

**EFFECT OF PROPOLIS PASTE AS INTRACANAL
MEDICAMENT ON POST-ENDODONTIC PAIN: A DOUBLE
BLIND RANDOMIZED CLINICAL TRIAL**

SYNOPSIS

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By

Dr. Juzer Shabbir Saifee



Dr. Ishrat-ul-Ibad Khan Institute of Oral Health Sciences

Dow University of Health Sciences

Karachi, Pakistan

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CORRESPONDING SUPERVISOR:

Dr. Fazal-ur-Rehman Qazi

CERTIFICATE

Researcher (first author):

Name: Dr. Juzer Shabbir Saifee

Designation: M.D.S. Trainee

Department: Operative Dentistry

Qualification: B.D.S., M.D.S trainee

Signature:



Supervisor (corresponding author):

Name: Dr. Fazal-ur-Rehman Qazi

Designation: M.D.S Program Director, Associate Professor.

Department: Operative Dentistry

Qualification: B.D.S., F.C.P.S.

Signature:



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ABSTRACT

Background:

Dental pain is a significant factor due to which the patient seeks treatment. Non-surgical Endodontic treatment is a major therapy to treat the pain and save the tooth. Pain control during this endodontic procedure is a challenging goal for dental practitioners. Patients having necrotic teeth have the highest incidence of post-endodontic pain, therefore, it needs special attention.

To prevent post-endodontic pain, different techniques have been adapted. Placing biocompatible medications having either potent antimicrobial activity or anti-inflammatory component or both inside the root canals is one of the eminent techniques to disinfect the canals and control the pain. Calcium hydroxide is the most common intracanal medicament to which all other medicaments are being compared but it carries certain drawbacks with it. It is ineffective against *E.faecalis* and Fungi, lacks anti-inflammatory component and is controversial in preventing pain. Presently, focus of research has shifted towards natural alternatives to synthetic intracanal medication. Propolis is an organic resinous substance obtained from bee hive. It is nontoxic, biocompatible, anti-inflammatory, anti-oxidant, and anti-microbial and is effective against *E.faecalis* and fungi.

Objective:

To evaluate the effect of Propolis paste on post-endodontic pain in comparison to calcium hydroxide at different time intervals.

Trial Design:

A parallel group prospective double blind randomized control (clinical) trial.

Methods:

This study will be conducted in Department of Endodontics, Dow International Dental College within 1 year after approval. 80 patients having painful, single rooted necrotic teeth with PAI index 3 and 4 will be selected and randomly assigned to either control (Group I) or experimental (Group II). Randomization will be computer generated and the produced sequence will be placed in sealed envelope

with allocation concealment from the principal researcher. Patients will be blinded to group assignment and the principal researcher will be blinded from the type of intracanal medicament being inserted. Standard non-surgical endodontic procedure will be performed by the principal researcher till root canal preparation is completed. Intracanal medicaments will then be inserted by a secondary operator in the first visit. In Group I, calcium hydroxide will be inserted. In group II (experimental), Propolis powder mixed with saline will be inserted. Visual Analogue Pain Scale will be provided to the patients to rate their pain intensity pre-operatively, then at 4 hours, 12 hours, 24 hours, 48 hours and 72 hours after treatment. Visual analogue scales will be collected after 4 days.

Statistical Analysis:

Analysis of the data will be done through IBM SPSS v24. Flare-up will be identified as increase of 20 or more points on Visual analogue scale from initial pain score. Repeated Measure ANOVA will be used to compare pain scores between the groups at various time intervals; Mann-Whitney U test will be applied for comparison of pain between gender; and Kruskal-Willis test will be applied for comparison of pain between age groups. Crosstabs will be used to report the rate of flare-up.

Key words:

Propolis, Calcium hydroxide, Pain, Flare up, Intracanal Medications, Necrotic teeth.

CHAPTER 1: INTRODUCTION

1.1 - Background:

Dental Pain is a significant factor, due to which the patient seeks treatment and endodontic therapy is a major treatment to alleviate the pain⁽¹⁾. The occurrence of mild pain after root canal preparation is not uncommon⁽²⁾. But sometimes, endodontic procedure can result in flare-up. Flare up can be defined as severe pain and/or swelling of the area of endodontically treated tooth occurring within few hours to few days following initiation and/or completion of root canal treatment⁽³⁾. Severe post-endodontic pain is an emergency, which requires a prompt intervention. Failure to control the post endodontic pain results in demotivation of the patient and eventual extraction of the affected tooth.

The cause of post-endodontic pain is the peri-radicular inflammation which results due to extrusion of irritants from the root canals into the periapical region⁽³⁾. These irritants might be of nonmicrobiological and microbiological origin⁽⁴⁾. Non-microbiological cause is mainly due to iatrogenic errors; inaccurate working length estimation, in-correct method of root canal preparation, overinstrumentation and extrusion of obturating materials, intracanal medicaments and chemical irrigants⁽³⁾. These iatrogenic errors can be controlled by carefully performing endodontic procedures. But sometimes, even after careful and judicious endodontic procedure, flare up occurs, which is due to microbiological cause⁽⁵⁾. The microbiological factor is the most common cause of peri-radicular inflammation. It includes the apical extrusion of infected debris, changes in endodontic microbiota or in environmental conditions, secondary intra-radicular infection and increase in oxidation-reduction potential⁽⁵⁾. The Bacteria which are predominant in symptomatic apical periodontitis are *Parvimonas micra*, *Eubacterium*, *Porphyromonas* and *Prevotella*⁽³⁾. Many chemical mediators are responsible for the occurrence of pain during inflammation. Few examples are; histamine, serotonin, prostaglandins, platelet activating factors and leukotrienes. Certain plasma mediators are also directly or indirectly involved in induction of pain, like; Hageman factor, Bradykinin and fibrinopeptides⁽⁶⁾.

In some studies, the incidence of flare-up is found to be upto 50% ⁽⁷⁻⁹⁾. According to a systemic review, mean post-treatment pain prevalence at 24 hours is 40%. Moreover, moderate pain severity was reported to be 24% at 24 hours⁽¹⁾. In a meta-analysis, frequency of flare-up was found to be 8.4%

⁽¹⁰⁾.

Management of flare up includes prescribing analgesics and antibiotics, performing occlusal reduction, re-instrumentation, placing of intracanal medications, incision and drainage, and cortical trephination ⁽¹¹⁾. Although, chemo-mechanical preparation using sodium hypochlorite irrigation is of paramount importance for reduction of bacterial load in root canals, but 40-60% of the canals still remain infected with pathogenic bacteria⁽¹²⁻¹⁴⁾. Intracanal medicaments are recommended to supplement the chemo-mechanical preparation and eliminate the persistent bacteria in the root canal

system ^(14, 15).

According to Walton⁽¹⁶⁾, The role of intracanal medicament is to; eliminate the microbes, render canal contents inert, control persistent periapical abscesses, prevent or control post-treatment pain and enhance anesthesia. The most commonly used intracanal medicament is Calcium hydroxide⁽²⁾. Incomplete elimination of gram-negative bacteria, questionable healing of periapical lesions and inept elimination and prevention of post-endodontic pain ^(2, 4, 17) are some limitations of using calcium hydroxide. Intracanal use of corticosteroid and antibiotic containing medication like ledermix paste has been found to be effective to control the post-endodontic pain⁽⁸⁾. But, yeasts are resistant to it⁽¹⁸⁾ and ledermix paste is associated with discoloration of tooth⁽¹⁹⁾. Also, it has been found to have a potential to cause increased degree of inflammation ⁽²⁰⁾. More recently trends have shifted towards finding a natural organic alternative ⁽²¹⁾ to synthetic inorganic intracanal medicaments. Propolis is a natural product which has been used extensively in past⁽²²⁾. It has anti-microbial and antiinflammatory properties and can be used as an intracanal medicament for disinfection of the root canal system⁽²³⁾. Propolis is found to be effective against *E. faecalis*, *S. aureus* and *C. albicans* and other endodontic pathogens ⁽²⁴⁻²⁶⁾. It is also effective against some gram-negative bacteria⁽²⁷⁾. Propolis also decreases

Lipopolysaccharide(LPS) induced inflammation⁽²⁸⁾. Although no harmful effect of propolis has been reported till date, the only drawback of propolis found is its potential to cause allergic contact dermatitis ⁽²⁹⁻³¹⁾.

As microbes are the most common cause of post endodontic pain, the incidence of post endodontic pain is reduced when intracanal medicaments are used for disinfection⁽⁵⁾. Furthermore, several studies have shown that components of Intracanal medicaments are able to diffuse through dentinal tubules, ramifications and apical foramen to exert their effect in inaccessible areas inside the tooth and periapical area ⁽³²⁻³⁸⁾. Owing to the fact that Propolis is effective against endodontic pathogens and has anti-inflammatory component; flavonoid⁽³⁹⁾, it is expected to reduce the occurrence and severity of post-endodontic pain in necrotic teeth. The aim of the present study is to test the clinical efficacy of propolis when used as intracanal medicament in reducing and preventing the post-endodontic pain as compared to calcium hydroxide.

1.2 - Literature Review:

As the non-surgical endodontics is developing, there have been significant development in prevention and treatment of post-endodontic pain but controversy remains on the effectiveness of the intracanal medicaments in reducing pain⁽³⁾. There is also no systemic review or meta-analysis published till date about the role of intracanal medicament in prevention of post-endodontic pain.

Calcium hydroxide has been broadly used for various purposes in dentistry since 1920s. Today, it is still the most widely used endodontic medicament all over the world⁽⁴⁰⁾. The mechanism of action by which calcium hydroxide kills the bacteria is related to its high pH. The micro-organisms are killed due to release of hydroxyl ions, which results in highly alkaline environment in which bacteria are unable to survive⁽⁴¹⁾. Calcium hydroxide has also shown to inactivate bacterial lipopolysaccharide (LPS) and assist in periapical tissue healing⁽⁴²⁾. In few studies, calcium hydroxide has been reported to be useful in controlling inflammatory exudate from peri-radicular region. Mechanism behind this property might be related to its antimicrobial effect⁽⁴³⁾, capillary contraction⁽⁴⁴⁾ and apical plug formation⁽⁴³⁾. Clinically, it was suggested that calcium hydroxide had pain-relieving property due to its

antibacterial and tissue altering effects⁽⁴⁵⁾. But some authors have disagreed with this suggestion and reasoned that calcium hydroxide could initiate or increase pain by starting or exacerbating inflammation⁽⁴⁶⁾. Likewise, few studies have shown that calcium hydroxide has no impact on prevention or reduction of post endodontic pain ⁽⁴⁷⁻⁵⁰⁾.

Propolis is a byproduct, prepared by honey bees which has broad spectrum of biological activities⁽⁵¹⁾. Raw propolis consists of 50% plant resins, 30% waxes, 10% aromatic and essential oils, 5% pollens and 5% other organic substances⁽³⁹⁾. Propolis has been found to be effective in treating colds, wounds and ulcers, sprains, rheumatism, heart disease, diabetes⁽⁵²⁻⁵⁵⁾ and dental caries⁽⁵⁶⁻⁶⁰⁾ due to its antiinflammatory^(55, 61-63), anti-microbial, anti-oxidant, anti-tumor⁽⁶⁴⁾, anti-ulcer and anti-HIV properties⁽⁶⁵⁾. The main constituents of temperate climate region propolis are flavonoids without Bring substituents, like chrysin, Galangin, pinocembrin and pinobanksin⁽³⁹⁾. Being a major component of propolis, flavonoids are greatly responsible for pharmacological activities of it.

Several studies have been conducted regarding potential use of propolis in dentistry. Some studies have shown that propolis is effective in preventing and treating gingival and periodontal disease ⁽⁶⁶⁻⁶⁹⁾. Propolis also has antiviral effects and can be used locally in viral infections⁽⁷⁰⁾. Propolis is extremely effective medium for avulsed tooth ⁽⁷¹⁻⁷³⁾. Local application of propolis assist in healing wounds after oral surgery procedures, reduces inflammation and has analgesic effect^(74, 75). Propolis has a positive effect on bone forming during expansion of palatine suture⁽⁷⁶⁾. It can reduce dentinal hypersensitivity by partially impregnating the tubules⁽⁷⁷⁾. Propolis can also be used effectively as a direct pulp capping agent ⁽⁷⁸⁻⁸⁰⁾.

There are several in-vitro studies regarding the use of propolis in endodontics. In few studies, it has been shown that Propolis can eliminate *E.faecalis* and *C.albicans* and reduce endotoxin when used as an intracanal irrigant^(81, 82). In some studies, propolis was found to be more effective than calcium hydroxide against endodontic pathogens when used as an intracanal medicament ^(83, 84). Furthermore, propolis has also been found to be superior to tri-antibiotic mixture against *E.faecalis*⁽⁸⁵⁾. Although, few studies have shown that chlorhexidine is more effective against *E.faecalis* as compared to propolis⁽⁸³⁾.

⁸⁶⁾. One study has shown that effectiveness of propolis is similar to chlorhexidine at 7 days⁽⁸⁷⁾. Regarding the biocompatibility and toxicity, propolis has been found to be least toxic and highly biocompatible as compared to other endodontic medicaments and materials ^(78, 88-91). The mechanism by which propolis induces its anti-inflammatory and analgesic action is through suppression of LPS-induced inflammatory response of key cells⁽⁹²⁾. Yet, there is no in-vivo study performed to show the efficacy of propolis paste in reducing inter-appointment pain.

1.3 - Rationale Of Study:

Necrotic teeth require an intracanal medicament which can effectively eliminate notorious bacteria and their byproducts from root canal system and thereby decrease chances of flare up and inter appointment pain indirectly by banishing the cause. Secondly, in order to eliminate and prevent pain and inflammation directly, an intracanal medicament must have an anti-inflammatory component in it. Calcium hydroxide has been proved to be ineffective against some of the detrimental endodontic pathogens and lacks anti-inflammatory component. To offset the draw back of a single intracanal medicament, two or more medicaments are mixed together which increases the cost. Propolis is a natural product which is effective against resistant microbes, is anti-inflammatory and cheaper than other synthetic medicaments. The literature lacks an in-vivo study that investigates the role of Propolis on post-endodontic pain. This study will be an attempt to fill this knowledge gap.

1.4 - Statement Of The Problem:

Do propolis paste have any significantly better effect on preventing and eliminating the postendodontic pain as compared to calcium hydroxide?

1.5 - Objectives:

To evaluate the effect of Propolis paste on post-endodontic pain in comparison to calcium hydroxide at different time intervals.

1.6 - Hypothesis:

Null hypothesis (H_0) = There will be no significant difference between Calcium hydroxide and Propolis paste in reducing and preventing post-endodontic pain.

Alternative hypothesis (H_A) = There will be a significant difference between Calcium hydroxide and Propolis paste group in reducing and preventing post-endodontic pain.

1.7 - Operational Definitions:

Necrotic teeth:

The teeth which are tender to vertical percussion, have visible periapical widening or radiolucency on periapical radiograph without bone expansion (PAI index= 3 and 4) and shows no bleeding when the pulp chamber is opened.

PAI index⁽⁹³⁾:

- 1-Normal Periapical structure
- 2-Small changes in bone structure not pathognomic of apical periodontitis
- **3-Changes in bone structure with some mineral loss characteristic of apical periodontitis**
- **4-Periodontitis with well-defined radiolucency**
- 5-Severe periodontitis with exacerbating features and bone expansion.

VAS scale⁽⁹⁴⁾:

- No pain= Pain score 0.
- Mild pain intensity with no requirement of analgesics= Pain score 1- 24.
- Moderate pain intensity with requirement of ibuprofen or similar medication= Pain score 25 – 49.

- Severe pain intensity with requirement of narcotic analgesic= Pain score 50 – 74.
- Extreme pain intensity, not relieved by any type of medication= Pain score 75 – 100.

Flare-up:

An increase of 20 or more points from initial intensity of pain on Visual Analogue Scale (VAS)⁽⁹⁴⁾.

CHAPTER 2 : METHODOLOGY

2.1 - Study Design:

The study will be a parallel group prospective double blind randomized controlled trial, with equal randomization (1:1). The patients and the principal researcher will be blinded from the type of intracanal medicament inserted.

2.2 - Study Setting:

The study will be a multi-center research. It will be conducted in a secondary healthcare center; outpatient department of operative dentistry/endodontics in institutes / campuses of D.U.H.S, Karachi, Pakistan. It is a major commercial city of Pakistan having population of over 23.5 million⁽⁹⁵⁾.

2.3 - Study Duration:

One year.

2.4 - Study Population:

Adults (aged 20 – 40) ***Inclusion***

criteria:

- Single rooted Necrotic teeth with symptomatic or asymptomatic periapical periodontitis having visible periapical widening or radiolucency without bone expansion (PAI index 3 and 4).
- Teeth with favorable root morphology.
- Teeth with closed apex.

Exclusion criteria:

- Teeth with PAI index 1, 4 and 5.
- Patients who are on antibiotics.
- Patient with recent trauma to the jaw.

- Teeth with open apex
- Multi-rooted teeth.
- Vital teeth.
- Non-restorable teeth.
- Unfavorable root morphology (severely curved, dilacerated, severely sclerosed or obliterated).
- Teeth associated with soft tissue abscess or swelling.
- Teeth with external and internal root resorption
- Re-treatment cases.
- Periodontally compromised teeth (like mobile teeth and teeth with excessive bone loss).
- Teeth requiring endodontic surgery.
- Teeth requiring non-surgical endodontic treatment of multiple teeth in the same or opposing quadrant.
- Medically compromised patients (ASA-III and above), patients with special communication needs or who doesn't understand urdu or English language.
- Patients allergic to bee pollen or honey products.

2.5 - Sample size:

Sample size was calculated using “Openepi” website, with following configuration:

- 90% power of the test
- 95% confidence interval (CI)
- With mean and standard deviation (SD) of Calcium hydroxide (2.42 ± 2.1) and Creosote (1.12 ± 0.66) from the article⁽⁹⁶⁾.

The calculated minimum sample size was 62 (31 per group). We intended to increase sample size up to 30% Hence, final sample size was 80 (40 in each group).

2.6 - Sampling technique:

Simple Random sampling technique will be used. Random allocation will be generated by computer with the help of independent person, not related to the study. Allocation concealment will be done by placing the sequence in sealed envelope by the independent person. The envelope will be given to the dental assistant not related to the study. After canal preparation is completed, the dental assistant will inform the secondary operator about which medicament to be inserted according to the sequence.

Details about primary operator:

Primary operator / principal researcher will be responsible for taking the written consent from the patients, diagnosis, selection of patients according to inclusion criteria and carrying out the endodontic procedure till the root canal preparation was completed. He will be blinded from the type of the medicament inserted into the root canal by the secondary operator. The primary operator / principal researcher will have an experience of 4 years of post-graduate training in the field of endodontics, with a total clinical experience of at least 6 years. The primary operator will also be responsible for; explaining the VAS scale to the patient, collecting the scale and data processing.

Details about secondary operator:

The secondary operator will be responsible for inserting the medicaments into the root canals after root canal preparation was completed by primary operator. He will have an experience of 4 years of post-graduate training in the field of endodontics, with a clinical experience of at least 10 years. Additionally, the secondary operator will be given the training of mixing and inserting the medicaments into the root canals by Principal investigator for a week on a plastic block, resembling canal of a single rooted tooth (simulated canal block). The purpose of giving training on a plastic block is that the insertion of the medicaments can easily be observed according to its length and density achieved.

2.7 - Data Collection Procedure:

Approval from Ethics Review Board will be obtained for this research. Written informed consent will be taken from patients.

The patients presenting in the Department of Endodontics will be included in the study according to inclusion criteria. Detailed medical and dental history will be obtained. Complete extra-oral and intraoral examination will be done and periapical radiograph will be taken. Diagnosis of the necrotic pulp with symptomatic or asymptomatic apical periodontitis will be made by the combination of history of pain, positive vertical percussion test (tender to percussion), Vitality test, periapical radiograph (having visible periapical widening or radiolucency) and no bleeding on opening of the pulp chamber.

The treatment will be performed by the principal researcher till the root canal preparation is completed. He will be blinded from the type of medicament being inserted by a secondary independent operator. In first visit, anesthesia (2% lidocaine, 1.8 ml with 1:100,000 epinephrine. Medicaine Inj.) will be given, rubber dam will be applied and standard infection control protocol will be followed⁽⁹⁷⁾. Chamber will be opened with a sterilized round bur (ISO 001/014, BR-41. Mani,inc, Japan) and extension and refinement will be done with straight fissure bur(ISO 110/014, SF21.Mani,inc. Japan). After Chamber opening, glide path will be formed with ISO k file size 06, 08 and 10(Mani,Inc. Japan). Working length will then be taken with apex locator (Dentaport ZX. J Morita MFG Corp, Japan) and confirmed with radiograph. The preparation will be carried out till manual 20k hand file. Further canal preparation will be done in a crown down manner and rotary endodontic file system (Protaper universal, .04 taper. Dentsply Maillefer, Switzerland) will be used with the recommended torque (3.5 N) and speed (300 rpm). Ethylenediamine tetra acetic acid (EDTA) (GlydeFile prep, Dentsply Maillefer, Switzerland) will be used for lubrication and chelation during canal preparation. After each file introduced into the canal, irrigation will be done with 2.5% Sodium hypochlorite with a disposable, open ended, beveled, 27-gauge needle with 5ml syringe kept 2 mm short of working length and solution expressed in a slow passive manner. After canal preparation is completed, root canals will be irrigated with 10 ml sterile saline solution and then flooded with 17% EDTA solution (MD-Cleanser,Meta Biomed, Korea) for 3 mins to neutralize sodium hypochlorite. Then, the final rinse of 5 ml saline solution will be carried out⁽⁹⁸⁾. Canals will be dried with sterile paper points (Dentsply Maillefer, Switzerland) corresponding to master apical file.

Patients will be randomly divided into 2 groups of 40 patients each, according to the intracanal medication inserted. The type of medicament to be placed will be informed to the secondary operator by a dental assistant through computer generated sequence, who will insert the assigned intracanal medicament. Group I (control [treatment as usual]) will consist of teeth in which Calcium Hydroxide paste (Calcipulpe, Septodont. France) will be inserted. In Group II (experimental), 95% propolis powder (Henan Fumei Bio-technology Co., Ltd. China reg no.: 411082100010933) mixed with saline in a ratio of 1:1.5(wt/vol) to form paste, will be inserted into the root canals. These medicaments will be inserted into the canal with lentulo-spiral (Dentsply Maillefer, Switzerland) one size smaller than the master apical file, keeping it 1 mm short from the actual working length. Sterilized dry cotton wool will be placed in pulp chamber after insertion of medicaments and cavity will be filled with temporary cement (Cavit. ESPE Dental AG, Seefeld, Germany). Patient will be given a Visual (pain) analogue scale to rate their pain score. Patients will have to mark their intensity of pain preoperatively, then at different time intervals; 4 hours, 12 hours, 24 hours(day 2), 48 hours(day 3), 72 hours(day 4). Patients will be recalled after 7 days, visual analogue scale will be collected and data will be processed. Obturation and core build-up will be done after 7 days.

2.8 - Study Variables:

- *Dependent variable:* pain score.
- *Independent variable:* gender, age, Necrotic teeth with PAI index 3 or greater
- .

2.9 - Statistical Analysis:

For data entry and analysis, IBM SPSS version 24 was used. For comparison of the mean pain scores between and within both the groups (Control and Experimental), repeated measure anova (mixed way anova) will be employed. Additionally, we will treat pain scores of patients taking pain killers (having pain scores of 25 or above) as missing values and the same analysis will be done; and a separate table will be reported for it. For multiple comparisons between and within groups, post hoc (LSD) test will be applied. For each group, descriptive statistics will be reported like mean, SD, minimum and

maximum of VAS pain scores. Furthermore, using mean pain scores of these tables, a line chart will be used to show the pain score trend with passage of time.

For comparison of pain score averages between the genders, Mann-Whitney U test will be applied.

Patients will be divided into four groups according to their ages; 20 to 24, 25 to 29, 30 to 34 and 35 to 40. For comparison of pain averages among the age groups, Kruskal Wallis test will be applied.

A p- value of 0.05 or less will be considered as significant and 0.01 or less as highly significant.

Descriptive statistics like frequencies will be used to report the statistics of: age (with percentages, mean age, SD, minimum and maximum); pre-operative pain status of sample; and the percentages of each type of single rooted teeth included in the study.

Similarly, the descriptive statistics like crosstabs will be used to analyze and report; the distribution of total number of males and females in each group; distribution of age groups in each group; the percentages of type of oral analgesics used by the patients according to different time intervals; the severity of pain experienced according to gender at different time intervals; and the severity of pain experienced by the patients according to age groups at different time intervals. Furthermore, the crosstab will also used to report flare-up rate according to each group. The flare-up will be determined as having pain score difference of 20 or more from previous time interval to the next one.

CHAPTER 3 : REFERENCES AND APPENDICES:

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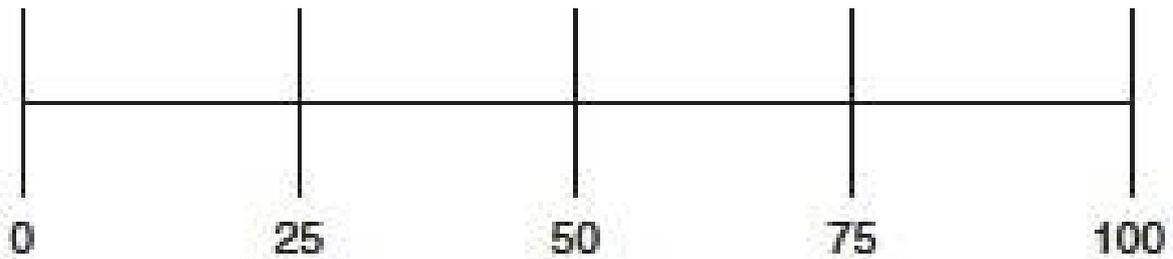
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3.2 – Appendices:

VISUAL(PAIN) ANALOGUE SCALE



On a scale from 0-100(given above), please mark the intensity of pain at different times using the criteria(chart) given on the right side:

1) - Before start of treatment =

2) - 04 hours =

3) - 12 hours =

4) - Day 2 =

5) - Day 3 =

6) - Day 4 =

Patient Serial No. =

0-24=> *No pain to mild pain, requires no pain killer.*

25-49=> *Moderate pain requires Ibuprofen, or similar medication for relief.*

50-74=> *Severe pain not relieved by above medication necessitating use of narcotic analgesics such as Codeincontaining preparations.*

75-100=> *Extreme pain not relieved by any measures taken.*

Chart: criteria for assessing the pain severity



Informed Consent Form

EFFECT OF PROPOLIS PASTE AS INTRACANAL MEDICAMENT ON POST-ENDODONTIC PAIN: A DOUBLE BLIND RANDOMIZED CLINICAL TRIAL

PRINCIPAL RESEARCHER	WITNESS	CONTACT DETAILS
DR. JUZER SHABBIR		Dr.juzer.shabbir@gmail.com

- I consent to participate in the project named above which is taking place in Doctor Isshrat-ul-ibad khan Institute of Oral Health Sciences. The particulars of participation have been explained to me.
- I acknowledge that:
 - (a) The possible effects of the use of these data have been explained to me to my satisfaction
 - (b) The project is for the purpose of research for assessment in higher education.
- I understand that:
 - (a) My identity will not be revealed in any report based on this project.
 - (b) This consent form and data I supply will be kept in confidence by the researchers.

Information consent (choose one): YES NO

- I authorize the researchers to record and analyze data for the stated purposes of the project.
- I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements.

Name	Age	Sex
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Thank you.