention of deciduous teeth in the dental arch in its normal form and function and free of pathology is of utmost importance. Early loss of primary teeth may further lead to malocclusion, masticatory, speech and esthetic problems in the permanent dentition. Therefore, it is of prime importance as a Pediatric Dentist to maintain the integrity of tooth in the dental arch till natural exfoliation takes place<sup>1</sup>.

Pediatric dentistry has been changing from surgical treatment planning to conservation of primary teeth till their natural exfoliation occurs for proper occlusal guidance and also aids in mastication. Historically, an extraction oriented practice had been followed for the management of teeth with an inflamed pulp tissue. Nevertheless, the focus has now amended and shifted towards the conservative approach emphasizing the vital role of primary teeth in maintaining the arch integrity<sup>2</sup>. Initiating from Minimally Invasive dentistry to the pulp therapy, the aim is to maintain the veracity of oral tissue in the young children. Restorative treatment is carried out in carious teeth involving enamel and dentine and pulp therapy in those which are showing pulp and peri-radicular involvement<sup>3</sup>.

This paradigm shift observed in terms of treating cariously involved teeth initiating from preventive therapy has been made true due to the advanced diagnostic

tools supplemented by the newer biomimetic materials. Nonetheless, this is applicable for the pulp therapy as well. The remarkable potential of self healing of dental pulp following any tissue trauma has made it possible especially in young children. To cite, it is the higher cellularity and vascularity in young pulpal tissue which is embarking towards the era of preservation<sup>2</sup>. Hence, pulp therapy serves the goals by successfully treating the cariously involved tooth allowing it to remain in the oral cavity in non-pathologic state, by maintaining the arch length and tooth space, thereby restoring them to enhance the process of mastication and preventing the speech abnormalities and any associated habits<sup>4</sup>.

Furthermore, the key decision to opt for vital or non-vital pulp therapy resides in depth of penetration of bacteria from the carious process to the pulpal tissue. The objectives and indications for the type of pulp therapy resides in the health status of the pulp. In vital and non-vital primary teeth diagnosed with irreversible pulpitis or necrosis of pulp, the most commonly implied procedure is pulpectomy which includes complete debridement of coronal and radicular pulp followed by cleaning and shaping the canals capable to best receive the restorative material<sup>5</sup>.

Pulpectomy procedure consists of various steps out of which absolute chemo-mechanical preparation of the root canal system is a requisite for a successful endodontic treatment. Indications for the pulpectomy resides in the following criteria such as chronically inflamed radicular pulp, spontaneous and persistent pain, restorable tooth with no evidence of internal and external resorption, minimal mobility or intra radicular bone loss or presence of an abscess or fistula in the periradicular region of the tooth<sup>6</sup>.

As it is well said, “Our treatment is a failure if the child departs in tears”. The most common reason for this is the pain which the child may feel post operatively. Thus, to analyze the post-operative pain becomes an essential modality while performing any procedures in the operatory that has been still neglected in dental practice. However, it is of prime importance as a Pediatric dentist to assure that the treatment of the child has been rendered tactfully keeping into consideration the child’s overall well being. While analyzing literature the preponderance of post operative pain, however not so high, but there exists a difference in the post operative pain after single and multiple visits pulpectomy in children. Also, single visit pulpectomy on evaluation has shown lesser post operative pain as compared to multi visit pulpectomy<sup>7</sup>. Therefore, successful root canal treatment in pediatric patients using single visit pulpectomy can be considered.

Studies have shown higher frequency of post-endodontic pain following multiple visits as compared to single-visit endodontic treatment<sup>8</sup>. The single visit pulpectomy works on the rationale of eradication of the remnant microbes or rendering them innocuous by burying them with three-dimensional obturation<sup>9</sup>. Moreover completing the treatment in single visit denies the intracanal microorganisms of nutrition resources required to survive and multiply. Visualizing the recompensations of single visit pulpectomy, it is of no surprise that this treatment modality has become so pertinent<sup>10</sup>.

“Of all the aspects of anatomic study in the human system, one of the most complex is the morphology of pulp cavity”. Over the past decades the concept of multi visit pulpectomy has been well accepted and considered as safe therapy worldwide. It is based on the rationale of using intra canal medicaments in between

the appointments which aids in ensuring the elimination of endodontic micro flora. Nevertheless, in the recent past single visit pulpectomy has been gaining recognition due to reduction of flare-ups, lessening of intra appointment leakage and by reducing the number of visits for the operative procedures.

Visualizing the past literature, the evaluation of efficacy of single visit and multi visit endodontic therapy has been well stated in terms of permanent teeth in every aspect initiating from intra appointment flare-ups to post endodontic pain. However, the results drawn from these studies cannot be implicated directly to that of the endodontically treated primary teeth. The reason such as multiple ramifications of the radicular pulp, ribbon shaped root canals, invariable morphological patterns of canals due to continuous secondary dentin deposition, lateral branching and ancillary canals can be cited for the same<sup>4,6,11</sup>.

Nonetheless, primary molar canals are frequently hourglass in shape, rounded at the buccal and lingual and tapered towards the tooth's center. Displacement of the secondary dentin is necessary to achieve any degree of canal uniformity. Following such reasons an appropriate mechanical instrumentation modality supplemented by constant irrigation of the canals is recommended<sup>12</sup>.

Conventionally, hand K-files have proven to be a gold standard providing excellent tactile control and sharp, long-lasting cutting surfaces. Despite the widespread use of hand instrumentation for pulpectomy in primary teeth, there is incidence of post operative pain due to linear filing motion<sup>3</sup>. It may be caused due to ongoing inflammatory processes or changes in the periapical tissue pressure after instrumentation<sup>13</sup>. Although, K-files have aided in the pediatric endodontic treatment

since ages and proved successful, yet there is a need felt to introduce a newer filing system to reduce the incidence of post operative pain<sup>14</sup>.

Rotary instruments were introduced to Pediatric dentistry by Barr et al in 2000. With the development of nickel–titanium (NiTi) rotary shaping systems in the recent past, a reduction in the timing and increased clinical efficacy has been seen<sup>14</sup>. The NiTi alloy proves more effective for cleaning the tortuous and irregular canal walls of the primary teeth due to, greater elasticity, central canal preparation, less apical transportation, use of lesser number of files. Hence it marks a far better choice for Pediatric endodontic procedures in the upcoming era<sup>15</sup>.

The amendments that have taken place over the last few years, however, have been of great magnitude and profundity. The microscopic, ultrasonic units with specially configured tips, superbly accurate microchip computerized apex locators, flexible nickel-titanium files in rotary engines, and greater emphasis on microscopic endodontic surgery have totally changed the way endodontics and endodontic surgery have been practiced over the years. Comparing these changes with formocresol medication, K-file and radiographic determination of working length are truly striking. These changes are bringing the specialty of endodontic practice into the twenty first century with greater precision, fewer procedural errors along with lesser discomfort to the pediatric patient<sup>16</sup>.

Moreover, the demands encountered in cleaning and shaping of the root canal system has fostered the development of many newer technologies aimed to facilitate this process. Priorities have included the development of flexible yet strong metals, variably tapered instrument shafts with both cutting and non-cutting tips, unique cutting edges or surfaces, rotary instrumentation and the incorporation of designs that

favor the removal of debris from the root canal through the coronal access preparation of the tortuous and ribbon shaped anatomy of the primary molars<sup>17</sup>.

Considering all the variations in morphology of the primary teeth, psychological management of a child along with efficient management and treatment in the operatory, a procedure involving lesser appointments, chair side time and causing less post operative pain is needed to be implemented. In spite of innumerable literature availability on varying pulp therapy techniques, instrumentation and post operative pain evaluation exists, there is still paucity regarding the evaluation of pain perception using advanced rotary instrumentation in a single visit root canal therapy for children.

So, an attempt was made to carry out this research to evaluate and compare post operative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children.

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## **AIM AND OBJECTIVES**

### **AIM OF THE STUDY:**

The aim of the study is to evaluate and compare the post operative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children.

### **OBJECTIVES OF THE STUDY:**

1. To evaluate the post operative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children.
2. To compare the post operative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children.

**RESEARCH HYPOTHESIS**

**NULL HYPOTHESIS:**

There is no statistically significant difference in the post operative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children.

**ALTERNATIVE HYPOTHESIS:**

There is a statistically significant difference in the post operative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children.

## **REVIEW OF LITERATURE**

### **LITERATURE RELATING TO PULPECTOMY**

“Nature has its own profuse hidden powers and mysteries, one among it is the complex pulp cavity morphology”. It can be ascribed in the primary teeth as they have multiple accessory canals together with the porous pulpal floor. Also, the radicular pulp follows thin, tortuous and branching path<sup>11</sup>. These multiple branching along with the continuous ramifications makes the conventional endodontic procedure more difficult than the permanent teeth.

Across the decade, the concept of multi visit pulpectomy has been highly accepted and considered as safe therapy worldwide. It is based on the rationale that ensures reduced microbial count with the use of intracanal medicament. Furthermore, in the recent decade it has been gaining acknowledgement due to reduced number of appointments and lessening intra appointment leakage.

Single sitting pulpectomy is carried out as an extension to pulpotomy procedure when the hemorrhage from the amputated pulp stump is uncontrollable. Other major indication is the history of spontaneous pain; though it is not done in case of abscess, sinus or fistula<sup>18</sup>.

The above stated indications lead us to a tooth having symptomatic or asymptomatic irreversible pulpitis which is the chief indication of the pulpectomy procedure. The diagnosis for a tooth having irreversible pulpitis could be made by analyzing certain signs and symptoms. If the pain from thermal stimulus is persistent, it indicates the widespread inflammation of the pulp into the radicular filaments<sup>12</sup>.

Spontaneous pain can be defined as a pain that persists even after the removal of stimulus. It appears to indicate irreversible pulp damage if it lasts for more than a few minutes<sup>19</sup>.

Owing to this, in a randomized control clinical trial assessment and evaluation of success rate of single visit and multi visit pulpectomy has been done among the cariously involved deciduous molars. In the study forty children were taken falling into the age group of four to seven years of age which were further randomly divided into two research groups equally. Endodontic treatment has been rendered in single and multi visit among control and experimental groups. It was followed by subsequent evaluation through recall visits which were scheduled after a week, one month, three months and six months respectively. Evaluation of success and failure both clinical and radiographic for the procedures imparted was made according to Gutmann criteria. The results showed no significant difference while assessing the two procedures. It was concluded that irrespective of equal success rates of both the procedures, the decision regarding selection of any technique should be made considering the cases individually. Moreover, it is advised to choose one course of treatment i.e. either treating the tooth in single visit or seeking an intracanal medicament that does not injure the periradicular tissues<sup>20</sup>.

In application to this a parallel group, double blind, randomized controlled trial discusses the clinical and radiographic outcomes among single visit and multi visit pulpectomy in primary teeth with apical periodontitis. It contained sixty four participants ranging from four to eight years of age among which block randomization was carried out by allocation concealment method using envelope. The reason cited by the author for choosing the study sample as such is because root formation of

primary molars is completed by three years of age and root resorption begins at six years of age. Thus, unresorbed roots leads to improvement in the quality of obturation along with reduction in apical extrusion of the obturating material. Owing to this single visit pulpectomy was carried out in control group while experimental group was subjected to multi visit endodontic treatment. Zinc oxide eugenol was used as an obturating material which was delivered using lentulospiral technique in both the groups respectively. Follow ups were scheduled at one, three and six months respectively. Gutmann criteria has been used for the subsequent evaluation of success rate. The results depicted no significant difference in the clinical and radiographic outcomes following the two procedures at the end of six months healing period. It was concluded that single visit pulpectomy can be considered as a feasible alternative while treating primary teeth with apical periodontitis<sup>10</sup>.

In accordance to the recommendation of single visit root canal therapy a clinical based randomized trial aimed to determine the intensity of post operative pain, number of visits while using crown down technique along with NiTi instrumentation for performing root canal treatment. In the study, two hundred participants having either vital or non-vital pulpally exposed teeth were taken which were subsequently divided into two equal groups using computerized allocation method. Single sitting endodontic therapy was rendered to one group while the another one was allotted treatment using multiple sitting root canal therapy. Instrumentation in both the groups was done by engine driven Protaper rotary NiTi files. It was followed by assessment of post operative pain using Visual Analogue Scale (VAS) at 6, 12, 24 and 48 hours post obturation. The results concluded equal levels of post operative pain as observed after single visit endodontic therapy as

compared to the multi visit therapy. However, there was insignificant difference in pre and post operative pain among vital and non-vital teeth in both the groups. Also, they added about the “tincture of time” which is included in multi visit therapy that reassures the effectiveness of biomechanical preparation pertaining to healing of any peri radicular pathosis<sup>21</sup>.

Owing to the available literature and yet a difficulty in the assessment of either methods of pulp therapy to be used for pulpectomy in children leading to lesser post operative pain, a systematic review was conducted to evaluate the effectiveness and post operative pain after single and multiple visit root canal treatment in the infected teeth through critical evaluation of dental literature. Initiating the search from 137 articles, after exclusion of the articles which did not meet the inclusion criteria, four articles were selected for the qualitative synthesis of the data. After risk of bias assessment and thorough evaluation of the articles a conclusion was laid down. It concluded the effectiveness of single visit root canal treatment over the multi visit therapy. The reason cited for this was the lesser visits, pain management and radiation exposure. Also, use of intracanal medicaments leads to reduction in the microbial load. Adding to it, there is no such association between the negative microbial culture and healing rate success in pulpectomy of primary teeth. However, lesser availability of the literature with adequate follow up period has been one of the major concerns for which it was recommended to conduct more studies<sup>22</sup>.

**LITERATURE IN RELATION TO HAND AND ROTARY  
INSTRUMENTATION**

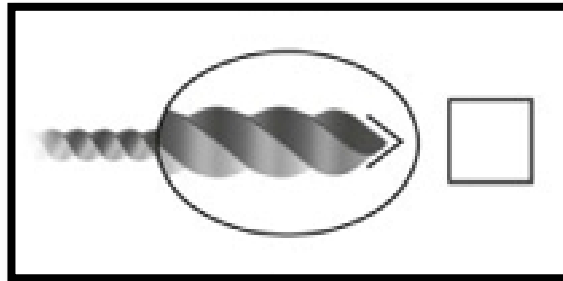
Reclaiming the variations in morphology of the primary teeth psychological management of a child along with efficient management and treatment in the operatory, a procedure involving lesser appointments, chair side time and causing less post operative pain is the need of an hour. Along with this, the key to a successful endodontic treatment lies in efficient chemo mechanical debridement. Adding to it, significant alterations and complexities of the root canals of primary teeth requires enhancement in instrumentation to prevent undesirable complications like ledges, strip perforations, apical zips and transportations.

Conventionally, hand files have proven to be the gold standard and are used widely for the endodontic treatment of primary teeth. They provide excellent tactile control and have long lasting cutting surfaces. But still higher incidence of post operative pain has been reported due to linear filing motion. It can also be caused due to persistent inflammation leading to alteration is the periradicular pressure after the instrumentation.

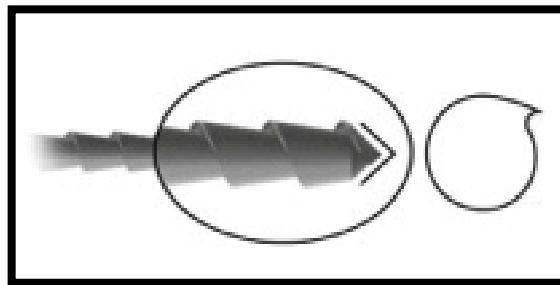
K files are manufactured by Kerr manufacturing company in early 1900s. They are made from stainless steel wire ground along its axis into four sided or square cross section. They have a cross sectional angle of 20° along with a positive rake angle. The blanks of these files are produced from the tight flutes and are used in penetration, rotation and retraction motion [Figure No. 1].

H files are also known as Hedstroem files and are made from round stainless steel wire to produce spiral flutes resembling cones of the screw. These have better

cutting efficiency than K instruments due to higher positive rake angle and a cross sectional angle of 60-65° respectively. These should be used only in a direction that is retraction and torquing action should not be used [Figure No. 1]<sup>17</sup>.



(a) Cross section of Kerr (K files)



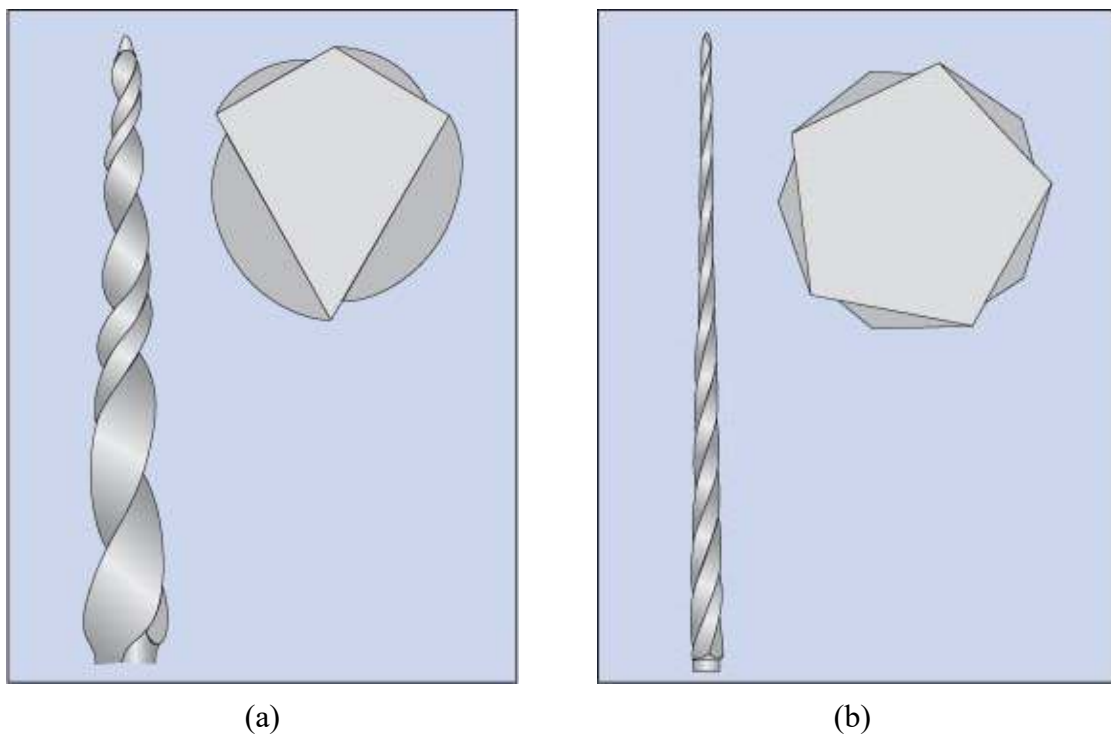
(b) Cross section of Hedstroem (H files)

**Figure No. 1: Photograph showing cross sections of Kerr (K files) and Hedstroem (H files)**

With the development of NiTi rotary shaping systems in the recent past, a reduction in the timing and increased clinical efficacy has been seen. It has been first introduced in primary teeth by Elizabeth S. Barr et al in 2000. She used ProFile with 0.04% taper to prepare the root canals of primary teeth. The use of first such rotary files in primary teeth were based on the notion of flexibility of these files that allows it to follow closely the original root canal path. Furthermore, they stated that the tortuous and irregular canal walls of primary molars can be treated effectively by NiTi based

files because of their clockwise motion which pulls pulp tissue and dentin out of the canal as these files are engaged<sup>23</sup>.

NiTi files are the super elastic files that does not exhibit proportional strain and have a higher fracture resistance. This unique property is due to transformation of austenitic crystalline structure to martensitic under stress. Nitinol exhibit the property of shape memory and has the ability to return back to its original shape. All the rotary instruments are designed keeping these exclusive properties along with incorporation of positive rake angle for enhanced cutting efficiency provided by a non cutting tip [Figure No. 2]<sup>17</sup>.



**Figure No. 2: Photograph showing cross sections of Rotary files**

Furthermore, on the basis of taper, blade design, shaft and groove of the rotary files, they have been classified into various generations. Various rotary file systems along with their specifications are enlisted as follows [Table No. 1, Figure No. 3]<sup>24</sup>.

**Table No. 1: Table showing generation wise rotary files used in Pediatric dentistry.**

Generation	Rotary system	Specifications	Advantages/ Disadvantages
First Generation	ProFile	Non-cutting tip, fixed taper (2%, 4%, and 6%), negative rake angle, and passive cutting blades	Requires several files to complete the root canal preparation
	Flex Master files	Convex triangular shape with sharp cutting edges, round passive tips and increased dentin cutting efficiency.	
	Hero 642 files	Inactive tip, a constant taper, and a triple helix geometry.	
Second Generation	Hero Shaper	Inactive tip, constant taper, and positive rake angle.	Canal transportation and instrumentation breakage
	K3 rotary files	Safe-ended tip	
	Mtwo files	S-shaped cross section and positive rake	
Third Generation	WaveOne rotary files	Single file system, modified tip with variable taper useful in reciprocating motion	M-Wire technology reduces cyclic fatigue, less chance of instrument breakage, better cleaning efficiency particularly in the coronal and middle one-third of root canals

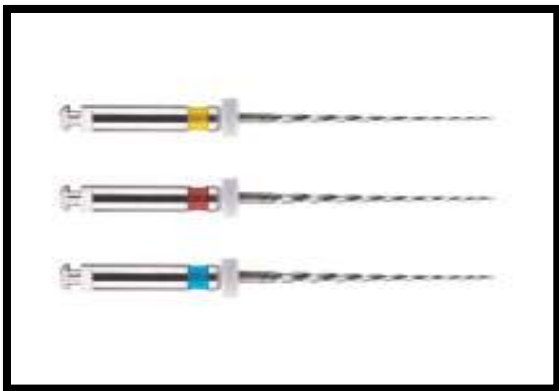
Fourth Generation	Reciproc	S-shaped cross section to be used in reciprocating motion to achieve greater cleaning efficiency in significantly shorter duration of time	Better cleaning efficiency, lesser instrumentation time	
Fifth Generation	Pro AF Baby Gold files	NiTi CM-Wire technology, flexible, constant taper of 4% and 6%.	Improved flexibility, maximum debris removal, lesser apical extrusion, controlled memory	
	Prime Pedo files	Triangular cross section, heat treated		
	DXL Pro TM files	Non-cutting tip, convex triangular cross section, controlled memory		
	Kedo S files	First Generation: Working length of 12 mm, total length of 16 mm, variable taper (4%–8%) with varying tip diameter.		Avoids over instrumentation, better cleaning efficiency.  Constant torque is needed, requires appropriate training.
		Second Generation: Heat-treated M-Wire technology		Heat treated M wire technology, efficient preparation , better obturation quality.
		Third Generation: Greater cyclic fatigue resistance with its titanium oxide coating		Super flexibility, greater cyclic fatigue resistance.
		Fourth Generation: Superior flexibility, less dentin removal, increased resistance to cyclic fatigue due to its TiO <sub>2</sub> coating		Reduced apical dentin removal, less aggressive preparation.



Pro AF Baby Gold files



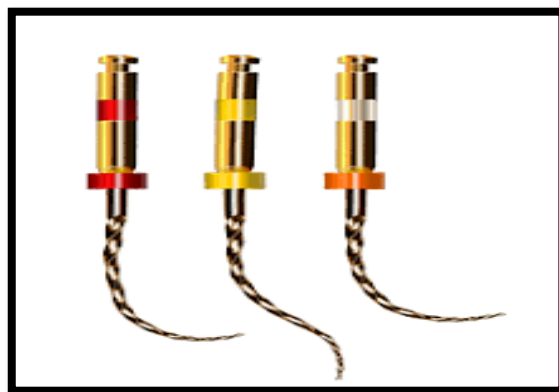
Kedo S files



Prime pedo files



Neoendo files



DXL Pro files

**Figure No. 3: Photograph showing various rotary files used in Pediatric dentistry.**

The NiTi alloy proves to be more effective for cleaning in the primary teeth due to greater elasticity, central canal preparation, less apical transportation, use of lesser number of files. Hence it marks a far better choice for Pediatric endodontic procedures in the upcoming era. Thus to conclude it's relevance, a glimpse and critical evaluation of literature is essential.

An in-vitro study was conducted to evaluate the cleaning efficiency of rotary and hand instrumentation while performing pulp therapy in primary molars. A sum of total twenty three extracted primary molars were taken constituting sixty eight canals all of which had at least two-third of the root length. The procedure initiated with the preparation of access cavity after which the India ink dye was inserted into the root canals with the help of an insulin syringe. It was followed by equal allocation of the teeth into three groups in which instrumentation was done using hand K-files, Flex master files and the third group was considered as the negative control group which was devoid of any instrumentation. The teeth were then subjected to decalcification cycles followed by sequential dehydration. It was summed up by analyzing the cleaning efficiency under stereomicroscope which was assessed by checking the remnant dye present in the canals. The results inferred lesser instrumentation time while using rotary instrumentation. However, no significant difference was observed in relation to the cleaning efficiency of the primary molar teeth. An additional reason cited by the author for the success of pulpectomy is the efficient cleaning and shaping whose objective lies in removal of soft and hard tissues containing bacteria which further provides a path for irrigants to reach the apical thirds. It aids in supplying space for medicaments and subsequently the obturation, rendering the integrity of radicular structure<sup>25</sup>.

In accordance to this, another in-vitro study was conducted to evaluate the cleaning efficiency of specially designed pediatric rotary files and hand files during pulp therapy in primary molars. A total of fifty four extracted primary molars were taken constituting at least two-third of the root length. The procedure initiated with the preparation of access cavity after which the India ink dye was inserted into the root canals with the help of an insulin syringe. It was followed by equal allocation of the teeth into three groups in which instrumentation was done using Prime Pedo files, DLX Pro files, hand H-files and the fourth group was considered as the negative control group which was devoid of any instrumentation. After the procedure the teeth were subjected to decalcification cycles followed by sequential dehydration. It was summed up by analyzing the cleaning efficiency under stereomicroscope which was assumed by checking the remnant dye present in the canals. The scoring was done from zero to three in which score zero determines total cleaning of the canals while three accounts for no ink removal after the instrumentation. The results inferred significant difference in relation to the cleaning efficiency of the primary molar teeth while using rotary instrumentation. The major reason cited by the author for the great success of pediatric rotary files is that they have a triangular cross-section, are heat treated and have controlled memory. The better cleaning efficacy of rotary files can be attributed to the triangular cross-section and positive rake angle. Furthermore, these rotary files possess controlled memory which allows these files to be centered and follow original canal anatomy in primary molars. They have higher flexibility and potential fatigue resistance. Increased fatigue resistance might reduce fracture of rotary files in curved root canals of primary molars as stated by the author<sup>1</sup>.

Visualizing the success of rotary instrumentation while treating primary teeth, a randomized controlled trial was conducted to evaluate the instrumentation time and cleaning efficiency while treating vital and necrotic human primary teeth. It involved children between four to seven years of age. The teeth included accounted to be forty five with hundred and two canals in total. After initial access cavity preparation the teeth were subjected to instrumentation using K-files, Light speed LSX files and Protaper in groups one, two and three respectively. It was followed by obturation with metapex in all the groups. The success was determined clinically and radio-graphically at an interval of six months till two years respectively. Obturation quality was assessed using Coll and Sadrian criteria. The results showed greater quality of obturation and lesser time using rotary instrumentation. The main reason with which the author concluded is the key factor in the architecture of the rotary files which is their flute design that leads to efficient shaping and cleaning of the primary teeth root canals which are more conical, favoring higher quality of root canal filing with increasing clinical success<sup>26</sup>.

Similarly, another double blind randomized controlled trial was conducted to compare and evaluate the instrumentation time and obturation quality while using hand and rotary file system. Children aged between four to seven were selected. Seventy five teeth having at least two third of the root length were included for the study. After access opening procedure these were randomly allocated into three equal groups in which instrumentation was done using K-files, H-files and rotary Kedo-S files respectively. It was followed by obturation with metapex in all the groups. The success was determined both clinically and radio-graphically. Obturation quality was assessed using Coll and Sadrian criteria. The results showed greater quality of

obturation and lesser time using pediatric rotary instrumentation files. The author also concluded the use of both hand and rotary instrumentation together. Key reason cited for the same is that incomplete cleaning of the isthmus of primary teeth is seen by rotary instruments due to their centric preparation. Therefore, the use of H-files along with this can aid in removal of the infected tissue from the ribbon shaped canals of the primary molars<sup>27</sup>.

In accordance to this, a randomized control trial was conducted to evaluate the efficiency of hand and rotary instrumentation while doing pulp therapy for primary molars. Sixty pulpally involved primary molars were taken in four to seven years of children. These were subjected to standard protocol of pulp therapy initiating from local anesthesia administration, isolation by rubber dam, access opening after which they were randomly allocated into two groups. Instrumentation was done using hand K-files in one group and rotary Hyflex files in another group. The obturation was done using a mixture of calcium hydroxide paste and zinc oxide powder. The post-operative evaluation was done after three months recall intervals till twelve months respectively. The quality of obturation was assessed using Coll and Sadrian criteria. The results showed lesser mean instrumentation time while using rotary system. However, there was no such significant difference in the quality of obturation on comparing the same. Still, the author recommends the use of rotary system for pulp therapy in children<sup>28</sup>.

Owing to the recommendation, a randomized clinical trial was conducted to evaluate efficiency of hand and rotary instrumentation while performing pulp therapy for primary molars. Forty five pulpally involved primary molars were taken in four to seven years of children. These were subjected to standard protocol of pulp therapy

initiating from local anesthesia administration, isolation by rubber dam, access opening after which they were randomly allocated into three equal groups. Instrumentation was done using hand K-files in one group followed by Protaper instrumentation and K3 instrumentation in the other groups. The obturation was done using metapex (Calcium hydroxide and iodoform). The post-operative evaluation was done after three months recall intervals till twelve months respectively. The quality of obturation was assessed using Coll and Sadrian criteria. The results showed lesser mean instrumentation time while using rotary system. Also, increased quality of obturation was seen with the same. The author described that primary teeth have softer root dentin, curved roots with undetectable root tip resorption and ribbon shaped root canal morphology. Hence, modified sequence of rotary instrumentation can prove useful for further use in Pediatric dentistry<sup>29</sup>.

## **LITERATURE IN RELATION TO QUALITY OF OBTURATION**

It is rightly said, “The history of the treatment of root canals is the discussion of medications used”. Visualizing the past literature and its practical application in routine Pediatric dentistry, it has become evident that chemo mechanical preparation is the most significant step which needs to be taken care of while doing pulpectomy in children. Nonetheless, the second most crucial step is to attain a completely sealed canal rendering an increased sustainability of the primary teeth in the oral cavity. This could be achieved by filling the canals with a suitable obturating material.

Obturating material can be considered as optimal for primary teeth if it has antibacterial properties, resorbs at the same rate as that as the roots of primary teeth while not harming the succedaneous tooth<sup>30</sup>. Furthermore, it should fill and can be removed from the canals at ease, adhere to the canal walls, resorb if extruded from the canals, have antiseptic properties, non-inflammatory and non-irritating to the permanent successors, do not cause discoloration and is radio opaque for visualization on radiographs<sup>31</sup>.

Owing to the task of complete debridement while relating to the complex root canal morphology and close proximity of the succedaneous tooth, it becomes essential for an obturating material to be biocompatible which aids in removing the residual pathogens from the root canal. Also, by neutralizing the endodontic toxins it should provide a favorable environment for the healing process to occur<sup>32</sup>.

Thus, post obturation it becomes essential to evaluate the quality of obturation. It can be assessed using various parameters like adequate filling of the canals, absence of voids, apical seal and extrusion of the obturating material.

In accordance to this a clinical trial was conducted to assess and compare the quality of obturation and instrumentation time using hand K file and two types of rotary instrumentation system that are Kedo S and Pro AF files for pulpectomy of primary molars. Forty five children in between five to nine years were selected for the study and were equally divided among the three groups. Single sitting pulpectomy was carried out followed by chemomechanical preparation using three instrumentation systems. In all the three groups, obturation was done using metapex. Subsequently, all the study groups were subjected to quality of obturation. In this, presence of voids and extent of fill was assessed. The criteria given by Khubchandani et al<sup>33</sup> was used for assessing the presence of voids. It was scored as,

Score 0 – Complete absence of voids

Score 1 – Presence of one void

Score 2 – Presence of two voids

Score 3 – Presence of three voids

Score 4 – Presence of four voids

Score 5 – Presence of five voids

Likewise, the extent of fill was assessed by Memarpur criteria, and was scored from Grade A to D,

Grade A – Less than one half of the canal obturated

Grade B – Greater than one half but less than optimal fill

Grade C – Optimal fill

Grade D – Extrusion of material beyond apex

The study concluded that superior quality of obturation was achieved using the rotary instrumentation when compared to the hand K files. Also, a much significant reduction in instrumentation time is seen among the rotary group when compared to the hand filing group. They added that rotary files can be used as an alternative to hand files for pulpectomy of primary teeth <sup>34</sup>.

Likewise, an another clinical trial was conducted to compare the quality of obturation in primary teeth using three different techniques of obturation namely lentulospiral, endodontic pressure syringe and tuberculin syringe respectively. The study included fifty children aged between five to nine years who require endodontic treatment with mandibular primary molars. A total of sixty teeth were selected which were equally divided among three groups. It was followed by single sitting pulpectomy procedure in which chemo mechanical preparation was done with the use of H files. After that the teeth were subjected to obturation using zinc oxide eugenol by various techniques of obturation. Subsequently, quality of obturation was assessed using the criteria put forth by the author which is later named as Subha Reddy and Shakunthala criteria.

It is graded as,

Grade A – Canals filled up to apical third

Grade B – Canals filled up to middle third

Grade C – Canals filled up to coronal third

The study concluded that the highest quality of obturation was achieved using lentulospiral followed by endodontic pressure syringe and tuberculin syringe respectively<sup>35</sup>.

Owing to this, another clinical trial was conducted to compare the quality of obturation in primary teeth using three different techniques of obturation namely incremental filling, lentulospiral and pressure syringe respectively. The study included children aged between four to five years old who require endodontic treatment with maxillary primary incisors. A total of eighteen teeth were selected which were equally divided among three groups. It was followed by single sitting pulpectomy procedure in which chemo mechanical preparation was done with the use of H files. After that the teeth were subjected to obturation using zinc oxide eugenol cement by various techniques of obturation. It was followed by assessment of quality of obturation which was assessed using different parameters like apical seal, presence of voids and extrusion of the obturating material.

The quality of obturation was assessed using Modified Coll and Sadrian criteria and was graded as,

- Underfilled – Canals with obturating material more than 2 mm short of the apex
- Optimal filled – Obturating material at or within 1mm short of the apex
- Overfilled – Canals with obturating material beyond the apex

Apical seal was evaluated horizontally in (mm) from the apical end of the filling material to the radiographic apex.

Voids were measured vertically in (mm) along the largest dimension if present within the filling material.

Extrusion was measured in (mm) for the largest dimension of any extruded material vertically beyond the radiographic apex.

The measurements were standardized wherein scale 1 measures (<1mm), scale 2 (1-2mm) and scale 3 (> 2mm) respectively. All of these were assessed on the basis of

this grading scale wherein 1 indicates the best possible results and 3 denotes the worst. The study summed up by stating no significant difference among the various techniques used for obturation of primary teeth. Also, the authors added that operators manual dexterity is one of the essential factor for the successful root canal therapy in primary teeth<sup>36</sup>.

## **LITERATURE IN RELATION TO POST OPERATIVE PAIN**

A randomized control trial was conducted to compare and evaluate the post endodontic pain while using hand and rotary instrumentation techniques. It consists of fifty three patients from which sixty teeth having symptomatic irreversible pulpitis were selected for the treatment. Distribution and randomization of these was done into two equal groups comprising of rotary Mtwo instrumentation and the other being the hand K-file group. Post operatively analgesic was prescribed six hourly. Assessment of post operative pain was done using Visual Analogue Scale after an interval of four, eight, twelve and twenty four hours. Regarding the post operative pain assessment it was found that the highest degree of pain is often experienced in the first twenty four hours and after forty eight hours the level of pain subsides significantly. Furthermore, the results showed significantly less pain in case of rotary instrumentation as compared to hand instrumentation. Moreover, the study concluded that Mtwo rotary files can be used effectively for root canal therapy owing to lesser post endodontic pain<sup>37</sup>.

Similarly, a prospective randomized clinical study discusses the intensity of post operative pain and its correlation with the preoperative status of the pulp and flare-ups while using single visit and multi visit pulpectomy. In the study, eighty cooperative children aged between five to eight years were included and were equally assigned into two groups each using simple randomization method. Teeth with irreversible pulpitis, necrosis, minimal root resorption with no periradicular pathology were included. In one group, teeth were treated using single visit endodontic treatment wherein teeth were obturated in the same appointment while in another, teeth were treated using multi visit endodontic treatment in which they were obturated in the subsequent appointment. Follow-ups were scheduled on 1<sup>st</sup>, 7<sup>th</sup> and 30<sup>th</sup> day post-obturation. The evaluation of

the post operative pain was done on the basis of three point pain rating scale considering values as none, mild, moderate/severe pain. The results showed up with 10% cases with post operative pain after 24 hours recall period. However, there was no associated post operative pain found at the subsequent recall visits. The study concluded lower incidence of post operative pain and found no statistically difference between single visit and multi visit treatment protocols with reference to it. Furthermore, no significant relation was found between vitality of pulp and incidence of post operative pain. The development of pain after the endodontic treatment is due to acute inflammatory response to microbial/physical/chemical injury to the periradicular tissues which is generally elicited few hours or days after the endodontic therapy<sup>9</sup>.

Owing to the equal efficacy cited by different authors an another randomized controlled clinical trial aimed to assess and compare the post obturation pain after one and two visit root canal therapy was carried out on teeth with vital pulps. The study group included one hundred participants which were randomly equally divided among the two groups. The treatment was carried out using engine driven ProTaper nickel-titanium instrumentation in a crown down technique and irrigation using 2.5% sodium hypochlorite (NaOCl). In one visit group the obturation was done on the same day while in two visit it was done after seven days recall interval. A modified descriptor scale was used to measure the pre and post obturation pain after 6, 24, 28 hours and one week. The post obturation pain assessment is reported more reliable using scales as the pain is a subjective entity which makes it difficult to define and differentiate the level of discomfort. Furthermore, pain perception is influenced by innumerable factors that may lead to confounding errors while evaluation of pain. Therefore, self reporting scales proved to be reliable. Post analyzing of results showed no statistically

significant difference in the post obturation pain while using both the methods. The study concluded that either of the methods can be used to treat the pulpally involved vital teeth<sup>38</sup>.

In accordance to this evidence, a clinical study was carried out to evaluate the incidence and severity of post operative pain following single visit root canal therapy of non-vital teeth while using hand and rotary instrumentation techniques. Inclusion of one hundred and eighty teeth with necrotic pulps with peri-apical lesion without sinus tract were selected. The teeth were equally divided into three groups which comprised of cleaning and shaping of root canals using Flex R files, Light speed LSX and K-file respectively. Post endodontic pain analysis was done after 24, 48 and 72 hours. The amount of analgesic consumption over this period was used to rate the intensity of pain post operatively. The result showed lesser incidence of post operative pain while using rotary instrumentation. The main reason cited for the same is that the hand instrumentation resulted in more apical extrusion of the contents of canal which in necrotic cases may result in flare-ups with post operative swelling and discomfort. Also, due to transportation of dentinal chips to the apical area, healing process may be impaired. However, no significant difference was reported between the groups<sup>8</sup>.

Likewise, in a prospective randomized clinical trial evaluation of postoperative pain after glide path performed using Pathfile and K-file was carried out. Recruitment of two hundred and eighty participants was done into two equal groups. These were then subjected to cleaning and shaping using NiTi rotary PathFile and K File. Evaluation of postoperative pain, analgesics consumption, and the number of days for pain resolution were done following 7 days. The analysis of pain was done using 5 level pain scale. The results of the study concluded that the glide path with NiTi Rotary

Path file led to less post operative pain and faster symptom resolution when compared to the use of hand K-file instrumentation. The two main reasons cited by the author are, the incidence of the post operative pain which is due to changes in periradicular pressure, number of virulence endodontic micro-flora along with the environmental conditions. Furthermore, this post operative pain reduction while using rotary instrumentation is seen because of greater elasticity, more centered canal preparations with less apical transportation, incidence of canal aberrations and rotational action usually causing lesser extrusion<sup>13</sup>.

In relevance to the advantages stated, another prospective case control study was conducted for evaluation of post endodontic pain after hand and rotary root canal preparation. A data of total eighty participants were collected to whom treatment was rendered using rotary instrumentation during a single visit therapy. Instrumentation was done using hand K-flex files in the control group while with Protaper, GTX rotary files in the experimental group. Questionnaire was distributed among the patients to record the occurrence of post operative pain and level of discomfort among both the study groups. The study concluded the higher incidence of postoperative pain after root canal preparation using hand instrumentation. Another finding of the study depicted that post operative pain lasted longer in patients treated using rotary instrumentation. One of the interesting finding reported by the author with respect to hybrid filing system is that, it provides an alternative to ensure larger apical diameters, reducing the risks of procedural errors. Furthermore, this also aids in reducing the apical transportation in curved canals<sup>39</sup>.

A collaborative answer to all varied studies has been provided in a systematic review which was done to evaluate the effectiveness and post operative pain after

pulpectomy using different instrumentation techniques through critical evaluation of dental literature. Initiating the search from 187 articles, after exclusion of the articles which did not meet the inclusion criteria, three articles were selected for the qualitative synthesis of the data. After risk of bias assessment and thorough evaluation of the articles a conclusion was laid down. It was concluded that the use of rotary instrumentation contributed to lesser post operative pain than the hand instrumentation. Moreover, paucity of the literature has been stated owing to the need for initiation of high quality randomized controlled studies assessing the effectiveness of different instrumentation for pulp therapy of primary teeth<sup>40</sup>.

A single blind randomized controlled clinical trial was conducted to compare the post operative pain following single visit and two visit pulpectomy in cariously involved primary teeth. The selection of hundred children aged between six to twelve was done and were randomly allocated to two groups each. The groups included pulp therapy in single and multiple visits respectively. These were subjected to cleaning and shaping using hand instrumentation using H-files. Analysis of post operative pain was done using Visual Analogue Scale which included rating the severity of pain from 0-9 during a week post operatively. The reason for choosing this method to analyze the post-operative pain is that, children often lack the required cognitive and linguistic skills to talk upon their physical discomfort and pain intensity. Due to the result of less verbal communication and differences in the level of maturity and understanding it becomes more difficult to evaluate the intensity of pain. Thus, in pediatric patients it serves as gold standard for pain assessment. On analyzing it, the results showed less post operative pain reported after multi-visit pulpectomy as compared to single visit pulpectomy. Moreover, amount of analgesic consumption

was also less in multi visit pulp therapy group. However, no statistically significant difference has been observed between the two groups. It concluded that single visit pulp therapy can be used as an effective treatment modality while treating cariously involved primary teeth<sup>41</sup>.

In order to determine the efficacy, a double blind randomized controlled trial was conducted to assess intensity of pain, the quality of obturation and instrumentation time using pediatric rotary Kedo-S files in primary anterior teeth. It included recruitment of forty five participants with cariously involved vital primary teeth. Randomization was done and they were equally divided among three groups containing the use of hand H-files, Protaper and Kedo-S files respectively. Analysis of pain was done using Wong Baker FACES pain rating scale after obturation. The results showed statistical decrease in the instrumentation time as well as perception of post operative pain while using Kedo-S files. The additional reason cited by the author for performing single sitting pulpectomy using pediatric rotary file is that, reduction in the chair side time increases the cooperativeness of the children for dental treatment. Moreover, using specially designed pediatric rotary files ascertained reduced flute length of the file making easy insertion and removal aiding in easier and simpler treatment for the children. However, no such statistical difference was observed in quality of obturation on comparison of all the groups. Summing up, the use of pediatric rotary files for pulp therapy has been recommended<sup>42</sup>.

On the basis of recommendation, a clinical study was conducted to evaluate the post obturation flare-ups after single and multi visit endodontic therapy in permanent teeth. It included the participation of sixty five children aged more than ten

years with cariously involved permanent first molar with or without slight periapical radiolucency. The treatment was done in single and multi visit in the groups one and two respectively. Visual Analogue Scale was employed to assess the post obturation pain after one week, one, three, six and nine months. The results depicted lesser post operative pain following single visit root canal treatment as compared to multi visit therapy. The major reason cited by the author is an impervious sealing at the coronal area which is vital for the successful prognosis of the endodontically treated tooth. However, no statistically significant difference was seen in the mean pain score<sup>43</sup>.

Similarly, a retrospective study was carried out to evaluate incidence of post operative pain after single and multiple visit endodontic procedures in cariously involved maxillary and mandibular teeth. Evaluation of three hundred and fifty nine participants was done which included patients with both vital and non-vital teeth and with/without periapical involvement. The post operative pain was analyzed using self reported pain through an individualized card. The main reason for choosing this modality lies in the fact that, anxiety and any alteration of the sequelae can lead to higher incidence of the reported pain. The study concluded no significant difference in postoperative pain for teeth with different anatomic locations. Also, there was no relation reported among pulpal status and the time of treatment and post operative pain. Moreover, single visit root canal therapy lead to lesser pain when compared with multi visit root canal therapy<sup>44</sup>.

Thus reclaiming, those who believe in successful root canal treatment in pediatric patients using single visit pulpectomy with rotary instrumentation owing to lesser post-operative pain, the rationale lies in the literature.

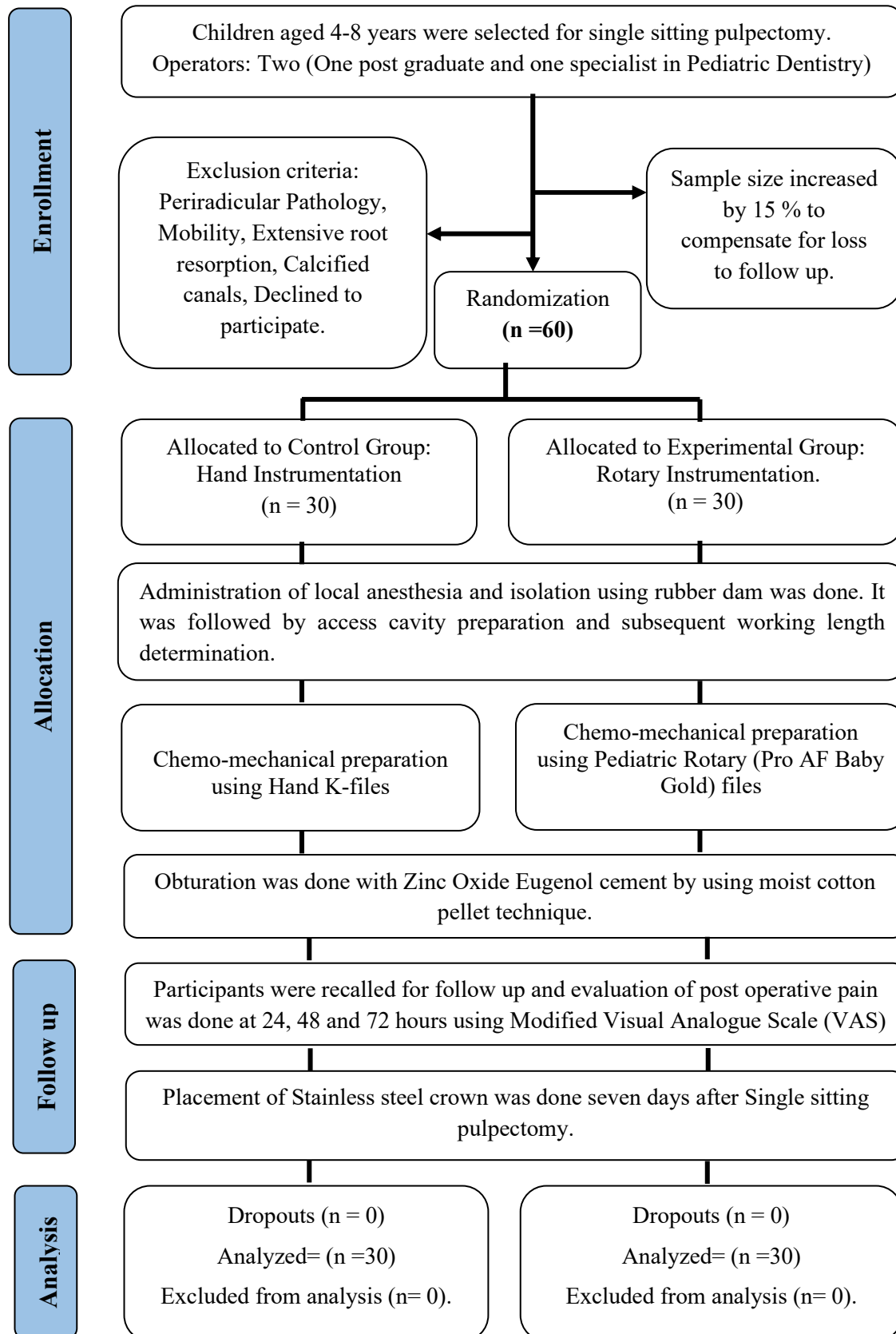
## **MATERIALS AND METHOD**

The present in vivo, two arm, parallel group randomized controlled study was designed to evaluate and compare the post operative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children.

The study was conducted in the Department of Pediatric and Preventive Dentistry, KLE Academy of Higher Education and Research's KLE VK Institute of Dental Sciences, Belagavi. Ethical clearance for the study was obtained from the Institutional Review Board (IRB) of the KLE VK Institute of Dental Sciences, Belagavi with registration number of KLEVKIDS/2020/1393 [**Annexure I**]. The study has been registered prospectively under Clinical Trials Registry – India (CTRI)<sup>45</sup> with the CTRI number of CTRI/2020/12/029470 [**Annexure II**].

The study has intended to improve the reporting of parallel group randomized controlled trial by following CONSolidated Standards of Reporting Trials (CONSORT)<sup>46</sup> guidelines, the flowchart of which has been represented in the following flow diagram.

**CONSORT FLOW DIAGRAM OF METHODOLOGY FOLLOWED IN THE STUDY**



The following are the armamentarium used for the clinical procedure in the study [Figure No. 4, 5, 6, 7, 8]:

- Dental chair with illumination
- Disposable mouth mask, head cap and gloves (Ramson's Care Plus, Ramson Health Care, Bangalore)
- Kidney trays
- Mouth mirror
- Straight probe
- Explorer
- Pair of tweezers.
- Spoon Excavator
- Cotton rolls (Prabhat Surgical Cotton Pvt. Ltd., Tumkur, Karnataka, India)
- Disposable 2ml syringes (Unolok Hindustan Syringes & Medical Devices Ltd., Faridabad, India).
- Rubber dam kit (Hygienic Fiesta Colour Coded clamps and Dental Dam – Coltene Whaledent Inc.)
- Airotor (NSK, 0910003)
- Round Carbide burs (No. 6), Endo Access burs
- Endo Z burs
- Diamond burs (Mani diamond burs, SS Dental Supply).
- K-files
- Paediatric Rotary files (Pro AF Baby Gold files, Kids-e-Dental Co.)
- NaCl Irrigating solution (Jedux Parental Pvt. Ltd., India)
- NaOCl Irrigating solution (Pyrax Polymars, India)

- EDTA gel (Dental Avenue, Avueprep EDTA gel)
- Rotary Endomotor ( X Smart, Dentsply, India)
- Apex locator (Root ZX mini, J Morita)
- Stopwatch
- Zinc Oxide Eugenol [Dental Product of Indian (DPI)]
- Type IX Glass Ionomer Cement (GC Gold label H.S. Posterior Extra, Lot no:1905201.
- Stainless steel crown (3M ESPE)

**MATERIAL & ARMAMENTARIUM USED IN THE STUDY**



**Figure No. 4: Photograph showing clinical armamentarium of Control group [Group A] used in the study.**



**Figure No. 5: Photograph showing clinical armamentarium of Experimental group [Group B] used in the study.**

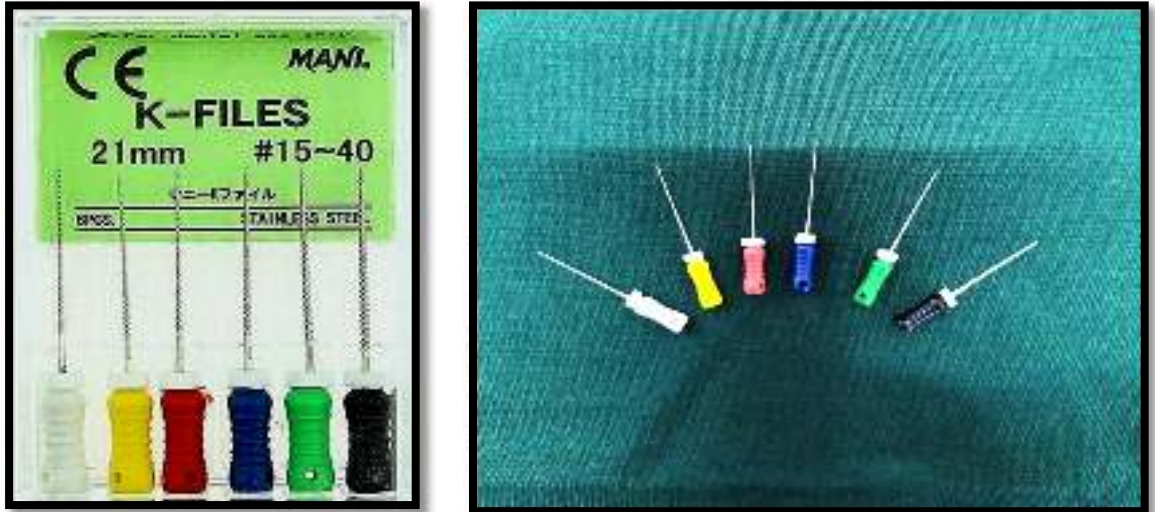


Figure No. 6: Photograph showing conventional hand files used in the study.



Figure No. 7: Photograph showing pediatric rotary files (Pro AF Baby Gold files) used in the study.



**(a) Rotary endomotor**



**(b) Apex locator**

**Figure No. 8: Photograph showing rotary endomotor (X smart) and Apex locator (Root ZX mini) used in the study.**

**SOURCE OF DATA:**

Patients reporting to the outpatient department (OPD) of the Department of Pediatric & Preventive Dentistry at KLE Academy of Higher Education and Research's, KLE VK Institute of Dental Sciences, Belagavi who fulfilled the inclusion and exclusion criteria were selected for the study.

Written informed consent was obtained from all the parents of children participating in the study [Annexure III(a), III(b), III(c)]. Assent was obtained from all the children participating in the study [Annexure IV].

**STUDY DESIGN:**

This is a two arm parallel group double blinded randomized controlled study with treatment provided in the Department of Pediatric and Preventive Dentistry. The participants were allocated to one of the groups in order to evaluate and compare the post operative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children.

**SELECTION OF SUBJECTS:**<sup>21</sup>

Subjects for the study were selected according to the following inclusion and exclusion criteria.

**INCLUSION CRITERIA USED IN THE STUDY:**

- Children in the age group of 4-8 years.
- Children with Frankl's behaviour rating scale of definitely positive (++) and positive (+).

- Tooth with the history of spontaneous pain.
- Radiographic evaluation of the tooth showing caries involving enamel, dentin and encroaching pulp with no PDL widening, loss of lamina dura, periapical lesion, interradicular or furcal radiolucency.
- Primary molars with minimum two third of the root length.
- Patients who are willing to undergo treatment.

**EXCLUSION CRITERIA USED IN THE STUDY:**

- Children with systemic diseases and special health care needs.
- Non-vital teeth having signs of abscess, sinus and fistula.
- Primary molars with pathologic mobility and evidence of root fracture, trauma.
- Primary molars having furcation radiolucency.
- Primary molars with calcified root canals.
- Primary molars with more than two third root resorption, internal and external resorption.

**SAMPLE SIZE:**

Samples required for the study was selected by referring the previous article<sup>13</sup>.

The sample size was calculated according to the following formula:

$$n = \frac{2S^2 (Z_\alpha + Z_\beta)^2}{d^2}$$

Where,

$S_1$  is standard deviation in first group = 2.2

$S_2$  is standard deviation in second group = 1.7

$S$  (standard deviation) =  $\frac{S_1 + S_2}{2}$

$d$  is mean difference between first and second group = 1.7

$\alpha$  error (%) = 5

$Z_\alpha$  = Z value for  $\alpha$  level = 1.96 at 5% alpha error

$Z_\beta$  = Z value for  $\beta$  level = 1.037 at 85% power

So,  $n$  (Sample size in each group) = 24

Based on the previous study where the confidence level is 85%, the probability is 0.05.<sup>13</sup> Thus, the sample size derived was 24 in each group. Considering the 15% dropout, the sample size chosen was 30 in each group.

So a total of 60 sample size was selected and divided into two study groups of thirty each.

**STUDY GROUP AND RANDOMIZATION:**

All the sixty samples of the study group were divided into two equal groups by simple random sampling using computer allocation method to ensure standardization.

**Group A (Control group):** 30 children were allocated to the control group who require single sitting pulpectomy using hand K-file.

**GROUP B (Experimental group):** 30 children were allocated to the experimental group who require single sitting pulpectomy using rotary Pro AF baby gold file.

The randomly generated sequence was sealed in closed envelope. An independent Paediatric dentist from the Department of Pediatric and Preventive Dentistry was designated in the allocation of the children to the two groups. The envelope was opened during the treatment after obtaining informed consent.

**METHOD OF COLLECTION OF DATA:**

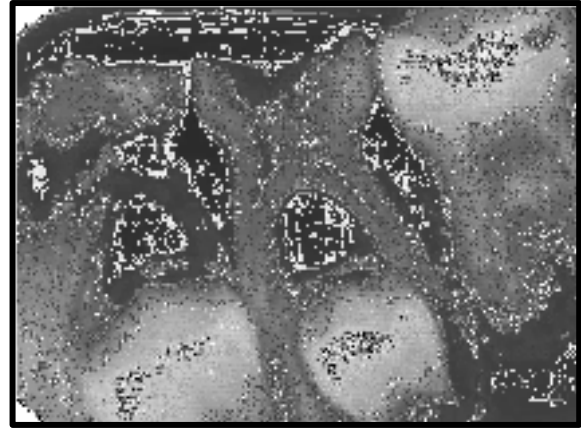
**A. SELECTION OF CASE AND RECORDING OF CASE HISTORY:**

After comfortably seating the patient on the dental chair, the procedure was completely explained to the parents as well as the children by the Principal Investigator (PI). A case history was recorded in a special format prepared for this study and also to have a systematic and methodological recording of all the observations and information [Annexure VI]. After recording the preliminary information, clinical and radiographic examination was carried out on a dental chair. Clinical assessment was done regarding the type of pain and the type of pulpal pathology. The findings were recorded and pre operative intra oral photographs and

intra oral periapical radiographs (IOPAR) were taken to assess the depth of the carious lesion [Figure No. 9 and 10].



(a) Pre-op clinical photograph

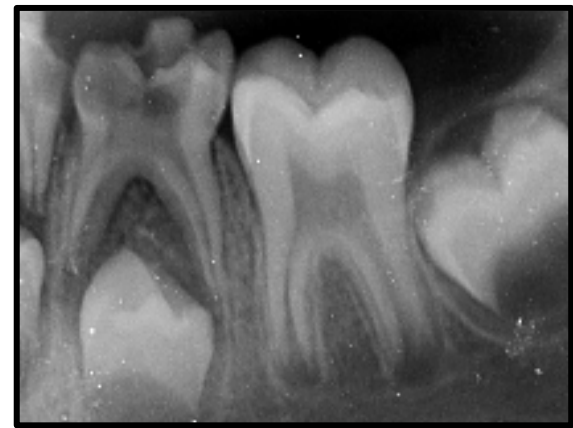


(b) Pre-op IOPAR

**Figure No. 9: Photograph showing pre-operative intraoral photograph and radiograph of left mandibular second primary molar (75) in control group using hand instrumentation [Group A].**



(a) Pre-op clinical photograph



(b) Pre-op IOPAR

**Figure No. 10: Photograph showing pre-operative intraoral photograph and radiograph of left mandibular second primary molar (75) in experimental group using rotary instrumentation [Group B].**

## **B. PROCEDURE OF SINGLE SITTING PULPECTOMY:**

The **Principal Investigator** performed all the clinical procedures as per the Standard Operating Protocols (SOPs). Single sitting pulpectomy was carried out on left mandibular second primary molar in both control group [Group A] and experimental group [Group B]. Administration of local anesthesia was done followed by isolation using rubber dam. Access opening was done using No. 330 endo access bur. Subsequently removal of all coronal pulp tissue was ensured. Pulp extirpation from all the canals was done using an endodontic file in both control and experimental groups respectively. Working length was determined using Ingle's radiographic method and apex locator.

In control group [Group A] chemo mechanical preparation was started with the first endodontic K-file that binded the canal. Further by using linear filing motion of the K-files, canals were enlarged three to four instrument sizes greater than the first file capable of working the apex.

In experimental group [Group B] chemo mechanical preparation was started with the first endodontic K-file that binded the canal. Further the canals were prepared up to No. 20 K file. It was subsequently followed by instrumentation using Pro AF baby gold files using rotary endomotor. It was used as a two file rotary system at a speed of 250-350 rpm and the torque was adjusted to 2.4N/cm. All the files were used after lubricating with EDTA gel. In canals with narrow apex, instrumentation was done using No. 20 (B1) file followed by No. 25 (B2) file having 4% taper. In canals with wider apex, instrumentation was done using No. 25 file with 4% taper (B2) followed by No. 25 file having 6% taper (B3). The extremely wider canals were

instrumented using No. 25 (B2) followed by No. 30 (B4) with 4% taper. After filing, the canals were irrigated to ensure the effective removal of debris.

After thoroughly drying the canals using cotton pellets and paper points, obturation was carried out using moist cotton pellet technique advocated by Donnenberg et al<sup>47</sup>. A thin mix of zinc oxide eugenol cement was coated on a file and placed inside the canals. This was followed by packing a thick mix of zinc oxide eugenol using a moist cotton pellet as the condenser. An intraoral periapical radiograph was obtained to ensure optimal obturation of the root canals. It was followed by filling with the suitable post endodontic core build up restorative material **[Figure No. 11 and 12]**.



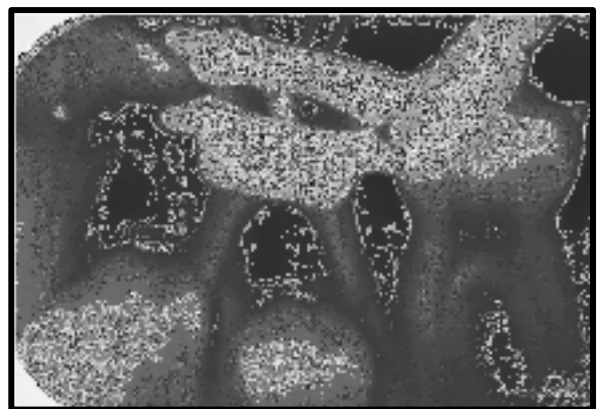
**(a) Isolation with rubber dam**



**(b) Access opening**



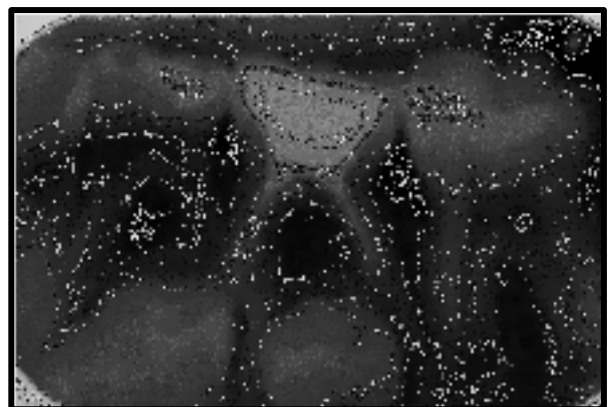
**(c) Working length determination**



**(d) Radiographical working length**



**(e) Chemo mechanical preparation by hand instrumentation using K file**



**(f) Obturation with zinc oxide eugenol cement**

**Figure No. 11 (a-f): Photograph showing clinical procedural steps of single sitting pulpectomy carried out on left mandibular second primary molar (75) in control group using hand instrumentation [Group A].**



**(a) Isolation with rubber dam**



**(b) Access opening**



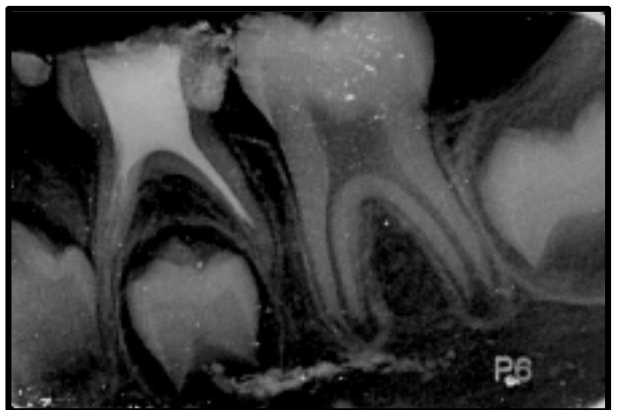
**(c) Working length determination**



**(d) Radiographical working length**



**(e) Chemo mechanical preparation by rotary instrumentation using Pro AF baby gold file**



**(f) Obturation with zinc oxide eugenol cement**

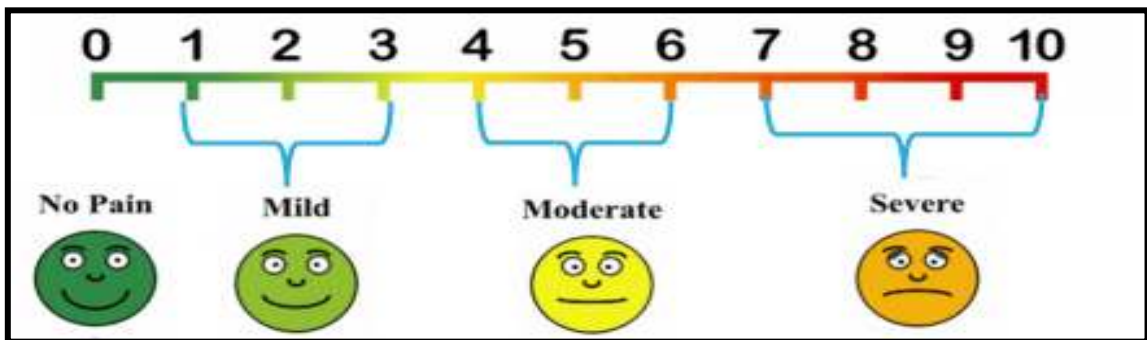
**Figure No. 12 (a-f): Photograph showing clinical procedural steps of single sitting pulpectomy carried out on left mandibular second primary molar (75) in experimental group using rotary instrumentation [Group B].**

**C. POST OPERATIVE INSTRUCTIONS:**

Patients were advised to avoid lip biting which may be caused due to the effect of anesthesia post-operatively. Patients were asked not to eat anything for one hour and have a soft diet for next 24 hours. Patients were prescribed plain Paracetamol or NSAID’s and were advised to take medication only if the pain occurs. Patients were asked to report to the dental clinic if any kind of pain, swelling or discomfort occurred which cannot be controlled by regular medication.

**D. POST- OPERATIVE EVALUATION:**

- Pain perception using both the file systems was assessed by Modified Visual Analogue Scale (VAS) <sup>48</sup>.
- Parents / Guardians were instructed to record post-operative pain on Modified Visual Analogue Scale (VAS) at 24, 48 and 72 hours which is given to them along with Patient information sheet [Figure No. 13, Table No. 2, Annexure V].



**Figure No. 13: Photograph showing Modified Visual Analogue Scale used for Post-operative Pain evaluation in both the study groups.**

**Table No. 2: Table showing interpretation of Modified Visual Analogue Scale.**

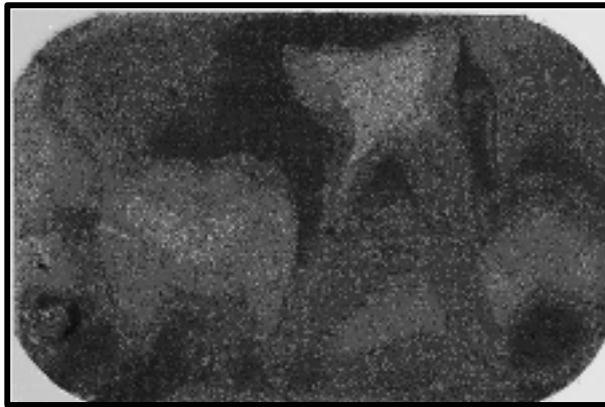
Sl. No.	Pain rating	Interpretation
1	0	No pain
2	1-3	Mild pain
3	4-6	Moderate pain
4	7-10	Severe pain

#### **EVALUATION OF INSTRUMENTATION TIME:**

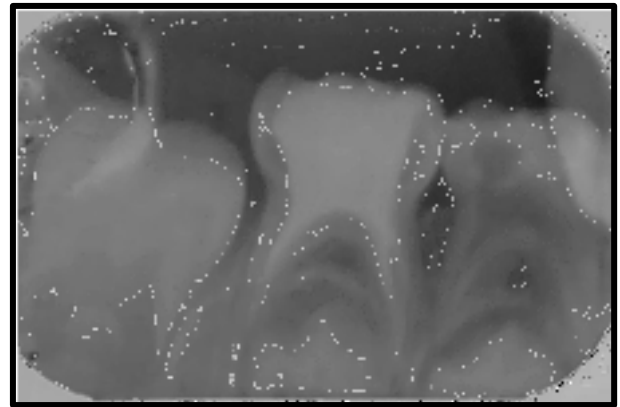
Instrumentation time while performing single sitting pulpectomy was recorded by using stopwatch in both the groups namely Hand instrumentation [Group A] and Rotary instrumentation [Group B] and was recorded as time taken (in minutes) at the start of chemo mechanical preparation till the last file used.

#### **EVALUATION OF QUALITY OF OBTURATION:<sup>49</sup>**

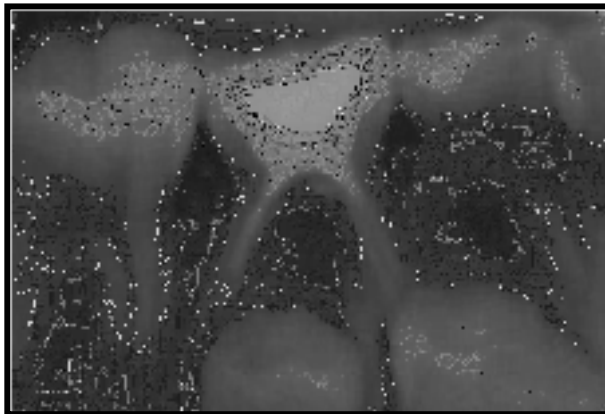
- Quality of obturation was assessed by various parameters like adequate filling of the canals, apical seal and extrusion of the obturating material.
- Modified Coll and Sadrian criteria was used for evaluation of the quality of obturation. It was assessed by measuring (mm) of the largest dimension of any voids within the filling material measured vertically from the radiograph.
- Obturation was gauged on the post-operative radiograph as Underfilled, Optimally filled and Overfilled.
- Under filled accounts to obturation in which all the canals were filled more than 2 mm short of the apex which is depicted radiographically in both the control and experimental groups respectively [**Figure No. 14 (a and b)**].
- Optimal filling is when one or more canal having ZOE ending at the radiographic apex or up to 2 mm short of the apex which is depicted radiographically in both the control and experimental groups respectively [**Figure No. 14 (c and d)**].
- Overfilling is when ZOE is seen outside the root canal which is depicted radiographically in both the control and experimental groups respectively [**Figure No. 14 (e and f)**].



(a)



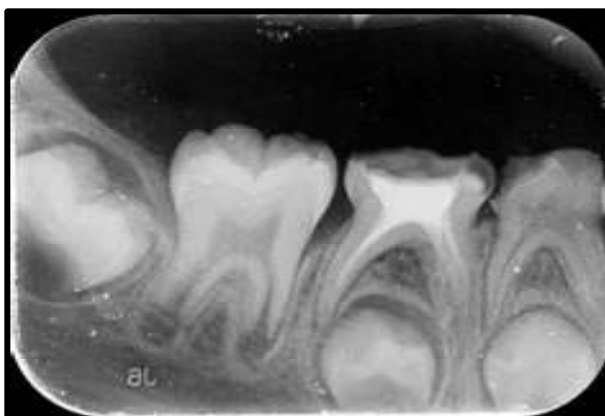
(b)



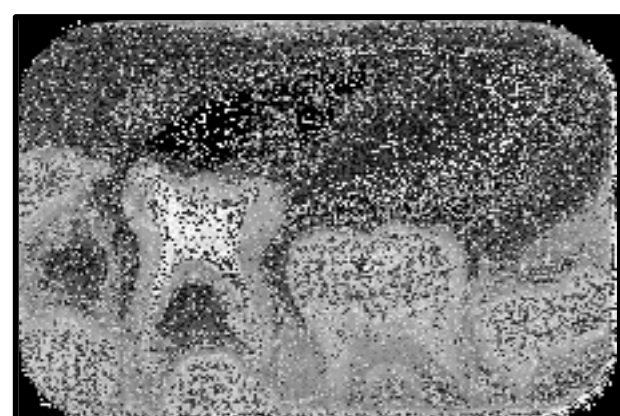
(c)



(d)



(e)



(f)

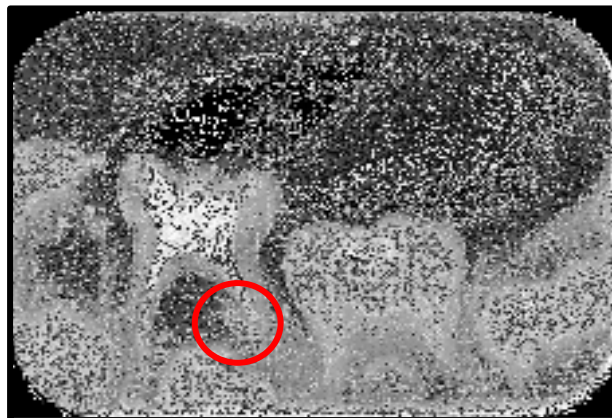
**Figure No. 14: Photograph showing radiographs of underfilled, optimally filled and overfilled root canals of primary molars in control group and experimental**

**EVALUATION OF EXTRUSION:<sup>36</sup>**

- Extrusion was measured in (mm) of the largest dimension of any extruded material vertically beyond the radiographic apex [Figure No. 15].

**Table No. 3: Table showing various scales designated to evaluate extrusion of the obturating material radiographically.**

Sl. No.	Scale no.	Interpretation (Extrusion)
1.	1	1mm beyond the radiographic apex
2.	2	1-2mm beyond the radiographic apex
3.	3	2mm beyond the radiographic apex



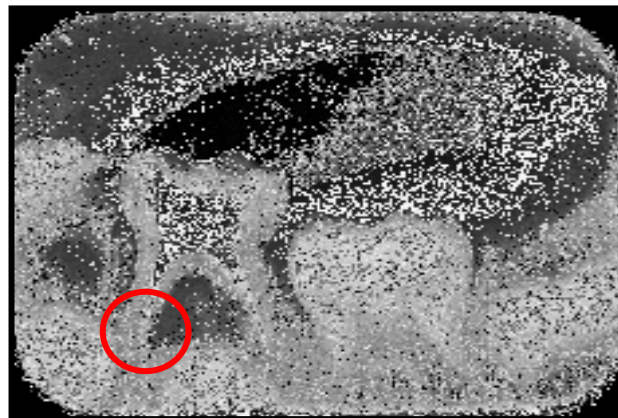
**Figure No. 15: Photograph showing extrusion of Zinc Oxide eugenol beyond the radiographic apex in the experimental group.**

**EVALUATION OF APICAL SEAL:<sup>36</sup>**

- Apical seal was evaluated horizontally in mm from the apical end of the filling material to the radiographic apex [Figure No. 16].

**Table No. 4: Table showing various scales designated to evaluate apical seal radiographically.**

Sl. No.	Scale no.	Interpretation (Apical seal)
1.	1	1mm horizontally from the apical end of the filling material
2.	2	1-2mm horizontally from the apical end of the filling material
3.	3	2mm horizontally from the apical end of the filling material



**Figure No. 16: Photograph showing inadequate apical seal in the control group.**

**E. FOLLOW UP AND EVALUATION:**

- If the pain persist after the given time period, patients were evaluated for the cause of pain and necessary treatment was carried out.
- Placement of Stainless Steel crown was done on the follow-up visit in control group and experimental group respectively [**Figure No. 17 (a and b)**].
- Patients were recalled after every three months for subsequent follow-up.



(a)



(b)

**Figure No. 17: Photograph showing placement of stainless steel crown in children with pulpectomised primary molar in both the study groups.**

**STATISTICAL ANALYSIS:**

The results were tabulated and entered on the excel sheet. Then the results were subjected to the following statistical tests using IBM SPSS software (version 21.0 Chicago IL, USA).

- Chi square test was used for the intergroup comparison of qualitative data between two groups.
- Mann-Whitney U test is used for intergroup comparison of single sitting pulpectomy using hand instrumentation and rotary instrumentation with different post operative treatment times with Modified Visual Analogue Scale (VAS) scores.
- Wilcoxon Matched pair test is used for intragroup comparison of different post operative treatment times with VAS scores in single sitting pulpectomy using hand instrumentation and rotary instrumentation.
- Level of significance was set at  $p=0.05$ . ( $p \leq 0.05$ : Statistically significant,  $p \leq 0.01$ : highly significant,  $p \leq 0.001$ : very highly significant and  $p \geq 0.05$  not significant).

## **RESULTS**

### **TABLES, GRAPHS AND OBSERVATIONS**

The study was designed to evaluate and compare the post operative pain in children undergoing single sitting pulpectomy using conventional hand files and rotary files in primary molars of children.

A total of sixty children between 4-8 years were selected for the study according to selection criteria. These sixty samples are equally divided into control group [Group A] and experimental group [Group B] with thirty samples in each. In control group, children undergoing single sitting pulpectomy received usage of hand files and in the experimental group rotary files respectively. Both the groups received obturation using Zinc Oxide Eugenol (ZOE) cement followed by filling with the suitable post endodontic core build up restorative material. All patients were given post operative instructions and were asked to report if any pain, swelling have occurred which is being further assessed using Modified Visual Analogue Scale (VAS).

The data was furthered entered in the Excel sheet and master chart was prepared [Table No. 5 and 6] which had been further subjected to the statistical analysis using standardized tests that are Chi square test, Independent 't' test, Mann Whitney 'U' test and Wilcoxon Matched pair analysis respectively.

**Table No. 5: Table showing master chart of the children undergoing single sitting pulpectomy in control group [Group A] using hand instrumentation.**

Sl. No.	Study Participant	Age	Sex	Tooth No. (FDI)	Evaluation of Post Operative Pain using Visual Analogue Scale (Control Group)		
					24Hours	48Hours	72Hours
1	C1	6	M	75	0	0	0
2	C2	8	M	85	0	0	0
3	C3	8	M	75	0	0	0
4	C4	5	F	85	0	0	0
5	C5	6	F	75	3	0	0
6	C6	6	F	75	0	0	0
7	C7	7	F	74	4	0	0
8	C8	8	F	85	0	0	0
9	C9	6	M	75	0	0	0
10	C10	5	F	75	0	0	0
11	C11	5	F	85	0	0	0
12	C12	4	F	85	0	0	0
13	C13	6	M	75	0	0	0
14	C14	6	M	85	0	0	0
15	C15	6	F	85	0	0	0
16	C16	6	M	85	0	0	0
17	C17	6	M	84	0	0	0
18	C18	6	M	75	0	0	0
19	C19	5	M	75	0	0	0
20	C20	5	M	74	0	0	0
21	C21	5	M	85	0	0	0
22	C22	8	M	75	0	0	0
23	C23	8	M	74	0	0	0
24	C24	6	F	85	0	0	0
25	C25	8	M	85	0	0	0
26	C26	7	F	75	0	0	0
27	C27	5	M	75	0	0	0
28	C28	5	M	75	0	0	0
29	C29	7	M	74	3	0	0
30	C30	8	F	85	0	0	0

**Table No. 6: Table showing master chart of the children undergoing single sitting pulpectomy in experimental group [Group B] using rotary instrumentation.**

Sl. No.	Study Participant	Age	Sex	Tooth No. (FDI)	Evaluation of Post Operative Pain using Visual Analogue Scale (Experimental Group)		
					24Hours	48Hours	72Hours
1	E1	5	M	75	0	0	0
2	E2	6	F	75	0	0	0
3	E3	5	F	85	0	0	0
4	E4	6	M	75	0	0	0
5	E5	5	M	75	3	0	0
6	E6	4	M	74	0	0	0
7	E7	8	M	75	0	0	0
8	E8	5	F	84	0	0	0
9	E9	8	M	75	0	0	0
10	E10	5	M	74	0	0	0
11	E11	8	M	85	0	0	0
12	E12	4	M	84	0	0	0
13	E13	4	F	75	0	0	0
14	E14	7	F	75	0	0	0
15	E15	5	M	55	0	0	0
16	E16	4	F	65	0	0	0
17	E17	8	M	75	0	0	0
18	E18	7	F	75	0	0	0
19	E19	7	F	74	0	0	0
20	E20	6	F	75	0	0	0
21	E21	8	M	74	0	0	0
22	E22	7	M	85	0	0	0
23	E23	5	F	85	0	0	0
24	E24	7	F	55	0	0	0
25	E25	4	F	75	0	0	0
26	E26	5	F	75	0	0	0
27	E27	4	F	65	0	0	0
28	E28	5	M	75	0	0	0
29	E29	6	F	84	0	0	0
30	E30	7	F	85	0	0	0

**Table No. 7: Table showing the Mean, Standard Deviation and intergroup comparison of both the study groups with respect to mean age using Chi square test.**

Sl. No.	Age	No. of children receiving pulpectomy using Hand Instrumentation (Group A)	%	No. of children receiving pulpectomy using Rotary Instrumentation (Group B)	%	Total	%
1.	4 years	1	3.33	6	20.00	7	11.67
2.	5 years	8	26.67	9	30.00	17	28.33
3.	6 years	11	36.67	4	13.33	15	25.00
4.	7 years	3	10.00	6	20.00	9	15.00
5.	8 years	7	23.33	5	16.67	12	20.00
	Total	30	100.0	30	100.0	60	100.0
	Mean age	6.23		5.83		6.03	
	SD age	1.19		1.42		1.31	
Chi-square= 8.2300 p = 0.0830							

**Graph No. 1: Graphical representation showing the intergroup comparison of both the study groups with respect to mean age using Chi square test.**

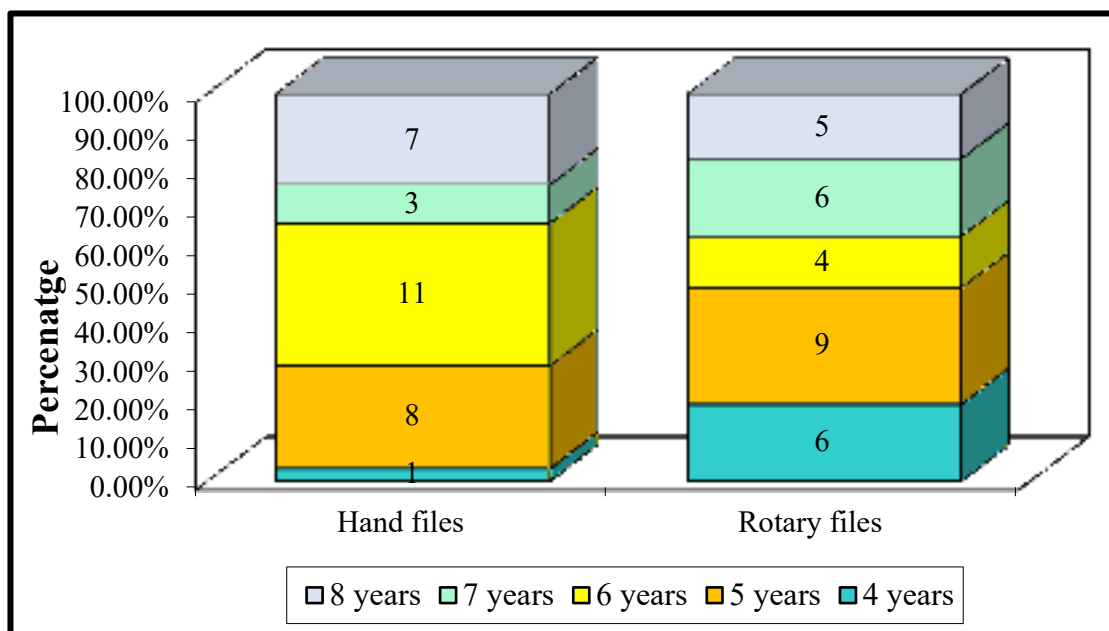


Table No. 7 and Graph No. 1: Showing distribution of participants according to age. In Control group [Group A], among four year age group, one child was enrolled; five years age group, eight children were enrolled; six years age group, eleven children were enrolled; seven years age group, three children were enrolled; and among eight years age group seven children were enrolled. In Experimental group [Group B], among four year age group, six children were enrolled; five years age group, nine children were enrolled; six years age group, four children were enrolled; seven years age group, six children were enrolled; and among eight years age group five children were enrolled.

When both the groups were compared for the distribution of participants according to age the mean age was found to be 6.03 ( $\pm 1.31$ ) with Chi square value of 8.2300 with 'p' value 0.0830 ( $p > 0.05$ ) which was found to be statistically not significant. So both the groups showed equitable distribution of participants according to age which had maintained standardization of selection criteria in our study.

**Table No. 8: Table showing intergroup comparison of distribution of samples undergoing single sitting pulpectomy according to gender in both the study groups using Chi square test.**

Sl. No.	Sex	Hand Instrumentation (Group A)	%	Rotary Instrumentation (Group B)	%	Total	%
1.	Male	18	60.00	14	46.67	32	53.33
2.	Female	12	40.00	16	53.33	28	46.67
	Total	30	100.00	30	100.00	60	100.00
Chi-square= 1.0710 p = 0.3010							

**Graph No. 2: Graphical representation showing intergroup comparison of distribution of samples undergoing single sitting pulpectomy according to gender in both the study groups using Chi square test.**

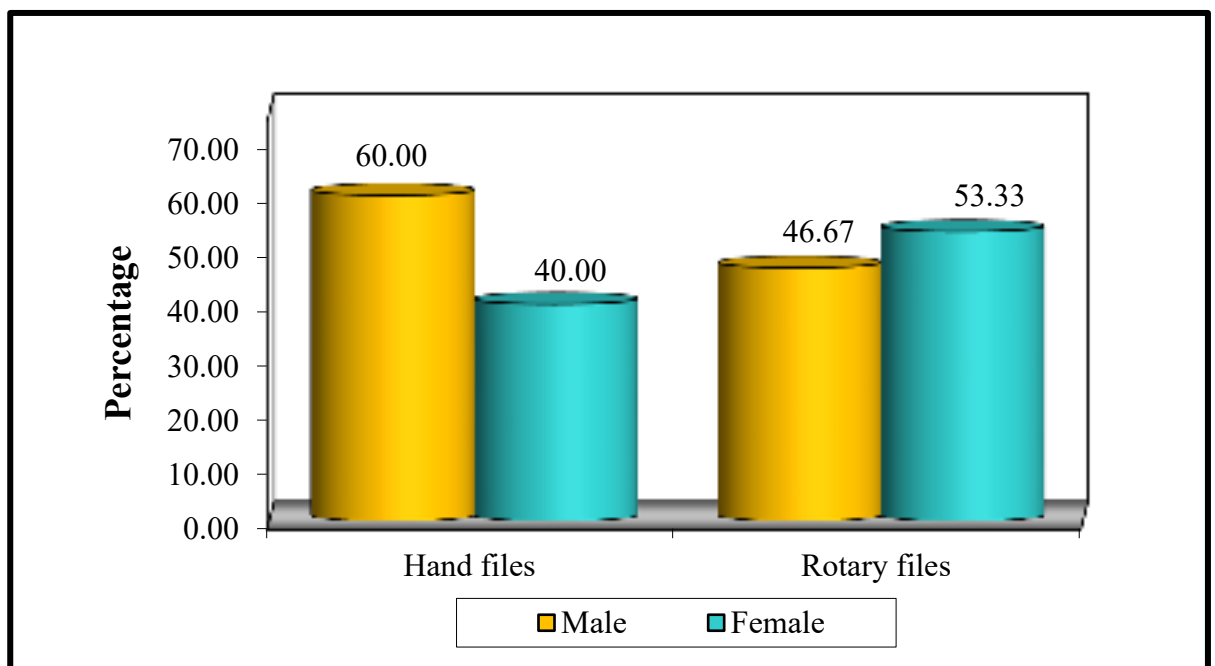


Table No. 8 and Graph No. 2: Showing distribution of participants according to gender during instrumentation in children undergoing single sitting pulpectomy using hand instrumentation in control group and rotary instrumentation in experimental group.

In Control group [Group A], among thirty samples eighteen (60%) were male and twelve (40%) were female. In Experimental group [Group B], among thirty subjects fourteen (46.66%) were male and sixteen (53.33%) were female respectively.

When both the groups were compared for gender distribution, the Chi square value of 1.0710 and 'p' value of 0.3010 ( $p > 0.05$ ) was obtained. It shows that there was no statistically significant difference in gender in the intergroup comparison. So, participants were equally distributed in both the groups which shows that standardization was followed.

**Table No. 9: Table showing intergroup comparison among children undergoing single sitting pulpectomy with respect to tooth number in both the study groups using Chi square test.**

Sl. No.	Tooth number (FDI)	Hand Instrumentation (Group A)	%	Rotary Instrumentation (Group B)	%	Total	%
1.	First primary molars	5	16.66	7	23.33	12	20
2.	Second primary molars	25	83.33	23	76.66	48	80
	Total	30	100	30	100	60	100

Chi-square= 7.9190 p = 0.0950

**Graph No. 3: Graphical representation showing intergroup comparison among children undergoing single sitting pulpectomy with respect to tooth number in both the study groups using Chi square test.**

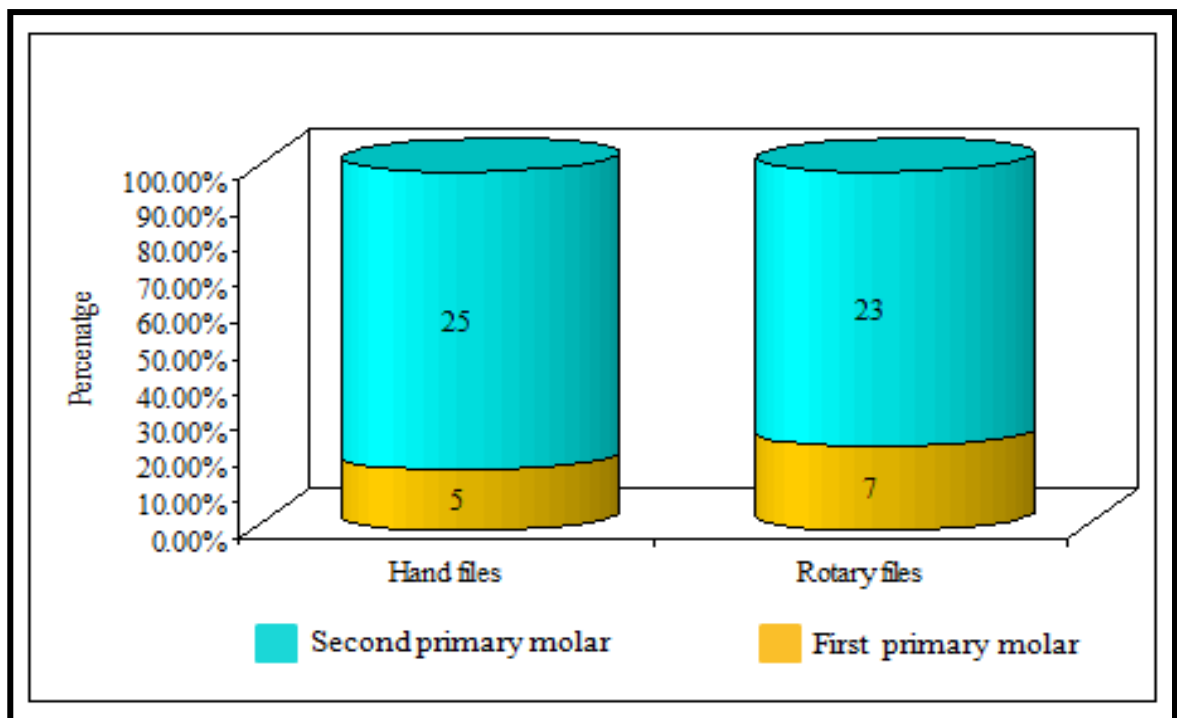


Table No. 9 and Graph No. 3: Showing number of teeth included for instrumentation in children undergoing single sitting pulpectomy using hand instrumentation in control group and rotary instrumentation in experimental group.

In Control group [Group A], among thirty samples, five (16.66%) were maxillary and mandibular first primary molars whereas twenty five (83.33%) were maxillary and mandibular second primary molars. In Experimental group [Group B], among thirty samples, seven were maxillary and mandibular first primary molar (23.33%) whereas twenty three were maxillary and mandibular second primary molars (76.66%) respectively.

When both the groups are compared on the basis of tooth selected for undergoing single sitting pulpectomy the Chi square value of 7.9190 and 'p' value of 0.0950 ( $p>0.05$ ) was found. It shows that there was no statistically significant difference in the inclusion criteria of the tooth chosen for single sitting pulpectomy using hand and rotary instrumentation owing to less bias and more standardization.

**Table No. 10: Table showing the Mean, Standard Deviation and intergroup comparison of both the study groups among children undergoing single sitting pulpectomy with respect to instrumentation time using Independent ‘t’ test.**

Files	Mean	SD	SE	t-value	P-value
Hand files	20.83	3.24	0.59	19.7974	0.0001*
Rotary files	8.33	1.21	0.22		

**Graph No. 4: Graphical representation showing intergroup comparison of both the study groups among children undergoing single sitting pulpectomy with respect to instrumentation time using Independent ‘t’ test.**

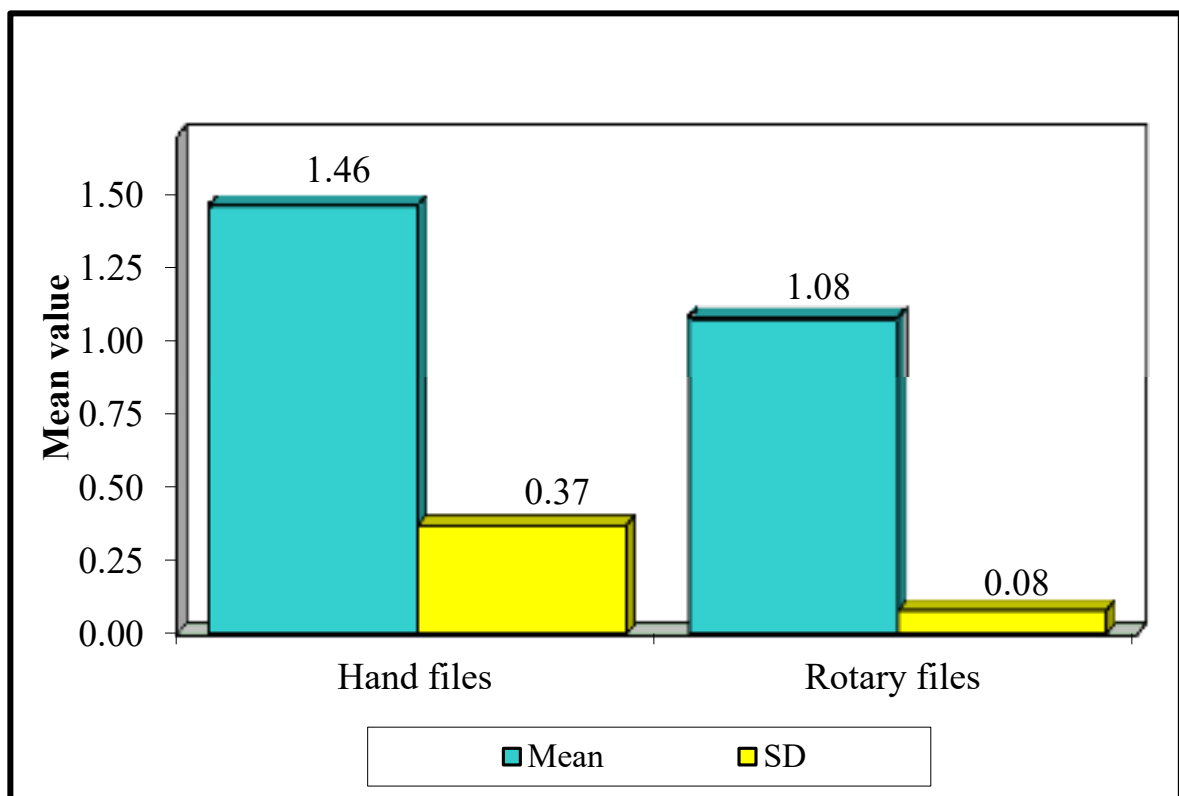


Table No. 10 and Graph No. 4: Showing duration of time taken during instrumentation in children undergoing single sitting pulpectomy using hand instrumentation in control group and Rotary instrumentation in experimental group.

In Control group [Group A], the mean instrumentation time (in minutes) was found to be 20.83 ( $\pm 3.24$ ). In Experimental group [Group B], the mean instrumentation time (in minutes) was found to be 8.33 ( $\pm 1.21$ ).

When both the groups are compared using Independent 't' test, 't' value was found to be 19.7974 with 'p' value of 0.001 ( $p < 0.001$ ) which was found to be highly statistically significant. Therefore, it has been inferred that mean instrumentation time taken by rotary instrumentation in Experimental group [Group B] is significantly lesser than the hand instrumentation in Control group [Group A].

**Table No. 11: Table showing the Mean, Standard Deviation and intergroup comparison of both the study groups among children undergoing single sitting pulpectomy with respect to post operative pain evaluation using Mann Whitney ‘U’ test.**

Post Operative pain evaluation	Hand Instrumentation (Group A)				Rotary Instrumentation (Group B)				‘U’ value	Z value	‘P’ value
	Mean	SD	Median	IQR	Mean	SD	Median	IQR			
24 Hrs	0.33	1.0	0.00	0.0	0.10	0.55	0.00	0.0	419.5	-0.450	0.652
48 Hrs	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0	450	0.000	1.000
72 Hrs	0.00	0.0	0.00	0.0	0.00	0.00	0.00	0.0	450	0.000	1.000
(24-48) Hrs	0.33	1.0	0.00	0.0	0.10	0.55	0.00	0.0	419.5	-0.450	0.652
(24-72) Hrs	0.33	1.0	0.00	0.0	0.10	0.55	0.00	0.0	419.5	-0.450	0.652
(48-72) Hrs	0.00	0.0	0.00	0.0	0.00	0.00	0.00	0.0	450	0.000	1.000

**Graph No. 5: Graphical representation showing intergroup comparison of both the study groups among children undergoing single sitting pulpectomy with respect to post operative pain evaluation using Mann Whitney ‘U’ test.**

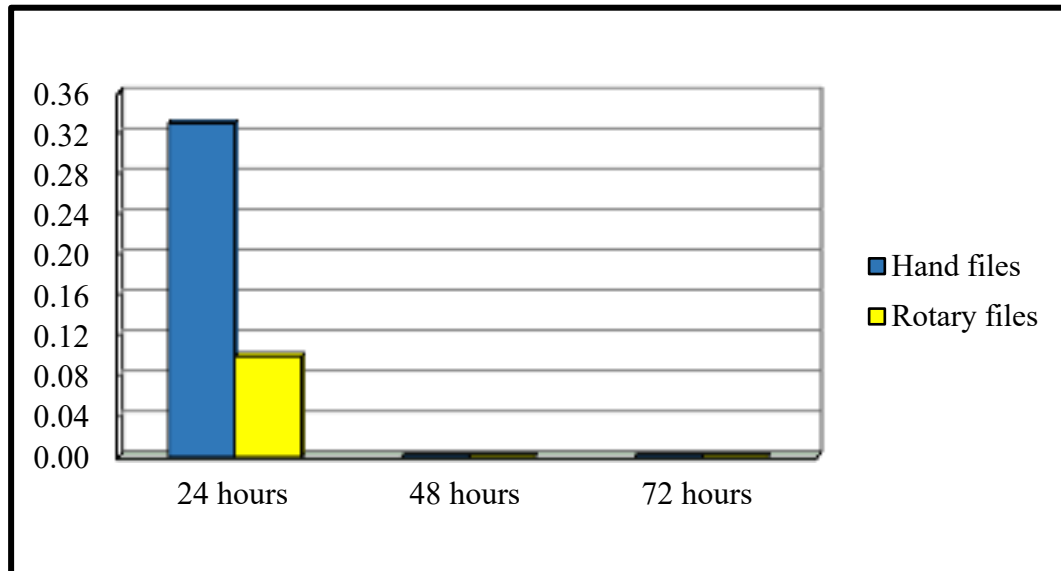


Table No. 11 and Graph No. 5: Showing intergroup comparison of post operative pain during instrumentation in children undergoing single sitting pulpectomy using hand instrumentation in control group and rotary instrumentation in experimental group using Modified Visual Analogue Scale at 24, 48 and 72 hours.

In Control group [Group A] the mean value of post operative pain after 24 hours is found to be  $0.33(\pm 1.0)$  where as  $0.10(\pm 0.55)$  in Experimental group [Group B]. Moreover, the mean value of post operative pain after 48 hours and 72 hours is 0.00 in both Control group [Group A] and Experimental group [Group B] respectively.

When both the groups are compared for the post operative pain using Mann-Whitney U test, it yielded a ‘U’ value of 419.5 after 24 hours interval and ‘p’ value of 0.6520 which indicates no significant difference in the post operative pain after single

sitting pulpectomy in both Control group [Group A] and Experimental group [Group B] respectively.

Furthermore, when comparison of post operative pain was done at 48 and 72 hours, a 'U' value of 450 and 'p' value of 1.000 ( $p>0.05$ ) is obtained which also indicates no significant difference in the post operative pain after single sitting pulpectomy in both Control group [Group A] and Experimental group [Group B] respectively.

Similarly, when both the groups are compared for the post operative pain with respect to time interval of (24-48) hours and (24-72) hours, it showed the mean value of  $0.33(\pm 1.0)$  in Control group [Group A] and  $0.10(\pm 0.55)$  in Experimental group [Group B] respectively. On intergroup comparison with respect to post operative pain by using Mann-Whitney U test, it yielded a 'U' value of 419.5 and 'p' value of 0.6520 ( $p>0.05$ ) which indicates no significant difference in the post operative pain after single sitting pulpectomy in both the Control group [Group A] and Experimental group [Group B] respectively.

Furthermore, when comparison of post operative pain was done at a time interval of (48-72) hours, a 'U' value of 450 and 'p' value of 1.000 ( $p>0.05$ ) is obtained which also indicates no significant difference in the post operative pain after single sitting pulpectomy in both the Control group [Group A] and Experimental group [Group B] respectively.

In accordance to this, when both the groups are compared with respect to post operative pain at 24, 48 and 72 hours, it yielded a 'Z' value of 0.4509, 0.00 and 0.00 respectively which indicates no significant difference in the post operative pain in between the groups.

**Table No. 12: Table showing the Mean, Standard Deviation and intragroup comparison of both the study groups among children undergoing single sitting pulpectomy with respect to post operative pain evaluation using Wilcoxon matched pair test.**

Groups	Post Operative pain evaluation	Mean	SD	Mean Diff.	SD Diff.	T value	Z value	'p' value
Hand Instrumentation [Group A]	24 hours	0.33	1.03					
	48 hours	0.00	0.00	0.33	1.03	0.00	1.6036	0.1088
	24 hours	0.33	1.03					
	72 hours	0.00	0.00	0.33	1.03	0.00	1.6036	0.1088
	48 hours	0.00	0.00					
	72 hours	0.00	0.00	0.00	--	0.00	0.0000	1.0000
Rotary Instrumentation [Group B]	24 hours	0.10	0.55					
	48 hours	0.00	0.00	0.10	0.55	0.00	0.0000	1.0000
	24 hours	0.10	0.55					
	72 hours	0.00	0.00	0.10	0.55	0.00	0.0000	1.0000
	48 hours	0.00	0.00					
	72 hours	0.00	0.00	0.00	--	0.00	0.0000	1.0000

**Graph No. 6: Graphical representation showing intragroup comparison of both the study groups among children undergoing single sitting pulpectomy with respect to post operative pain evaluation using Wilcoxon matched pair test.**

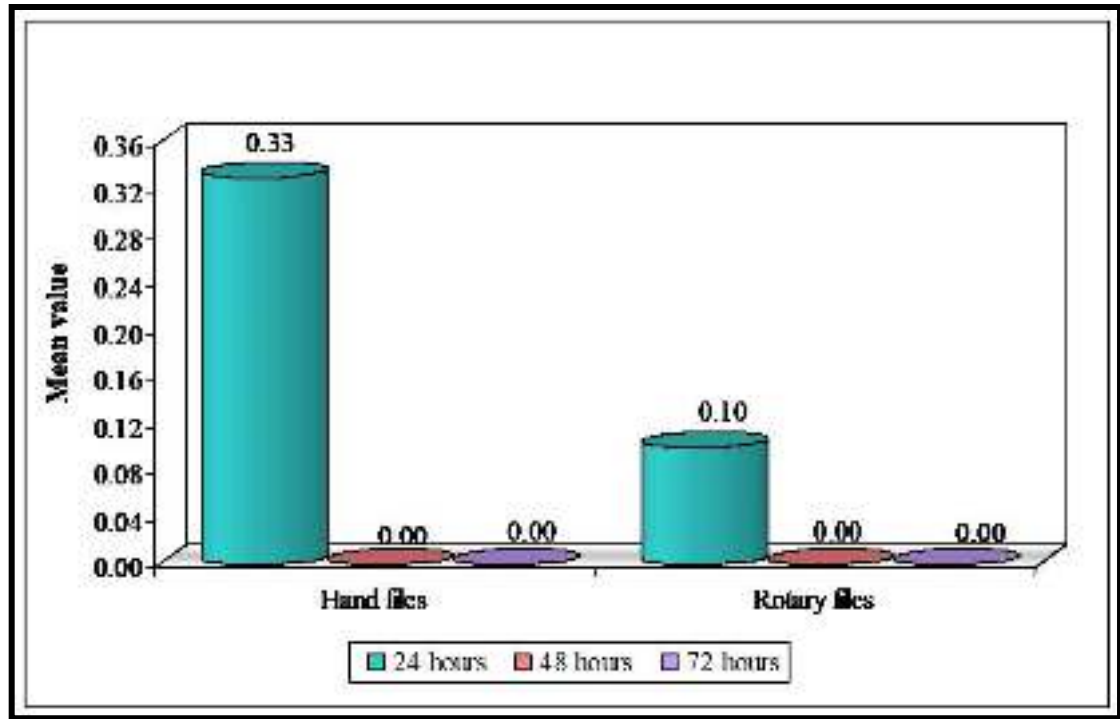


Table No. 12 and Graph no. 6: Showing intragroup comparison of post operative pain during instrumentation in children undergoing single sitting pulpectomy using hand instrumentation in Control group and rotary instrumentation in experimental group using Modified Visual Analogue Scale at 24, 48 and 72 hours.

In Control group [Group A] the mean value of post operative pain after and interval of 24 to 48 hours was found to be  $0.33(\pm 1.03)$ . In between 24 to 72 hours it was found to be  $0.33(\pm 1.03)$  and in between 48 to 72 hours is found to be zero respectively. When an intragroup comparison was made for the Control group [Group A] using Wilcoxon matched pair test, it yielded a 't' value of 0.00 and 'p' value of 0.1088 ( $p > 0.05$ ) which indicates no significant intragroup difference in the post operative pain after single sitting pulpectomy in Control group [Group A].

Similarly, in Experimental group [Group B] the mean value of post operative pain after and interval of 24 to 48 hours was found to be 0.10( $\pm 0.55$ ). In between 24 to 72 hours it was found to be 0.10( $\pm 0.55$ ) and in between 48 to 72 hours is found to be zero respectively. When an intragroup comparison was made for the Experimental group [Group B] using Wilcoxon matched pair test, it yielded a 't' value of 0.00 and 'p' value of 0.1000 ( $p > 0.05$ ) which indicates no significant intragroup difference in the post operative pain after single sitting pulpectomy in Experimental group [Group B].

In accordance to this, when intragroup comparison was made for Control group [Group A] and Experimental group [Group B] with respect to post operative pain at 24, 48 and 72 hours, it yielded a 'Z' value of 1.6036 in hand instrumentation [Group A] and rotary instrumentation [Group B] respectively which indicates no significant difference in the post operative pain among the group.

**Table No. 13: Table showing intergroup comparison of both the study groups among children undergoing single sitting pulpectomy with respect to quality of obturation using Chi square test.**

Sl. No.	Quality of Obturation	Hand Instrumentation [Group A]	%	Rotary Instrumentation [Group B]	%	Total	%
1.	Optimally filled	26	86.67	27	90.00	53	88.33
2.	Over filled	2	6.67	3	10.00	5	8.33
3.	Under-filled	2	6.67	0	0.00	2	3.33
	Total	30	100.0	30	100.0	60	100.00
Chi-square= 2.2190 p = 0.3300							

**Graph No. 7: Graphical representation showing intergroup comparison of both the study groups among children undergoing single sitting pulpectomy with respect to quality of obturation using Chi square test.**

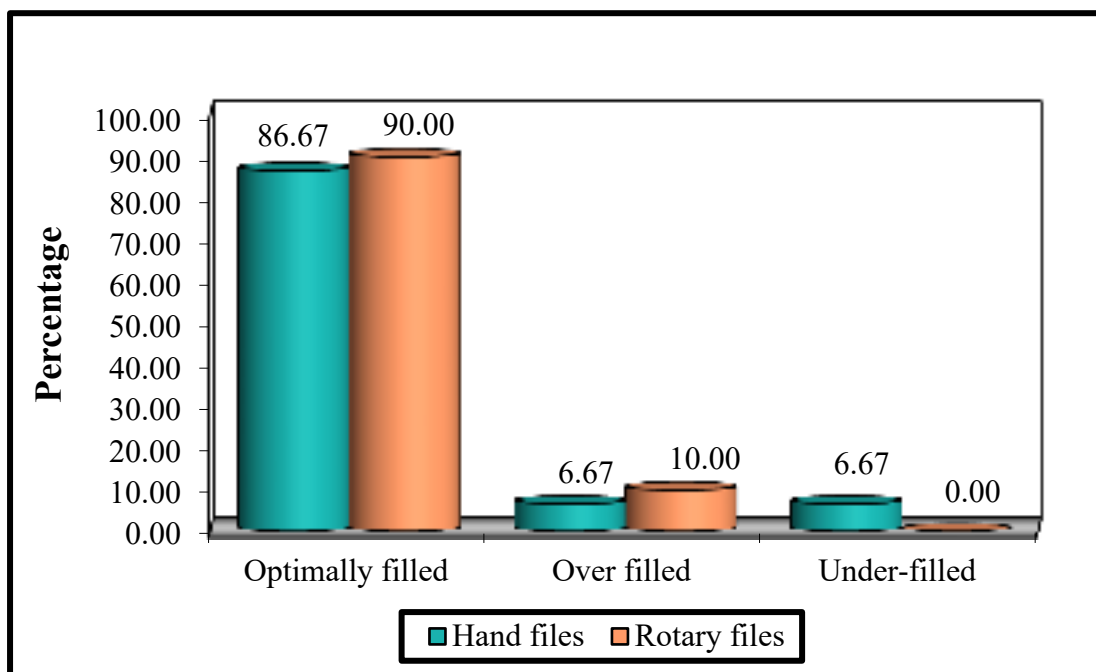


Table No. 13 and Graph No. 7: Showing comparison in quality of obturation after instrumentation in children undergoing single sitting pulpectomy using hand instrumentation in Control group and rotary instrumentation in experimental group.

Quality of obturation is assessed by measuring (mm) of the largest dimension of any voids within the filling material measured vertically from the radiograph. It was being assessed by using Modified Coll and Sadrian criteria.

In Control group [Group A], among thirty samples, the total percentage of optimally filled canals were 86.67% and over filled and under filled canals were 6.67% each whereas in Experimental group [Group B], the total percentage of optimally filled canals were 90.00% and over filled and under filled canals were 10.00% and 0.00 respectively.

When both the groups were compared for the quality of obturation, Chi square value of 2.2190 and 'p' value of 0.3300 ( $p > 0.05$ ) was obtained. It shows that there was no statistically significant difference in the quality of obturation in the intergroup comparison. However, higher quality of obturation is seen among the Experimental group using rotary instrumentation [Group B] owing to 90% optimally filled root canals. Although more overfilled canals accounting to 10% were seen in the Experimental group [Group B] whereas more underfilled canals 6.67% were in the Control group using hand instrumentation [Group A].

**Table No. 14: Table showing intergroup comparison of both the study groups among children undergoing single sitting pulpectomy with respect to apical seal using Chi square test.**

Apical seal	Hand Instrumentation [Group A]	%	Rotary Instrumentation [Group B]	%	Total	%
Scale 1	28	93.33	28	93.33	56	93.33
Scale 2	2	6.67	2	6.67	4	6.67
Scale 3	0	0.00	0	0.00	0	0.00
Total	30	100.00	30	100.00	60	100.00

Chi-square= 0.0000 p = 1.0000

**Graph No. 8: Graphical representation showing intergroup comparison of both the study groups among children undergoing single sitting pulpectomy with respect to apical seal using Chi square test.**

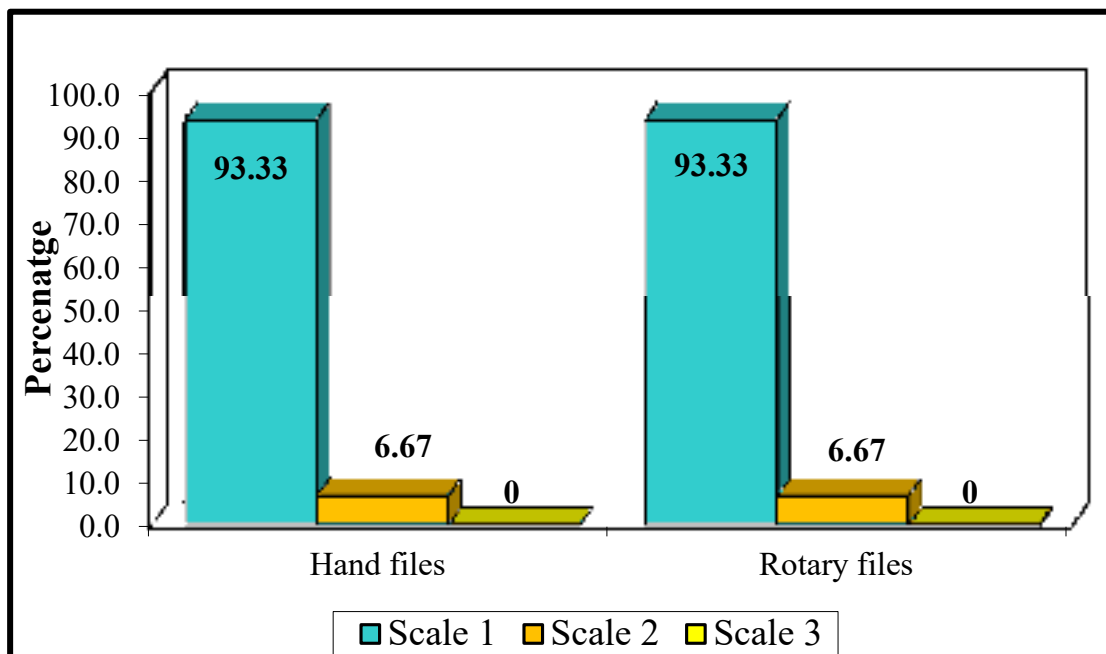


Table No. 14 and Graph No. 8: Showing comparison in achieving the apical seal after instrumentation in children undergoing single sitting pulpectomy using hand instrumentation in Control group and rotary instrumentation in experimental group.

Apical Seal was assessed on the basis of a grading scale ranging from Scale 1 to Scale 3 wherein 1 indicates the best possible results and 3 denotes the worst. Apical seal was evaluated horizontally in mm from the apical end of the filling material to the radiographic apex.

In Control group [Group A], among thirty samples, the total percentage of samples falling into Scale 1 was found to be 93.33%, Scale 2 was found to be 6.67% and Scale 3 was found to be zero whereas in Experimental group [Group B], the total percentage of samples falling into Scale 1 was found to be 93.33%, Scale 2 was found to be 6.67% and Scale 3 was found to be zero respectively.

When both the groups were compared for the attainment of apical seal, Chi square value of 0.00 and 'p' value of 1.000 ( $p > 0.05$ ) was obtained. It shows that there was no statistically significant difference in the attainment of apical seal in the intergroup comparison.

**Table No. 15: Table showing intergroup comparison of both the study groups among children undergoing single sitting pulpectomy with respect to extrusion using Chi square test with Yates’s correction.**

Extrusion	Hand Instrumentation [Group A]	%	Rotary Instrumentation [Group B]	%	Total	%
Scale 1	29	96.67	28	93.33	57	95.00
Scale 2	1	3.33	2	6.67	3	5.00
Scale 3	0	0.00	0	0.00	0	0
Total	30	100	30	100	60	100

Chi-square with Yates's correction = 0.000 p = 1.000

**Graph No. 9: Graphical representation showing intergroup comparison of both the study groups among children undergoing single sitting pulpectomy with respect to extrusion using Chi square test with Yates’s correction.**

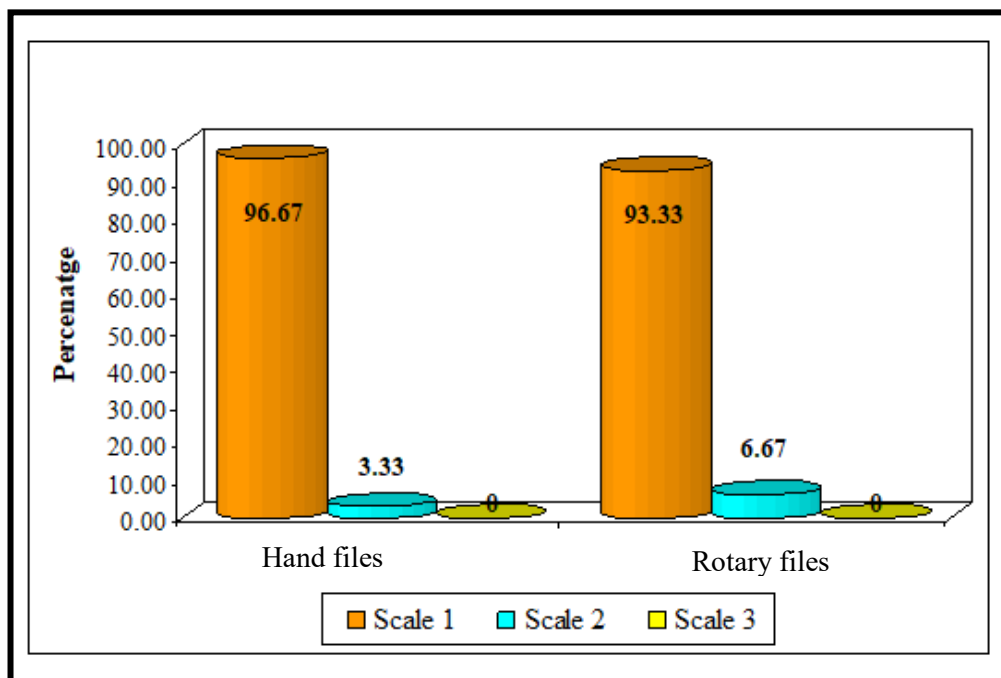


Table No. 15 and Graph No. 9: Showing comparison in extrusion of the obturating material after instrumentation in children undergoing single sitting pulpectomy using hand instrumentation in Control group and rotary instrumentation in experimental group.

Extrusion was assessed on the basis of a grading scale ranging from Scale 1 to Scale 3 wherein 1 indicates the best possible results and 3 denotes the worst. Extrusion was defined as a measuring (mm) of the largest dimension of any extruded material vertically beyond the radiographic apex.

In Control group [Group A], among thirty samples, extrusion was observed in one sample whereas it was seen among two samples in Experimental group [Group B].

When both the groups were compared for assessing the extrusion a Chi square value with Yates's correction was found to be 0.00 and 'p' value of 1.000 ( $p > 0.05$ ) was obtained. It shows that there was no statistically significant difference in the extrusion observed in the intergroup comparison. However, slightly higher extrusion is seen among the Experimental group [Group B].

## **DISCUSSION**

Dentistry for children is one of the most needed specialty of dentistry. It incorporates the treatment regimens initiating from the comprehensive management to the rehabilitation of the oral cavities of the children<sup>2</sup>. Moreover, as we are stepping ahead towards the preservation era, it is of prime importance to preserve the integrity of primary teeth in the oral cavity.

Primary teeth act as a natural space maintainer which guides the eruption of permanent teeth to their optimal position in the dental arch. Along with maintaining the arch integrity they aid in physiological functions of speech and mastication. Following the paradigm shift of Pediatric dentistry from the surgical treatment planning to the conservation of primary teeth until their natural exfoliation we have endorsed the preservation of primary teeth as of utmost importance.

Nevertheless, this has given rise to minimally invasive dentistry wherein the key role is to conserve the tooth and refrain it from extensive dental procedures. Historically, an extraction oriented practice was lead wherein primary teeth with an inflamed pulp were extracted. But, now the emphasis has been made to preserve the vitality of tooth embarking the remarkable healing potential of the dental pulp especially in children. However, pulp therapy is considered as a viable option in cases where pulp is irreversibly inflamed. Despite of the extensive progress we still encounter children with a number of complications and poorly treated primary teeth. This could be sufficed by exact diagnosis, thorough knowledge of the pulpal conditions and treatment protocols along with its efficient management.

Pulp therapy serves these goals by successfully treating the cariously involved tooth allowing it to remain in the oral cavity in non-pathologic state<sup>4</sup>. If the tooth is irreversibly inflamed or necrosis is observed, then the best treatment regime implied is pulpectomy which involves complete debridement of coronal and radicular pulp followed by cleaning and shaping the canals capable to best receive the restorative material<sup>5</sup>.

Pulpectomy is a procedure involving complete removal of diseased or necrotic pulp from the root canals and the coronal portion of dental primary teeth in order to maintain the tooth in the dental arch<sup>50</sup>. It consists of various steps out of which chemo mechanical preparation of the root canals is a requisite for the successful endodontic treatment.

Thus, it is very essential to understand the morphological changes that occur continuously in primary teeth by the clinician before initiating any pulp therapy procedures. Multi visit pulpectomy has been well acknowledged and considered as safe therapy across the world. Furthermore it's primarily based on the motive of complete eradication of the endodontic micro flora with the use of suitable intracanal medicaments in between the appointments. However, single visit pulpectomy has been gaining popularity because of decreased endodontic complications such as lessening of intra appointment leakage and decreased range of visits for the operative procedures.

Analyzing the past literature, the equitable success of single visit and multi visit endodontic therapies has been well documented pertaining to permanent teeth in every aspect initiating from inter appointment complications to post endodontic pain.

However, these results cannot be directly implicated to the endodontically treated primary teeth.

In accordance to this, the present study was designed to evaluate and compare postoperative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children.

In our study, sixty participants ranging from four to eight years of age were selected [Table No. 7 and Graph No. 1]. The main reason which can be cited for choosing the study sample as such is the root formation of primary molars which is completed by three years of age and root resorption begins at six years of age<sup>10</sup>. Thus, unresorbed roots lead to improvement in the quality of obturation along with reduction in apical extrusion of the obturating material.

Moreover, as stated by American Academy of Pediatric Dentistry, non-vital pulp therapy is indicated in a primary tooth with history of spontaneous pain, irreversible pulpitis or necrosis or a tooth treatment planned for pulpotomy in which the radicular pulp exhibits clinical signs of irreversible pulpitis or pulp necrosis in the form of suppuration, purulence etc. and the roots exhibiting minimal or no resorption. Our inclusion criteria pertaining to the study is in accordance with the above mentioned guidelines<sup>5</sup>.

In the due respect to adhere to these guidelines, historically, pulpectomy was performed in multiple visits so as to ensure the sterility of the canals before obturation has been done. However in the existing literature regarding comparison of single and multi visit pulpectomy no such significant difference has been found. Similarly, in a study conducted by Singh S et al, they reported no significant difference in multi and

single visit pulpectomy in primary teeth. However, they added about the “tincture of time” which is included in multi visit therapy that reassures the effectiveness of biomechanical preparation pertaining to healing of any peri-radicular pathosis if present<sup>21</sup>.

However, Di Renzo A et al reported no significant difference in the multi and single visit therapy. Additionally, they stated that pulp extirpation alone is probably the most significant factor in reducing the post operative pain and thus efficacious removal of it leads to success of the endodontic therapy in primary teeth may it be single or multiple visit<sup>51</sup>.

Also, due to the inability of achieving complete sterilization through chemo mechanical preparation due to the tortuous canals and complex anatomy of the primary teeth, intracanal medicaments were used to ensure proper eradication of microflora. This is achieved mainly by the use of phenolic compounds which in addition to killing of micro organisms also lead to the irritation of the periradicular tissues. Overzealous use of these medicaments leads to post operative complications that are the sole reason for persistent periradicular infections<sup>20</sup>.

Owing to the available literature and yet a difficulty in the assessment of either methods of pulp therapy to be used for pulpectomy in children, systematic review concluded the effectiveness of single visit root canal treatment over the multi visit therapy. The reason cited by this was the lesser visits, pain management and radiation exposure. Also, as stated by many authors about intracanal medicaments which leads to reduction in the microbial load, there is no such compulsion. Adding to it, there is no such association between the negative microbial culture and healing rates success in root canal treatment of primary teeth<sup>22</sup>. This led clinicians with two roads of choice,

either the completion of the root canal in single visit or opting for a optimal intracanal medicament.

Reclaiming the variations in morphology of the primary teeth psychological management of a child along with efficient management and treatment in the operatory, a procedure involving lesser appointments, chair side time and causing less post operative pain is the need of an hour. Affirming to the school of thought, the present study advocates the use of single visit root canal treatment/ single sitting pulpectomy for the treatment of pulpally involved primary molars in children.

Out of sixty participants included in our study fifty three were male (53.33%) and forty six were female (46.67%) [Table No.8, Graph No.2]. In Control Group [Group A], out of thirty subjects eighteen (60.00%) were male and twelve (40.00%) were female whereas in Experimental Group [Group B], out of thirty samples fourteen (46.67%) were male and sixteen (53.33%) were female. Hence, participants were equally distributed in both the groups so as to ensure standardization. After recruiting the patients in the subsequent groups, single sitting pulpectomy was done while maintaining the standard operating protocols.

Single sitting pulpectomy procedure was carried out subsequently using hand instrumentation in control group and rotary instrumentation in the experimental group respectively.

As we all know that the key to a successful endodontic treatment lies in efficient chemo mechanical debridement of the root canals. Therefore, the instrumentation method implied during the procedure holds a great value. The rationale lies in providing aseptic root canal preparation suitable to receive an

obturating material<sup>6</sup>. Thus the paramount step determining the success of pulpectomy is efficient chemo mechanical preparation.

Traditionally, hand K files are considered as gold standard in paediatric dentistry as they have exceptional tactile perception. They are incorporated with such a blade design which makes them best suited for cutting the dentine using pull and push motion. Still the incidence of post operative pain is seen higher due to linear filing motion of the instruments. Adding to this is the significantly altered morphology of root canals in primary teeth which requires improvement in instrumentation to avoid post operative complications like zip formations, strip perforations, ledges, apical transportations etc.<sup>29</sup>.

Likewise, in a study conducted by Mario Z et al<sup>52</sup>, they reported much apical extrusion with the use of stainless steel hand filing instruments. Also, they resulted in higher incidence of other procedural errors such as strip perforations and instrument fracture in primary teeth<sup>54</sup>. The results of another study conducted by Jeffery S et al are in accordance with the same. They concluded higher lesser wear resistance observed in case of hand instruments compared to the rotary filing instruments<sup>53</sup>.

The potential limitations are increased instrumentation time, uneven preparation of root canal space with the use of hand files despite its widespread usage for the instrumentation of primary root canals as reported by the some authors<sup>42, 54</sup>. Although, handfiles have aided in the pediatric endodontic treatment since ages and proved successful yet there is a need felt to introduce a newer filing system to reduce the incidence of post endodontic pain.

With the development of NiTi rotary shaping systems, a reduction in the time taken and increase in the clinical efficacy has been observed. Due to, greater elasticity,

central canal preparation, less apical transportation, use of lesser number of files, NiTi alloys have proven to be more effective in cleaning the tortuous and irregular canal walls of the primary teeth. Hence, it proves to be a far better choice for pediatric endodontic procedures in the upcoming era.

Furthermore, keeping in mind the complex anatomy of root canals of primary teeth, instrumentation is carried out with the main objective to remove the infection which can lead to success of the pulpectomy procedure<sup>24</sup>. Chemo mechanical preparation with the use of rotary files in primary teeth has gained popularity after the first case reported by Barr et al in 2000 who had used ProFile with 0.04% taper and 21mm length to prepare the canals of primary teeth. These were NiTi alloy based rotary files and the key advantages then reported by the author are, ease of debridement of the tissue and debris, ease of access to canals due to NiTi alloy based texture of the files and more uniform funnel shaped preparation is observed due to constant taper and flute design<sup>23</sup>.

In accordance to the work initiated then, with the use of NiTi alloys from then till now, a number of rotary files have been developed for the ease of endodontic practice. However, the same principles cannot be applied to that of Pediatric endodontics. Therefore, chemomechanical preparation can be successfully done if aided with a specially designed Pediatric rotary NiTi based file system. Nonetheless, one of such rotary system of files has been put forth by Rathi N. et al<sup>55</sup> which is named as Pro AF Baby Gold files which is an exclusive Pediatric rotary files. These are short 17mm files providing ease of use in primary teeth made with advanced NiTi controlled memory (CM) wire technology for better canal centricity. These are heat treated resulting in nearly no instrument separation and are suitable for

conservative canal preparation. These are provided with the sequential taper of 4% and 6% which leads to improve cleaning and shaping of the canals. Furthermore, it is a two file canal preparation system which reduces the instrumentation time during the pulpectomy procedure.

In our study, we have used this Pro AF Baby file rotary files in comparison to the conventionally used hand H-files. The results of present study are in accordance to the literature with regards to the instrumentation time. In the Hand instrumentation group [Group A] the mean instrumentation time (in minutes) was found to be 20.83 ( $\pm 3.24$ ) whereas in the Rotary instrumentation group [Group B] it was 8.33 ( $\pm 1.21$ ) owing to a 'p' value of 0.001 ( $p < 0.001$ ) [Table No. 10 and Graph No. 4]. It showed a highly significant difference between the instrumentation time taken for doing single sitting pulpectomy using hand and rotary files respectively.

Along with the duration of procedure another most important factor that affects the treatment is pain, especially in Pediatric dental procedures. Therefore, it makes it essential to evaluate pain, if any felt by the child postoperatively.

It is well said, "Endodontic treatment is a failure if the child departs in tears". Eventually post operative pain could be the most common reason for the same. Thus, it becomes an essential modality to assess the post operative pain which is till now the most neglected one in the dental practice. However, as a Pediatric dentist key significance is to ensure that the treatment of the child has been provided thoughtfully keeping into concern the child's overall welfare. While assessing the past literature regarding the predominance of post operative pain, no significant difference in the post operative pain while using single visit and multiple visits pulpectomy was found in children.

The results of our study are also in accordance with the same. In the present study we have evaluated the post operative pain after single sitting pulpectomy after the interval of 24, 48 and 72 hours. The major reason for analyzing the pain during these time intervals can be cited as, the highest degree of pain is often experienced in the first twenty four hours after the reduction in the process of inflammation and after forty eight hours the level of pain subsides significantly<sup>37</sup>.

Furthermore, in our study we have used Modified Visual analogue scale (VAS) for the evaluation of post operative pain after single sitting pulpectomy. The reason for choosing this method to analyze the post-operative pain is that, children often lack the required cognitive and linguistic skills to talk upon their physical discomfort and pain intensity. Due to the result of less verbal communication and differences in the level of maturity and understanding it becomes more difficult to evaluate the intensity of pain. Thus, in pediatric patients it serves as gold standard for pain assessment<sup>41</sup>.

In the present study, when the evaluation of post operative pain was done after single sitting pulpectomy, in control group [Group A] the mean value of post operative pain after 24 hours is found to be  $0.33(\pm 1.0)$  where as  $0.10(\pm 0.55)$  in experimental group [Group B]. Moreover, the mean value of post operative pain after 48 hours and 72 hours is 0.00 in both control [Group A] and experimental Group [Group B] respectively [Table No. 11 and Graph No. 5]. It showed no significant difference between the post operative pain after single sitting pulpectomy using hand and rotary instrumentation. However, slightly lesser post operative pain is seen among the rotary instrumentation group comparably. Our results are in accordance with the

study conducted by Vieyra et al<sup>26</sup> and Pasqualini et al<sup>13</sup> who inferred no statistically significant difference among the two instrumentation methods.

While cumulating the reasons regarding the occurrence of post operative pain after the endodontic treatment, a few key reasons have been encountered to fill the paucity of literature. The main reasons are, the incidence of the post operative pain which is due to changes in periradicular pressure, number of virulence endodontic micro-flora along with the environmental conditions. Furthermore this post operative pain reduction while using rotary instrumentation is because of greater elasticity, more centered canal preparations with less apical transportation, incidence of canal aberrations and rotational action usually causing lesser extrusion<sup>39</sup>.

Moreover, the other reasons cited by some authors are preflaring and crown down preparation leading to lesser post operative pain which is seen in case of rotary file system<sup>56</sup>. Adding to this some authors stated it as multi factorial cause of pain associated with the interaction between the host immune response, infection and physical damage caused due to remnant infection<sup>57</sup>.

Also, the main reason cited for higher post operative pain while using hand instrumentation is that they result in more apical extrusion of the contents of canal which in necrotic cases may result in flare-ups with post operative swelling and discomfort. Due to transportation of dentinal chips to the apical area, healing process may be impaired<sup>13</sup>.

Therefore, along with the sound chemo mechanical preparation, success of pulpectomy lies in achieving a three dimensional obturation with minimum number of voids. Inadequate obturation of the tooth leads to its exposure to periapical fluids. It further acts as a nidus for various micro organisms leading to their localization in the

dead spaces which eventually becomes a root cause for sequelae of inflammation. Additionally, extrusion of the material into periapical areas leads to its irritation, causing further necrosis of bone and cementum. Henceforth, the quality of obturation significantly influences the success rate of pulpectomy<sup>58</sup>.

In the present study we have used Ingle's radiographic technique for the estimation of working length as it one of the most common and reliable methods used in determining the working length. Also, moist cotton pellet technique given by Donnenberget al<sup>47</sup>; is used for the obturation in both the groups so as to maintain standardization of technique and to prevent further bias. Zinc Oxide Eugenol (ZOE) cement was used as an obturating material. The first single sitting pulpectomy using ZOE was reported back in 1972 by Gould JM et al, reclaiming its higher success rates. Zinc Oxide Eugenol as an obturating material has properties like anti inflammatory, analgesic, greater zone of bacterial inhibition, ease of availability, radioopacity, cost effectiveness, ease of usage and manipulation and insolubility in the tissue fluids<sup>50</sup>. All these properties make it a good obturating material to be used in primary teeth.

Quality of obturation can be assessed by various parameters like adequate filling of the canals, absence of voids, apical seal and extrusion of the obturating material. To assess the quality of obturation there are various criteria given by Coll and Sadrian et al, Mermarpur et al, Shubha Reddy and Shakunthala et al etc.<sup>34, 35,49</sup> So as to maintain standardization in the present study we have used Modified Coll and Sadrian criteria for evaluation of the quality of obturation. It is assessed by measuring (mm) of the largest dimension of any voids within the filling material measured

vertically from the radiograph. Likewise in our study, obturation is gauged as Underfilled, Optimally filled and Overfilled<sup>49</sup>.

In the present study, higher quality of obturation is seen among the experimental group using rotary instrumentation [Group B] owing to 90% optimally filled root canals as compared to hand instrumentation group [Group A] which has 86.67%. Although more overfilled canals accounting to 10% were seen in the rotary instrumentation group. No underfilled canals are seen in the experimental group whereas more underfilled canals 6.67% were seen in the control group using hand instrumentation [Group A] [Table No. 13 and Graph No. 7].

Apical seal is another important criteria to be assessed so as to ensure quality obturation. It is evaluated horizontally in mm from the apical end of the filling material to the radiographic apex. It was assessed on the basis of a grading scale ranging from Scale 1 to Scale 3 wherein 1 indicates the best possible results and 3 denotes the worst<sup>36</sup>. In the present study, both the instrumentation methods have attained good apical seal of 93.33% and there was no statistically significant difference between both control and experimental groups [Table No. 14 and Graph No. 8].

Extrusion can be defined as a measuring (mm) of the largest dimension of any extruded material vertically beyond the radiographic apex. It was assessed on the basis of a grading scale ranging from Scale 1 to Scale 3 wherein 1 indicates the best possible results and 3 denotes the worst<sup>36</sup>. In the present study, extrusion was observed in one sample among thirty samples in hand instrumentation group [Group A], whereas it was seen among two samples in rotary instrumentation [Group B] respectively [Table No. 15 and Graph No. 9]. However, there is no significant

difference found comparably between the two groups re. Our study is in accordance to the in-vitro study conducted by Rathi N et al wherein they have concluded no significant difference in the extrusion seen using hand H-file and rotary Pro AF Baby gold files. Also, they have added that amount of apical extrusion of debris was significantly less for the Pro AF Baby rotary files group compared to other Pediatric rotary file systems<sup>55</sup>.

Nonetheless, “It is wiser to find out than to suppose”.

With this, our study signifies no significant difference in the post-operative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children. Additional analysis summaries no significant difference in the quality of obturation while using hand and rotary instrumentation. However, a significant difference has been observed in the instrumentation time while using rotary method of instrumentation while performing pulpectomy.

Thus, both the methods of instrumentation namely hand filing and rotary filing can be used and are recommended for the single visit pulpectomy procedure. However, due to lesser instrumentation time taken in the rotary system it could be used for ensuring shorter span of appointments pertaining to the pediatric patient. Moreover, it is not the instrumentation but the operator’s skill which matters<sup>39</sup>.

The study depicts that both the methods of instrumentation have shown equality in the post operative pain and obturation quality is also similar in both the groups. Therefore, the null hypothesis formulated at the beginning of the study was accepted.

Even though our study showed that there is no difference in the post operative pain after single sitting pulpectomy using hand and rotary instrumentation there are some of the limitations of our study such as single rotary file has been compared to the conventional filing method. Also smaller sample size and shorter duration of evaluation of post operative pain was made. Thus to justify the conclusion drawn from the study, a clinical trial involving larger sample size and longer follow up period and comparative evaluation of multiple rotary files should be carried out.

In the future we would like to conduct many more multicentric clinical trials with larger sample size and newly available pediatric rotary endodontic files to assess pulp therapy in primary teeth for the overall well being of child's oral health and also their implications in the pediatric dental practice.

As quoted by Albert Einstein,

“If we knew what it was we were doing, it would not be called research, would it?”

## CONCLUSION

The advancement in dentistry and development of Ni-Ti rotary shaping system in the primary teeth has led to increase in clinical efficiency and reduction in time taken while doing pulpectomy in children. However, there still exists a need to ponder upon of the fact that which method can prove to be a far better choice to be used in pediatric dentistry in the upcoming era.

The following conclusions are drawn from the present study:

1. Even though there was lesser post operative pain seen in the experimental group using rotary instrumentation [Group B] when compared with the control group using hand instrumentation [Group A] there was no significant difference found in post operative pain after single sitting pulpectomy in children.
2. In rotary instrumentation [Group B] time taken for the chemo mechanical preparation was lesser as compared to the hand instrumentation [Group A]. A statistically significant difference was found in the instrument time taken during chemo mechanical preparation during single sitting pulpectomy in children.
3. There was no significant difference found in the quality of obturation after single sitting pulpectomy using hand instrumentation in Control group [Group A] and rotary instrumentation in Experimental group [Group B].

Thus, so as to conclude, “No matter where the newer technology can lead us; we should never forget the loudest treatment lies in the root of the human touch”.

**SUMMARY**



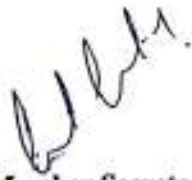

The present study was conducted on children with the aim to evaluate and compare the post operative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children. Sixty children were selected according to the selection criteria. Children were randomly divided into two groups namely Group A as Hand instrumentation using K-file and Group B as Rotary instrumentation using Pro AF baby gold files.

Following the standard operating protocols single sitting pulpectomy was carried out using both the methods of instrumentation. The values for post operative pain, instrumentation time and quality of obturation was noted and tabulated during the study. Children were recalled for follow up after a week on which placement of stainless crown was done. Further follow ups are scheduled every three months after the treatment.

Our study showed that both the groups namely control group using hand K-file and experimental group using rotary Pro AF baby gold files have shown minimal amount of post operative pain after single sitting pulpectomy procedure. Additional analysis states that the time taken by rotary instrumentation was found less as compared to the hand instrumentation group. A statistically significant difference was found in the instrumentation time taken among both the groups respectively. However, quality of obturation in both the groups was found optimal with no statistically significant difference in both the groups respectively.

Our study aids in rendering the improvement in quality of treatment in children by lessening the appointment time, absence of pain and imparting worthy treatment which are three main assets required for a successful pediatric dental practice.

**ANNEXURE I****ETHICAL CLEARANCE CERTIFICATE**

	<b>Research and Ethics Committee</b> <b>KLE V K INSTITUTE OF DENTAL SCIENCES</b> <b>KLE University</b>	
Accredited 'A' Grade by IAAC      Placed in Category 'A' by MHRD (Govt)		
Nehru Nagar, Belagavi - 590 010, Karnataka State		
☎: 0831-2470382 FAX: 0831-2470640	Web: <a href="http://www.kledental-bgm.edu.in">http://www.kledental-bgm.edu.in</a> E-mail: <a href="mailto:principal@kledental-bgm.edu.in">principal@kledental-bgm.edu.in</a>	
		SL No. : 1393
<div style="border: 1px solid black; padding: 5px; display: inline-block; margin: 10px 0;"><b>CERTIFICATE</b></div>		
<p><i>This is to Certify that the synopsis titled</i></p> <p><u>Comparative evaluation of post-operative pain after single sitting pulpectomy using hand and rotary instrumentation in primary molars of children -</u></p> <p><u>A Randomised Control study.</u>      Submitted by</p> <p><u>Dr. Nivedita Saxena</u>      P. G. Student /</p> <p><u>Staff, Guided by Dr. Shivayogi. M. Hugar</u> from Department of</p> <p><u>Pediatric &amp; preventive dentistry</u> has been critically evaluated by</p> <p>committee members and granted ethical clearance to conduct the above</p> <p>mentioned study</p>		
Date :		
<b>Member Secretary</b>		
Research and Ethical Committee	Research and Ethical Committee	
KLEVK Institute of Dental Sciences	KLEVK Institute of Dental Sciences	
Research & Ethics Committee	Research & Ethics Committee	
KLE V K Institute of Dental Sciences	KLE V K Institute of Dental Sciences	

**ANNEXURE II****CLINICAL TRIAL REGISTRY – INDIA CERTIFICATE**

CLINICAL TRIALS REGISTRY - INDIA ICMR - National Institute of Medical Statistics		PDF of Trial CTRI Website URL - <a href="http://ctri.nic.in">http://ctri.nic.in</a>	
<b>Clinical Trial Details (PDF Generation Date &gt; Tue, 01 Dec 2020 11:41:52 GMT)</b>			
<b>CTRI Number</b>	CTR(2020/12/029470 (Registration on: 01/12/2020) Trial Registered Prospectively		
<b>Last Modified On</b>	25/11/2020		
<b>Post Graduate Thesis</b>	Yes		
<b>Type of Trial</b>	Interventional		
<b>Type of Study</b>	Dentistry		
<b>Study Design</b>	Randomized, Parallel Group Trial		
<b>Public Title of Study</b>	EVALUATION OF PAIN AFTER SINGLE SITTING ROOT CANAL TREATMENT USING HAND AND ROTARY INSTRUMENTS		
<b>Scientific Title of Study</b>	COMPARATIVE EVALUATION OF POST-OPERATIVE PAIN AFTER SINGLE SITTING PULPECTOMY USING HAND AND ROTARY INSTRUMENTATION IN PRIMARY MOLARS OF CHILDREN – A RANDOMISED CONTROL STUDY		
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>	
	NIL	NIL	
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>		
	<b>Name</b>	Dr Nivedita Saxena	
	<b>Designation</b>	Post graduate Student	
	<b>Affiliation</b>	KLE VK Institute of Dental Sciences	
	<b>Address</b>	DEPARTMENT OF PEDIATRIC AND PREVENTIVE DENTISTRY KLE VK INSTITUTE OF DENTAL SCIENCES, KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH (KAHER), NEHRU NAGAR, BELAGAVI, KLE VK INSTITUTE OF DENTAL SCIENCES, KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH (KAHER), NEHRU NAGAR, BELAGAVI, Belgaum KARNATAKA 590010 India	
	<b>Phone</b>	8375287558	
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<b>Details Contact Person (Scientific Query)</b>	<b>Details Contact Person (Scientific Query)</b>		
	<b>Name</b>	Dr Shivayogi M Hugar	
	<b>Designation</b>	Professor and Head	
	<b>Affiliation</b>	KLE VK Institute of Dental Sciences	
	<b>Address</b>	DEPARTMENT OF PEDIATRIC AND PREVENTIVE DENTISTRY KLE VK INSTITUTE OF DENTAL SCIENCES, KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH (KAHER), NEHRU NAGAR, BELAGAVI, KLE VK INSTITUTE OF DENTAL SCIENCES, KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH (KAHER), NEHRU NAGAR, BELAGAVI, Belgaum KARNATAKA 590010 India	
	<b>Phone</b>	2385435448	
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	<b>Email</b>	dr.hugarism@gmail.com	
<b>Details Contact Person (Public Query)</b>	<b>Details Contact Person (Public Query)</b>		
	<b>Name</b>	Dr Nivedita Saxena	

CLINICAL TRIALS REGISTRY - INDIA		PDF of Trial		
ICMR - National Institute of Medical Statistics		CTRI Website URL - <a href="http://ctri.nic.in">http://ctri.nic.in</a>		
<b>Designation</b>	Post graduate Student			
	<b>Affiliation</b>	KLE VK Institute of Dental Sciences		
	<b>Address</b>	Department of Pediatric and Preventive Dentistry, KLE V. K. Institute of Dental Sciences, KLE Academy of Higher Education And Research (KAHER), Nehru Nagar, Belagavi, KLE V. K. Institute of Dental Sciences, KLE Academy of Higher Education And Research (KAHER), Nehru Nagar, Belagavi Belgaum KARNATAKA 560010 India		
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	<b>Email</b>	niveditasaxena40@gmail.com		
	<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>		
	> KLE VK INSTITUTE OF DENTAL SCIENCES			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
	<b>Name</b>	Department of Pediatric and Preventive Dentistry		
	<b>Address</b>	Department of Pediatric and Preventive Dentistry, KLE VK Institute of Dental Sciences, Belagavi.		
	<b>Type of Sponsor</b>	Research Institution and Hospital		
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	NIL	NIL		
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	India			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
	Dr Nivedita Saxena	Department of Pediatric and Preventive Dentistry	KAHER, KLE VK Institute of Dental Sciences, Nehru Nagar, Belagavi, Belgaum, KARNATAKA	6375267558 niveditasaxena40@gmail.com
<b>Details of Ethics Committee</b>	<b>Name of Committee</b>	<b>Approval Status</b>	<b>Date of Approval</b>	<b>Is Independent Ethics Committee?</b>
	Research and Ethics committee KLE VK Institute of Dental Sciences	Approved	01/02/2020	No
<b>Regulatory Clearance Status from DCGI</b>	<b>Status</b>		<b>Date</b>	
	Not Applicable		No Date Specified	
<b>Health Condition / Problems Studied</b>	<b>Health Type</b>		<b>Condition</b>	
	Patients		Pupils	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Comparator Agent	Manual, K Files	The operator (Principal Investigator) shall perform all the procedures under Standard Operating Protocols. Local anesthesia will be given and rubber dam will be applied. Access cavity preparation will	

CLINICAL TRIALS REGISTRY - INDIA ICMR - National Institute of Medical Statistics		PDF of Trial CTRI Website URL - <a href="http://ctri.nic.in">http://ctri.nic.in</a>	
			to be done using round diamond bur followed by chemo-mechanical instrumentation using K files in Group A. After that obturation will be done by Zinc Oxide Eugenol followed by filling with the suitable restorative material. Patient will be recalled after a week for the placement of Stainless Steel crown.
	Intervention	Pediatric rotary files	The operator (Principal Investigator) shall perform all the procedures under Standard Operating Protocols. Local anesthesia will be given and rubber dam will be applied. Access cavity preparation will be done using round diamond bur followed by chemo-mechanical instrumentation using Pediatric Rotary files in Group B. After that obturation will be done by Zinc Oxide Eugenol followed by filling with the suitable restorative material. Patient will be recalled after a week for the placement of Stainless Steel crown.
Inclusion Criteria	<b>Inclusion Criteria</b>		
	Age From	4.00 Year(s)	
	Age To	8.00 Year(s)	
	Gender	Both	
	Details	<ol style="list-style-type: none"> <li>1. Children in the age group of 4-8 years.</li> <li>2. Children with Frank's behaviour rating scale of positive (+) and definitely positive (++).</li> <li>3. Teeth with the history of spontaneous pain.</li> <li>4. Radiographic evaluation of the tooth showing irreversible pulpitis.</li> <li>5. Primary molars with minimum two third of the root length.</li> <li>6. Patients who are willing to undergo treatment.</li> </ol>	
Exclusion Criteria	<b>Exclusion Criteria</b>		
	Details	<ol style="list-style-type: none"> <li>1. Children with systemic diseases and special health care needs.</li> <li>2. Non vital teeth having signs of abscess, sinus and fistula.</li> <li>3. Primary molars with pathologic mobility and evidence of root fracture, trauma.</li> <li>4. Primary molars having furcation radiolucency.</li> <li>5. Primary molars with calcified root canals.</li> <li>6. Primary molars with more than two third root resorption, internal resorption and developmental anomalies.</li> <li>7. Patients who are not willing to undergo treatment.</li> </ol>	
Method of Generating Random Sequence	Computer generated randomization		
Method of Concealment	On-site computer system		

CLINICAL TRIALS REGISTRY - INDIA ICMR - National Institute of Medical Statistics		PDF of Trial CTRI Website URL - <a href="http://ctri.nic.in">http://ctri.nic.in</a>	
Blinding/Masking	Participant and Investigator Blinded		
Primary Outcome	Outcome	Timepoints	
	Post operative pain	24 hours 48 hours 72 hours	
Secondary Outcome	Outcome	Timepoints	
	Reduction in pain, swelling and increasing the quality of life	After 24hours, 48 hours, 72hours	
Target Sample Size	Total Sample Size=60 Sample Size from India=60 Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials		
Phase of Trial	N/A		
Date of First Enrollment (India)	01/01/2021		
Date of First Enrollment (Global)	No Date Specified		
Estimated Duration of Trial	Years=0 Months=6 Days=0		
Recruitment Status of Trial (Global)	Not Applicable		
Recruitment Status of Trial (India)	Not Yet Recruiting		
Publication Details	None		
Brief Summary	<p>Primary teeth act as a natural space maintainer and guide the eruption of permanent teeth to their optimal position in the dental arch. The retention and preservation of the primary tooth in the dental arch in its normal function and free of pathology is of utmost importance. Therefore, it is of prime importance as a Pediatric Dentist to maintain the integrity of teeth in the dental arch till natural exfoliation takes place.<sup>1</sup> Paediatric dentistry is changing from surgical treatment planning to conserving primary teeth till their natural exfoliation occurs for proper occlusal guidance and also aid in mastication. Restoration is carried out in carious teeth involving enamel and dentine and pulp therapy in those which are showing pulpal and peri radicular involvement.<sup>2</sup></p> <p>Pulpectomy procedure consists of various steps out of which absolute chemo-mechanical preparation of the root canal system is a requisite for a successful endodontic treatment. Studies have shown higher frequency of post-endodontic pain following multiple visits as compared to single-visit endodontic treatments.<sup>3</sup></p> <p>Conventionally, manual K-files have proven to be a gold standard providing excellent tactile control and sharp, long-lasting cutting surfaces. Despite the widespread use of manual instrumentation for pulpectomy in primary teeth, there is incidence of post-operative pain due to linear filing motion.<sup>2</sup> The post-endodontic pain may be caused due to ongoing inflammatory processes or changes in the periapical tissue pressure post instrumentation.<sup>4</sup></p> <p>Although, K-files have aided in the pediatric endodontic treatment since ages and proved successful yet there is a need felt to introduce a newer filing system to reduce the incidence of post endodontic pain.<sup>5</sup> Rotary instruments were introduced to Paediatric dentistry by Barr et al in 2000. With the development of nickel-titanium (NiTi) rotary shaping systems in the recent past, a reduction in the timing and increased clinical efficacy has been seen.<sup>6</sup></p>		

**ANNEXURE III (a)**

**CONSENT FORM (ENGLISH)**

**KLE Academy of Higher Education and Research(KAHER)**

**K.L.E. V.K. Institute of Dental Sciences, Belagavi.**

**Department of Pediatrics and Preventive Dentistry**

“Comparative Evaluation of Post-operative Pain after Single Sitting Pulpectomy using Hand and Rotary Instrumentation in Primary Molars of Children – A Randomized Control Study.”

**Date:**

- I, the undersigned, authorize the performance upon my son/ daughter, Mst. / Miss ..... the advised treatment to be performed Dr. Nivedita Saxena under the direction of Dr. Shivayogi M Hugar.
- I consent to the administration of anesthetics as may be considered necessary or advisable by the doctor responsible for this service,
- I consent to the photographing or video recording of the operation or procedures to be performed including appropriate portions of my child’s body, for medical, scientific or educational purposes provided his/ her identity is not revealed by the pictures or by the descriptive texts accompanying them.
- For the purpose of advancing dental education I consent to the admittance of observers to the operating room.
- At any time if I don’t like I will quit from the study without any guarantee.
- I give my consent to publications and presentations of this study.
- The nature and purpose of the operation, possible alternative methods of treatment, the risk involved and the possibility of complications have been fully explained to me in my vernacular language. No guarantee or assurance has been given by anyone as to the results that may be obtained.

(Relation to the patient)

(Signature)

**ANNEXURE III (b)****CONSENT FORM (KANNADA)**

ಸಮ್ಮತಿ ಪತ್ರ

ಚಿಕ್ಕ ಮಕ್ಕಳ ದಂತ ವಿಭಾಗ

ಕೆ.ಎಲ. ಇ. ವಿಶ್ವನಾಥ್ ಕೆತ್ತಿ ದಂತ ಮಹಾವಿದ್ಯಾಲಯ

ಕೆ.ಎಲ. ಇ. ವಿಶ್ವವಿದ್ಯಾಲಯ ಬೆಳಗಾವಿ

ನಾನು ಸ್ತ್ರೀ / ಸ್ತ್ರೀಮತಿ ----- ಎಲ್ಲ ಮಾಹಿತಿಯನ್ನು ಪಡೆದುಕೊಂಡಿದ್ದೇನೆ ಮತ್ತು ನನ್ನ ಮಗ / ಮಗಳು -----  
 -----ವಯಸ್ಸು ----- ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸಲು ಅನುಮತಿಯನ್ನು ನೀಡಿ ಸಹಕರಿಸುತ್ತೇನೆ.

1. ನನ್ನ ಮಗ / ಮಗಳ ಬಗ್ಗೆ ಎಲ್ಲಾ ಮಾಹಿತಿ ಹಸರು ವಯಸ್ಸು, ಆರೋಗ್ಯ ದ ಬಗ್ಗೆ ಮಾಹಿತಿ ಕೊಡಲು ಒಪ್ಪುತ್ತೇನೆ.
2. ನನ್ನ ಮಗ / ಮಗಳ ಬಾಯಿಯ ತಹಾಸಜೆ ಹಾಗೂ ಚಿಕಿತ್ಸೆ ಮಾಡಲು ಸಹಕರಿಸುತ್ತೇನೆ.
3. ನನ್ನ ಮಗ / ಮಗಳ ಬಾಯಿಯ ಹುಳುಕು ಹಲ್ಲುಗಳನ್ನು ಸ್ವಚ್ಛಗೊಳಿಸಿ ಬೇರು ಸಾಲಿನ ಚಿಕಿತ್ಸೆ ಮಾಡಲು ಸಹಮತಿ ನೀಡುತ್ತೇನೆ
4. ನಾನು ತಜ್ಞರು ಕೊಟ್ಟಿರುವ ಸೂಚನೆಗಳನ್ನು ಪಾಲಿಸುತ್ತೇನೆ.
5. ಈ ಸಂಶೋಧನೆ ಯನ್ನು ಪ್ರಕಟಿಸಲು ಅನುಮತಿ ಕೊಡುತ್ತೇನೆ
6. ಭಾಗವಹಿಸಿ ದಕ್ಕೆ ಪ್ರತಿಯಾಗಿ ಏನೂ ಕೇಳುವಿಲ್ಲ.
7. ಈ ಚಿಕಿತ್ಸೆ ಯಲ್ಲಿ ಏನಾದರೂ ತೊಂದರೆಯಾದಲ್ಲಿ ಟ್ರನಸ್ಲರು ಎಲ್ಲಾ ಜವಾಬ್ದಾರಿಯನ್ನು ತೆಗೆದುಕೊಳ್ಳುತ್ತಾರೆ
8. ಯಾವುದೇ ಕಾರಣಕ್ಕಾಗಿ ನನ್ನ ಮಗ / ಮಗಳು ಭಾಗವಹಿಸಿದ್ದಲ್ಲಿ ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು
9. ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಗುಪ್ತವಾಗಿದಲಾಗುವುದು
10. ಈ ಸಂಶೋಧನೆ ಯಲ್ಲಿ ಭಾಗವಹಿಸಿರುವುದರಿಂದ ಯಾವ ಹಾನಿ/ ಅವಾಯ ಇಲ್ಲ.
11. ಬೇರೆ ಚಿಕಿತ್ಸೆ ಬಗ್ಗೆ ಮಾಹಿತಿ ಕೊಡಲಾಗುವುದು.

ನಾನು ಮೇಲೆ ತಿಳಿಸಿದ ಎಲ್ಲಾ ವಿಷಯವನ್ನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಅರ್ಥ ಮಾಡಿಕೊಂಡು ಸಹಿ ಮಾಡಿದ್ದೇನೆ

ದಂತ ವೈದ್ಯರ ಹೆಸರು : ಡಾ|| ನಿವೇದಿತಾ ಸ್ವನಾ

ಮಾರ್ಗದರ್ಶಕರು : ಡಾ || ಶಿವಯೋಗಿ ಮ. ಹೂಗಾರ್

ವಿಳಾಸ : ಚಿಕ್ಕ ಮಕ್ಕಳ ದಂತ ಚಿಕಿತ್ಸೆ ವಿಭಾಗ

ಕೆ.ಎಲ. ಇ. ವಿಶ್ವನಾಥ್ ಕೆತ್ತಿ ದಂತ ಮಹಾವಿದ್ಯಾಲಯ

ಬೆಳಗಾವಿ -10

ವಾಲಕರ ಹೆಸರು :

ವಾಲಕರ ಸಹಿ :

ಸಾಕ್ಷಿ ಹೆಸರು :

ಸಾಕ್ಷಿ ಸಹಿ

ದಿನಾಂಕ:

ಉರು :

**ANNEXURE III(c)****CONSENT FORM (MARATHI)****छोट्यामुलांचादंतउपचारविभाग**

काहेरके.एल.ई.वि.के. इन्स्टिट्यूटऑफडेंटलसायन्सेसबेळगावी  
 का.एल.ई विश्वविद्यालय बेळगावी  
 सम्मतीपत्र

- मीश्री/श्रीमती \_\_\_\_\_, हेमान्यकरतआहेकीमलामाझ्यामुलाचा / मुलीचा (नाव \_\_\_\_\_, वय \_\_\_\_\_ वर्ष)
- उपचारांबद्दलमाहितीदिलीआहेआणिमीडॉ. निवेदिता सक्सेना आणि शिवयोगी एम.हुगार ह्यांचाअभ्यासालापूर्णसम्मतीदेतआहे.
- मीमाझामुलाची/मुलीचीव्यक्तिकमाहितीजसेकी,नाव,वय,लिंग,पत्ता,मागीलवसध्याचीदंतउपचाराचीमाहितीवअन्यतपशीलदेण्याससहमतआहे.
  - मीदंतचिकित्सकह्यांनात्यांच्याअभ्यासासाठीपुर्णसहकार्पदिईन.
  - दंतचिकित्सकह्यांचाअभ्यासचालूअसताना,मीत्यांनीदिलेल्यासर्वसुचनांचेपालनकरीन.
  - मीदंतचिकित्सकह्यांनीसांगितलेल्यावेळेलावतारखेलात्यांच्याअभ्यासासाठीहजरराहीन
- पक्षांचामाहितीसाठी:-**
- दंतचिकित्सकह्यांच्याअभ्यासादरम्यानत्यांनीप्राप्तकेलेलीमाझीसर्वमाहितीवअभ्यासाचेपरिणाममाझीओळखनउघडताकुठल्याहीप्रकाशनातसादरकरावलामाझीपरवानगीआहे.
  - मीदंतचिकित्सकह्यांच्याअभ्यासाचेस्वरूपसमजलेआहेवमीत्यांनाआवश्कअसेलतेउपयोगकरण्यासपरवानगीदेतआहे.
  - मीदंतचिकित्सकह्यांच्याअभ्यासातमाझेसहकार्पदिल्याबद्दलकोणत्याहीपरताव्याचादावाकरणारनाही,त्यांचाअभ्यासकोणत्याहीएजन्सिमार्फतप्राप्पोजितकेलाअसेलतरीहीमीपरताव्याचादावाकरणारनाही. मीमाझ्यास्वतःच्याइच्छेनेह्याअभ्यासातसहभागीहोतआहे.
  - मीकोणत्याहीकारणास्तवअभ्यासातभागघेऊशकतनसीन,तरमीह्याअभ्यासातुनबाहेरपडुशकतो/शकते.
  - मीपुर्णशुद्धीतवमाझ्यामनाच्याउपस्थितीत,सर्वप्रक्रिावत्यांचेक्वचितहोऊशकणारेदुष्परिणामसमजुन,माझ्यामातृभाषेतह्याअभ्यासातसहभागीहोण्याससम्मतीदेतो/देते.

तारीख :

दंतवैद्यनाव :

रुग्णाचानाव :

पत्ता :

फोननंबर :

स्वाक्षरी:

स्वाक्षरी:

पालकनाव :

**ANNEXURE IV**

**ASSENT FORM**

**KLE Academy of Higher Education and Research.K.L.E.V.K. Institute  
of Dental Sciences, Belagavi.**

**Department of Pediatric and Preventive Dentistry**

We, Dr. Nivedita Saxena and Dr. Shivayogi M. Hugar are doing a study to evaluate the pain you may/may not feel after using the two different instrumentation techniques for cleaning your teeth root canal followed by filling your teeth with a medicament after which final restoration will be given. The entire procedure will be carried under the local anesthesia which ensures the painless treatment.

You can ask questions at any time that you might have about this study. Also, if you decide at any time not to finish, you may stop whenever you want. Signing this paper means that you have read this or had it read to you and that you want to be in the study. If you don't want to be in the study, don't sign the paper. Your parent(s) know that we are asking you to do these things. Remember, being in the study is up to you, and no one will be angry if you don't sign this paper or even if you change your mind later.

Signature of participant \_\_\_\_\_ Date \_\_\_\_\_

Signature of investigator \_\_\_\_\_ Date \_\_\_\_\_

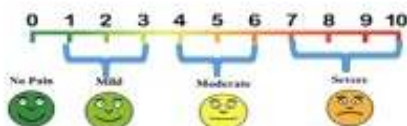
## ANNEXURE V

### PATIENT INFORMATION SHEET

#### KAHER'S KLE V.K. INSTITUTE OF DENTAL SCIENCES DEPARTMENT OF PEDIATRIC AND PREVENTIVE DENTISTRY

#### PATIENT INFORMATION SHEET

- I am conducting a study titled, Comparative Evaluation of Post-operative Pain after Single Sitting Pulpectomy using Hand and Rotary Instrumentation in Primary Molars of Children – A Randomized Control Study.
- I will be doing a common procedure in which removal of decayed tooth will be done. Two different instrumentation techniques for cleaning your teeth root canal will be used one of which is the commonly used technique and another advanced technique followed by filling your teeth with a medicament after which final restoration will be given using Stainless steel crown.
- The entire procedure will be carried under the local anesthesia which ensures the painless treatment. All the procedures are carried out on the same day.
- Analgesics are prescribed and you have to take it only if the pain occurs. You have to record the Post-operative pain on 4 point Visual Analogue Scale at 24, 48 and 72 hours. The pain intensity rating is explained to you.



Pain Intensity	Interpretation
None	No pain
Mild	Any discomfort of any duration that does not require analgesics
Moderate	Pain that requires and is relieved with analgesics
Severe	Any pain that is not relieved with analgesics

Sl. No.	OPD No.	Tooth No.	Age	Sex	Post-Operative Pain Evaluation on Visual Analogue Scale		
					24 hours	48 hours	72hours

- I consent to the photographing or video recording of the operation or procedures for medical, scientific or educational purposes provided his/ her identity is not revealed by the pictures or by the descriptive texts accompanying them.
- For the purpose of advancing dental education, I consent to the admittance of observers to the operating room.
- At any time if I don't like I will quit from the study without any guarantee.
- I give my consent to publications and presentations of this study.
- I, undersigned hereby provide my consent for the same.

Signature	Signature	Signature
Name of the Parent /Guardian Mobile No: Email Id:	<b>Dr. Nivedita Saxena</b> Principal Investigator	<b>Dr. Shivayogi M. Hugar</b> Guide, Prof. And HOD Department Of Pediatric And Preventive Dentistry

**ANNEXURE VI**

**CASE-HISTORY FORM**

**KLE Academy of Higher Education and Research.K.L.E.V.K. Institute of Dental  
Sciences, Belagavi.**

**Department of Pediatric and Preventive Dentistry**

Name: \_\_\_\_\_ Sex: \_\_\_\_\_  
Age: \_\_\_\_\_ Parent/Guardian: \_\_\_\_\_  
Address: \_\_\_\_\_ Contact Number: \_\_\_\_\_

**HISTORY:**

Chief Complaint:

History of Present Illness:

Relevant Medical History:

Previous Dental History:

**NATAL HISTORY:**

**POST NATAL HISTORY:**

**GENERAL EXAMINATION:**

**INTRA-ORAL EXAMINATION**

Soft Tissue Examination:

Hard Tissue Examination:

No of Teeth:

Decayed Teeth:

Filled Teeth:

Missing Teeth:

Root Stumps:

Mobility:

**PROVISIONAL DIAGNOSIS:**

**INVESTIGATION:**Intra-oral periapical radiograph

**FINAL DIAGNOSIS:**

**TREATMENT PLANNING:**

DMFT Index



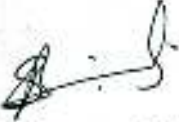
17	16	15	14	13	12	11	21	22	23	24	25	26	27
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
47	46	45	44	43	42	41	31	32	33	34	35	36	37

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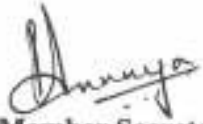
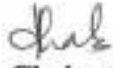
55	54	53	52	51	61	62	63	64	65
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
85	84	83	82	81	71	72	73	74	75

**ANNEXURE VII:**

**BIOSTATISTICS CERTIFICATE**

	<p>KLE <b>VISHWANATH KATTI</b> INSTITUTE OF DENTAL SCIENCES, A Constituent college of K.L.E. Academy of Higher Education and Research J.N.M.C. Campus, Nehru Nagar Belagavi -590010 Karnataka, India. Department of Pediatric and Preventive Dentistry</p>	
<p><b><u>BIOSTATISTICS CLEARANCE CERTIFICATE</u></b></p>		
<p>This is to certify that the Biostatistics part of Dissertation / Research work of <b>Dr. Nivedita Saxena</b>, Postgraduate student under the guidance of <b>Dr. Shivayogi M. Hugar</b>, Professor and Head, Department of Pediatric and Preventive Dentistry entitled, "Comparative Evaluation of Post-Operative Pain after Single Sitting Pulpectomy using Hand and Rotary Instrumentation in Primary molars of Children – A randomised control study" has been done under my guidance and considered satisfactory.</p>		
<p><b>Place:</b> Belagavi <b>Date:</b> 15.09.2021</p>	<p> Name &amp; Signature of Biostatistician (<b>Dr. S.B. Javali</b>) USM-KLE IMP Belagavi.</p>	

**ANNEXURE VII:****PLAGIARISM REPORT**

<b>Scientific Correspondence and Review Committee</b>	
<b>KLE VK Institute of Dental Sciences</b>	
	
<b>A Constituent Unit of KLE Academy of Higher Education and Research</b> <b>(Deemed-to-be-University u/s 3 of the UGC Act, 1956)</b> Nehru Nagar, Belagavi - 590 010, Karnataka State	
Accredited 'A' Grade by NAAC (2nd Cycle)	Placed in Category 'A' by MHRD (GoI)
☎: 0831-2470362 FAX: 0831-2470640	Web: <a href="http://www.kledental-bgm.edu.in">http://www.kledental-bgm.edu.in</a> E-mail: <a href="mailto:principal@kledental-bgm.edu.in">principal@kledental-bgm.edu.in</a>
Date : 26-10-2021	Serial No. : 063
<b>PLAGIARISM CHECK REPORT</b>	
Name of the Applicant : DR. NIVEDITA SAXENA	
UG / PG / Ph.D / Staff : POST GRADUATE	
Batch & Year : 2019-22	
Department : PEDIATRIC AND PREVENTIVE DENTISTRY	
The soft copy of <u>Research Work / Manuscript</u> by <u>DR. NIVEDITA SAXENA</u> entitled <u>"COMPARATIVE EVALUATION OF POST-OPERATIVE PAIN AFTER</u> <u>SINGLE SITTING PULPECTOMY USING HAND AND ROTARY</u> <u>INSTRUMENTATION IN PRIMARY Molars OF CHILDREN -</u> <u>A RANDOMIZED CONTROL STUDY</u> under the guidance of <u>DR. SHIVAYOGI HUGAR</u> .....has been submitted for Anti-Plagiarism check to the Scientific Correspondence & Review Committee of KLE VK Institute of Dental Sciences using "Turn-it-in" software.	
The scan has been carried out and the scanned output reveals a Similarity Index of .....2.....%, which is <u>within</u> / <u>not within</u> the acceptable limits of 10% as per the UGC guidelines.	
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