

**The Effect of Triple Antibiotic Paste as an  
Intracanal Medication with an Anti-Inflammatory  
Drug on Post-Operative Pain of Asymptomatic  
Uniradicular Necrotic Teeth  
(A Double Blind Randomized Clinical Trial).**

**A Thesis**

*Submitted to the Faculty of Dentistry,*

*Cairo University*

*In partial fulfillment of the requirements of Doctorate degree in  
Endodontics*

**By**

**Mohamed Omaia Ahmed Salah**

B.D.S, 2009, October 6 University

M.S.C, 2015, Cairo University

**Faculty of Dentistry**

**Cairo University**

**2018**

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

قُلْ لِّمَنَ عِبَادِي

صَدَقَ اللَّهُ الْعَظِيمُ

سورة طه / من الآية ١١٤

## **SUPERVISORS**

### **Prof. Dr. Maged M. Negm**

Professor of Endodontics

Faculty of Dentistry

Cairo University

### **Assoc. Prof. Dr. Yousra M. Nashaat**

Associate professor of Endodontics

Faculty of Dentistry

October 6 University

### **Dr. Nehal Nabil**

Lecturer in Endodontics

Faculty of Dentistry

Cairo University

### **Assoc. Prof. Dr. Amal Sabry Othman**

Associate professor of Microbiology

Faculty of Applied Medical Sciences

October 6 University

## **Judgment Committee**

### **Prof. Dr. Medhat Abdel Rahman Kataia**

Professor of Endodontics

Faculty of Dentistry

Cairo University

### **Prof. Dr. Wael Hussein**

Professor of Endodontics

Faculty of Dentistry

Azhar University

### **Prof. Dr. Maged M. Negm**

Professor of Endodontics

Faculty of Dentistry

Cairo University

### **Assoc. Prof. Dr. Yousra M. Nashaat**

Associate professor of Endodontics

Faculty of Dentistry

October 6 University

### **Assoc. Prof. Dr. Amal Sabry Othman**

Associate professor of Microbiology

Faculty of Applied Medical Sciences

October 6 University

*This work is dedicated to:*

*My Beloved  
Parents and Wife*

*who have been my constant sources of  
inspiration.*

*They have given me the drive and  
discipline to tackle any task with  
enthusiasm and determination.*

*Without their love and support this study  
would not have been possible.*

## ACKNOWLEDGEMENTS

*First grace and foremost thanks to **Allah** for blessing this work until it has reached its end, as a little of his generous help throughout my life.*

*I am greatly indebted to **Prof. Dr. Maged M. Negm**, Professor of Endodontics, Faculty of Dentistry, Cairo University for his guidance, valuable advice, support, endless help and supervision during the entire course of this study and also for his father dealing sympathy.*

*I would like to express my sincere thanks to **Assoc. Prof. Dr. Yousra M. Nashaat**, Associate Professor of Endodontics, Faculty of Dentistry, October 6 University, for her unlimited kindness, care, concern, valuable cooperation and helpful remarks.*

*Great thanks and gratitude are extended to **Dr. Nehal Nabil**, Lecturer in Endodontics, Faculty of Dentistry, Cairo University, for her concern, assistance and keen supervision throughout the research.*

*No words can fulfill the feelings of gratitude and respect I carry to **Assoc. Prof. Dr. Amal Sabry Othman**, Associate professor of Microbiology, Faculty of Applied Medical Sciences, October 6 University, for her constructive guidance, compassion, patience, kindness and encouragement during this study.*

*I wish to thank the volunteers who participated in this study.*

# **LIST OF CONTENTS**

<b>Introduction.....</b>	<b>1</b>
<b>Review of Literature</b>	
➤ Evidence-Based Dentistry .....	<b>3</b>
➤ Pain Evaluation .....	<b>4</b>
➤ Pain Assessment.....	<b>8</b>
➤ Pain Management .....	<b>16</b>
➤ Pathogenicity of bacterial species.....	<b>19</b>
➤ Antimicrobial effect of different intracanal medicaments against bacterial species.....	<b>21</b>
<b>Aim of the Study.....</b>	<b>32</b>
<b>Materials and Methods</b>	
➤ Materials.....	<b>34</b>
➤ Methods.....	<b>37</b>
➤ Statistical analysis.....	<b>52</b>
<b>Results.....</b>	<b>54</b>
<b>Discussion.....</b>	<b>79</b>
<b>Summary and Conclusion.....</b>	<b>90</b>
<b>References.....</b>	<b>93</b>
<b>Appendices.....</b>	<b>I</b>
<b>Arabic Summary.....</b>	<b>A</b>

## **LIST OF TABLES**

<b>Table (1):</b> Different outcomes measured in the study and their measuring device and unit.....	<b>32</b>
<b>Table (2):</b> Materials' specifications, compositions and manufacturers .....	<b>36</b>
<b>Table (3):</b> Variables of the study.....	<b>41</b>
<b>Table (4):</b> Interaction between variables .....	<b>42</b>
<b>Table (5):</b> Grades of pain according to VAS.....	<b>52</b>
<b>Table (6):</b> Mean and Standard deviation (SD) of Age for different tested groups.....	<b>56</b>
<b>Table (7):</b> Frequency (N) and Percentage (%) of gender for different tested groups.....	<b>57</b>
<b>Table (8):</b> Frequency (N) and Percentage (%) of tooth type distribution and position for different tested groups.....	<b>57</b>
<b>Table (9):</b> Mean and Standard deviation (SD) of VAS for different tested groups .....	<b>60</b>
<b>Table (10):</b> Frequency (N) and Percentage (%) of VAS Score for different tested groups.....	<b>63</b>
<b>Table (11):</b> Speaman's rho correlation between pain intensity and different variables for different tested groups.....	<b>65</b>
<b>Table (12):</b> Frequency (N) and Percentage (%) of analgesic drug intake for different tested groups.....	<b>66</b>
<b>Table (13):</b> Mean and Standard deviation (SD) of Bacterial Count (Log (CFU/ml) for different tested groups.....	<b>68</b>
<b>Table (14):</b> Mean and Standard deviation (SD) of Optical Density for different tested groups.....	<b>73</b>



## **LIST OF FIGURES**

<b>Fig. 1.</b> Non setting calcium hydroxide (Metapex).....	<b>34</b>
<b>Fig. 2.</b> Triple antibiotic paste .....	<b>34</b>
<b>Fig. 3.</b> Diclofenac potassium anti-inflammatory drug (Catafast).....	<b>35</b>
<b>Fig. 4.</b> Working length determination using patency file size 20.....	<b>44</b>
<b>Fig. 5.</b> Sterile paper point size 25 placed in the canal.....	<b>44</b>
<b>Fig. 6.</b> Vortex in which test tubes were vortexed for 1 minute .....	<b>45</b>
<b>Fig. 7.</b> Incubator used for plates storage.....	<b>46</b>
<b>Fig. 8.</b> Blood agar culture plate.....	<b>46</b>
<b>Fig. 9.</b> X smart motor and reducing handpiece.....	<b>47</b>
<b>Fig. 10.</b> Assorted ProTaper NiTi files.....	<b>47</b>
<b>Fig. 11.</b> Calcium hydroxide application into the canal through the disposable tip.....	<b>48</b>
<b>Fig. 12.</b> TAP+Catafast application into the canal through the disposable tip .....	<b>49</b>
<b>Fig. 13.</b> Visual Analog Scale .....	<b>50</b>
<b>Fig. 14.</b> CONSORT flow diagram of the study .....	<b>54</b>
<b>Fig. 15.</b> Bar chart showing mean age for tested groups.....	<b>56</b>
<b>Fig. 16.</b> Stacked Bar chart showing gender distribution for tested groups.....	<b>57</b>

<b>Fig. 17.</b> Stacked Bar chart showing tooth type distribution for tested groups.....	<b>58</b>
<b>Fig. 18.</b> Stacked Bar chart showing tooth position distribution for tested groups...	<b>58</b>
<b>Fig. 19.</b> Bar chart showing mean VAS for tested groups.....	<b>60</b>
<b>Fig. 20.</b> Line chart showing mean VAS for different follow-up periods.....	<b>61</b>
<b>Fig. 21.</b> Stacked Bar chart showing VAS for tested groups.....	<b>64</b>
<b>Fig. 22.</b> Bar chart representing analgesic drug intake for tested groups.....	<b>67</b>
<b>Fig. 23.</b> Bar chart showing mean Bacterial Count (Log (CFU/ml) for tested groups.....	<b>69</b>
<b>Fig. 24.</b> Line chart showing mean Bacterial Count (Log (CFU/ml) after different steps for tested groups.....	<b>70</b>
<b>Fig. 25.</b> Bar chart showing mean Optical Density for tested groups.....	<b>74</b>
<b>Fig. 26.</b> Line chart showing mean Optical Density for tested groups for -1 dilution.....	<b>77</b>
<b>Fig. 27.</b> Line chart showing mean Optical Density for tested groups for -2 dilution.....	<b>77</b>
<b>Fig. 28.</b> Line chart showing mean Optical Density for tested groups for -3 dilution.....	<b>78</b>

# INTRODUCTION

## **INTRODUCTION**

The elimination of intracanal microorganisms is essential for the long-term success of root canal treatment. This may be achieved by mechanical cleaning and shaping in conjunction with irrigation and antibacterial agents. However, endodontic therapy essentially is directed toward one specific set of aims: to cure or prevent periradicular periodontitis.

Microorganisms as *E. faecalis* are able to form a biofilm that helps it to resist destruction by enabling the bacteria to become a thousand times more resistant to phagocytosis, antibodies and antimicrobials than nonbiofilm producing organisms.

It is resistant to inter appointment medicaments including calcium hydroxide and may also reside in canals as single species without the support of other organisms. It was also reported that this microorganism has the ability under specific conditions to infect the whole length of the tubules within 2 days.

Our challenge as endodontists is to implement methods to eliminate this microorganism during and after root canal treatment.

Systemic antibiotics appear to be clinically effective as an adjunct in certain surgical and nonsurgical endodontic procedures. Their administration is not without the potential risk of adverse systemic effects, such as allergic reactions, toxicity and the development of resistant strains of microbes. Furthermore, the systemic administration of antibiotics relies on patient's compliance with the dosing regimens followed by absorption through the

gastro-intestinal tract and distribution via the circulatory system to bring the drug to the infected site. Hence, the infected area requires a normal blood supply which is no longer the case for teeth with necrotic pulps and for teeth without pulp tissue. Therefore, local application of antibiotics within the root canal system may be a more effective mode for delivering the drug.

A successful endodontic treatment is therefore dependent on the initial eradication of all the bacteria, i.e. those present in the root canal as well as those already penetrated in depth. The achievement of microbicidal doses becomes critical in the endodontic environment, because in such harsh conditions bacteria may aggregate to form a biofilm or enter a stationary phase, thus acquiring a resistant phenotype. Accordingly, in endodontic therapy the local use of antibiotics allows the use of the necessary very high concentrations. Moreover, some antibiotics like tetracyclines may represent the optimal choice to grant long-lasting antimicrobial effects, since they readily attach to dentine and are gradually released, retaining their antibacterial activity.

Because root canal infections are polymicrobial consisting of both aerobic and anaerobic bacterial species, single antibiotic may not be effective in canal disinfection. Therefore, combination of antibiotics, mainly consisting of ciprofloxacin, metronidazole, and minocycline, referred to as triple antibiotic (TA) paste has been suggested for root canal disinfection.

# REVIEW OF LITERATURE

## **REVIEW OF LITERATURE**

### ***I. Evidence Based Dentistry:***

Evidence-based dentistry is defined by the American Dental Association as an approach to oral health care that requires the integration of systematic assessments of clinically relevant scientific evidence with the patient's treatment needs and preferences and the dentist's clinical experience <sup>(1)</sup>.

The hierarchy of evidence is a core principal of evidence-based practice, as it determines the “best available evidence” to be used as a guide for decision making. Study design and quality are the key factors used for ranking on the evidence hierarchy pyramid. Systematic reviews have the highest level of strength followed by randomized clinical trials (RCTs) then cohort studies, case control studies, case series and case studies <sup>(2)</sup>.

Randomized clinical trials is the strongest design of experimental studies related to therapeutic or preventive interventions. In a RCT, participants are randomly allocated to either one intervention (such as a drug treatment) or another (such as placebo treatment), both groups are followed up for a specified time period and analyzed in terms of specific outcomes defined at the outset of the study. As the groups are identical apart from the intervention due to randomization, any differences in outcome could be attributed to the intervention with a certain degree of certainty that the results are a valid estimate of the truth <sup>(3)</sup>.