COMPARATIVE EVALUATION OF POST - OPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC TREATMENT USING PROTAPER NEXT AND PROTAPER GOLD ROTARY FILE SYSTEMS: A RANDOMIZED CLINICAL TRIAL

By

DR. CHAITRA SURESH BAKARE

REG. NO. IE0218002

Dissertation

Submitted to

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH (KLE UNIVERSITY'S)

KLE VK INSTITUTE OF DENTAL SCIENCES,

Belagavi, Karnataka

In partial fulfillment of the requirement for the degree of

MASTER OF DENTAL SURGERY

In

CONSERVATIVE DENTISTRY AND ENDODONTICS

(BRANCH – IV)

Under the guidance of

Dr. SONAL B. JOSHI M.D.S

DEPARTMENT OF CONSERVATIVE DENTISTRY AND ENDODONTICS

KLE VISHWANATH KATTI INSTITUTE OF DENTAL SCIENCES, BELAGAVI, KARNATAKA

2018-2021

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

(KLE UNIVERSITY'S) KLE VK INSTITUTE OF DENTAL SCIENCES, BELAGAVI, KARNATAKA

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation/thesis entitled ***"COMPARATIVE EVALUATION OF POST - OPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC TREATMENT USING PROTAPER NEXT AND PROTAPER GOLD ROTARY FILE SYSTEMS: A RANDOMIZED CLINICAL TRIAL"*** *is a bonafide and genuine research work carried out by me under the guidance of* ***Dr. SONAL B. JOSHI*** *M.D.S Professor & Dean, Department of Conservative Dentistry and Endodontics, KLE's Vishwanath Katti Institute of Dental Sciences, K.L.E University, Belagavi.*

Date:

Place: Belagavi

DR. CHAITRA S BAKARE

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

(KLE UNIVERSITY'S) KLE VK INSTITUTE OF DENTAL SCIENCES, BELAGAVI, KARNATAKA

CERTIFICATE BY THE GUIDE

This is to certify that the dissertation entitled ***"COMPARATIVE EVALUATION OF POST - OPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC TREATMENT USING PROTAPER NEXT AND PROTAPER GOLD ROTARY FILE SYSTEMS: A RANDOMIZED CLINICAL TRIAL"*** *is a bonafide research work done by* ***Dr. CHAITRA S BAKARE,*** *Post-graduate student in partial fulfillment of the requirement for the degree of* ***MASTERS IN DENTAL SURGERY*** *in Conservative Dentistry and Endodontics.*

Date :

Place : Belagavi

Dr. SONAL B. JOSHI **M.D.S**
Professor & Dean,
Department of Conservative Dentistry and Endodontics,
KLE's V.K. Institute of Dental Sciences,
K.L.E. University, Belagavi.

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

(KLE UNIVERSITY'S) KLE VK INSTITUTE OF DENTAL SCIENCES, BELAGAVI, KARNATAKA

ENDORSEMENT BY THE HEAD OF DEPARTMENT, PRINCIPAL OF THE INSTITUTION

This is to certify that the dissertation entitled ***"COMPARATIVE EVALUATION OF POST - OPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC TREATMENT USING PROTAPER NEXT AND PROTAPER GOLD ROTARY FILE SYSTEMS: A RANDOMIZED CLINICAL TRIAL"*** *is a bonafide research work done by* ***Dr. CHAITRA S BAKARE****, post graduate student under the guidance of* ***Dr. SONAL B. JOSHI*** ***M.D.S*** *Professor & Dean, Department of Conservative Dentistry and Endodontics, KLE's Vishwanath Katti Institute of Dental Sciences, Belagavi.*

Head of Department
Dr. PREETI DODDWAD **M.D.S**
Professor & Head,
Department of Conservative Dentistry and Endodontics,
KLE's V.K. Institute of Dental Sciences,
Belagavi.

Date:
Place: Belagavi

Principal
Dr.(Mrs) ALKA KALE **M.D.S, Ph.D**
Principal,
KLE's V. K. Institute of Dental Sciences,
Belagavi.

Date :
Place : Belagavi

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

(KLE UNIVERSITY'S) KLE VK INSTITUTE OF DENTAL SCIENCES, BELAGAVI, KARNATAKA

COPYRIGHT

DECLARATION BY THE CANDIDATE

*I hereby declare that **K.L.E University, Belagavi, Karnataka** shall have the rights to preserve, use and disseminate this dissertation/thesis in print or electronic format for academic/research purpose.*

Date:

Place: Belagavi

DR. CHAITRA S BAKARE

UNDERTAKING

I, **Dr. Chaitra S Bakare**, hereby declare that the information and data mentioned in my thesis entitled **"COMPARATIVE EVALUATION OF POST - OPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC TREATMENT USING PROTAPER NEXT AND PROTAPER GOLD ROTARY FILE SYSTEMS: *A RANDOMIZED CLINICAL TRIAL*"** belongs to me and is original.

I am aware of the definition of plagiarism as detailed below:

- An act or instance of using or closely imitating the language and thoughts of another author without authorization and the representation of that author's work as one's own, as by not crediting the original author.
- A piece of writing or other work reflecting such unauthorized use or imitation.
- The deliberate or reckless representation of another's words, thoughts or ideas as one's own without attribution in connection with submission of academic work, whether graded or otherwise.

I hereby declare that the thesis prepared by me is original one and does not involve plagiarism anywhere. In case at later stage it is found that I have indulged in plagiarism, then I am solely responsible for the same and the Institution is at liberty to take any disciplinary action against me including cancellation of dissertation or any other penalties imposed by the University.

Place: Belagavi **Dr. Chaitra S Bakare**

Date: _____

This dissertation is dedicated to

ALMIGHTY GOD,

My Parents,

&

My Family Members

ACKNOWLEDGEMENT

*To begin with, I bow my head in gratitude to **Almighty God**, without whose blessings, I could not have reached so far in my life, without his grace and blessings no endeavour of mine would ever be a success.*

*I would have not finished this dissertation without the unconditional support of my family who has always been there for me whenever I needed them, the encouragement they give to me and their love to empower me all the time. I thank my parents **Dr. Suresh Bakare and Dr.Mrs. Asha S Bakare and my dear sister Ms. Bhavika Bakare & dear brother Mr. Abir Bakare** to whom I owe every success and joy of my life and I humbly acknowledge that everything I am today is because of their sacrifice, love and support.*

A sense of satisfaction overcomes me with the completion of my dissertation, more so I feel a sense of gratitude towards all my mentors and well-wishers whom I wish to acknowledge.

*I am at a loss of words in expressing my heartfelt and deep sense of gratitude, appreciation and profound indebtedness to my revered teacher and guide **Dr. Sonal B. Joshi** **M.D.S.**, Professor & Dean, Department of Conservative Dentistry and Endodontics, K.L.E.S's Institute of Dental Sciences, Belagavi. I humbly acknowledge her loving guidance, fervent personal interest, critical evaluation, scientific approach, vital suggestions and vast experience. Her timely advice, constructive guidance, encouragement during this study and for always being a continuous source of inspiration and motivation have helped me at every step in performing this study. Her unlimited patience and meticulous supervision at every step has enabled me to*

complete my dissertation and has also helped me tremendously during my post graduate career.

My sincere thanks to ***Dr. Preeti Doddwad*** ***M.D.S.*****, *HOD & Professor*, *Department of Conservative Dentistry and Endodontics, K.L.E. VK Institute of Dental Sciences, Belagavi for giving enthusiastic encouragement, persistent support and insurmountable help during my post-graduation.*

I would also like to thank ***Dr. (Mrs.) Alka D. Kale*** ***MDS, Ph.D*** *(Principal), K.L.E.S's Institute of Dental Sciences, Belagavi, who has been a constant source of help and inspiration.*

I would like to express my solemn gratitude, respect & special debt of thanks to my beloved teachers ***Dr. Anand C Patil*** ***M.D.S.*** *Professor,* ***Dr. Avinash Patil*** ***M.D.S*** *Reader,* ***Dr. Sunita Shivanand*** ***M.D.S*** *Reader,* ***Dr. Neha Dhaded*** ***M.D.S*** *Reader,* ***Dr. Shavina Patil*** ***M.D.S.*** *Reader,* ***Dr. Suresh Shenvi*** ***M.D.S*** *,* ***Dr. Sneha Patil*** ***M.D.S,*** ***Dr. Aniket Chavan*** ***M.D.S,*** ***Dr. Mateen Peerzade*** ***M.D.S*** **, Dr. Neeraj Godbole** ***M.D.S*** **, Dr. Vaidehi Dhopavkar** ***M.D.S*****, Dr. Olivia Banerjee** ***M.D.S*** *who have unselfishly devoted their time and patience whenever needed. Their colossal contribution all through these years will never be history.*

I express my sincere thanks to ***Dr. Javali,*** *Statistician,* ***Mr. Bagalkoti,*** *store incharge and the* ***non-teaching staff*** *for their help during the course of my study.*

I would also like to thank my seniors and confidants ***Dr. Carmine Pereira and Dr. Akash Debray*** *for always being there for me. I extend my heartfelt gratitude to my junior & friend* ***Dr Priyanka Kore*** *for always being helpful and proof reading my dissertation.*

I would also like to thank my senior, best friend and confidant ***Dr.Ankita Amonkar*** *for being the driving force behind my thesis completion.*

It gives me immense pleasure to extend my heartfelt gratitude to my senior friends ***Dr. Pratik Haldankar, Dr. Neha Deshpande****,* ***Dr. Suraj S,*** *my colleagues****, Dr. Ashish, Dr. Deepti, Dr. Felbin*** *and my junior colleagues* ***Dr. Shefali, Dr. Mahima, Dr. Abhijeet*** *for their help and co-operation..*

My heartfelt thanks to my dear friends ***Dr. Vishal Tathed, Dr. Shrutika Salkar & Dr. Bhavna Sharma, Dr. Rohita P, Dr. Harshali L*** *for standing beside me at all times, for providing the light moments in those good and bad times.*

I thank my best friend and fiancé ***Mr.Sanket Keskar*** *for being my moral support and having immense faith in me.*

I thank ***Mr. Anand*** *&* ***Mr. Arun*** *of Sri Vighneswara Associates, Xerox & DTP Centre, for the formatting, printing and binding of my dissertation.*

Thank you, one and all.

Dr. Chaitra Bakare

Date:

Place : Belagavi.

ABSTRACT

Introduction: Postoperative pain and swelling are the unfavourable sequalae of endodontic treatment if debris produced while instrumentation gets expulsed beyond periapex. The amount of debris varies with every different instrumentation technique and design characteristics. Among the various advanced technologies and instruments available as of today are the thermal treated alloys and also the offset centre of mass. Examples of these designs are PTG & PTN respectively. In-vitro studies reported PTN expulses less debris than PTG. Nonetheless, in clinical scenario's, the periapex tissues could act as natural barrier, the response may be affected due to hosts immunity response. Therefore, the aim of the study is to evaluate and compare post-operative pain following single visit endodontic treatment using PTN & PTG rotary file systems.

Methodology: 70 patients fulfilling the inclusion and exclusion criteria were assigned in two groups, they were to be instrumented by PTN & PTG. Single visit endodontic treatment was done in which pain was assessed by the modified VAS scale at time intervals 6hrs, 24hrs, 48hrs, 72hrs. Various variables of age & sex were also compared in between the two. Wilcoxon matched pairs test was used for intragroup pair comparison. Mann-Whitney U test was used for intergroup pairwise comparison of VAS scores at different points. Chi-square test was used for evaluating association between variables. Independent t-test was used for evaluation of time required for instrumentation .

Results: Post-operative pain was significantly higher in PTG group than PTN group. Greatest pain was observed at 6hrs reducing as the time elapsed. No pain was present beyond that.

Conclusion: The postoperative pain was significantly higher in patients undergoing canal instrumentation with ProTaper Gold rotary instruments compared with the ProTaper Next rotary instruments

Key words: Postoperative pain, ProTaper Gold, ProTaper Next, Single visit endodontics.

LIST OF ABBREVIATIONS

NiTi	Nickel – Titanium
NaOCl	Sodium Hypochlorite
K file	Kerr file
EDTA	Ethylenediamine Tetraacetic acid
^{0}	Degree
#10	Tip diameter – 0.10mm
#15	Tip diameter – 0.15mm
mm	Millimetre
%	Percentage
i.e	That is
ISO	International Organization for Standardization
PTG	ProTaper Gold File system
PTN	ProTaper Next file system
Sx	ProTaper Gold orifice opener
S1	ProTaper Gold Shaping file 1
S2	ProTaper Gold Shaping file 2
F1	ProTaper Gold Finishing file 1
F2	ProTaper Gold Finishing file 2
X1	ProTaper Next Shaping file 1
X2	ProTaper Next Shaping file 2
EAL	Electronic Apex Locater
WL	Working length

M	Male
F	Female
VAS	Visual Analogue Scale
Post op	Post operative
min	Minutes
hrs	Hours
yrs	Years
<	Less than
>	Greater than
=	Equal to
Fig.	Figure
vs.	Versus
IOPAR	Intraoral periapical radiograph

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ANNEXURES

INTRODUCTION

"The science of today is the technology of tomorrow."

Furtherance in technology and medicine has prompted a surge in the lifespan of individuals.[1] In this day and age, extraction of teeth has become sporadic as it is contemplated as a trauma to the body and endodontic interceding as a promising alternative.[2] Technological growth in the form of development of finer instruments, materials, rigorous knowledge of internal tooth anatomy, thorough and updated modern techniques and treatment modalities all put together could not promise a complication-free endodontic treatment.[3]

One of the most well-known endodontic complication is the unpleasant commencement of post-operative pain which can occur in a few hours to days after treatment. This post-operative pain is an unappealing experience for both clinicians as well as patients. The ambit of incidence for this post-operative pain in patients is delineated to be 3% - 58%.[4] The occurrence of the post-endodontic pain is polyetiological which can be depending on various operator dependent factors which can be; mechanical, chemical and microbial factors. [8] Also, the host depending factors could be due to existence of pre-treatment pain or trauma or immunity of the host. [5] Of which the mechanical factors such as excessive instrumentation, periapical extrusion of debris / root filling materials has been found to be one of the most prudent causes of post-treatment pain. [9]

Various studies have found co-relation between the method and type of instrumentation used for endodontic treatment and post-endodontic pain.[10]The sum total of debris extruded by each instrumentation technique and / or instrument is

different which depends on various physical and mechanical properties of the material. [10]

Although the endodontic instruments are refrained from crossing the apical foramen, the entirety of instrumentation procedures dispose to expulse dentinal flakes, pulpal tissue residues, necrosed tissues, microorganisms and irrigants into the region of periapex. An alliance was depicted between apically expulsed materials, peri-radicular inflammation and development of post-operative pain and flare-ups.[112]

Owing to the "wave of technological evolution" of endodontic instruments metallurgical advancement occurred from Stainless Steel instruments to Rotary NiTi instruments, which is the mainstream of instrumentation systems today.

According to the investigations by Reddy and Hicks collating the effect of manual and rotary NiTi instrumentation process, the latter caused debris expulsion into the periapical area causing an inflammatory reaction.[10]

Rotary NiTi since its introduction has been under continuous evolution for advancing the properties of the endodontic materials and making endodontic treatment an effortless procedure.

It improved the speed and efficiency of root canal treatment. The beneficial properties of super elasticity and shape memory are the reasons it has succeeded in endodontics. The current developments of controlled memory wire (CM NiTi™), M-wire, R-phase wire and the Gold-wire represent the modern range of NiTi alloys with improved flexibility and fatigue resistance.[13]

NiTi instruments have also experienced a steady transformation in the radial land, helical angle and pitch, cross sectional shape and tip design in search of better clinical effectiveness. Most of the new-age instruments have radial lands to allow the instrument to remain centered, a non-cutting tip to guide the instrument and variable pitch and taper for increased safety. Changes in cross section transpired to decrease the apical expulsion of debris.[14]

A cliché 360-degree rotary motion was originally used in NiTi files. Of late innovations have also occurred in this aspect resulting in commencement of reciprocating motion. Not only this motion resulted in good resistance to instrument separation and shaping ability,[15] but has also shown more apical expulsion of debris.[16]

Last few decades have seen the unravelling of various hybrid techniques, enormous number of file brands and sequences that can be vouched for shaping the canals.[17]

One of the more commonly used Rotary NiTi by dental practitioners is ProTaper Universal (PTU) byDentsply-Maillefer (Ballaigues, Switzerland). Its disadvantages include the use of additional number of files required for preparation, increased learning curve, greater chances of instrument fatigue[17] and exorbitant apical extrusion of debris.[18]

The current 5th generation of shaping files have the center of mass and/or the center of rotation at an offset. This very design, in its motion, produces a snake like swaggering type of motion that traverses through the operative length of the file keeping low the engagement of file to the root dentin. As well as the progressively tapered design of ProTaper Universal (PTU) file is in with the ProTaper Next

(Dentsply-Maillefer, Ballaigues, Switzerland) which is an example of this generation of file systems[14]. Fabricated through M-wire technology and thermal treatment process that delineated increase in flexibility and resistance to cyclic fatigue.

From the third generation of Rotary systems ProTaper Gold (PG) (PG; Dentsply, Tulsa Dental Specialties, Tulsa, OK, USA)" was launched. PG rotary files are considered as a twin to ProTaper Universal (PU) (PU; DentsplyMaillefer, Ballaigues, Switzerland), as the PG was developed with proprietorial advanced metallurgy with two-stage distinct transformation behavior and elevated austenite finish temperature for advanced flexibility. It has a formulaic progressively tapered design that asserts to ameliorate the cutting efficiency and safety.[113]

Literature has evinced that all instruments expel debris apically during instrumentation, the responsibility is on opting for a file system which reduces or eliminates the apically extruded debris.[11]

In-vitro studiesconcluded that the ProTaper Next (PTN) extruded comparatively low amount of debris as to the ProTaper Gold file system.[18] Few additional *in-vitro* studiesconcluded that the ProTaper Gold (PTG) extruded lesser debris to conventional and commonly used ProTaper Universal file system.[114]

Nonetheless, in clinical scenarios, tissues at the apical periphery behave as a natural hurdle, positive and negative pressure at the apex, normal or necrosedperiapical tissues and immature root growth can affect debris expulsion in the periapical region.Also, the host immune response could influence the predisposition of postoperative pain.[20]A randomized clinical trial assessing the two

above mentioned systems with regards to the postoperative pain was aimed for as it provides high level of support for evidence based clinical practice.[21]

Patients can be treated in a single visit endodontic treatment or multiple visits. Patients are inclined towards single visit endodontic treatment owing to curtailed number of operative procedures, a nil chance of interappointment leakage, lesser time, cost effectiveness and diminished postoperative pain. [22, 23]

Hence, this study aims at evaluating and comparing the post - operative pain after single visit endodontic treatment using ProTaper Gold and ProTaper Next rotary file systems.

AIM AND OBJECTIVES

AIM OF THE STUDY

To evaluate and compare the post - operative pain after single visit endodontic treatment using ProTaper Gold and ProTaper Next rotary file systems in a randomized clinical trial.

OBJECTIVES OF THE STUDY

1) To evaluate the incidence of post - operative pain after single visit endodontic treatment using ProTaper Next and ProTaper Gold rotary file systems, at 6, 24, 48 and 72 hours using Visual Analogue Scale.
2) To evaluate the intensity of the post - operative pain after single visit endodontic treatment using ProTaper Next and ProTaper Gold rotary file systems, at 6, 24, 48 and 72 hours using Visual Analogue Scale.
3) To compare the incidence of the post - operative pain after single visit endodontic treatment using ProTaper Next and ProTaper Gold rotary file systems, at 6, 24, 48 and 72 hours using Visual Analogue Scale.
4) To compare the intensity the post - operative pain after single visit endodontic treatment using ProTaper Next and ProTaper Gold rotary file systems, at 6, 24, 48 and 72 hours using Visual Analogue Scale.
5) To evaluate and compare the association of variables (age and sex) between the groups.
6) To evaluate and compare the time required for instrumentation of the canals in both groups.

RESEARCH HYPOTHESIS

NULL HYPOTHESIS

There will be no difference in the post - operative pain after single visit endodontic treatment using ProTaper Next and ProTaper Gold rotary file systems.

ALTERNATE HYPOTHESIS

There will be a difference in the post - operative pain after single visit endodontic treatment using ProTaper Next and ProTaper Gold rotary file systems.

REVIEW OF LITERATURE

1. A study reported that various chemical, mechanical as well as microbial injury could cause pain and flare ups after an endodontic procedure. This pain is reportedly due to change in the type of microbes or their environmental conditions or any secondary infection.[115]

2. A study compared the shaping ability of PTU, PTN, BT-Race, Mtwo on 80 root canals with curvatures ranging from 25-39°. The study drew an inference that BT-Race lead to more canal straightening than others. As well as there was no significant difference with regards to canal transportation. The time required for instrumentation with PTN was the least.[106]

3. Another study comparing the debris expulsion apically by PTG, PTN, PTU and Reciproc groups in curved canals summarized that PTU group had significantly higher expulsion of debris. The debris expulsed was higher in PTG than in PTN and no difference in the PTN and Reciproc group.[114]

4. A review states the benefits of NiTi Rotary systems and their unique properties of superelasticity and shape memory. The effect of different tapers, shapes, cutting edges.[116]

5. A study reported by Genet et al about the various preoperative and operative factors related to pain after the initial endodontic treatment and found direct proportion to the presence of pain ante-treatment, radiolucency appreciable up to 5mm, the quantity of root canals of the tooth treated; women disclosed more postoperative pain than men.[75]

6. A study has observed that the prevalence and gravity of post endodontic pain is higher in teeth with vital pulps than teeth with necrosed or retreated teeth.[117]

7. A longitudinal prospective study investigated the frequency of post-treatment pain during root canal treatment and the factors influencing it. The researchers deducted that the frequency of post-treatment pain was high and the factors influencing it included pre-treatment pain, kind of tooth, systemic steroid therapy and preoperative swelling.[5]

8. A randomized clinical trial using three different rotary instrumentation systems on post treatment pain inferred that ProTaper had greater incidence of pain than the Mtwo and K3 group. The less PIP could be due to the S-shaped profile section of Mtwo system. This S-shaped core provides for greater space for debris accumulation and removal and lesser expulsion thereby reducing PIP. [118]

9. A randomized clinical trial using two different rotary instrumentation of PTN and PTU drew a conclusion that PTN caused decreased post-treatment pain than PTG due to its offset center of rotation and only two-point contact of the instrument with the canal walls. This decreased the debris expulsion and thereby postoperative pain.[119]

10. A CBCT based study comparing the canal shaping ability of PTG and PTU reported that both the systems had similar canal shaping abilities and there were no significant differences in the canal centering, transportation and amount of dentin being removed.[120]

11. An in-vitro study compared the debris expulsion in the apical area between PTU, PTG and Twisted File Adaptive and drew the inference that PTG and Twisted file Adaptive systems expulsed lesser debris than PTU systems. The TFA system uses continuous and reciprocating motion during canal preparation which increases debris eradication and flexibility allowing the file to adjust inside the canal depending on the torsional forces in the canal. (Chaudhary)

12. A study was conducted to compare the incidence, degree, and length of postoperative pain in 300 endodontically treated teeth, with and without apical patency, in relation to some diagnostic factors (vitality, existence of ante-operative pain, group). It was deducted that the maintenance of apical patency does not contribute to the incidence, degree, or duration of postoperative pain when considering all variables together.[24]

13. A randomized controlled trial was conducted to compare the incidence and intensity of post-obturation pain after single or dual visit root canal treatment (RCT) on anterior teeth with vital pulps and a single root and canal. It was found that the episodes and potency of post-obturation pain experience following one- or two-visit RCT on teeth with vital pulps and a single canal were not significantly different.[25]

14. A study was done to investigate and compare the postoperative pain after single visit root canal treatment on vital teeth using three different obturation techniques. The techniques compared include cold lateral compaction of guttapercha, thermafil technique and backfill-thermafilobturation technique. They concluded that postoperative pain was significantly associated with the

obturation techniques used, with thermafil technique producing higher levels of discomfort.[26]

15. A prospective randomized clinical study investigated the familiarity of post-treatment pain after one visit root canal treatment and measured the influence of factors affecting the pain experience. It was concluded that the presence of post-operative pain was low (4%). The principal prognostic determinants of post-treatment pain were: senileage, female, lower arch teeth, and existence of pre-operative pain. The vital condition of the tooth fails to affect the amplitude and frequent occurrence of post-obturation pain.[21]

MATERIALS AND METHODS

The study "Comparative evaluation of post-operative pain after single visit endodontic treatment using ProTaper Next and ProTaper Gold rotary file systems-A randomized clinical trial"was approved by the Research and Ethical Committee, KLE University's VishwanathKatti Institute of Dental Sciences (Reg. No 906; Dated: 30th October 2014) (Annexure I) and was conducted in the Department Of Conservative Dentistry and Endodontics, KAHER's V.K. Institute of Dental Sciences, Belagavi, Karnataka.

ARMAMENTARIUM USED IN THE STUDY:-

- Electric pulp vitality tester (ParkellInc., Edgewood, NY)
- Rubber dam kit (Hygienic, Coltene-Whaledent)
- Mouth mirror (GDC®, Germany)
- Probe (GDC®, Germany)
- Tweezer (GDC®, Germany)
- DG- 16 probe (GDC®, Germany)
- Spoon excavator (GDC®, Germany)
- Disposable needles and syringes (Unolok, Hindustan syringes, India)
- Disposable saliva ejector
- Airotor (NSK *PANA AIR*)
- Endo access bur (Dentsply-Maillefer, Ballaigues, Switzerland)
- Endo Z bur (Dentsply-Maillefer, Ballaigues, Switzerland)
- Mini Endo block (Dentsply-Maillefer, Ballaigues, Switzerland)
- Stainless Steel K- files # 10, 15, 20 (Mani Inc., Tochigi, Japan)

- Rotary ProTaper Gold Files (Dentsply-Maillefer, Ballaigues, Switzerland)- Sx -F2
- Rotary ProTaper Next Files (Dentsply-Maillefer, Ballaigues, Switzerland)- X1, X2
- CanalPro2 (Coltene/ Whaledent, New York, USA)

MATERIALS USED IN THE STUDY:-

- Local anesthetic agent – 2% lignocaine with 1:80,000 adrenaline(Xicaine 30ml. ICPA Health Products Ltd.Ankleshwar, Gujarat, India)
- Irrigants
    - Normal Saline (0.9% w/v) (Amanta healthcare Ltd. Gujarat, India)
    - Sodium Hypochlorite 3% (Vishal Dentocare Pvt Ltd., Ahmedabad, India)
    - 17% Di-sodium edetate solution (Canalarge; Ammdent, Chandigarh, India)
- Lubricant - EDTA gel 15% (Well-Prep, Vericom, Korea)
- 30% w/v Hydrogen Peroxide (Thermo Fisher Sci India Pvt. Ltd., Mumbai, India)
- 5% w/v Povidine Iodine (Sun Pharmaceutical Ind. Ltd., Mumbai, India)
- Sodium Thiosulphate (Ranbaxy Fine Chemicals Limited, New Delhi, India)
- Sterile cotton
- IOPA Films (Carestream Health France, Noisy-Le-Grand Cedex, France)
- Paper points (DiaDent MMPP, DiaDent Group International, Korea)
- Guttapercha (ProTaper / ProTaper Next matching guttapercha points)
- AH Plus® Sealer "(DentsplyDeTrey, Konstanz, Germany)"
- Cavit G (3M ESPE Dental-Medizin GmbH Co, Seafeld, Germany)
- Tab Ibuprofen 400mg (Abbott India Ltd.)

METHODOLOGY

Seventypatients, taking into account 10% dropouts if present, requiring endodontic treatment on permanent maxillary premolar teeth in accordance to the inclusion and exclusion criteria were selected for the study from the regular pool of patients presenting to the Department of Conservative Dentistry And Endodontics, KLE VishwanathKatti Institute of Dental Sciences, Belagavi.The procedure was explained to the patient in his/her own language and a written informed consentwas obtained (Annexure II).

INCLUSION CRITERIA:-

1. Patients requiring endodontic treatment of upper arch premolar teeth with two root canals, diagnosed clinically as vital using pulp sensitivity tests.
2. Patients in the age range of 18-50 years.
3. Patients with non-contributory medical history.
4. Teeth with no pre-operative pain
5. Teeth with adequate coronal structure.

EXCLUSION CRITERIA:-

A. PATIENT SPECIFIC:

1. Patients who refuse to consent for the procedure.
2. Patients with any systemic diseases, pregnancy or immuno-compromised conditions.
3. Patients on any antibiotic therapy in the recent 3 months
4. Patients on any analgesic drugs in the past 7 days
5. Patients allergic to lignocaine in 1:80,000 concentration adrenaline
6. Patients allergic to Ibuprofen
7. Patients requiring endodontic treatment of two or more teeth ipsilaterally

B. SPECIFIC TO DIAGNOSIS:

1. Teeth with acute apical periodontitis
2. Teeth with acute periapical abscess
3. Teeth with periapicalradiolucencies of diameter greater than 0.5 cm (5 mm)
4. Teeth with an inflammatory exudate draining through the canal.
5. Necrotic painful teeth with absence of sinus tract for drainage
6. Re-treatment cases
7. Dilacerated teeth
8. Teeth with aggressive periodontitis or grade III mobility

C. TOOTH SPECIFIC:

1. Teeth with calcified canals, immature apex and internal and external resorption.
2. Two root canals ending with a single apical foramen.
3. Severe labially or linguallymalpositioned teeth in which obtaining straight-line access is difficult.
4. If a #10 K-file was very resistant to movement or if a #20 K-file easily went to length, then teeth with such canals were excluded (apical gauging).

An electric pulp-testing device (Parkell Inc., Edgewood, NY) was used to assess pulp vitality. Important prognostic determinants (variables) of postoperative pain like age and gender were recorded.

A lone clinician assessed all patients, using radiographic and clinical findings, followed by treatment of all cases. Exclusion criteria was strictly maintained and confounding variables taken care of by random allocation usingcomputer generated table of random numbers.

After obtaining written informed consent (Annexure II) from the patient for his/her participation in the study, local anaesthesia (2% lignocaine 1:80,000 adrenaline) (Xicaine, ICPA Health Products Ltd. Ankleshwar, Gujarat, India) was delivered and rubber dam (Hygienic, Coltene/Whaledent) applied on tooth for isolation.

After isolation, tooth crown was scoured with pumice and cleansed with normal saline. The tooth was then disinfected with 30% w/v hydrogen peroxide (Thermo Fisher Scientific India Pvt. Ltd., Mumbai, India) and 5% w/v Povidine Iodine (Sun Pharmaceutical Ind. Ltd., Mumbai, India) for 60 seconds each using sterile cotton rolls and cotton pellets. The iodine was later inactivated by sodium thiosulphate(Ranbaxy Fine Chemicals Limited, New Delhi, India).[46]

After disinfection procedure, a conventional endodontic access cavity preparation was executed and canal patency was assessed by #10 K-file. (Mani Inc., Japan). The working length (WL) was determined using an apex locator (DentaPort ZX, J. Morita Mfg. Corp., Kyoto, Japan) and reconfirmed with conventional radiograph. Glide path was formed by #15 K-file (Mani Inc., Tochigi, Japan).

The electronic working length recorded with the apex locator was checked twice during the treatment. The initial WL was recorded with a #10 stainless-steel K-

file during canal scouting, before glide path. A second WL was recorded after glide path and coronal enlargement.

Subsequently, root canal preparation was effectuated by one of the following two instrumentation systems, in Group A (n = 35) with full-sequence rotary ProTaper Next files upto size F2 and in Group B (n = 35) ProTaper Gold files upto size X2 in compliance the manufacturer's instructions.

GROUP A (ProTaper Next):

The protocol used for ProTaper Next rotary files was as follows: The ProTaper Universal Sx file was utilized for coronal enlargement, the WL was reconfirmed and then X1 (017/04) in one or more passes was used until WL was reached. X2 (025/06) was used in similar manner as X1 until WL in a passive manner.The CanalPro2™ (Coltene-Whaledent, New York, USA)Endomotor was used for instrumentation with the manufacturer recommended speed and torque settings of 300 rpm and 2.5Ncm respectively for each file.

GROUP B (ProTaperGold ®):

The protocol used for ProTaper Gold rotary files was as follows: The S1 file was introduced passively with a brushing movement into the canal two-thirds of the length of the canal. Afterwards, an Sx (019/04) file was introduced into the canal with a brushing movement two thirds of its blade length, the WL was reconfirmed and then S1 (018/02), S2 (020/04), F1 (020/07) and F2 (025/08) files were used to the working length, respectively. The CanalPro2™ (Coltene-Whaledent, New York, USA) endomotor was used for instrumentation with the manufacturer recommended speed (250 rpm) and torque 3 Ncmsettings for each file.

The canals of all teeth during preparation were irrigated with 3% NaOCl and 17% EDTA according to following protocol.[47]

- After access cavity: flushed with 3% NaOCl
- Between instruments: 2 mL of 3% NaOCl per canal
- After shaping: 5 mL of 3% NaOCl followed by 5 mL of 17% EDTA per canal.
- At completion of preparation, the canals were irrigated with 3 mL of normal saline and dried with sterile paper points.

An Intraoral periaical radiograph (IOPAR) with the placement of master cone was taken and both groups were obturated with single cone obturation technique (either using ProTaper Next or ProTaper Gold matching gutta-percha points)with an epoxy resin based sealer AH Plus® Sealer (DentsplyDeTrey, Konstanz, Germany)

Once completed it was temporarily restored (Cavit G, 3M ESPE Dental-Medizin GmbH Co, Seafeld, Germany) and post-obturation IOPAR was taken. According to the single-visit treatment protocol, all canals were shaped, cleaned and obturated in the same visit.

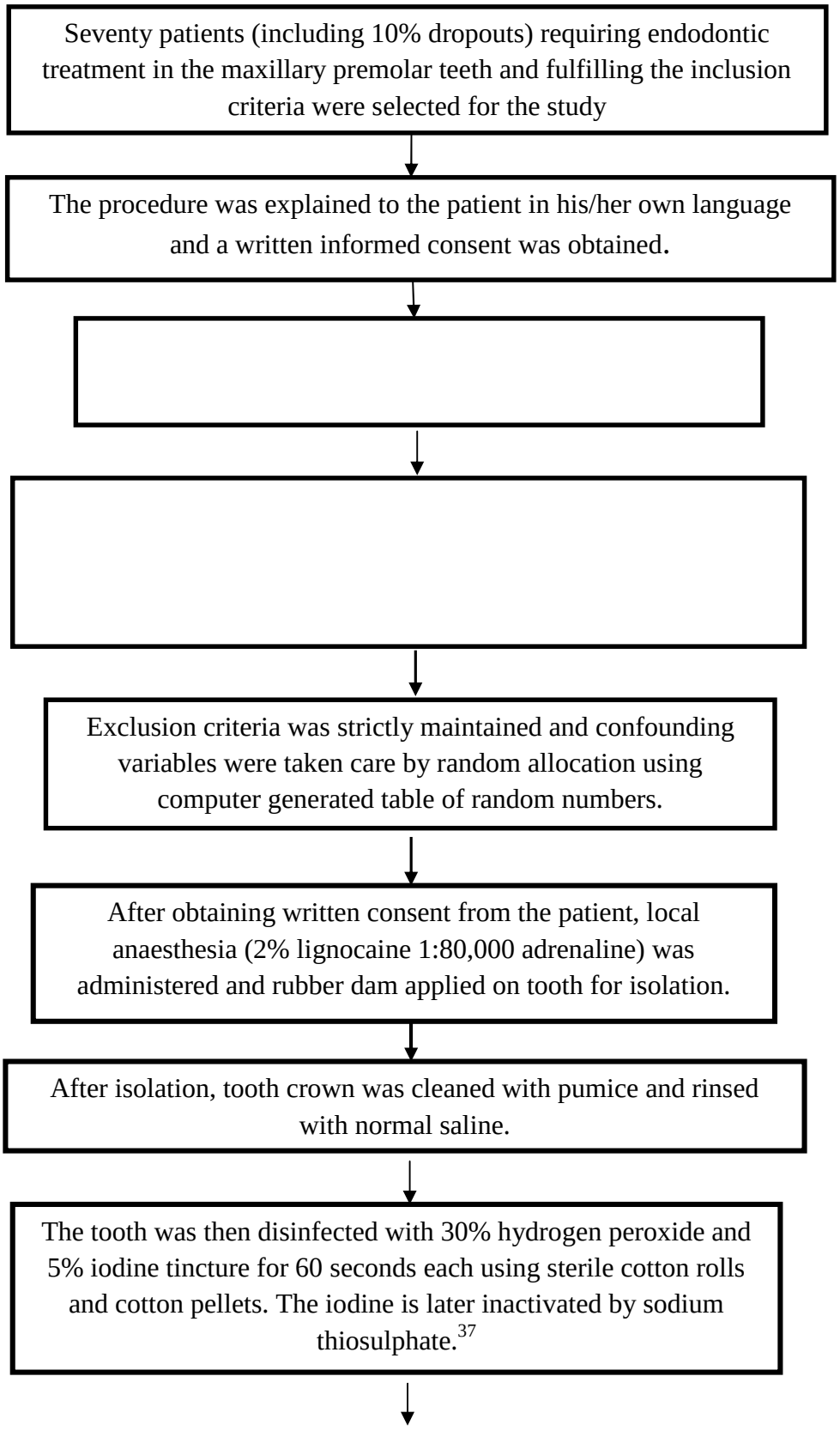
For both the groups, time for canal preparation was measured from the first file that was used to assess patent canal till the last file that was used to instrument the canal. This included the time for canal preparation, time required to change the files and time for irrigation.[48]

The patients were directed to utilize mild analgesics (400 mg of ibuprofen), only if they experienced pain. The presence or absence of postoperative pain, or the appropriate degree of pain was recorded as none, slight, moderate, or severe, by using a modified Visual Analogue Scale (VAS), validated in previous studies.[49]

- **No pain** (0) - The treated tooth felt normal. Patients don't have any pain.
- **Mild pain** (1) - Recognizable, but not discomforting, pain, which required no analgesics.
- **Moderate pain** (2) - Discomforting, but bearable, pain (analgesics, if used, were effective in relieving the pain)
- **Severe pain** (3) - Difficult to bear (analgesics had little or no effect in relieving the pain).

The patients were trained about the scoring criteria of Visual Analogue Scale (VAS). The patient took along the VAS form (Annexure III) after treatment to jot down their pain readings at post-operative periods of 6, 24, 48 and 72 hours. Regular reminders were given to the patient to make an entry of their pain readings and to return the VAS form duly filled. Any analgesic, if consumed, was taken down on the pain scale, at that particular time interval. The patients were notified to contact the clinic if appropriate pain relief was not obtained with the prescription.

METHODOLOGY WITH FLOWCHART-



After disinfection procedure, Access cavity preparation was done and canal patency checked by #10 K-file

↓

Glide path was created by #15 K-file.

↓

Seventy patients were randomly divided into two groups (Group A and

↓

Teeth in Group A (n = 35) were instrumented with Protaper Next rotating files according to the manufacturer's instructions, whilst those in Group B (n = 35) were instrumented with the Protaper Gold rotary files in accordance with the specifications given by the manufacturer.

↓

Both techniques maintained an apical diameter of 0.25mm for standardization purposes.

↓

The canals of all teeth during preparation were irrigated with 3% NaOCl and 17% EDTA

1. After access : cavity flooded with 3% NaOCl
2. Between instruments: 2 mL of 3% NaOCl per canal
3. After shaping: 5 mL of 3% NaOCl followed by 5 mL of 17% EDTA per canal.
4. At completion of preparation, the canals were irrigated with 3 ml of normalSaline and dried with sterile paper points.[9]

↓

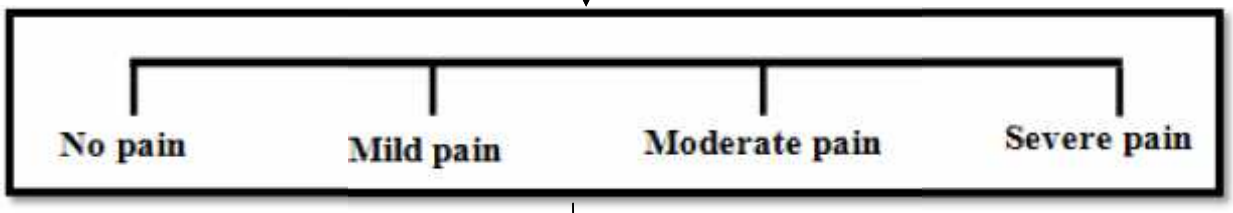
The teeth were obturated with single cone obturation technique (either Protaper Next or Protaper Gold matching gutta-percha points) with AH Plus sealer. All canals were shaped, cleaned and obturated in a single-visit.

↓

The patients were instructed to take mild analgesics (400 mg of ibuprofen), only if they experienced pain.

The presence or absence of pain, or the appropriate degree of pain were recorded as none, slight, moderate, or severe, by using a modified Visual Analogue Scale (VAS), validated in previous studies.[8]

- **No pain** (0) - The treated tooth felt normal. Patients don't have any pain.
- **Mild pain** (1) - Recognizable, but not discomforting, pain, which required no analgesis.
- **Moderate pain** (2) - Discomforting, but bearable, pain (Analgesis, if used, were effective in relieving the pain)
- **Severe pain** (3) - Difficult to bear (Analgesics had little or no effect in relieving the pain).



The patient was trained about the scoring criteria of Visual Analogue Scale (VAS).

The patient will carry the VAS form along with them after treatment to note their pain readings at post-operative periods of 6, 24, 48 and 72 hours.

The amount of analgesic, if taken, was recorded at that particular time interval.

The amount of analgesic, if taken, will be recorded at that particular time interval.

STATISTICAL ANALYSIS:

Statistical analysis was executed using SPSS software (version 20). The data was analyzed using the following tests:-

- Intergroup pair wise comparison with VAS scores at different time points was done using Mann-Whitney U test.
- Intragroup pair wise comparison with VAS scores at different time points was done using Wilcoxon matched pairs test.
- To assess the association of variables (age and sex) with VAS scores, Chi-square test was used.
- Time required for instrumentation of the canals in both groups was compared using independent t-test.

PHOTOGRAPHS

Fig.1 Diagnostic Instruments and Materials

Fig.2 Local Anaesthesia and Rubber Dam Armamentarium

Fig.3 Local Anaesthesia administration

Fig.4 Rubber Dam Isolation

Fig.5 Material for sterilization protocol

Fig.6. Sterilization Protocol; Step 1 -30% Hydrogen Peroxide

Fig 7.Sterilization Protocol; Step 2 -5% Povidine Iodine

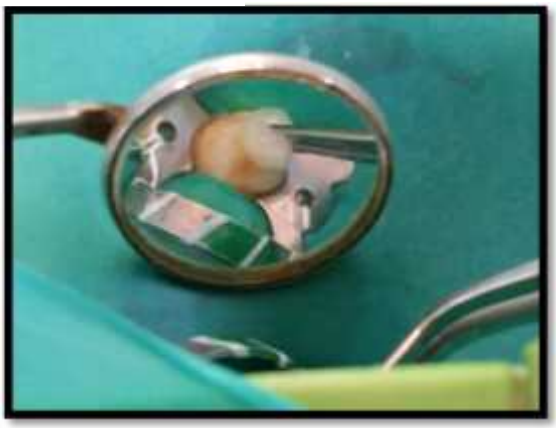


Fig.8. Sterilization Protocol; Step 3 – Sodium Thiosulphate

Fig. 9 Access cavity preparation armamentarium

Fig.10 Access cavity preparation

Fig.11 Prepared access cavity

Fig. 12 Cleaning and shaping armamentarium and materials

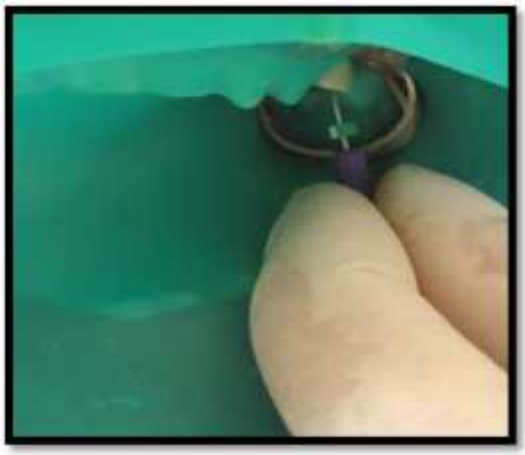


Fig. 13 Checking canal patency by #10 K-File

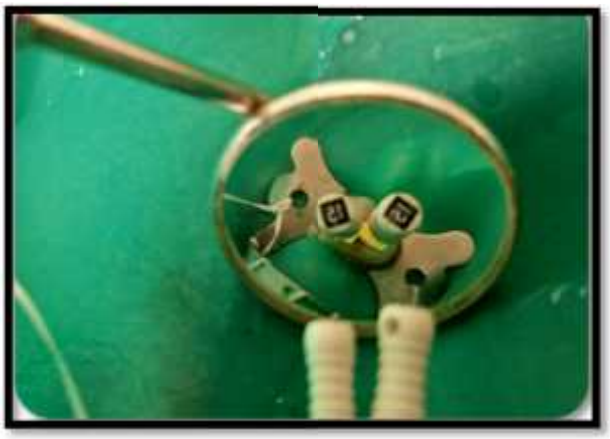


Fig.14 Working length files

Fig.15 Working length determination using EAL

Fig.16 Working length confirmation using IOPAR

Fig.17 Glide path creation with #15 K-file

Fig.18 Instrumentation using ProTaperNext rotary files (Group A)

Fig 19. Speed and torque for ProTaper Next rotary files

Fig.20 Instrumentation using ProTaper Gold rotary files (Group A)

Fig.21 Speed and torque ProTaper Gold rotary files

Fig.22 Obturation materials and armamentarium

Fig.23 Master cone IOPAR with corresponding gutta-percha points (Group A)

Fig.24 Post obturation IOPAR (Group A)

Fig.25 Master cone IOPAR with corresponding gutta-percha points (Group B)

Fig.26 Post obturation IOPAR (Group B)

RESULTS

Table 1: Patient wise information with VAS scores in group A

S. No. (Patient)	Age (years)	Sex	Time (min.)	6 hrs	24 hrs	48 hrs	72 hrs
1	26	M	6	0	0	0	0
2	20	F	7.5	0	0	0	0
3	24	M	4.5	0	0	0	0
4	23	M	5	0	0	0	0
5	21	F	7.5	1	0	0	0
6	35	M	5	0	0	0	0
7	43	F	4.5	0	0	0	0
8	30	M	6	1	0	0	0
9	24	M	5	0	0	1	0
10	30	F	4.5	0	0	0	0
11	31	M	6	0	0	1	0
12	33	F	5.5	0	0	0	0
13	29	M	4.5	2	1	0	0
14	35	M	6	0	0	1	0
15	26	M	4.5	0	0	0	0
16	20	M	6.5	0	0	0	0
17	24	M	7	0	0	0	0
18	44	M	7.5	0	0	0	0
19	34	F	4.5	2	1	1	0
20	41	F	6.5	1	0	0	0

S. No. (Patient)	Age	Sex	Time (min.)	6 hrs	24 hrs	48 hrs	72 hrs
21	22	M	4	0	0	1	0
22	29	M	5.5	0	0	0	0
23	30	F	5	1	0	0	0
24	30	F	6	2	1	0	0
25	40	M	7.5	0	0	0	0
26	34	F	5	2	1	0	0
27	24	M	6	0	0	0	0
28	28	F	7.5	0	0	0	0
29	33	M	4.5	0	0	0	0
30	25	M	4	0	0	0	0
31	27	F	5.5	0	0	0	0
32	24	F	4.5	0	0	0	0
33	35	M	7	1	0	0	0
34	30	F	6.5	2	1	0	0
35	36	F	5.5	0	0	0	0

Table 2: Patient wise information with VAS scores in group B

S. No. (Patient)	Age (years)	Sex	Time (min.)	6 hrs	24 hrs	48 hrs	72 hrs
1	24	M	12	0	0	0	0
2	22	F	10.5	1	0	0	0
3	38	M	13	2	1	0	0
4	26	M	8	0	0	0	0
5	33	F	12	2	1	0	0
6	27	F	14	2	1	0	0
7	23	M	10	0	0	0	0
8	30	M	9	2	1	0	0
9	44	F	11.5	2	2	1	0
10	22	F	12.5	0	0	0	0
11	40	F	11	2	2	1	0
12	25	M	12.5	0	0	0	0
13	24	F	10.5	0	0	0	0
14	25	F	14	2	2	1	0
15	34	M	13	0	0	0	0
16	27	F	10	2	1	0	0
17	30	F	11.5	0	0	0	0
18	36	M	11	0	0	0	0
19	27	M	10	0	0	0	0
20	24	M	9.5	0	0	0	0
21	24	F	10	2	2	1	0
22	30	M	11.5	2	1	0	0
23	22	F	9.5	0	0	0	0

S. No. (Patient)	Age (years)	Sex	Time (min.)	6 hrs	24 hrs	48 hrs	72 hrs
24	25	M	11	0	0	0	0
25	21	F	12	1	1	0	0
26	30	F	11.5	0	0	0	0
27	34	M	10	0	0	0	0
28	38	M	9	1	0	0	0
29	22	F	12.5	0	0	0	0
30	31	M	11.5	0	0	0	0
31	22	M	10	0	0	0	0
32	25	F	9	1	1	0	0
33	35	F	11.5	2	2	1	0
34	32	F	9.5	2	2	1	0
35	28	M	9	0	0	0	0

Table3: Distribution of male and females in group A and group B

Sex	Group A	%	Group B	%	Total	%
Male	20	57.14	17	48.57	37	52.86
Female	15	42.86	18	51.43	33	47.14
Total	35	100.00	35	100.00	70	100.00
Chi-square= 0.5162 P = 0.4731						

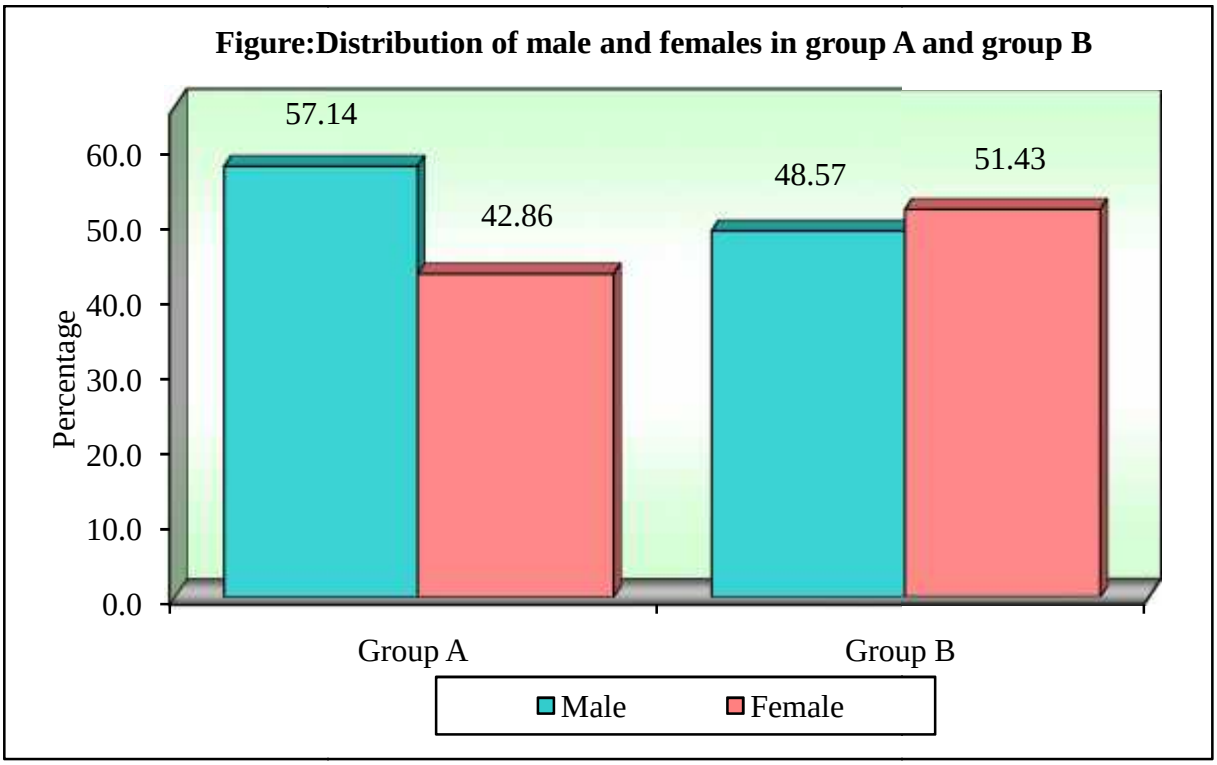


Fig 27: Distribution of males and females in group A and group B

Table 4: Comparison of Group A and Group B by age groups

Age groups	Group A	%	Group B	%	Total	%
20-29yrs	17	48.57	20	57.14	37	52.86
30-39yrs	14	40.00	13	37.14	27	38.57
>=40yrs	4	11.43	2	5.71	6	8.57
Total	35	100.00	35	100.00	70	100.00
Mean age	29.71		28.57		29.14	
SD age	6.40		5.94		6.16	
Chi-square=0.9472 P = 0.6231						

Figure: Comparison of Group A and Group B by age groups

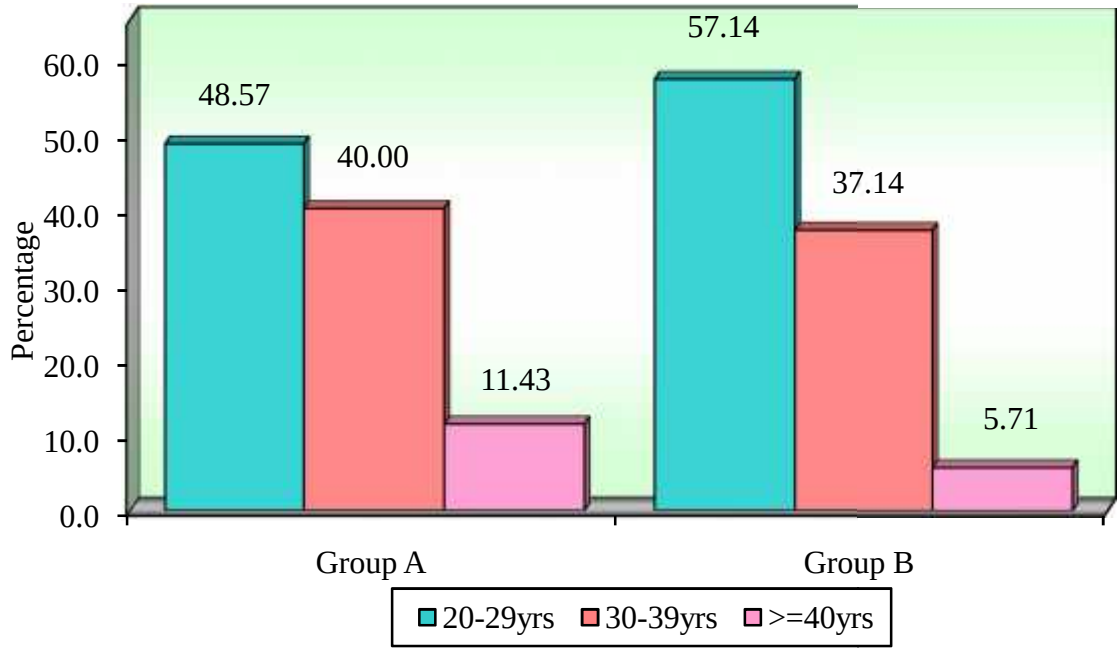


Fig 28: Comparison of Group A and Group B by age groups

Table 5: Comparison of Group A and Group B with mean time by independent t test

Groups	n	Mean	SD	SE	t-value	P-value
Group A	35	5.66	1.11	0.19		
Group B	35	10.94	1.49	0.25	-16.8376	0.0001*

*p<0.05

Figure: Comparison of Group A and Group B with mean time

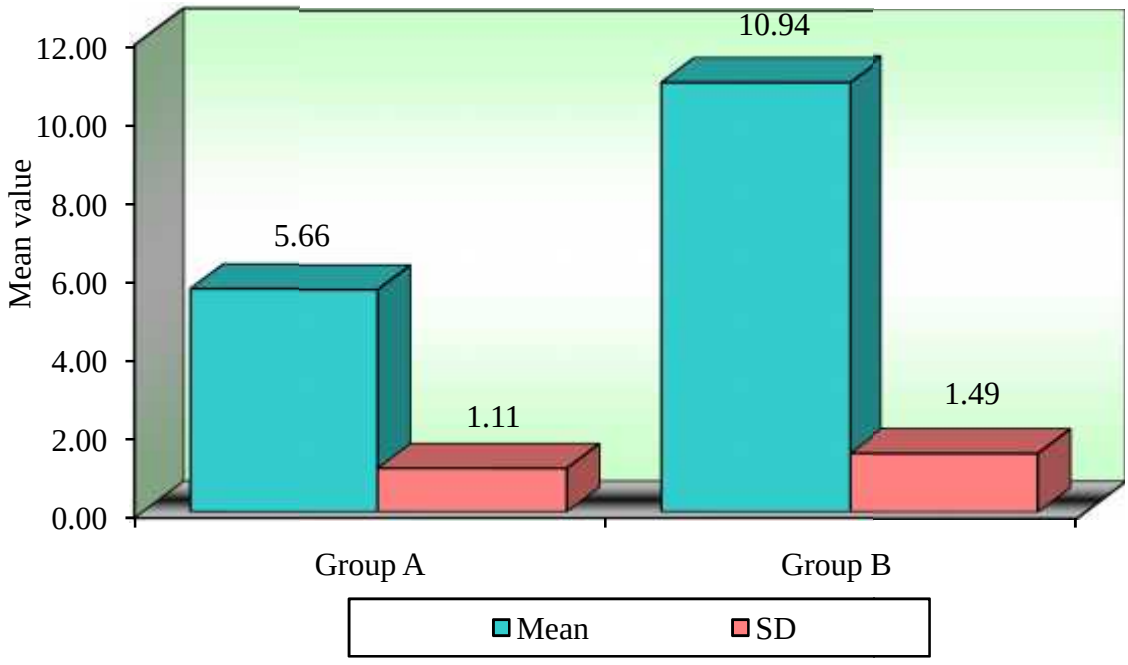


Fig 29: Comparison of Group A and Group B with mean time

Table 6: Comparison of Group A and Group B with visual analog scale scores at different time points using Mann-Whitney U-test

Time points	Group A	%	Group B	%	Total	%
6 hours						
Score 0	25	71.43	19	54.29	44	62.86
Score 1	5	14.29	4	11.43	9	12.86
Score 2	5	14.29	12	34.29	17	24.29
Mann-Whitney U test, Z=-1.4683, p=0.1420						
24 hours						
Score 0	30	85.71	21	60.00	51	72.86
Score 1	5	14.29	8	22.86	13	18.57
Score 2	0	0.00	6	17.14	6	8.57
Mann-Whitney U test, Z=-2.0262, p=0.0428*						
48 hours						
Score 0	30	85.71	29	82.86	59	84.29
Score 1	5	14.29	6	17.14	11	15.71
Score 2	0	0.00	0	0.00	0	0.00
Mann-Whitney U test, Z=-0.2056,p=0.831						
72 hours						
Score 0	35	100.00	35	100.00	70	100.00
Score 1	0	0.00	0	0.00	0	0.00
Score 2	0	0.00	0	0.00	0	0.00
Mann-Whitney U test, Z=0.0000, p=1.0000						
Total	35	100.00	35	100.00	70	100.00

*p<0.05

Table 12: Comparison of Group A and Group B with visual analog scale scores at different time points

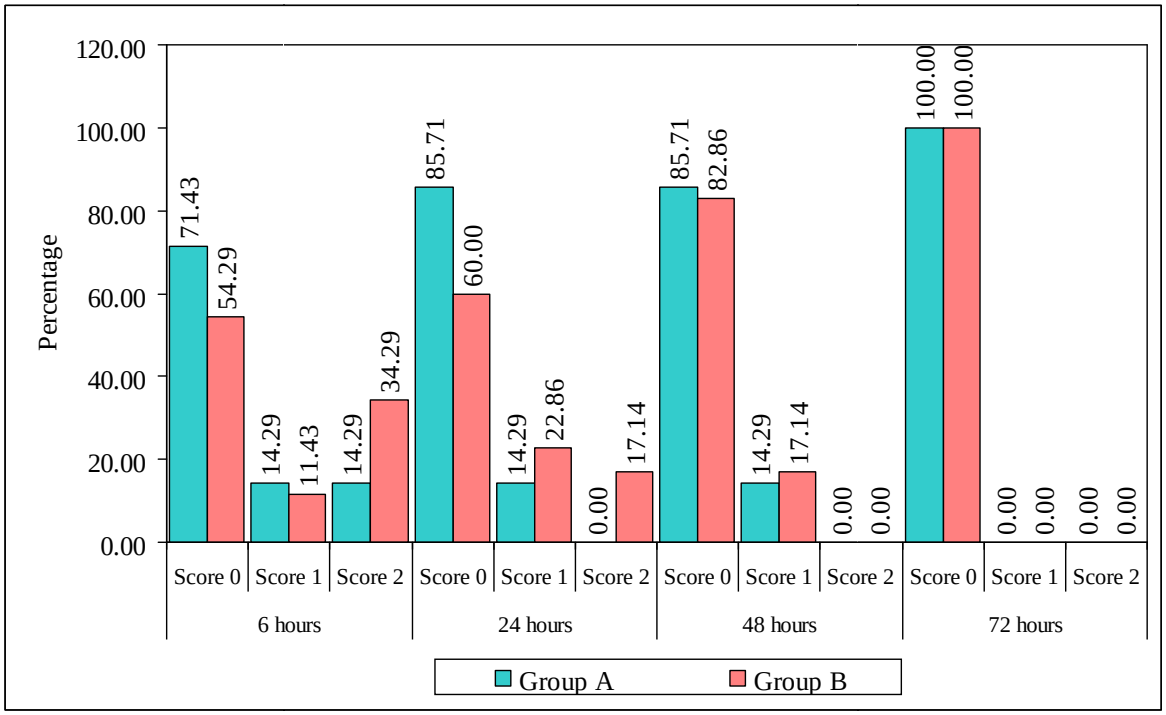


Fig 30: Comparison of Group A and Group B with VAS scores at different time points

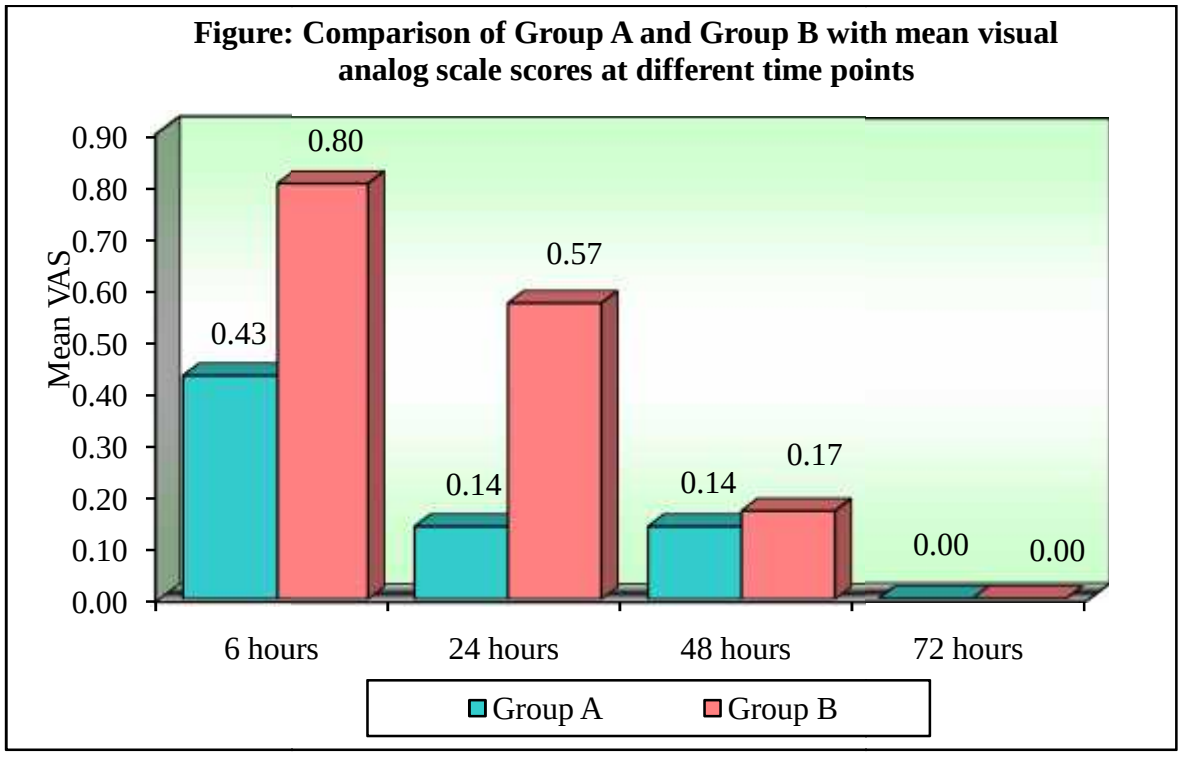


Fig 31.Comparison of Group A and Group B with mean visual analog scale scores at different time points

Table 7: Intra-group (Group A) pair wise comparison of visual analog scale scores at 6hrs, 24 hrs, 48 hrs, and 72 hrs by Wilcoxon matched pairs test

Time points	% of change	T-value	Z-value	p-value
6 hrs versus 24 hrs	66.67	0.00	2.8031	0.0051*
6 hrs versus 48 hrs	66.67	22.00	1.9147	0.0555
6 hrs versus 72 hrs	100.00	0.00	2.8031	0.0051*
24 hrs versus 48 hrs	0.00	18.00	0.0000	1.0000
24 hrs versus 72 hrs	100.00	0.00	2.0226	0.0431*
48 hrs versus 72 hrs	100.00	0.00	2.0226	0.0431*

*p<0.05

Table 8: Intra-group (Group B) pair wise comparison of visual analog scale scores at 6hrs, 24 hrs, 48 hrs, and 72 hrs by Wilcoxon matched pairs test

Time points	% of change	T-value	Z-value	p-value
6 hrs versus 24 hrs	28.57	0.00	2.5205	0.0117*
6 hrs versus 48 hrs	78.57	0.00	3.5162	0.0004*
6 hrs versus 72 hrs	100.00	0.00	3.5162	0.0004*
24 hrs versus 48 hrs	70.00	0.00	3.2958	0.0010*
24 hrs versus 72 hrs	100.00	0.00	3.2959	0.0010*
48 hrs versus 72 hrs	100.00	0.00	2.2014	0.0277*

*p<0.05

Table 9: Association between age and sex with 6hrs VAS scores in group A and group B

Groups		VAS Absent	%	VAS Present	%	Total	Chi-square	P-value
Group A	Age groups							
	20-29yrs	15	88.24	2	11.76	17	5.5280	0.0630
	30-39yrs	7	50.00	7	50.00	14		
	>=40yrs	3	75.00	1	25.00	4		
	Sex							
	Male	17	85.00	3	15.00	20	0.0630	0.0400*
	Female	8	53.33	7	46.67	15		
Group B	Age groups							
	20-29yrs	13	65.00	7	35.00	20	3.6470	0.1610
	30-39yrs	6	46.15	7	53.85	13		
	>=40yrs	0	0.00	2	100.00	2		
	Sex							
	Male	13	76.47	4	23.53	17	3.6470	0.0100*
	Female	6	33.33	12	66.67	18		
	Total	19	54.29	16	45.71	35		

*p<0.05

Table 10: Association between age and sex with 24hrs VAS scores in group A and group B

Groups		VAS Absent	%	VAS Present	%	Total	Chi-square	P-value
Group A	Age groups							
	20-29yrs	16	94.12	1	5.88	17	3.9800	0.1370
	30-39yrs	10	71.43	4	28.57	14		
	>=40yrs	4	100.00	0	0.00	4		
	Sex							
	Male	19	95.00	1	5.00	20	0.1370	0.0700
	Female	11	73.33	4	26.67	15		
Group B	Age groups							
	20-29yrs	14	70.00	6	30.00	20	4.0380	0.1330
	30-39yrs	7	53.85	6	46.15	13		
	>=40yrs	0	0.00	2	100.00	2		
	Sex							
	Male	14	82.35	3	17.65	17	4.0380	0.0090 *
	Female	7	38.89	11	61.11	18		
	Total	21	60.00	14	40.00	35		

*p<0.05

Table 11: Association between age and sex with 48hrs VAS scores in group A and group B

Groups		VAS Absent	%	VAS Present	%	Total	Chi-square	P-value
Group A	Age groups							
	20-29yrs	15	88.24	2	11.76	17	1.3380	0.5120
	30-39yrs	11	78.57	3	21.43	14		
	>=40yrs	4	100.00	0	0.00	4		
	Sex							
	Male	16	80.00	4	20.00	20	0.5120	0.2650
	Female	14	93.33	1	6.67	15		
Group B	Age groups							
	20-29yrs	18	90.00	2	10.00	20	10.4130	0.0050*
	30-39yrs	11	84.62	2	15.38	13		
	>=40yrs	0	0.00	2	100.00	2		
	Sex							
	Male	17	100.00	0	0.00	17	10.4130	0.0090*
	Female	12	66.67	6	33.33	18		
	Total	29	82.86	6	17.14	35		

*p<0.05

The patient-wise information along with VAS scores of both groups has been presented in Tables 1 and 2.

As this was a randomized clinical trial, the distribution of variables of age and sex was not under our control.

Age distribution among groups:

In Group A, 88.57% samples were below the age of 39yrs, 11.43% were between 40-50 yrs of age (Table 4) (Fig.28)

In Group B, 94.28% samples were below the age of 39yrs, 5.71% were between 40-50 yrs of age (Table 4) (Fig.28)

The mean age in Group A was 29.71 +/- 6.40yrs while the mean age in Group B was 28.57+/- 5.94yrs (Table 4) (Fig.28)

Sex distribution among groups:

In Group A (n=35), 57.14% of the samples were male while 42.86% of the samples were female. (Table 3) (Fig.27)

In Group B (n=35), 48.57% of the samples were male while 51.43% of the samples were female. (Table 3) (Fig.27)

Distribution of VAS scores with different time points in Group A and Group B:

The highest score in Group A was score 2 (moderate pain) which was observed in 5 samples at the end of 6 hrs out of which it continued for 24 hrs among 0 samples. (Table 6)

The highest score in Group B was score 2 (moderate pain) which was observed in 12 samples at the end of 6 hrs and did not continue for any other time period. (Table 6)

Comparison of Group A and Group B with VAS scores at different time points using Mann-Whitney U test:

At the end of 6hrs, though not statistically significant (p=0.1420), higher VAS scores were observed in Group B than Group A, which were clinically significant. (Table 6) (Fig. 31)

A statistically significant difference was observed with VAS scores between groups A and B at the end of 24 hrs (p=0.0428) and not statistically significant 48 hrs (p=0.831) with higher VAS scores observed in Group B than Group A. (Table 6) (Fig. 30)

Intra-group (Group A) pair wise comparison of VAS scores at6 hours, 24 hours, 48 hours and 72 hours by Wilcoxon matched pairs test:

A statistically significant difference ($p<0.05$) was observed between the VAS scores at at all time periods 6 hours vs 24 hours, 6 hours vs 72 hours, 24 hours vs 72 hours, 48 hours vs 72 hours (Table 7)

Intra-group (Group B) pair wise comparison of VAS scores at Pre-op, 6hours, 24hours, 48hours and 72hours by Wilcoxon matched pairs test:

A statistically significant difference ($p<0.05$) was observed between the VAS scores at at all time periods 6 hours vs 24 hours, 6 hours vs 48 hours, 6 hours vs 72 hours, 24 hours vs 48 hours, 24 hours vs 72 hours, 48 hours vs 72 hours (Table 8)

Association between age and sex and VAS scores in Group A and B:

A higher VAS scores were obtained in age group 31-50 yrs Group A after 6 hrs (p=0.0630) (Table 9), 24 hrs (p=0.1370) (Table 10) and 48 hours (p=0.5120) (Table 11) which were not statistically significant.

A statistically significant difference was observed with VAS scores between males and females in groups A at the end of 6 hrs (p=0.040) (Table 9), not statistically significant at 24 hrs (p=0.070) (Table 10) and 48 hrs (p=0.2650) (Table 11) with higher VAS scores observed in females than males.

A statistically insignificant difference was observed with VAS scores with age in Group B at the end of 6 hrs (p=0.1610) (Table 9) and 24 hrs (p=0.1330) (Table 10) statistically significant difference at the end of 48 hrs (p=0.0050) (Table 11) with higher VAS scores observed in 31-50 yrs age group.

A statistically significant difference was observed with VAS scores between males and females in Group B at the end of 6 hrs (p=0.010) (Table 9), at the end of 24 hrs (p=0.0090) (Table 10), at the end of 48 hrs (p=0.0090) (Table 11) with higher VAS scores observed in females than males.

Comparison of time required for instrumentation of the canals in both groups:

The canal preparation time was significantly shorter in the Group B in comparison with the Group A (5.66+/-1.16 min versus 10.94+/-1.49 min (p=0.0001) (Table 5) (Fig.29).

DISCUSSION

"Change is the only constant"- Heraclitus.

Change is the very core of evolution and without it, everything would look alike and behave the same way. Evolution, hence is and will always be the most primary virtue of change and **technology** is no exception!!!

Endodontics has come a long way from its origin with a constant upheaval in technology.Manual stainless-steel instruments were initially used to prepare the root canals. The downside of these files was its decreased flexibility, constant taper mandating greater number of instruments for shaping the canal, thus making it an arduous task. In addition, these files resorted to the push – pull motion that acts as a piston to push the debris out apically leading to post-operative pain .[10, 14, 55, 56]

In an attempt to negate the lacunae's observed in the stainless-steel files newer files were introduced by Walia et al made from Nickel Titanium alloy. These files were endowed with unique features of "super-elasticity" and "shape memory".[57]

Change in technology also saw improvisation in the dental handpiece used to mount the stainless-steel files to a more precision oriented endodontic handpieces specific to the everchanging Rotary NiTi instrument systems since their genesis.[59]

Clinicians have always expected the newly introduced file systems to incorporate the promising design features from the past, and amalgamate to it the more recent technological advancements, enhancing its safety, making it more efficient and simpler. The search for an ideal file system has seen the evolution of five generations with the researchers still striving hard to fulfil the ideal requirements.

First Generation file systems were first launched into the market in the mid-1990s which imbibed the features of "passive cutting radial lands along with fixed 0.04–0.06 tapers over the full working lengths." The examples being LightSpeed Endodontics (1992), Profile-Dentsply (1993) and GT system-Dentsply (1998).[9,10]

Second Generation NiTi rotary files were introduced into in 2001 with redesigned attributes of active cutting edges with greater cutting efficiency, with inferior number of instruments required to achieve complete cleaning and shaping than the previous generation. "Noteworthy systems in this generation are ProTaper Universal-Dentsply, Hero Shaper-Micro-Mega, K3-SybronEndo.

In third generation of the NiTi rotary files, the metallurgic properties of the alloys were tested using heating and cooling procedures. Incorporating M-wire, R-phase and EDM technologies renders the instruments with high memory shapes and low risk of separation. [19-22] Examples being: Profile GTX Series–Dentsply, K3 XF Files-SybronEndo, (HyFlex CM)–Coltene, ProTaper Gold controlled memory (CM) Files are examples of files in this series.

Reciprocation as a motion of canal preparation led to development of the fourth generation of NiTi rotary instruments. Examples being: Wave One-Dentsply, self-adjusting file (SAF)-ReDent Nova.[9,23,25-29]

In the Fifth Generation, the offset the center of rotation is the prime feature increasing the efficiency of canal shaping. Examples: HyFlex/electrical discharge machining (EDM)-Coltene, and ProTaper Next-Dentsply are important files of the fifth generation.[23]

ProTaper Next (PTN) is a 5th Generation rotary system with offset center of mass, when in action mimics a “snake-like” movement. It is a conglomeration of five files for instrumenting the canals, namely X1-corresponding to size 17/04 and colour coding yellow, X-2 size-25/06 colour coding red, X-3 size-30/07 colour coding blue, X-4 size-40/06 colour coding double black, and X5 size-50/06 colour coding double yellow. Speed at which they are used is 300rpm and torque at 2.0-5.2Ncm. Along with its offset design there is an unique intersection of two noteworthy design features, the progressive percentage tapers on a single file and M-wire technology.[14]

ProTaper Gold (PG) (PG; Dentsply, Tulsa Dental Specialties, Tulsa, OK, USA) came about with advanced metallurgy claiming to improve the cutting efficiency and safety. PG rotary files feature twinning geometries as ProTaper Universal (PU) system. It has been metallurgically aggrandized through heat treatment technology.[9] PG files are available in eight sizes: SX (tip size 19 , taper of 0.04), S1 (18,0.02), S2 (20,0.04), F1 (20,0.07), F2 (25,0.08), F3 (30,0.09), F4 (40,0.06), and F5 (50,0.05).[10]

It has been observed that all instrumentation techniques, either manual or mechanical even with the revisions of the file systems still cause unintentional extrusion of debris into the periapical region. The extrusion of debris is attributed even in cases where the instrumentation is limited to the minor apical foramina and not exceeding it. The debris may include chips of dentin, microorganisms, remnants of pulp tissue, irrigants or necrosed tissue.[51] Extrusion of this debris beyond the apex, leads to injury resulting in inflammatory reaction.

The neurogenic component of inflammation, substance P and Calcitonin gene related peptide (CGRP) amongst the various neuropeptides are expressed in the periodontal ligament.[39] The result of liberation of the inflammatory mediators causes changes in local adaptation and periapical tissue pressure, thus, causing pain.[30] All these factors culminate to affect the sensory nerve fibres. Regardless of the type of injury, the vehemence of the periradicular inflammatory response is directly proportional to the graveness of the tissue injury.[8]This postoperative pain affects the patient's quality of life[52] and in turn serves as a exemplar to judge the clinician's skill. Hence, postendodontic pain is an unwelcome occurrence for even the clinicians.

Studies also state that particular instruments and instrumentation techniques express lesser debris as opposed to others.[10] Thus, causing comparatively low postoperative pain. On this account, constant research is in progress in terms of their designs, alloy types and the motions employed to bring about an ideal preparation with minimal postoperative pain.[3]

In-vitro studies contemplating the amount of apical extrusion of debris with ProTaper Universal, ProTaper Next and ProTaper Gold file systems have concluded that ProTaper Next and ProTaper Gold files were associated with significantly lesser apical debris extrusion as compared to ProTaper Universal system. However, in *in-vitro* (simulated) studies the outcomes cannot be directly deducted to *in-vivo* situations .In clinical scenario's the dental pulp and periapical tissues may function as an innate hurdle for expulsion of this debris.[18, 33, 34] as also, positive and negative pressure at the apex, normal or morbid periapical tissues, prematurely developed roots may affect debris extrusion in the periapical region. Demonstration of postoperative pain could also be attributed to the host immune response.[20]

Single visit RCT's were demonstrated to have lower incidences of post-operative pain and so were naturally opted by the patients.

Thus, a prospective randomized clinical trial was conducted with the aim of clinically evaluating the postoperative pain after single visit endodontic treatment using, ProTaper Next against the newly introduced ProTaper Gold rotary file system.

A study of the association of variables of age, sex along with the time required for instrumentation of the canals was performed for comparison of the post-treatment pain in the two groups.

"In the present study, samples were selected from the regular pool of patients reporting to the Department of Conservative Dentistry And Endodontics, KLE V.K. Institute of Dental Sciences, Belagavi. A total of 70 maxillary premolar teeth requiring endodontic treatment were chosen by a single clinician after evaluation of clinical and radiographic findings which were in accordance with specific inclusion and exclusion criteria quoted in the materials and methods section."

Sample size was estimated using the formula:

$$n = \frac{(Z_\alpha + Z_\beta)^2 (pq)^2}{d^2} = 35$$

$p = p1 + p2 \div 2$, q=1-p

% of change in 1st group p1 = 27.59

% of change in 2nd group p2 = 62.50

Difference=d= 34.91

Z_α=1.96 at 5% α-error

Z_β=1.037 at 5% β-error

Sample size was estimated to be 35 per group including 10% dropout.

The acceptable rate ofdropout for randomized clinical trials is set at 10% any value higher than 10% could affect the reliability and validity of the study.

The dentist-patient tie-up is a contract, requiring the patient to be above 18 years of age to enter the contract. As well as, individuals above 50 have reported to have calcifications of some sort in the canals which would act as a hindrance during treatment of the tooth as well as affect the total time required for preparation of the canals.

Maxillary premolar teeth with two roots/ two canals were selected for the study as they have straight roots which curtails frictional stress and torque demand on the instrument. The instrument hence requires lesser force to be directed apically to reach the working length minimizing the apical extrusion of the debris. Apical gauging was done to exclude teeth where a #10 K-file was very resistant to movement or if a #20 K-file easily went to working length.

A single clinician treated all the cases, to eliminate interpersonal variability in the treatment between clinicians.

An apical preparation of ISO size 25 meets the requirements of canal preparations. Therefore, the final preparation was done using ProTaper Next X2 and ProTaper Gold F2 both having a tip diameter of 0.25mm. This eliminated any variation that could occur due to non-standardization using different tip diameters.

In a study by Glennonet al[5] it was observed that preoperative pain significantly influenced postoperative pain. Hence, teeth which were diagnosed as asymptomatic irreversible pulpitis due to carious exposure or teeth treated for prosthetic reasons

were only included in our study. More than two teeth requiring root canal treatment homolaterally were precluded since they can give a false positive reading due to pain caused by any of these teeth which cannot be differentiated from one another.[5]

Isolation of badly mutilated teeth without adequate coronal structure is challenging and hence warranting their exclusion. Teeth demonstrating negative responses to percussion, palpation and mobility tests were included in our study as there is a greater risk of post-operative pain in teeth with chronic apical periodontitis.[49]

To detect the pulpal status, cold test and electric pulp tests were performed. Teeth showing a negative response i.e non-vital teeth were excluded to eliminate any bias that could have been created due to the pulpal status. This is in accordance with Seltzer et al who stated an association of increased postoperative pain in asymptomatic non vital teeth.[71-75]

In cases where we can get false VAS score due to patients with systemic disease or immune incompetence, with the history of taking analgesic drugs and/or antibiotic drugs or steroidal drugs that tend to reduce the prevalence and severity of pain were not included from the study.

The patients were divided into two groups by randomization using the method of ‘table of random numbers’:

Group 'A' consisted of 35 teeth which were instrumented using ProTaper Next (Dentsply-Maillefer) files upto size X2.

The Sx file was used to flare up the orifice in brushing stokes in outwards directions, to eradicate the hindrances of dentinal triangles, relocating the coronal most aspect of the canal distant from external root concavities, replicating the desired shape .The X1 (17/04) file was carried through the access and passively inserted with outward brushing motion to full body of canal. This was followed by using X2 (25/06) in the same manner till the working length.

Group 'B' consisted of 35 teeth which were instrumented using ProTaper Gold (Dentsply-Maillefer) files upto size F2.

The ProTaper Gold instruments used in this study were Sx, S1, S2, F1 and F2. The instrumentation was implemented as guided by the manufacturer's instructions. Coronal flaring was done by the Sx file to remove any hinderances over the canal orifices for better accessibility. Following the flaring the successive S1 and S2 files were then used. The Shaping files (S1, S2) are responsible for shaping the coronal and middle third parts of the canal. The small diameter at the tip (S1 - 0.17mm, S2 - 0.19mm) along with a narrow taper, increases as distance increases from the tip. This results in the tip acting to guide the body of the instrument along the canal path which minimizes file fracture. The Finishing files have a fixed taper for the apical 3mm of the file which shapes the apical third of the root canal. The Finishing files used in this study were the F1 (Tip diameter = 0.20mm) and F2 (Tip diameter = 0.25mm).[61]

No.10 K-file was moved in the canal during instrumentation to check the apical patency while ensuring that there was no binding or enlargement of the apical

foramen. Studies have proven that this procedure has little/no effect on the post-operative pain.

Prior to instrumentation, the working length determination was done using an apex locator (DentaPort ZX, J. Morita Mfg. Corp., Kyoto, Japan) which was confirmed radiographically. Studies by Brunton et al, Hoer et al &Attin[80] observed that adjunctive use of electronic apex locator and radiograph was highly accurate to determine WL than the radiographic technique by itself. According to study Torabinejad states that unintentional overextension of root canal files during WLD does not affect the post-operative pain.

After determination of WL, glide path was prepared with a #15 SS K-file by "fed it in & pull" action which was in accordance to Ruddle's technique. Due to this motion the debris gets suspended in the irrigating solution instead of being forced out beyond the apex which helps to reduce the risk of post treatment pain.

The irrigation protocol was as follows:

- After access cavity: flushed with 2mL of 3% NaOCl
- Between instruments: 2 mL of 3% NaOCl per canal
- After shaping: 5 mL of 3% NaOCl followed by 5 mL of 17% EDTA per canal.

At completion of preparation, the canals were irrigated with 3 mL of normal saline and dried with sterile paper points.

Bystrom and Sundqvist 1983 proved that sodium hypochlorite has strong antimicrobial activity irrespective of its concentrations and kills bacteria very rapidly. However, concentrations above 2% have vital and necrotic tissue dissolving

characteristics[75-tejas]. Therefore 3% sodium hypochlorite (Vishal Dentocare Pvt Ltd., India) was used as it is an effective antimicrobial which dissolves pulp remnants[83].

EDTA is a chelating agent. When used as 17%EDTA (Canalarge; Ammdent, Chandigarh, India) solution as anirrigant it helps to remove inorganic debris from root canal and chelate the dentin. Similar name for this debris is smear layer which hinders thorough irrigation of root canal system. Bystrom and Sundqvist in 1985 reported that using 17%EDTA adjunctively to NaOCl ameliorates the antibacterial effectiveness of NaOCl when it is used as an antibacterial agent. Hence 15% EDTA gel (Well Prep, Vericom, Korea) was used in the current study.

To neutralize the various chemicals used as irrigants 0.9% sterile normal saline (Amanta Healthcare Ltd., Gujarat, India) was used to flush out irrigants.

An epoxy resin based sealer (AH Plus® Sealer (DentsplyDeTrey, Konstanz, Germany) was used in appurtenance to the guttapercha cones which corresponded to the final instrument used for chemo-mechanical preparation followed by obturation as this combination is reported to be the benchmark for obturation.[87, 88]

Pain is very subjective. It depends on patient's pain perception and highly governed by the various environmental factors, physical and psychological factors.(Turk &Melzack 1992).[90]

The questions should be framed such that the patients completely understood it, they can be easily explicated by statisticians and researchers alike.[24] A modified VAS (Visual Analogue Scale) was used for grading the intensity of pain as the scale used here is 0–3 instead of 0–10 or 0–100. Smaller scales provided pronounced relevance for comparing between groups rather than having a full gamut of values. To

describe the pain very distinct descriptive words were used such as “no pain”- (0), “mild pain”- (1), “moderate pain”- (2) and “severe pain”- (3) These were co-related to numbers, and the combination had been validated in previous studies. This made the scale easily understandable by the patients. A study reported in the Cochrane Database of Systematic Review has advocated this scale for pain occurring post endodontic treatment. They proposed that the magnitude of discomfort/pain must be appraised in categories arranged in advanced order and exactly recounted with use of analgesics. Thus, making it unerring basis for quantifying pain.[49]

The time at which pain score was marked down was at 6, 24, 48 and 72 hours after completion of endodontic treatment. The time period of 12 hours was ostracized as it was found to be unsuitable to contact the patient at that time.[25]In a study reported by Pak et al and Pasqualini et al, presence of pain 4 days postoperatively is low, whatever might be the type of technique or medication utilized.[92, 93] Therefore no time period was recorded after 72 hours.

Nonsteroidal anti-inflammatory drugs have been advocated as primary choice medication for postoperative pain management after endodontic treatment. Ibuprofen has been used in multitudinous investigations for pain relief after root canal treatment.[94]It was advised only on-demand and not regularly as this could modify the outcome of the study.

With true WLD operator dependent chemical factors such as irrigant extrusion,wedging of irrigating needle and mechanical factors such as over-instrumentation during root canal preparation and over obturation were averted.

Thus, the post-operative pain in this study could be narrowed down to unmeant apical extrusion of debris created during root canal instrumentation.

The outcome obtained in this study stipulate that the postoperative pain observed after root canal instrumentation with ProTaper Gold rotary file system (Group B) was consistently higher than in instrumentation with ProTaper Next system (Group A). Hence, the null hypothesis was repudiated.

Caciki et al in their in-vitro study observed that ProTaper Gold expulsed higher amount of debris apically in comparison to ProTaper Next. Apical expulsion of debris is firmly connected to the postoperative pain after endodontic treatment, we can draw the inference that our result's are homogeneous to the above mentioned studies.

The design characteristics of ProTaper Next file system brags about its off-centered rectangular cross section ensuring a "two point" contact to the root canal wall at all times. The offset center results in the axis of rotation in the ProTaper Next system to differ from the center of mass. This leads "snake-like motion" in the canal could have amplified the removal of debris out of the canal coronally and not apically.[14, 18] Thus, reducing the postoperative pain.

Five files in ProTaper Gold group (Group B) in comparison to three files in ProTaper Next (Group A), steered increased debris production which is in accordance to the previous studies stating file instrumentation time leading to higher with each subsequent file. This debris gets compacted tightly along dentine walls which made it harder to be flushed out of the canal.[98]

In addition, the sizeable taper of 8% in PTG F2 file (Group B) as compared to PTN X2 (Group A) which has only 6% taper, consequenced in more contact of the instrument with the dentinal walls within the canal and therefore resulting in aggressive cutting , thus increased debris production.[34]

The M-wire alloy used for assembly of ProTaper Next (Group B), in comparison to the Gold metallurgy system used in ProTaper Gold (Group A), results in higher flexibility due to low modulus of elasticity of the PTN files. Manufacturers have claimed that this file design using R-phase treatment increase debris removal and flexibility and allow the file to adjust to intra-canal torsional forces depending on the amount of pressure placed on the file. This helps to sustain the canal curvature well, causing lesser canal transportation than PTG[100]. Keeping up with the canal curvature well has been observed to show lesser iatrogenic defects and thus reduced potential to create and extrude debris[100] and thus, inferior amount of postoperative pain.

No significant differences was observed between the postoperative pain in Group A (PTN) and B (PTG) at 6 hours.

A major factor for this inconsequential difference could be the “Hawthorne effect”. According to this effect there is change in behaviour of a subject owing to the fact that special attention and status was received due to participation in an investigation.[102] Which could elicit them to overestimate their pain levels at the start causing an apparent dissension until a day has passed.[26]Also the local anaesthetic effect starts to wears off in a few hours which could be correlated to the pain experienced at the end of 6 hours.

In the outcomes of the present study, a motif was seen regarding the intensity of pain encountered by patients within the group wherein the pronounced intensity of pain, if any, was recorded 6 hours after the therapy, and subsequently it lowered continuously (statistically significant, $p<0.05$) resulting in no pain at all in both the groups at 72 hours.

As we have already stated in the above mentioned studies that post endodontic pain does not last more than 72 hours, we found similar results in our study that no pain was present at the end of 72 hours.

Pain scores of 1 and 2 come in the group of "post-operative discomfort". Not a single patient reported with a VAS score of 3 that denotes severe pain. The outcomes of the present study were similar to study conducted by Arora et al, where the highest reading obtained at any time during the study was 2.

Time required for canal preparation was taken from the first file used to check canal patency till the last file used to instrument the canal for both the groups. This measurement was including the time for canal preparation, time required to change the files and time for irrigation.[48]The active time of canal preparation required when using an instrumentation system is a vital factor contemplated by most clinicians because of its impact on patient's comprehensive comfort.[16]

This study also remarked that as the age advanced among the samples, the severity of pain also decreased. These results are contradictory to Gufran Ali et al who reported that increased pain in older individuals could be due to decreased pain tolerance, reduced blood flow leading to more localization of infection and inflammation and impeded healing.[21]

On the other hand, few other studies have reported that foreseen and encountered pain outcome levels associated with endodontic therapy notably decreased with increasing age. This can be attributed to stoicism that increases with age and potentially accounts for lower pain reports. No conclusive data that progressive loss of sensitivity to nociceptive stimuli occurs with age. [108]

In the present study, it was observed that the female patients experienced more pain as compared to their male counterparts. These results are similar to Gufran Ali et al[21] and Ryan et al[110] This could be attributed to fluctuating female hormone levels.[21]

The results obtained are in contrast with Arias et al[28] who did not find any relationship between gender and postoperative pain. This could be due to different treatment protocol used in the studies.

The epitome of success in endodontics cannot be tallied directly to postoperative pain. The short-term post-operative pain does not govern the success/failure of endodontic treatment, rather it is based on long-term results.[111]

It should be noted that the results of this one clinical study are not exclusive to all clinical cases, and further studies with a greater sample size and association ofvariables are called for. Future research comparing the postoperative pain after root canal preparation experienced by symptomatic patients is suggested.

Echoeing with the thought of SukantRatnakar, “Our future success is directly proportional to our ability to understand, adapt and integrate new technology into our work” the endodontists have adapted and excelled.

CONCLUSION

Within the limitations of this study, the following conclusions are drawn:

- Postoperative pain was similar in patients irrespective of the file system used at the end of 6 hours.
- Postoperative pain was significantly higher in patients undergoing root canal instrumentation with the ProTaper Gold rotary instruments as compared to ProTaper Next file system at the end of 24 hours.
- Highest intensity of pain was observed at 6 hours after the treatment, after which the intensity of pain decreased in both the groups, with no pain observed at 72 hours follow up.
- Higher postoperative pain was observed with older individuals. Moreover, higher postoperative pain was observed with females as compared to males.
- The canal preparation time was significantly lesser in the ProTaper Next group in comparison with the ProTaper Gold group.

SUMMARY

The present randomized clinical trial was ventured on to evaluate and compare two different rotary file systems, the ProTaper Nextsystem and the newly introduced ProTaper Gold file system, on the occurrence of postoperative pain after a single visit endodontic treatment. A total of 70 asymptomatic vital maxillary premolar teeth requiring endodontic therapy in obedience to the specific inclusion and exclusion criteria were chosen from the regular pool of patients presenting to the Department of Conservative Dentistry and Endodontics, KLE V.K. Institute of Dental Sciences, Belgaum. They were randomly divided into two groups:

1. Group 'A' consisted of 35 teeth which were instrumented using ProTaper Next (DentsplyMaillefer) files up to size F2

2. Group 'B' consisted of 35 teeth which were instrumented using ProTaper Gold (DentsplyMaillefer) files up to size X2

Important prognostic determinative factors (variables) of postoperative pain like age and gender were recorded.

After obtaining written consent from the patient, local anesthesia (2% lignocaine 1:80,000 adrenaline) was administered and rubber dam (Hygienic, Coltene/Whaledent) applied on tooth for isolation. After sterilization protocol, conventional endodontic access cavity was prepared. The working length (WL) was determined using an apex locator (DentaPort ZX, J. Morita Mfg. Corp., Kyoto, Japan) and reconfirmed with conventional radiograph. Glide path was then created by #15 K-file.

Subsequently, root canal preparation was accomplished by one of the following two instrumentation systems, either with full-sequence rotary ProTaper Gold files up to size F2 or full-sequence rotary ProTaper Next files up to size X2 in obedience to the manufacturer's instructions. An apical diameter of 0.25mm was maintained for standardization purposes. For both the groups time required for instrumentation was also measured.

Obturation was done with single cone obturation technique (either using or ProTaperGold or ProTaper Next matching gutta-percha points) with an epoxy resin-based sealer (AH Plus,DentsplyDeTrey, Konstanz, Germany). All canals were shaped, cleaned and obturated in a single-visit.

The assessment of postoperative pain experienced by the patients was done with a Visual Analogue Scale (VAS)at 6, 24, 48 and 72 hours. A list of adjectives was used to designate the increasing pain intensities such as "no pain"- (0), "mild pain"- (1), "moderate pain"- (2) and "severe pain"- (3) and for ease of recording these adjectives were allocated numbers.

Intergroup pair wise comparison of VAS scores at different time points was done using Mann-Whitney U test. Intragroup pair wise comparisonwas done using Wilcoxon matched pairs test. Time required for instrumentation of the canals in both groups was compared using unpaired t-test. The association of variables with postoperative pain was compared in each group using chi square test.

A statistically significant difference was observed with VAS scores between groups A and B at the end of 24 hrs (p=0.0428) with higher VAS scores observed in Group B than Group A.

The highest pain was observed at 6 hrs after the treatment after which the intensity of pain decreased with no pain observed at 72 hrs in both the groups.In Group A, a statistically significant difference ($p<0.05$) was observed between the VAS scores at at all time periods 6 hours vs 24 hours, 6 hours vs 72 hours, 24 hours vs 72 hours, 48 hours vs 72 hours. In Group B, a statistically significant difference ($p<0.05$) was observed between the VAS scores at at all time periods 6 hours vs 24 hours, 6 hours vs 48 hours, 6 hours vs 72 hours, 24 hours vs 48 hours, 24 hours vs 72 hours, , 48 hours vs 72 hours.

Higher VAS scores were obtained with increasing age. Also, higher VAS scores were obtained in females as compared to males. It was also observed that the canal preparation time was significantly shorter in the Group B in comparison with the Group A (5.49+/-1.06 min versus 11.28+/-1.72 min ($p=0.0001$)

Thus, it can be concluded that postoperative pain was significantly higher in patients undergoing canal instrumentation with ProTaper Gold rotary instruments compared with the ProTaper Next rotary instruments.

BIBLIOGRAPHY

1. Müller F, Naharro M, Carlsson GE. What are the prevalence and incidence of tooth in the adult and elderly population in Europe? Clin Oral Impl Res 2007;18:2- 14.
2. Castellucci A. Magnification in endodontics: the use of the operating microscope. PractProcedAesthet Dent. 2003 Jun;15(5):377-84
3. Kim S. Modern endodontic practice: instruments and techniques. Dent Clin NorthAm. 2004 Jan;48(1):1-9
4. Sathorn C, Parashos P, Messer H. The prevalence of postoperative pain and flare-up in single- and multiple-visit endodontic treatment: a systematic review.IntEndod J. 2008 Feb;41(2):91-9
5. Glennon JP, Ng YL, Setchell DJ, Gulabivala K. Prevalence of and factors affecting postpreparation pain in patients undergoing two-visit root canal treatment. IntEndod J. 2004 Jan;37(1):29-37
6. Yu CY. Role of occlusion in endodontic management: report of two cases. AustEndod J. 2004 Dec;30(3):110-5.
7. Caviedes-Bucheli J, Azuero-Holguin MM, Correa-Ortiz JA, Aguilar-Mora MV, Pedroza-Flores JD, Ulate E, Lombana N, Munoz HR. Effect of experimentally induced occlusal trauma on substance p expression in human dental pulp and periodontal ligament. J Endod. 2011 May;37(5):627-30
8. Siqueira JF Jr, Rôças IN, Favieri A, Machado AG, Gahyva SM, Oliveira JC, Abad EC. Incidence of postoperative pain after intracanal procedures based on an antimicrobial strategy. J Endod. 2002 Jun;28(6):457-60

9. Ruiz-Hubard EE, Gutman JL, Wagner MJ: A quantitative assessment of canal debris forced periapically during root canal instrumentation using two different techniques. J Endod 13: 554-558, 1987

10. Reddy SA, Hicks ML. Apical extrusion of debris using two hand and two rotary instrumentation techniques. J Endod. 1998 Mar;24(3):180-3

11. Adl A, Sahebi S, Moazami F, Niknam M. Comparison of apical debris extrusion using a conventional and two rotary techniques. Iran Endod J. 2009 Fall;4(4):135-8

12. Haapasalo M, Shen Y (2013) Evolution of nickel–titanium instruments: from past to future. *Endodontic Topics*29, 3–17

13. Shen Y, Zhou HM, Zheng YF, Peng B, Haapasalo M. Current challenges and concepts of the thermomechanical treatment of nickel-titanium instruments. J Endod. 2013 Feb;39(2):163-72

14. Ruddle CJ, Machtou P, West JD. The shaping movement: fifth-generation technology. Dent Today. 2013 Apr;32(4):94, 96-9

15. Yared G. Canal preparation using only one Ni-Ti rotary instrument: preliminary observations. Int Endod J. 2008 Apr;41(4):339-44

16. Bürklein S, Schäfer E. Apically extruded debris with reciprocating single-file and full-sequence rotary instrumentation systems. J Endod. 2012 Jun;38(6):850-2

17. Gambarini G, Laszkiewicz J. A scanning electron microscopic study of debris and smear layer remaining following use of GT rotary instruments. IntEndod J. 2002 May;35(5):422-7

18. Koçak MM, Çiçek E, Koçak S, Sağlam BC, Yılmaz N. Apical extrusion of debris using ProTaper Universal and ProTaper Next rotary systems. IntEndod J. 2015 Mar;48(3):283-6

19. Hashem AA, Ghoneim AG, Lutfy RA, Foda MY, Omar GA: Geometric analysis of root canals prepared by four rotary NiTi shaping systems, J Endod, 38:7, pp. 996-1000, 2012.

20. Kustarci A, Akdemir N, Siso SH, Altunbas D. Apical extrusion of intracanal debris using two engine driven and step-back instrumentation techniques: an in-vitro study. Eur J Dent. 2008 Oct;2(4):233-9

21. Ali SG, Mulay S, Palekar A, Sejpal D, Joshi A, Gufran H. Prevalence of and factors affecting post-obturation pain following single visit root canal treatment in Indian population: A prospective, randomized clinical trial. ContempClin Dent. 2012 Oct;3(4):459-63

22. Sathorn C, Parashos P, Messer HH. Effectiveness of single- versus multiple-visit endodontic treatment of teeth with apical periodontitis: a systematic review and meta-analysis. IntEndod J. 2005 Jun;38(6):347-55

23. Lohbauer U, Gambarini G, Ebert J, Dasch W, Petschelt A. Calcium release and pH-characteristics of calcium hydroxide plus points. IntEndod J. 2005Oct;38(10):683-9

24. Arias A, Azabal M, Hidalgo JJ, de la Macorra JC. Relationship between postendodontic pain, tooth diagnostic factors, and apical patency. J Endod. 2009 Feb;35(2):189-92

25. Wang C, Xu P, Ren L, Dong G, Ye L. Comparison of post-obturation pain experience following one-visit and two-visit root canal treatment on teeth with vital pulps: a randomized controlled trial. IntEndod J. 2010 Aug;43(8):692-7

26. Alonso-Ezpeleta LO, Gasco-Garcia C, Castellanos-Cosano L, Martín-González J, López-Frías FJ, Segura-Egea JJ. Postoperative pain after one-visit root-canal treatment on teeth with vital pulps: comparison of three different obturation techniques. Med Oral Patol Oral Cir Bucal. 2012 Jul 1;17(4):e721-7

27. Bhagwat S, Mehta D. Incidence of post-operative pain following single visit endodontics in vital and non-vital teeth: An in vivo study. ContempClin Dent. 2013 Jul;4(3):295-302

28. Arias A, de la Macorra JC, Hidalgo JJ, Azabal M. Predictive models of pain following root canal treatment: a prospective clinical study. IntEndod J. 2013 Aug;46(8):784-93

29. Gambarini G. The influence of three different instrumentation techniques on the incidence of postoperative pain after endodontic treatment. Annali di Stomatologia 2013; IV (1): 152-155

30. Kara Tuncer A, Gerek M. Effect of working length measurement by electronic apex locator or digital radiography on postoperative pain: a randomized clinical trial. J Endod. 2014 Jan;40(1):38-41.

31. Capar ID, Ertas H, Ok E, Arslan H, Ertas ET. Comparative study of different novel nickel-titanium rotary systems for root canal preparation in severely curved root canals. J Endod. 2014 Jun;40(6):852-6

32. Arias A, Singh R, Peters OA. Torque and force induced by ProTaper universal and ProTaper next during shaping of large and small root canals in extractedteeth. J Endod. 2014 Jul;40(7):973-6

33. Capar ID, Arslan H, Akcay M, Uysal B. Effects of ProTaper Universal, ProTaper Next, and HyFlex instruments on crack formation in dentin. J Endod. 2014 Sep;40(9).

34. Ozsu D, Karatas E, Arslan H, Topcu MC. Quantitative evaluation of apically extruded debris during root canal instrumentation with ProTaper Universal, ProTaper Next, WaveOne, and self-adjusting file systems. Eur J Dent. 2014 Oct;8(4):504-8

35. Karataş E, Gündüz HA, Kırıcı DÖ, Arslan H, Topçu MÇ, Yeter KY. Dentinal crack formation during root canal preparations by the twisted file adaptive, ProTaper Next, ProTaper Universal, and WaveOne instruments. J Endod. 2015 Feb;41(2):261-4.

36. Uzunoglu E, Turker SA, Görduysus M. Effects of Different Rotary Files Combined with Different Irrigation Needles on Apically Extruded Debris. Braz Dent J. 2015 Jul- Aug;26(4):347-50

37. Çiçek E, Aslan MA, Akkoçan O. Comparison of the Resistance of Teeth Instrumented with Different Nickel-Titanium Systems to Vertical Root Fracture: An In Vitro Study. J Endod. 2015 Oct;41(10):1682-5

38. Topçuoğlu HS, Zan R, Akpek F, Topçuoğlu G, Ulusan Ö, Aktı A, Düzgün S, Ağırnaslıgil M. Apically extruded debris during root canal preparation using

Vortex Blue, K3XF, ProTaper Next, and Reciproc instruments. IntEndod J. 2015 Nov 7

39. Kherlakian D, Cunha RS, Ehrhardt IC, Zuolo ML, Kishen A, da SilveiraBueno CE. Comparison of the Incidence of Postoperative Pain after Using 2 Reciprocating Systems and a Continuous Rotary System: A Prospective Randomized Clinical Trial. J Endod. 2016 Feb;42(2):171-6

40. Özer SY. Comparison of root canal transportation induced by three rotary systems with noncutting tips using computed tomography. Oral Surg Oral Med Oral Pathol Oral RadiolEndod. 2011 Feb;111(2):244-50

41. Alí A, Olivieri JG, Duran-Sindreu F, Abella F, Roig M, García-Font M. Influence of preoperative pain intensity on postoperative pain after root canal treatment: A prospective clinical study. J Dent. 2016 Feb;45:39-42.

42. da Silva Limoeiro AG, Dos Santos AH, De Martin AS, Kato AS, Fontana CE, Gavini G, Freire LG, da SilveiraBueno CE. Micro-Computed Tomographic Evaluation of 2 Nickel-Titanium Instrument Systems in Shaping Root Canals. J Endod. 2016 Mar;42(3):496-9

43. Eken R, Sen OG, Eskitascioglu G, Belli S. Evaluation of the Effect of Rotary Systems on Stresses in a New Testing Model Using a 3-Dimensional Printed Simulated Resin Root with an Oval-shaped Canal: A Finite Element Analysis Study. J Endod. 2016 Aug;42(8):1273-8

44. Topçuoğlu G, Topçuoğlu HS, Akpek F. Evaluation of apically extruded debris during root canal preparation in primary molar teeth using three different rotary systems and hand files. Int J Paediatr Dent. 2016 Sep;26(5):357-63

45. Eyuboglu TF, Olcay K, Özcan M. A clinical study on single-visit root canal retreatments on consecutive 173 patients: frequency of periapical complications and clinical success rate. Clin Oral Investig. 2016 Sep 22. [Epub ahead of print]

46. Möller AJ. Microbiological examination of root canals and periapical tissues of human teeth. Methodological studies. OdontolTidskr. 1966 Dec 20;74(5):Suppl:1-380

47. Schafer E. Irrigation of the root canal: ENDO; 2007 1(1): 11-27

48. Bürklein S, Benten S, Schäfer E. Quantitative evaluation of apically extruded debris with different single-file systems: Reciproc, F360 and OneShape versus Mtwo. IntEndod J. 2014 May;47(5):405-9

49. Figini L, Lodi G, Gorni F, Gagliani M.Single versus multiple visits for endodontic treatment of permanent teeth. Cochrane Database Syst Rev 2007; issue 4

50. Silva EJ, Carapiá MF, Lopes RM, Belladonna FG, Senna PM, Souza EM, De-Deus G. Comparison of apically extruded debris after large apical preparations by full-sequence rotary and single-file reciprocating systems. IntEndod J. 2016 Jul;49(7):700-5

51. Fava LR. A comparison of one versus two appointment endodontic therapy in teeth with non-vital pulps. IntEndod J 1989 ; 22 : 179-183

52. Risso PA, Cunha AJ, Araujo MC, Luiz RR. Postobturation pain and associated factors in adolescent patients undergoing one- and two- visit root canal treatment. J Dent. 2008;36:928–34.

53. El Mubarak AH, Abu- bakr NH, Ibrahim YE. Post- operative pain in multiple- visit and single- visit root canal treatment. J Endod. 2010;36:3~~0~~9

54. Veltri M, Mollo A, Mantovani L, et al. A comparative study of Endoflare-Hero Shaper and MtwoNiTi instruments in the preparation of curved root canals. IntEndod J 2005;38:610–6

55. Weine FS, Kelly RF, Lio PJ. The effect of preparation procedures on original canal shape and on apical foramen shape. J Endod. 1975 Aug;1(8):255-62

56. Peters OA. Current challenges and concepts in the preparation of root canal systems: a review. J Endod. 2004 Aug;30(8):559-67.

57. Walia HM, Brantley WA, Gerstein H. An initial investigation of the bending and torsional properties of Nitinol root canal files. J Endod. 1988 Jul;14(7):346-51.

58. Ferraz CC, Gomes NV, Gomes BP, Zaia AA, Teixeira FB, Souza-Filho FJ. Apical extrusion of debris and irrigants using two hand and three engine-driven instrumentation techniques. IntEndod J. 2001 Jul;34(5):354-8.

59. Hargreaves, K. and Cohen, S. Cohen's pathways of the pulp expert consult.10th ed; St Louis: Mosby;2010

60. Brantley W, Alapati SB. Heat Treatment Of Dental Alloys: A Review. INTECH Open Access Publisher; 2012.

61. C J Ruddle, TheProTaper technique, Endodontic Topics, 10, (2005), 187-190.

62. Brito-Júnior M, Faria-E-Silva AL, Camilo CC, Pereira RD, Braga NM, Sousa-Neto MD. Apical transportation associated with ProTaper Universal F1, F2 and

F3 instruments in curved canals prepared by undergraduate students. J Appl Oral Sci. 2014 Apr;22(2):98-102

63. Lee W, Song M, Kim E, Lee H, Kim HC. A survey of experience-based preference of Nickel-Titanium rotary files and incidence of fracture among general dentists. Restor Dent Endod. 2012 Nov;37(4)

64. Tanalp J, Kaptan F, Sert S, Kayahan B, Bayirl G. Quantitative evaluation of the amount of apically extruded debris using three rotary instrumentation systems. OOOE.2006;101:252-9.

65. Logani A, Shah N. Apically extruded debris with three contemporary Ni-Ti instrumentation systems: An ex vivo comparative study. Indian J Dent Res. 2008;19: 182-5.

66. Bhatti N, Sroa R, Sikri VK. Evaluation of surface preparation and maintenance of canal curvature following instrumentation with hand 'K' file and three different Ni-Ti rotary systems: A radiographic and SEM study. Contem clinic dent. 2010; 1: 88-93.

67. Su Y, Wang C, Ye L. Healing rate and post-obturation pain of single- versus multiple-visit endodontic treatment for infected root canals: a systematic review. J Endod. 2011 Feb;37(2):125-32

68. Bastia BK, Kuruvilla A, Saralaya KM (2005) Validity of consent--a review of statutes. Indian J Med Sci 59: 74-78.

69. Kumar G. Orban's Oral Histology & Embryology. New Delhi: Elsevier Health Sciences APAC; 2014.

70. Tanalp J, Güngör T. Apical extrusion of debris: a literature review of an inherent occurrence during root canal treatment. IntEndod J. 2014 Mar;47(3):211-21.

71. Seltzer S, Naidorf IJ. Flare-ups in endodontics: I. Etiological factors. J Endod1985;11:472-478.

72. Albashaireh ZS, Alnegrish AS. Post obturation pain after single and multiple-visit endodontic therapy. J Dent 1998;26:227-232.

73. Clem WH. Post treatment endodontic pain. J Am Dent Assoc1970;81:1166-1670.

74. Mor C, Rotstein I, Friedman S. Incidence of interappointment emergency associated with endodontic therapy. J Endod1992;18:509-511.

75. Genet J, Hart A, Wesselink P, Thoden Van Velzen S. Preoperative and operative factors associated with pain after the first endodontic visit. IntEndod J1987; 20: 53–64.

76. Siqueira JF Jr, Rocas IN, Favieri A, Lima KC. Chemomechanical reduction of the bacterial population in the root canal after instrumentation and irrigation with 1%, 2.5%, and 5.25% sodium hypochlorite. J Endod 2000;26:331–4

77. Jalalzadeh SM, Mamavi A, Shahriari S, et al. Effect of pretreatment prednisolone on postendodontic pain: a double-blind parallel-randomized clinical trial. J Endod 2010;36:978–81.

78. Smith RG, Patterson SS, El-Kafrawy AH. Histologic study of the effects of hydrocortisone on the apical periodontium of dogs. J Endod. 1976 Dec;2(12):376-80

79. BruntonPA, AbdeenD, MacFarlane T V. The effect of an apex locator on exposure to radiation during endodontic therapy. J Endod 2002;28:524–6.

80. Hoer D, Attin T. The accuracy of electronic working length determination. IntEndod J 2004;37:125–31.

81. Torabinejad M, Kettering JD, McGraw JC, et al. Factors associated with endodontic interappointment emergencies of teeth with necrotic pulps. J Endod 1988;14:261–6.

82. Ruddle CJ. Cleaning and shaping the root canal system. In: Cohen S, Burns RC, eds. Pathways of the Pulp, 8th ed. St Louis, MO: Mosby; 2002:231–91.

83. Spratt DA, Pratten J, Wilson M, Gulabivala K. An in vitro evaluation of the antimicrobial efficacy of irrigants on biofilms of root canal isolates. IntEndod J. 2001 Jun;34(4):300-7.

84. A Byström, G Sundqvist, Bacteriologic evaluation of the effect of 0.5 percent sodium hypochlorite in endodontic therapy. Oral Surgery Oral Medicine Oral Pathology Journal, 55, (1983), pp. 307-312.

85. Violich DR, Chandler NP. The smear layer in endodontics - a review. IntEndod J. 2010 Jan;43(1):2-15.

86. A Byström, G Sundqvist, The antibacterial action of sodium hypochlorite and EDTA in 60 cases of endodontic therapy, International Endodontic Journal, 18, (1985), pp. 35-40.

87. Brackett MG, Martin R, Sword J, Oxford C, Rueggeberg FA, Tay FR, Pashley DH. Comparison of seal after obturation techniques using a polydimethylsiloxane-based root canal sealer. J Endod. 2006 Dec;32(12): 1188-90

88. Assmann E, Scarparo RK, Böttcher DE, Grecca FS. Dentin bond strength of two mineral trioxide aggregate-based and one epoxy resin-based sealers. J Endod. 2012 Feb;38(2):219-21. doi: 10.1016/j.joen.2011.10.018

89. DiRenzo A, Gresla T, Johnson BR, Rogers M, Tucker D, BeGole EA. Postoperative pain after 1-and 2-visit root canal therapy. Oral Surgery Oral Medicine Oral Pathology 2002; 93(5) : 605-609.

90. Turk DC &MelzackR.The measurement and assessment of people in pain. In Handbook of Pain Assessment (Turk DC &Melzack R eds). The Guildford Press, New York, pp. 3–12.

91. Ng YL, Glennon JP, Setchell DJ, Gulabivala K. Prevalence of and factors affecting post-obturation pain in patients undergoing root canal treatment. IntEndod J. 2004 Jun;37(6):381-91.

92. Pak JG, White SN. Pain prevalence and severity before, during, and after root canal treatment: a systematic review. J Endod. 2011 Apr;37(4):429-38.

93. Pasqualini D, Mollo L, Scotti N, Cantatore G, Castellucci A, Migliaretti G, Berutti E. Postoperative pain after manual and mechanical glide path: a randomized clinical trial. J Endod. 2012 Jan; 38(1):32-6.

94. Keiser K, Byrne BE. Endodontic pharmacology. In: Hargreaves KM, Cohen S, eds. Pathways of the Pulp, 10th ed. St Louis: Mosby Elsevier; 2011:671–90.

95. Arias A, de la Macorra JC, Azabal M, Hidalgo JJ, Peters OA. Prospective case controlled clinical study of post-endodontic pain after rotary root canal preparation performed by a single operator. J Dent. 2015 Mar;43(3):389-95

96. Gondim E Jr, Setzer FC, Dos Carmo CB, Kim S. Postoperative pain after the application of two different irrigation devices in a prospective randomized clinical trial. J Endod. 2010 Aug;36(8):1295-301

97. Capar ID, Arslan H, Akcay M, Ertas H. An in vitro comparison of apically extruded debris and instrumentation times with ProTaper Universal, ProTaper Next, Twisted File Adaptive, and HyFlex instruments. J Endod. 2014 Oct;40(10):1638-41

98. Li H, Zhang C, Li Q, Wang C, Song Y. Comparison of cleaning efficiency and deformation characteristics of Twisted File and ProTaper rotary instruments. Eur J Dent. 2014 Apr;8(2):191-6

99. Wu H, Peng C, Bai Y, Hu X, Wang L, Li C. Shaping ability of ProTaper Universal, WaveOne and ProTaper Next in simulated L-shaped and S-shaped root canals. BMC Oral Health. 2015 Mar 1;15:27

100. Ansari I, Maria R. Managing curved canals. ContempClin Dent. 2012 Apr;3(2):237-41

101. Nekoofar MH, Sheykhrezae MS, Meraji N, Jamee A, Shirvani A, Jamee J, Dummer PM. Comparison of the effect of root canal preparation by using WaveOne and ProTaper on postoperative pain: a randomized clinical trial. J Endod. 2015 May; 41(5):575-8.

102. Wolfe F, Michaud K. The Hawthorne effect, sponsored trials, and the overestimation of treatment effectiveness. J Rheumatol. 2010 Nov; 37(11):2216-20.

103. Relvas JB, Bastos MM, Marques AA, Garrido AD, Sponchiado EC Jr. Assessment of postoperative pain after reciprocating or rotary NiTi instrumentation of root canals: a randomized, controlled clinical trial. Clin Oral Investig. 2015 Dec 19.

104. Peñarrocha-Diago M, Maestre-Ferrín L, Peñarrocha-Oltra D, Gay-Escoda C, von-Arx T, Peñarrocha-Diago M. Pain and swelling after periapical surgery related to the hemostatic agent used: anesthetic solution with vasoconstrictor or aluminum chloride. Med Oral Patol Oral Cir Bucal. 2012 Jul 1;17(4):e594-600.

105. Marshall JG. Consideration of steroids for endodontic pain. Endod Topics 2002; 3:41-51.

106. Bürklein S, Mathey D, Schäfer E. Shaping ability of ProTaper NEXT and BT-RaCe nickel-titanium instruments in severely curved root canals. IntEndod J. 2015 Aug;48(8):774-81

107. Blum JY, Machtou P, Micallef JP. Location of contact areas on rotary Profile instruments in relationship to the forces developed during mechanical preparation on extracted teeth. IntEndod J 1999; 32:108–14.

108. Watkins CA, Logan HL, Kirchner HL. Anticipated and experienced pain associated with endodontic therapy. J Am Dent Assoc. 2002; 133:45-54.

109. Walco GA. Toward an integrated model of pain over the life course. Pain. 2004; 108:207-8.

110. Ryan JL, Jureidini B, Hodges JS, Baisden M, Swift JQ, Bowles WR. Gender differences in analgesia for endodontic pain. J Endod. 2008; 34:552–6.

111. J ParedesVieyra, J Acosta Guardado. Incidence and severity of post-operative pain following root canal treatment of teeth with non-vital pulps using hand and rotary instrumentation techniques. Endodontic practice. 2009 Aug;2(3): 27-30

112. Kashefinejad M, Harandi A, Eram S, Bijani A. Comparison of single visit post endodontic pain using Mtwo rotary and hand K-file instruments: a randomized clinical trial. Journal of dentistry (Tehran, Iran). 2016 Jan;13(1):10.

113. ElnaghyAM,Elsaka SE. Shaping ability of ProTaper Gold and ProTaper Universal files by using cone-beam computed tomography. Indian Journal of Dental Research. 2016 Jan 1;27(1):37.

114. Cakici F, Cakici EB, Küçükekenci FF, Uygun AD, Arslan H. Apically extruded debris during root canal preparation using ProTaper Gold, ProTaper Universal, ProTaper Next, and RECIPROC instruments. The International Journal of Artificial Organs. 2016 Mar;39(3):128-31.

115. Sipavičiūtė E, Manelienė R. Pain and flare-up after endodontic treatment procedures. Stomatologija. 2014;16(1):25-30.

116. Kuzekanani M. Nickel–Titanium rotary instruments: Development of the single-file systems. Journal of International Society of Preventive & Community Dentistry. 2018 Sep;8(5):386.

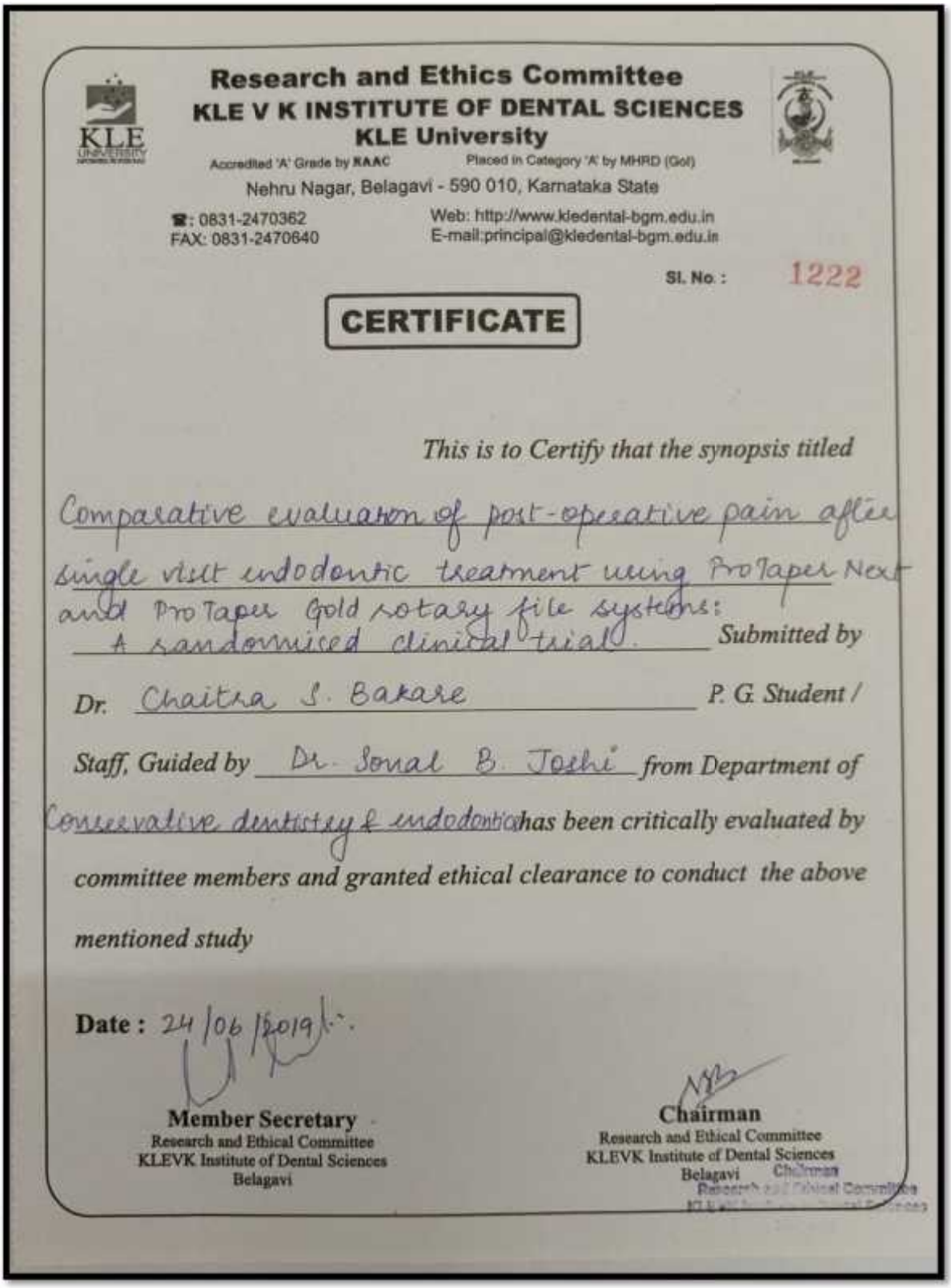
117. Gotler M, Bar-Gil B, Ashkenazi M. Postoperative pain after root canal treatment: a prospective cohort study. International journal of dentistry. 2012 Mar 15;2012.

118. Subbiya A, Cherkas PS, Vivekanandhan P, Geethapriya N, Malarvizhi D, Mitthra S. Effect of three different rotary instrumentation systems on postinstrumentation pain: A randomized clinical trial. Journal of conservative dentistry: JCD. 2017 Nov;20(6):467.

119. Arora N, Joshi SB. Comparative evaluation of postoperative pain after single visit endodontic treatment using ProTaper Universal and ProTaper Next rotary file systems: A randomized clinical trial. Indian Journal of Health Sciences and Biomedical Research (KLEU). 2017 May 1;10(2):124.

120. ElnaghyAM,Elsaka SE. Shaping ability of ProTaper Gold and ProTaper Universal files by using cone-beam computed tomography. Indian Journal of Dental Research. 2016 Jan 1;27(1):37.

ANNEXURE – I – ETHICAL CLEARANCE LETTER



Research and Ethics Committee
KLE V K INSTITUTE OF DENTAL SCIENCES
KLE University
Accredited 'A' Grade by NAAC Placed in Category 'A' by MHRD (GoI)
Nehru Nagar, Belagavi - 590 010, Karnataka State
☎: 0831-2470362
FAX: 0831-2470640
Web: http://www.kledental-bgm.edu.in
E-mail:principal@kledental-bgm.edu.in

Sl. No.: 1222

CERTIFICATE

This is to Certify that the synopsis titled

Comparative evaluation of post-operative pain after single visit endodontic treatment using ProTaper Next and ProTaper Gold rotary file systems: A randomised clinical trial.

Submitted by

Dr. Chaitra S. Bakare *P. G. Student /*

Staff, Guided by Dr. Sonal B. Joshi *from Department of* Conservative dentistry & endodontics *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

Date : 24/06/2019

Member Secretary
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

ANNEXURE – II – BIOSTATISTICS VLEARANCE LETTER

KLE V.K. Institute of Dental Sciences
(A Constituent unit of KLE Academy of Higher Education & Research
Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi-590 010 INDIA
Re-Accredited 'A' grade by NAAC (2nd Cycle) & Placed in Category 'A' by MHRD (GoI)
☎ 0831-2470362
FAX: 0831-2470640
Web: http://www.kledental-bgm.edu.in
E-mail: principal@kledental-bgm.edu.in

Biostatistics Clearance Certificate

This is to cerify that the Biostatistics aspect of the Dissertation / Research work of Dr. Chaitra S. Bakare

entitled Comparative evaluation of post-operative pain after Single visit endodontic treatment using Protaper Next and ProtaperGold rotary file systems: A randomised clinical trial.

has been done under my guidance and considered satisfactory.

Place : Belagavi
Date : 18/09/2020

Name & Signature of Biostatistician
(Dr. S.B. Javali)

ANNEXURE – III – PLAGARISM REPORT

Scientific Correspondence and Review Committee

KLE VK Institute of Dental Sciences
A Constituent Unit of KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi - 590 010, Karnataka State
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
☎: 0831-2470362 Web: http://www.kledental-bgm.edu.in
FAX: 0831-2470640 E-mail:principal@kledental-bgm.edu.in

Date : 28-9-2020 Serial No. : 047

PLAGIARISM CHECK REPORT

Name of the Applicant : Dr. Chaitra Suresh
UG / PG / Ph.D / Staff : Post Graduate
Batch & Year : 2018 - 2019
Department : Conservative dentistry & Endodontics

The soft copy of Research Work / Manuscript by Dr. Chaitra Suresh entitled "Comparative Evaluation of post-operative pain after single visit endodontic treatment using protaper next and protaper gold rotary file system - a randonized clinical trial" under the guidance of .....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 8%, which is **within / not within** the acceptable limits of 10% as per the UGC guidelines.

Member Secretary
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER-Belagavi

Chairman
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER - Belagavi

ANNEXURE – IV – CONSENT FORM

Department of Conservative Dentistry and Endodontics,

K.L.E. V.K. Institute of Dental Sciences, Belgaum

CONSENT FORM

"Comparative Evaluation Of Post - Operative Pain After Single Visit Endodontic Treatment Using Protaper Next And Protaper Gold Rotary File Systems: *A Randomized Clinical Trial*"

ನಾನು..... ವಯಸ್ಸಿನ ವಯಕ್ತಿಯಾಗಿದ್ದುನನಗೆ ತಿಳಿದಿರುವ ಭಾಷೆಯಲ್ಲಿಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ನನ್ನ

ಭಾಗವಹಿಸುವುದ್ರ ಬಗ್ಗೆನನಗೆ ತಿಳಿಸಲಾಗಿದೆ

೧. ನಾನು ಕೆಲವು ಖಾಸಗಿ ಮಾಹಿತಿಗಳಾದ ಹೆಸರು ವಯಸ್ಸು ಲ್ಲಂಗ ವಿಳಾಸ ಹಲ್ಲಿನತಪಾಸಣೆಯ/ ಚಿಕ್ಕತ್ಸೆಯ ಮಾಹಿತಿಯನ್ನುನ ಮತ್ತು ಈ

ಅಧ್ಯಯನಕಾಗಿ ಬೋಕಾದ ಎಲಿವಿವರಣೆಗಳನ್ನುನ ಕೊಡಲು ಒಪ್ಪಿಕೊಳ್ಳುತ್ತಿದ್ದೇನೆ.

೨. ನನ್ನನ ದೊಗಾದ ಪರಿಸ್ಥಿತಿಗೆಬೋಕಾದ ಚಿಕ್ಕತ್ಸೆಯ ವಿಧಾನಗಳನ್ನುನನಗೆ ಸಂಪೂರ್ಣವಾಗಿ ತಿಳಿಸಲಾಗಿದೆ.

೩. ನನಗೆ ನೋಡುವ ಚಿಕ್ಕತ್ಸೆ ಅಧ್ಯಿಂದ ಉಂಟಾಗುವ ತ್ತೊಂದ್ರೆ ಹಾಗೂ ಅದ್ಯಾಗಿ ಬೋಕಾಗುವ ಚಿಕ್ಕತ್ಸೆಗಳ ಬಗ್ಗೆ ವೈದ್ಯರನ್ನುನ

ಪರಶ್ನನಸಲು ಸಾಕಷ್ಟುವು ಅವಕಾಶಗಳನ್ನುನ ನೋಡಲಾಗಿರುತ್ತದೆ.

೪. ಈ ಅಧ್ಯಯನಕಾಗಿ ನನ್ನನ ದಂತ ವೈದ್ಯರು ನನ್ನನನ್ನುನ ಕರೆದಾಗಲೆಲ್ಲಿ ನಾನು ಬರುವೆನೆಂದ್ದು ಒಪ್ಪಿಕೊಂಡಿದ್ದುತ್ತಿದ್ದೇನೆ.

೫. ನಾನು ನನ್ನನ ದಂತ ವೈದ್ಯರಿಗೆ ನನ್ನನ ಬಗ್ಗೆನೋಡಿರುವ ಮಾಹಿತಿಯನ್ನುನ ಈ ಅಧ್ಯಾಯನದ ಫಲ್ಲಿತಾಂಶದ್ದಿ ಅಳವಡಿಸ್ಕ

ಪರಸುತಿಸಲುಮನವಿ ನೋಡಿರುತ್ತಿದ್ದೇನೆ.

೬. ನಾನು ನನ್ನನ ದಂತ ವೈದ್ಯರು ನನಗೆ ಈ ಅಧ್ಯಯನದ್ದಿನೋಡುವ ನೋಟನೆಗಳನ್ನುನ ತಪಿದೆ ಪಾಲ್ಗುಸುತ್ತಿದ್ದೇನೆ. ೭. ಯಾವುದೋ

ಕಾರಣದಿಂದಾಗಿ ನಾನು ಈ ಅಧ್ಯಯನದ್ದಿಭಾಗವಹಿಸಲು ಆಸಫಲನಾದ್ರೆ/ ಆಸಫಲಳಾದ್ರೆ

ಅಧ್ಯಯನದಿಂದ ಹೊರಬರಲು ನನಗೆ ಅನುಮತಿ ನೋಡಲಾಗಿದೆ.

ಮೇಲಾಂಡ ಮಾಹಿತಿಯನ್ನುನ ನಾನು ಓದಿತಿಳಿದ್ದುಕೊಂಡಿದುದ್ದೇನೆ ಹಾಗೂ ನಾನು ಈ ಅರ್ಜಿಯಲ್ಲಿ ಸಹಿ ಮಾಡಿದುದ್ದೇನೆ.

ದಂತ ವೈದ್ಯ ರಹೆಸರು: ಅಧ್ಯರ್ಥಿಯ ಹೆಸರು ಮತ್ತುಸಹಿ

ವಿಳಾಸ:

ದೊರವಾಣಿ ಸಂಖೆಯ:

ದಂತ ವೈಧಯರ ಸಹಿ:

Department of Conservative Dentistry and Endodontics,
K.L.E. V.K. Institute of Dental Sciences, Belgaum

CONSENT FORM

"Comparative Evaluation Of Post - Operative Pain After Single Visit Endodontic Treatment

मी ..... वय ..... सहभागी होत असलेल्या वरील संशोधना बद्दल मला समजत असलेल्या भाषेत सर्व माहीती दिली आहे

1. मी माझी माहीती जसे की नांव , वय , लिंग, पुर्व दंत उपचार महिती आणि इतर लागणारी माहीती देण्यास तयार आहे.
2. माझी दंत वैद्याकीय तपासणी करणार असल्याची मला कल्पना आहे आणि दिलेली माहीती मला समजली आहे.
3. मी या संशोधना बद्दल माहिती विचारु शकतो/शकते.
4. मी परिक्षणा वेळी दंत वैद्याकानी दिलेल्या सुचना पाळेन.
5. मी दिलेली माहीती आणी येणारा निकल वापरण्यास, मांडण्यास आणि प्रकाशीत करण्यास पुर्ण सम्मती देत आहे.
6. जरी एखाद्या एजेन्सीने मी दिलेली माहीती वापरली तरी मी कोणतीही फर मागणी करणार नाही
7. मी या संशोधनात स्वइच्छेने भाग घेण्याची परवानगी देत आहे .
8. कोणत्याही काणास्तव माझा सहभाग मी माघारी घेऊ शकतो/ शकते.
9. दंतवैद्यकाने दिलेली वरील महिती मी वाचली आहे आणि ती मला समजली आहे. म्हणुन मी या अर्जावर नोंदणी व स्वाक्षरी केली आहे.

दंतवैद्यकाचे नांव :
दंतवैद्यकाची स्वाक्षरी :
तारीख

पालकांची सही :
स्थळ :

ANNEXURE – V – PROFORMA

Department of Conservative Dentistry and Endodontics
K.L.E. V.K. Institute of Dental Sciences, Belgaum

"Comparative Evaluation Of Post - Operative Pain After Single Visit Endodontic Treatment Using ProTaper Universal And ProTaper Next Rotary File Systems: *A Randomized Clinical Trial"*

Case History, Patient Assessment, Diagnosis And Treatment Plan

Name of the Patient :

O.P.D. Number :

Sex :

Age :

Address :

Chief Complaint :

History Of Present Illness :

Past Dental History :

Medical History :

History Of Allergy :

Clinical Examination :

Clinical Diagnostic Tests :

Pulp Vitality Test [Electric Pulp Test] :

Percussion :

Mobility :

Radiographs [IOPA] :

Diagnosis :

Treatment plan :

ANNEXURE – VI

'VISUAL ANALOGUE SCALE' SCORE SHEET

Department of Conservative Dentistry and Endodontics

K.L.E. V.K. Institute of Dental Sciences, Belgaum

Proforma(to be handed over to the patient)

"Comparative Evaluation Of Post - Operative Pain After Single Visit Endodontic Treatment Using ProTaper Universal And ProTaper Next Rotary File Systems: *A Randomized Clinical Trial"*

Name of the Patient :

O.P.D. Number :

Sex :

Age :

Address :

6 hours

No pain **Mild pain** **Moderate pain** **Severe pain**

24 hours

No pain **Mild pain** **Moderate pain** **Severe pain**

48 hours

No pain **Mild pain** **Moderate pain** **Severe pain**

72 hours

No pain **Mild pain** **Moderate pain** **Severe pain**

Medication taken, if any, when:_____

Signature of the patient

Thank you for your participation in the study