COMPARATIVE EVALUATION OF SOFT TISSUE HEALING IN DENTAL IMPLANT SITE AUGMENTED WITH PRF AND GELATAMP

A dissertation submitted in

partial fulfillment of the requirements

for the degree of

MASTER OF DENTAL SURGERY

BRANCH – III

ORAL AND MAXILLOFACIAL SURGERY

THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY

CHENNAI – 600 032

2014 – 2017

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation titled **"COMPARATIVE EVALUATION OF SOFT TISSUE HEALING IN DENTAL IMPLANT SITE AUGMENTED WITH PRF AND GELATAMP "** is a bonafide and genuine research work carried out by me under the guidance of **Dr.K.PRABHUSANKAR, M.D.S., Professor, Head of the Department,** Department of Oral and Maxillofacial Surgery, Best Dental Science College, Madurai – 625104.

Dr. L. BALAMURUGAN.

CERTIFICATE BY GUIDE

This is to Certify that **Dr .L. BALAMURUGAN,** Post Graduate student (2014 – 2017) in the Department of Oral and Maxillofacial Surgery, Best Dental Science College, Madurai – 625104 has done this dissertation titled **"COMPARATIVE EVALUATION OF SOFT TISSUE HEALING IN DENTAL IMPLANT SITE AUGMENTED WITH PRF AND GELATAMP "** under my direct guidance and supervision in partial fulfillment of the regulations laid down by The Tamil Nadu Dr. M.G.R Medical University Chennai – 600032, for M.D.S. Oral and Maxillofacial Surgery (Branch III) Degree Examination.

Dr. K. PRABHUSANKAR, M.D.S

DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY

Professor & Guide

Head of the Department

Dr K. PRABHU SANKAR, B.D.S. M.D.S.
PROFESSOR & HOD
Dept of Oral & Maxillofacial Surgery
Best Dental Science College
Madurai.

Department of Oral and Maxillofacial Surgery,

Best Dental Science College,

Madurai – 625104.

ENDORSEMENT BY HEAD OF THE DEPARTMENT /

HEAD OF THE INSTITUTION

This is to certify that the dissertation titled **"COMPARATIVE EVALUATION OF SOFT TISSUE HEALING IN DENTAL IMPLANT SITE AUGMENTED WITH PRF AND GELATAMP "** bonafied research work done by **Dr .L. BALAMURUGAN**, Post Graduate student (2014 - 2017) in the Department of Oral and Maxillofacial Surgery under the guidance of **DR.K.PRABHUSANKAR, M.D.S., Professor and Guide,** Department of Oral and Maxillofacial Surgery, Best Dental Science College, Madurai – 625104.

Dr .K.PRABHUSANKAR, M.D.S

Professor & Head of the Department

Department of Oral and Maxillofacial Surgery,

Dr K. PRABHU SANKAR, B.D.S. M.D.S.,
PROFESSOR & HOD
Dept of Oral & Maxillofacial Surgery
Best Dental Science College
Madurai.

Dr. K.VIJAYALAKSHMI, M.D.S

Principal

PRINCIPAL
BEST DENTAL SCIENCE COLLEGE
MADURAI-625104

Best Dental Science College,

Madurai – 625104.

BEST DENTAL SCIENCE COLLEGE
RUN BY
ULTRA TRUST
MADURAI

ACKNOWLEDGEMENT

"*No one who achieves success does so without acknowledging the help of others. The wise and confident acknowledge this help with gratitude.*"

-Alfred North Whitehead

While a completed dissertation bears the single name of the student, the process that leads to its completion is always accomplished in combination with the dedicated work of other people. I wish to acknowledge my gratitude to few people. Without the support, patience and guidance of the following people, this work would not have been completed. It is to them that I owe my deepest gratitude.

I am immensely thankful to our beloved chairman Prof.**K.ARUMUGAM. M.Pharm.**, and vice chairman Dr.**A. BABU THANDAPANI**. **M.Pharm., Ph.D**., for their motivation , encouragement, and source of inspiration for my dissertation work.

I offer my sincere thanks to **Principal Dr. K. VIJAYALAKSHMI.M.D.S** for providing permission and valuable support to conduct this project.

I would like to thank from the bottom of my heart, My Vice Principal **DR.K.S PREM KUMAR .M.D.S** for the continuous support at difficult times, the approachability and availability, made me realize that I am blessed to learn in this college under his noble guidance.

I would like to acknowledge and thank my beloved Professor, my Guide and Head of the department **Dr. K.PRABHU SANKAR M.D.S, Professor and Head, Department Of Oral and Maxillofacial Surgery**, for his valuable guidance, scholarly inputs and consistent encouragement, which i have received throughout this work. Thank you Sir, for all your help and support.

I am privileged to express my extreme gratefulness to my respected co guide, **K.USHA. M.D.S** for her undying enthusiasm and selfless guidance which helped me to complete this study. Her constructive criticism and valuable suggestions conferred upon me and have encouraged me.

I would like to take this opportunity to thank **DR. MSP.SUNDARAVEL. M.D.S** for his encouraging words, thoughtful criticism, and for their time and attention. Their help and suggestions have really made a difference.

I express my heartfelt thanks to **DR.M.VARUN. M.D.S** who has been an integral part of my post graduate course for his everlasting inspiration, academic and moral support, innovative ideas, incessant encouragement, friendly guidance and thought provoking suggestions.

I am grateful to my colleague, **Dr. G. Muralidharan** for his patient endurance, co-operation and support he offered me during my postgraduate course. I extend my sincere thanks to my beloved junior colleagues **Dr.Avinash Balaji, Dr.Ani John Peter , Dr.Rajapandiyan ,** for all their help throughout my course, and my department nursing assistant **Mrs. Pandiyammal,** for their kindly help and support.

My special thanks to our Administrative officer **Mr.G.Babu** for his help, librarian **Mr.Shankar,** for providing a conducive atmosphere to work as a team.

My sincere thanks to **Mrs. Divyadharshini** who helped me in the statistical analysis of the study with her valuable calculations and interpretations.

I also express my thanks to **Mr. Rajeshkumar.M.sc** (Tamizh computers) for his valuable and timely help for this presentation in a proper manner.

My Dynasty… My priceless family….

I also express my heartfelt thanks to my beloved wife **Dr. K. Divyapriya** for sharing her enthusiasm and took more pain to bring me to this level and supported me during the past three years and comments on my work, and my daughter **L.B.Nethra** and my son **B.Visakan** for their prayers and support. Without them it would have been impossible.

Above all, I thank GOD **The Almighty** for **HIS** Blessings and Grace all throughout my life in achieving unexpected Goals and proceed towards new height of destination.

DECLARATION

TITLE OF DISSERTATION	COMPARATIVE EVALUATION OF SOFT TISSUE HEALING IN DENTAL IMPLANT SITE AUGMENTED WITH PRF AND GELATAMP
PLACE OF STUDY	BEST DENTAL SCIENCE COLLEGE, MADURAI – 625104.
DURATION OF THE COURSE	3 YEARS
NAME OF THE GUIDE	DR.K.PRABHUSANKAR
HEAD OF THE DEPARTMENT	DR.K.PRABHUSANKAR

I hereby declare that no part of the dissertation will be utilized for gaining financial assistance/any promotion without obtaining prior permission of the Principal, Best Dental Science College, Madurai – 625104. In addition, I declare that no part of this work will be published either in print or in electronic media without the guide who has been actively involved in dissertation. The author has the right to reserve for publish of work solely with the prior permission of the Principal, Best Dental Science College, Madurai – 625104.

HOD

Dr. K. PRABHU SANKAR, B.D.S.
PROFESSOR & HOD
Dept. of Oral & Maxillofacial Surgery
Best Dental Science College
Madurai.

GUIDE

Dr. K. PRABHU SANKAR, B.D.S. M.D.S.,
PROFESSOR & HOD
Dept. of Oral & Maxillofacial Surgery
Best Dental Science College
Madurai.

Signature of the candidate

DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY

TRIPARTITE AGREEMENT

This agreement herein after the "Agreement" is entered into on this day 30th Dec 2016, between the Best Dental Science College represented by its **Principal** having address at Best Dental Science College, Madurai – 625104, (hereafter referred to as, 'the College')

And

MR. Dr .K. PRABHUSANKAR aged 43 years working as **Professor** in Department of Oral and Maxillofacial Surgery at the College, having residence address at 23, Telephone Road , Aruppukottai – 626101 (herein after referred to as the 'Principal Investigator')

And

Mr. Dr. L.BALAMURUGAN aged 38 years currently studying as **Post Graduate student** in Department of Oral and Maxillofacial Surgery, Best Dental Science College, Madurai-625104 (here in after referred to as the 'PG/Research student and co-investigator')

Whereas the PG/Research student as part of his curriculum undertakes to research on **"COMPARATIVE EVALUATION OF SOFT TISSUE HEALING IN DENTAL IMPLANT SITE AUGMENTED WITH PRF AND GELATAMP "** for which purpose PG/Principal Investigator shall act as Principal Investigator and the college shall provide the requisite infrastructure based on availability and also provide facility to the PG/Research student as to the extent possible as a Co-investigator.

Whereas the parties, by this agreement have mutually agreed to the various issues including in particular the copyright and confidentiality issues that arise in this regard.

Now this agreement witnessed as follows

1. The parties agree that all the Research material and ownership therein shall become the vested right of the college, including in particular all the copyright in the literature including the study, research and all other related papers.
2. To the extent that the college has legal right to do so, shall grant to license or assign the copyright so vested with it for medical and/or commercial usage of interested persons/entities subject to a reasonable terms/conditions including royalty as deemed by the College.
3. The royalty so received by the college shall be shared equally by all the parties.
4. The PG Student and Principal Investigator shall under no circumstances deal with the copyright, Confidential information and know – how generated during the course of research / study in any manner whatsoever, while shall sole vest with the college.
5. All expenses pertaining to the research shall be decided upon by the Principal Investigator/Co-investigator or borne solely by the PG/Research Student, (co-investigator).
6. The college shall provide all infrastructure and access facilities within and in other institutes to the extent possible. This includes patient interactions, introductory letters, recommendation letters and such other acts required in this regard.
7. The Principal Investigator shall suitably guide the Student Research right from selection of the Research Topic and Area till its completion. However the selection and conduct of research, topic and area of research by the student researcher under guidance from the Principal Investigator shall be subject to the prior approval,

recommendations and comments of the Ethical Committee of the College constituted for this purpose.

8. It is agreed that as regards other aspect not covered under this agreement, but which pertain to the research undertaken by the PG student, under guidance from the Principal Investigator, the decision of the college shall be binding and final.
9. If any dispute arises as to the matters related or connected to this agreement herein, it shall be referred to arbitration in accordance with the provisions of the Arbitration and Conciliation Act1996.

In witness whereof the parties herein above mentioned have on this day, month and year herein above mentioned set their hands to this agreement in the presence of the following two witnesses.

College represented by its **Principal**

PRINCIPAL
BEST DENTAL SCIENCE COLLEGE
MADURAI-625104

PG Student

Witnesses

1. Usha
(Dr. Usha. V.)

2.
(Dr. Varun M.)

Student Guide

Dr. K. PRABHU SANKAR, B.D.S., M.D.S.
PROFESSOR & HOD
Dept. of Oral & Maxillofacial Surgery
Best Dental Science College
Madurai.

COPYRIGHT

DECLARATION BY THE CANDIDATE

I hereby declare that The Tamil Nadu Dr. M.G.R Medical University, Tamil Nadu shall have the rights to preserve, use and disseminate this research in print or electronic format for academic / research purpose.

Date: 30/12/2016

Signature of the Candidate

Place: MADURAI

DR. L. BALAMURUGAN.

ABSTRACT

ABSTRACT

AIM:

To evaluate and compare the soft tissue healing in dental implant site augmented with PRF(Platelet Rich Fibrin) and GELATAMP (colloidal silver impregnated with gelfoam).

MATERIALS AND METHODS

The Study was performed in a series of 5 patients (10 implants) aged between 20 – 50 years with bilaterally missing mandibular molars requiring teeth replacement attending the Department of Oral and Maxillofacial Surgery. After placement of implant the sites were augmented with PRF and GELATAMP and assessment was done to compare the soft tissue healing , pain, swelling on 1^{st} ,3^{rd} ,and 7^{th} post operative days. The results were recorded, based on Soft Tissue Healing Index ,Visual Analog Scale (VAS), Swelling Assessment by Tape Measurement. The 't' test was used to test the significance between PRF and GELATAMP group. 'p' value < 0.05 was taken to denote significant difference.

RESULTS

Soft tissue healing assessment and pain score showed high statistical significance ($p < 0.005$) on GELATAMP side compare to PRF side on 1^{st}, 3^{rd}, and 7^{th} postoperative day. Regarding swelling assessment, There was no statistical significant difference between 2 groups.

CONCLUSION

It was concluded that, GELATAMP augmented implant site resulted in effective soft tissue healing, reduced postoperative complications compared to PRF group. Hence GELATAMP could be augmented on a routine basis on dental implant site.

KEY WORDS

PRF, GELATAMP , Soft tissue healing,

LIST OF ABBREVIATIONS

ABBREVIATIONS	ACRONYM
ASTM	American Society for Testing and Material
ADA	American Dental Association
GELATAMP	Gelatin sponge impregnated with colloidal silver
PRF	Platelet Rich Fibrin
PPP	Platelet Poor Plasma
IAN	Inferior Alveolar Nerve
V_3	Mandibular branch
Ag NP	Silver Nano Particle
ROS	Reactive Oxygen Species
NS	Nano Silver
L-PRF	Leukocyte - Platelet Rich Fibrin
PRFM	Platelet Rich Fibrin Matrix
ARP	Alveolar Ridge Preservation
PRGF	Platelet Rich Growth Factors
GTR	Guided Tissue Regeneration
SSI	Surgical Site Infection
MRAS	Methicillin Resistant Staphylococcus Aureus
OPG	Orthopantomogram
VAS	Visual Analog Scale
PIE	Peri Implant Epithelium
PISE	Peri Implant Sulcular Epithelium
OE	Oral Epithelium

ABBREVIATIONS	ACRONYM
JE	Junctional Epithelium
Ag [o]	Pure Metallic Silver
Ag[+1], Ag[+2]	Ionized Form of Silver
SSD	Silver Sulfadiazine
JCAHO	Joint Commission for Accreditation of Health Care Organization
BG/ CS	Bioactive Glass with Calcium Sulfate
FDBA	Freeze Dried Bone Allograft
CPB	Corticancellous Porcine Bone Xenograft
CS	Calcium Sulfate
BAS	Bio absorbable Acid Sponge
NAM	Non absorbable membrane

LIST OF TABLES

LIST OF FIGURES

TABLE OF CONTENT

INTRODUCTION

INTRODUCTION

History of Dental Implants dates back to many centuries ago where many attempts was made to replace the missing teeth in different ways to restore a comfortable masticatory function and facial esthetics. Prior to the era of osseointegration there were various types of dental implants and its frameworks used to support complete dentures and partial dentures with various success rates. Different types of material used in implants are porcelain, cobalt-chromium, iridioplatinum, but the discovery of titanium changed the course of implant history.[1]

Branemark was the first person who coined the term "osseo integration" which greatly influenced the implant treatment concepts. After this, materials like titanium and other various materials were used which were biocompatible with human body. In recent decades, many types of dental implants were introduced and have revolutionized dentistry to achieve a proper rehabilization.

CHRONOLOGICAL REVIEW

Ancient Era: The history of the dental implant goes back to 3000 B.C., to the period when the Ancient Egyptian civilization prospered.

1600-1800: In 1687, According to Times of Allen's report in 1800s period there was mention of dental replantation and transpalantion and it was where surgery was started in this era. The first person to publish a description of the technique of modern dental implants was a French dentist, Maggiolo J who described a method to implant 18-karat gold alloy, with three branches into the jawbone, and to install a porcelain crown as a suprastructure in his book: "Le Manuel de l'Art du Dentiste" (1809)[1].

1900-1950 : Few revolution was seen in materials in 1937, when cobalt-chromium-molybdenum alloy was developed and used on patients by Stock at Harvard University**,** and showed great results in patients after many years of follow-up. In 1940, Dahl was the first

person who attempted subperiosteal implant, but this approach did not become popular before being employed by Gershkoff and Goldberg in 1948.

1950-1980: In the 1950's, Dr. Bodine showed that holes for the screws were located in areas where the bone had the greatest strength and thickness and he found that fewer struts or girders were needed in the hardware and frame work design were useful. This decade also included the new discovery of Dr. Lee who introduced the use of an endosseous implant with a central post. The concept of Osseo integration which was given by by brånemark in Europe (1950), said that titanum can be integrated with bone very well. This concept revolutionized the dental implant history. The Branemark technique utilized biocompatible titanium-alloy implants that were atraumatically inserted into the alveolar process. This is known as Branemark's theory and the concept of osseointegration flourished rapidly in the 1980s, which brought about a defining moment in the clinical field of implant dentistry.[1]

In 1951, the Academy of Implant Dentures was established, which is presently known as the American Academy of Implant Dentistry**.** In 1956, Dr. Yamane established an independent institute to experiment on animals, which produced many experts in the field of artificial roots. This experimental institute is currently known as the Japan Institute for Advanced Dentistry. Implant designs saw a breakthrough in1960's with the basic spiral design was modified by Dr. Leonard Linkow in 1963. The blade type implant were introduced by Linkow, making it possible to place it in either the maxilla or the mandible and is now recognized as an endosseous implant.[1-3]

Ventplant is the first screw type implant, which was introduced in 1963 and currently referred to as self-tapping implant, with screw threads with an open-cage design. Cobalt-chromium alloy was used as the implant material, and it was replaced by titanium due to the results of Branemark's research. Therefore, the Ventplant disappeared before it saw the light of day. Although this trend was also seen in Japan, Kawahara and Kyocera Co. Ltd. succeeded in the formation of monocrystalline alumina in 1975.

Bioceram, which is the product name, became the first implant made in Japan for both domestic and overseas use. It has been said that the Bioceram was implanted in over 60,000 patients and was the most pervasive and well-researched implant among the dental implants manufactured in Japan.

In the 1980s, Professor Zarb of the University of Toronto played a central role in holding the Toronto Conference on Osseointegrationin Clinical Dentistry, where Branemark presented the results of his research over 30 years and his clinical practice for nearly 20 years. With this Conference as a turning point, the Branemark Regimen spread over North America and rest of the world later . The typical Branemark regimen during this period consisted of implanting four to six fixtures between the mental foramen of the lower jaw, with subsequent placement of bilateral cantilever, as the standard prosthesis and advocated two-stage surgical technique which became popular throughout the world and many clones of this design were produced and are still in use today.[1]

1980-2000: Towards the late 1980s, the revolutionary movement of the Branemark regimen swept over Japan in the same manner , and a surge in dental implant research took place. This movement was a different kind seen with Linkow's Blade-type or the Bioceram that had its struggles, and has continued its uses till today.

Professor Branemark published a paper covering all the data he had gathered regarding titanium implants in 1981. He followed his original group of dental implant patients over the period of 20 years. The Toronto Conference on Osseointegration in Clinical Dentistry created the first guidelines for what would be considered successful implant dentistry was held in 1982. In 1988 Dr. David Scharf placed his first dental implant published his data in 1993 in the Journal of Oral and Maxillofacial Implants showing that implants can have the same high success rate when placed in a dental office setting under aseptic conditions as when they are placed in an operating room. During the 1980s, dental implantology was

considerably developed due to its immense therapeutic possibilities. The clinical success of the method was based on the following points.

- use of grade II ASTM titanium (American Society forTesting and Materials) threaded implants adapted to the patient's specific anatomy.
- a drilling at low speed with copious irrigation to avoid a thermal injury which is particularly harmful to osseointegration
- locking the fixture at the end of screwing (also called 'primary locking') for a torque of 20—30 N .
- suture of the gingival tissue above the implant.
- placement of the prosthesis on the implant after a 6-month

2000 -2015: An ADA survey in 2002 showed wide acceptance of dental implants as the preferred method of tooth replacement as a fixed dental prosthosis. In 2013 Mehrali et al gave a significant design of dental implants for porous bone exhibits biological adaptation and are called functionally graded materials (FGMs). These are gaining a significant attention in dental implant applications.[1,2]

Dental implants can be classified into several types, such as subperiosteal, endosseous, and transosteal implant. Moreover, the currently used endosseous implant can be classified roughly into blade-type and root-form according to its shape. The root-form implant can largely be divided into one-stage type and two-stage type, in accordance with the operative methods used. It is possible to use the two-stage implant as a one-stage implant and such usage has been increasing in recent years

Advancements in biomaterials, implant design, nanotechnology, biotechnology, and an understanding of the bone–implant interface have resulted in improved outcomes and an expanded utilization of implants. Improved imaging techniques help aid in diagnosis . A varied availability of implant geometries, surfaces, and refined surgical techniques has made

it possible for most healthy patients to receive implants. Numerous materials are available to aid in bone regeneration in the maxillofacial region, including bone substitutes, composite grafts, and autogenous bone.

In the recent clinical studies, Blaschke et al reported that dental implants made from zirconia are a feasible alternative to titanium dental implants. In addition to excellent cosmetic results, zirconia implants allow a degree of osseointegration and soft tissue response that is superior to that of titanium dental implants.

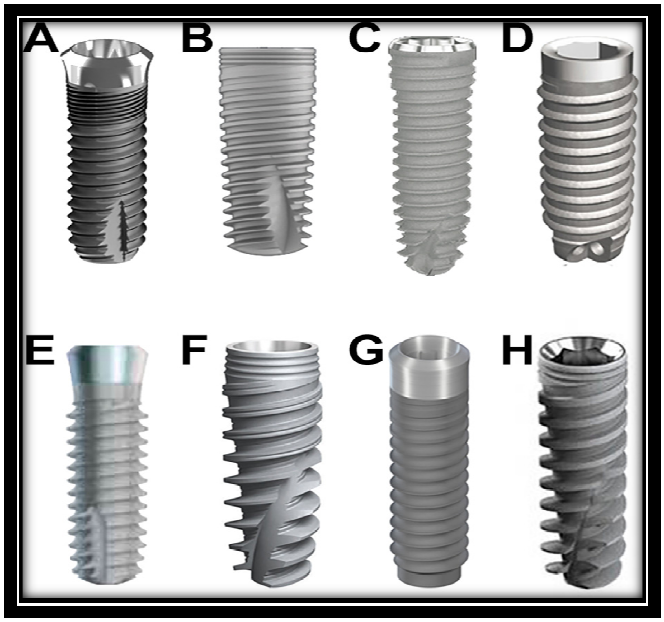


Figure : 1 Different types of dental implants proposed by several companies.

A. ETK, implant Aesthetica./ B. MIS, implantC1/ C. TBR, implant Infinity / D. Anthogyr, implant Axiom /. E. Zimmer, implant Swiss plus / F. Nobel Biocare, implantActive/ G. Straumann, implant Standard plus/ H.ADIN ,implant Touare[3]

A combination of biological and biomechanical factors particularly, perimucositis and periimplantitis are major risk factors for the failure of dental implants. The pristine surfaces of the implants lack the desired indigenous microbiota and demand the early colonizers to set the stage for the complex communities to develop .The pellicle starts forming on the implant surface as early as 30 minutes after the implant is placed in the oral cavity. [4]

In cases of perimucositis and peri-implantitis , although conventional and surgical therapy has the potential to significantly reduce the population of several periodontal pathogens count sometimes tend to shift back towards pre operative values and show elevated counts for several target microorganisms 1 month after treatment.[5]

Among the various chemotherapeutic agents to augment the extracted socket , silver, have been extensively used against the periodontal and periimplant bacteria due to their proven antibacterial efficacy in various applications. silver is the most well studied antibacterial metal ion for the treatment of periodontitis and peri-implantitis.[6]

Gelatamp™（Coltène/Whaledent Inc. USA）is made of 95% foam gelatin sponge and 5% finely dispersed colloidal silver which forms silver ions in moist conditions. The small quantities of these ions have antimicrobial property without developing any resistance. Gelatamp is effective against wide range of micro-organisms which are found in the oral cavity.[7]

Gelatamp releases silver ions in moist conditions, which continuously acted against the infection at the defect area, helping reduce bone resorption. Its long-lasting antibacterial effect may due to the “zombies” effect . Bacteria cells destroys after its death and release silver ions to “infect” other surviving bacteria present inside the defect. This kind of chain reaction contributes to its long-lasting antibacterial effect.[8]

Platelet Rich Fibrin (PRF) is the second and latest generation of platelet concentrates. It consists of a fibrin matrix polymerized in a tetramolecular structure, the incorporation of platelets, leukocyte, and cytokines, and the presence of circulating stem cells. It is a promising, completely autologous leukocyte and platelet concentrate which is being successfully used in various fields of dentistry and medicine.[9]

PRF has shown successful results when used in the treatment of bone preservation of extracted socket .There are many studies showing accelerating wound healing of PRF in periodontal defects, cyst cavities and sinus floor augmentation in the literature. There are limited studies on the effects of PRF on postoperative pain and swelling[9]

However, limited research is available for PRF and GELATAMP(Gelatin impregnated with colloidal silver) as a augmenting material in dental implant site and its effectiveness to reduce postoperative complications like infection and implant failure .

The purpose of this study is to compare the clinical advantages of tissue healing in dental implant site augmented with autologous PRF and GELATAMP by assessing soft tissue healing, pain , and swelling on the 1st, 3rd , and 7th post operative day between two sides of the mouth .

AIMS AND OBJECTIVES

AIMS AND OBJECTIVES

The aim of the present study is to evaluate and compare soft tissues healing in dental implant site augmented with PRF and GELATAMP (colloidal silver impregnated with gelfoam) .

OBJECTIVES

The objectives of this study included:

To clinically evaluate and compare the use of PRF and GELATAMP in soft tissue healing of the dental implant site (alveolar ridge) by assessing the following parameters:

1. Soft tissue healing assessment post operatively on 1^{st} , ^{3rd} , and 7^{th} day in PRF side (Left side) & GELATAMP side (Right side)
2. Pain experienced post operatively on 1^{st}, 3^{rd} , and 7^{th} day in PRF side (Left side) & GELATAMP side (Right side)
3. Swelling assessment post operatively on 1^{st} , 3^{rd} , and 7^{th} day in PRF side (Left side) & GELATAMP side (Right side)

SURGICAL ANATOMY

SURGICAL ANATOMY

INFLUENCE OF BONE DENSITY ON IMPLANT SUCCESS RATES:

The amount of bone present in implant site is particularly important which describes the external architecture or volume of the edentulous area considered for implants. The internal structure of bone is described either by quality or density, which shows a number of biomechanical properties, such as strength and modulus of elasticity. The external and internal architecture of bone controls virtually every aspect of implant dentistry. The density of available bone in an edentulous site is a determining factor in treatment planning, implant design, surgical approach, healing time, and initial progressive bone loading during prosthetic reconstruction.

Bone density and its relation to oral implantology have existed for more than 25 years. In 1970 Linkow classified bone density into three categories.

Class I: Ideal bone type consists of evenly spaced trabeculae with small cancellated spaces

Class II: Slightly larger cancellated spaces with less uniformity of osseous pattern

Class III: Large marrow filled spaces exist between bone trabeculae.[10]

In 1988 Misch proposed four types of bone density independent of regions of the jaws, based on macroscopic cortical and trabecular bone characteristics.[11] (Table-1) (Fig-2). Many literatures and the surveys of completely and partially edentulous patients post-surgery indicated that the location of different bone densities often may be superimposed on different regions of the mouth[11] (Table-2). A key determinant for clinical success is the proper diagnosis of the bone density in a potential implant site. The strength of the bone is directly related to bone density. The treatment plan may be modified by reducing the force on the prosthesis or increasing the area of load by increasing implant number, implant position, implant size, implant design, or implant body condition.

TABLE – 1

MACROSCOPIC CORTICAL AND TRABECULAR BONE CHARACTERISTICS

Bone density	Description	Tactile analog	Typical anatomical location
D1	Dense cortical	Oak or maple wood	Anterior mandible
D2	Porous cortical and coarse trabecular	White pine or spruce wood	Anterior mandible Posterior mandible Anterior maxilla
D3	Porous cortical (thin) and fine trabecular	Balsa wood	Anterior maxilla Posterior maxilla Posterior mandible
D4	Fine trabecular	Styrofoam	Posterior maxilla

FIGURE - 2

DIFFERENT TYPES OF BONE DENSITY

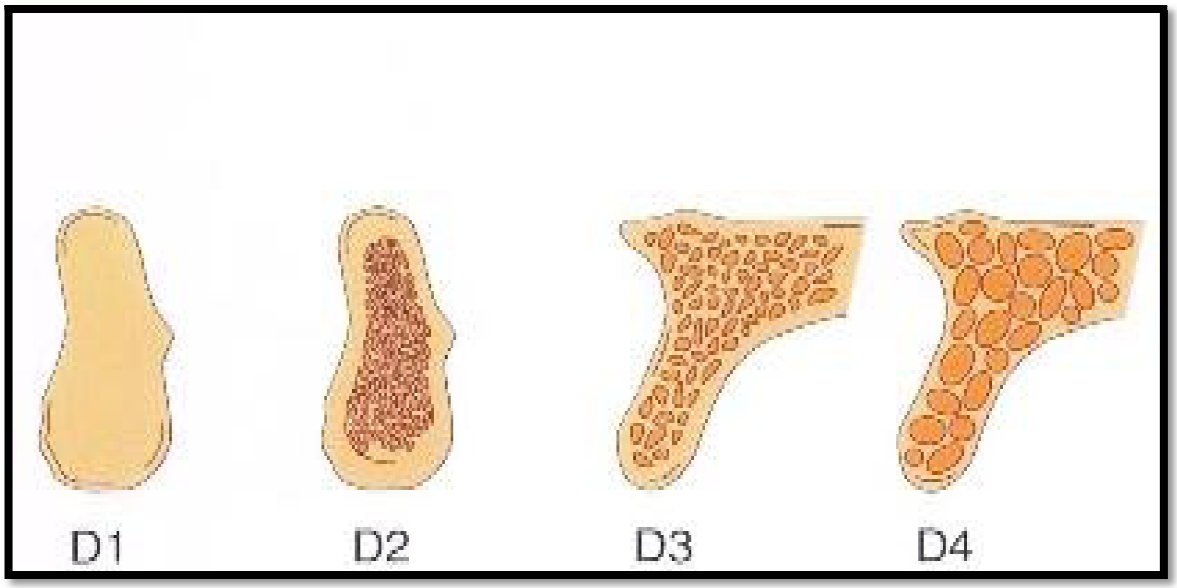


TABLE -2

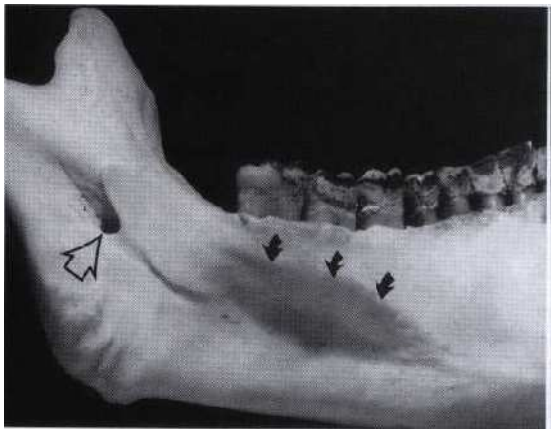
USUAL ANATOMIC LOCATION OF BONE DENSITY TYPES (% OCCURRENCE)

Bone	Anterior maxilla	Posterior maxilla	Anterior mandible	Posterior mandible
D1	0	0	6	3
D2	25	10	66	50
D3	65	50	25	46
D4	10	40	3	1

- The mandible is a horseshoe-shaped bone connected to the skull by the temporomandibular joints. It presents several landmarks of great surgical importance.
- The mandibular canal, occupied by the inferior alveolar nerve and vessels, begins at the mandibular foramen on the medial surface of the mandibular ramus and curves downward and forward, becoming horizontal below the apices of the molars.[12]

FIGURE – 3

MANDIBLE, LINGUAL SURFACE VIEW



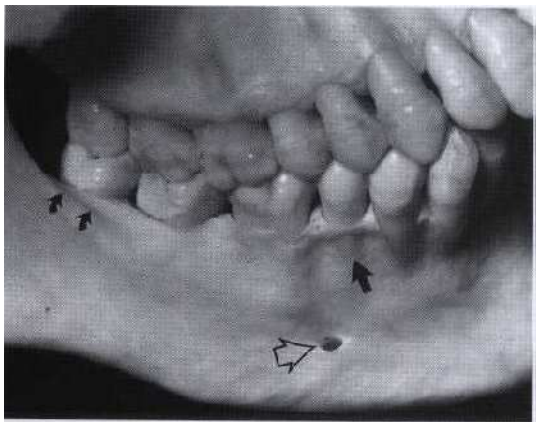
Note the lingual or mandibular foramen (open arrow) where the inferior alveolar nerve enters the mandibular canal and the mylohyoid ridge (solid arrows).

- The distance from the canal to the apices of the molars is shorter in the third molar area and increases as it goes forward.

- In the premolar area, the canal divides in two:
    - the incisive canal, which continues horizontally to the midline, and the mental canal, which turns upward and opens in the mental foramen.
- The mental foramen, from which the mental nerve and vessels emerge, is located on the buccal surface of the mandible below the apices of the premolars, sometimes closer to the second premolar and usually halfway between the lower border of the mandible and the alveolar margin.[12]

FIGURE – 4

MANDIBLE, FACIAL SURFACE VIEW



Note the location of the mental foramen (open arrow), slightly distal and apical to the apex of the second premolar, and the shelflike area in the region of the molars (curved solid arrows), created by the external oblique ridge. Note also the fenestration present in the second premolar (straight solid arrow).

- The opening of the mental foramen faces upward and distally, with its posterosuperior border slanting gradually to the bone surface.
- As it emerges, the mental nerve divides into three branches. One branch of the nerve turns forward and downward to supply the skin of the chin. The other two branches course anteriorly and upward to supply the skin and mucous membrane of the lower lip and the mucosa of the labial alveolar surface.

- Surgical trauma to the mental nerve can produce paresthesia of the lip, which recovers slowly. Familiarity with the location and appearance of the mental nerve reduces the likelihood of injury.
- In partially or totally edentulous jaws, the disappearance of the alveolar portion of the mandible brings the mandibular canal closer to the superior border. When these patients are evaluated for placement of implants, the distance between the canal and the superior surface of the bone must be carefully determined to avoid surgical injury to the nerve.[12]

FIGURE -5
MENTAL NERVE

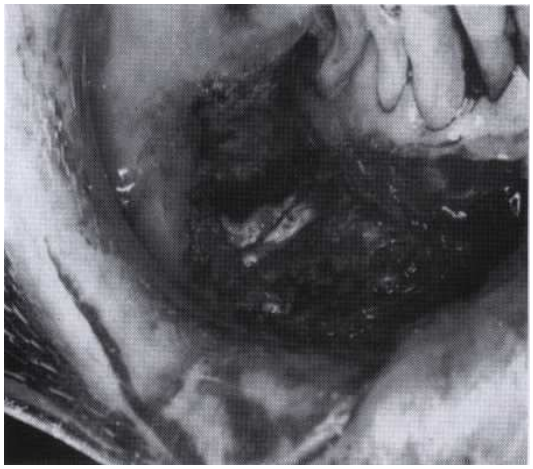
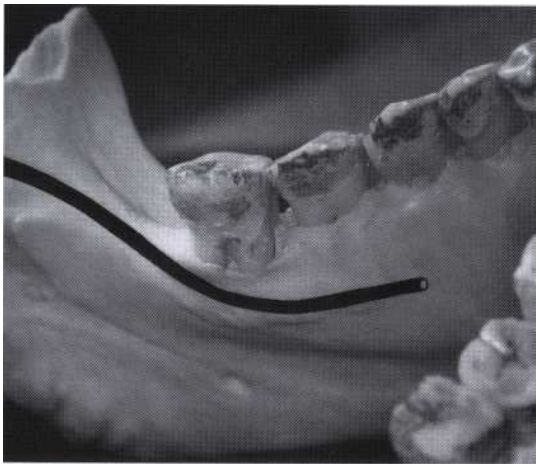


FIGURE-6
LINGUAL VIEW (MANDIBLE)

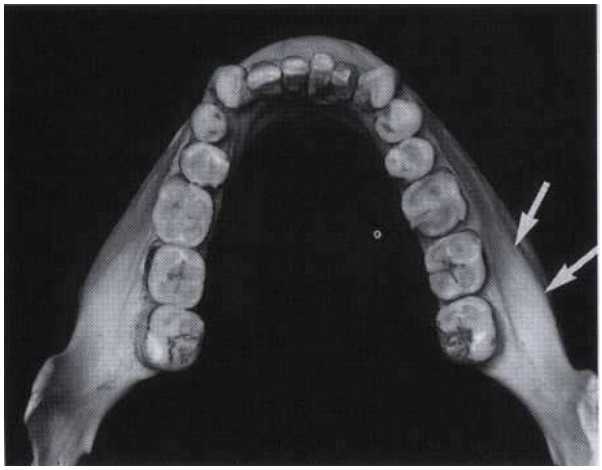


- The lingual nerve, along with the inferior alveolar nerve, is a branch of the posterior division of the mandibular nerve and descends along the mandibular ramus medial to and in front of the inferior alveolar nerve.
- It lies close to the surface of the oral mucosa in the third molar area and goes deeper as it goes forward.
- It can be damaged during anesthetic injections and during oral surgery procedures such as third molar extractions.
- Less commonly, it may be injured when a periodontal partial thickness flap is raised in the third molar region or releasing incisions are made.

- The alveolar process, which provides the supporting bone to the teeth, has a narrower distal curvature than the body of the mandible, creating a flat surface in the posterior area between the teeth and the anterior border of the ramus.[11]

FIGURE -7

OCCLUSAL VIEW OF MANDIBLE.

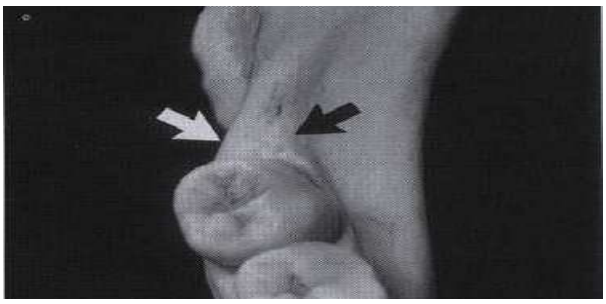


Note the shelf created in the facial molar areas by the external oblique ridge. Arrows on the right show the attachment of the buccinator muscle.

- This results in the formation of the external oblique ridge, which runs downward and forward to the region of the second or first molar creating a shelflike bony area.

FIGURE – 8

MANDIBLE - OCCLUSAL VIEW OF RAMUS AND MOLARS



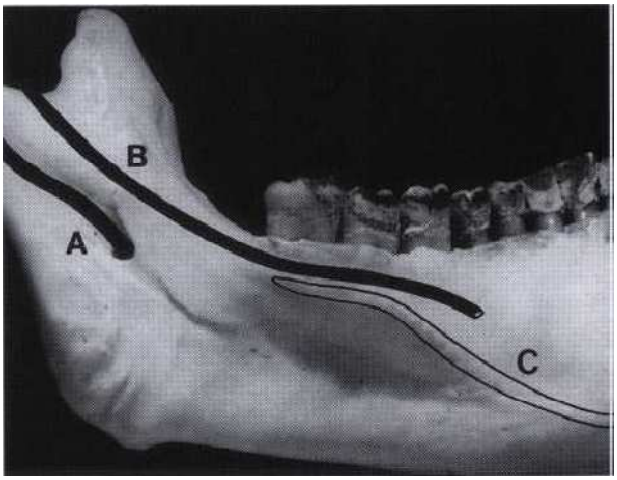
Note the retromolar triangle area distal to the third molar (arrows).

- Distal to the third molar, the external oblique ridge circumscribes the retromolar triangle. This region is occupied by glandular and adipose tissue covered by unattached nonkeratinized mucosa.[12]

- The inner side of the body of the mandible is traversed obliquely by the mylohyoid ridge, which starts close to the alveolar margin in the third molar area and continues anteriorly, increasing its distance from the osseous margin as it goes forward.

FIGURE -9

MANDIBLE - LINGUAL VIEW



- Showing the inferior alveolar nerve entering the mandibular canal (A), the lingual nerve traverseing near the lingual surface of the third molar (B), and inferiorly, the attachment of the mylohyoid muscle (C).
- The mylohyold muscle, inserted at this ridge, separates the sublingual space, located more anteriorly and superiorly, from the submandibular space, located more posteriorly and inferiorly

INNERVATION OF LOWER JAW AND ASSOCIATED STRUCTURES:

INFERIOR ALVEOLAR (DENTAL) NERVE (IAN)

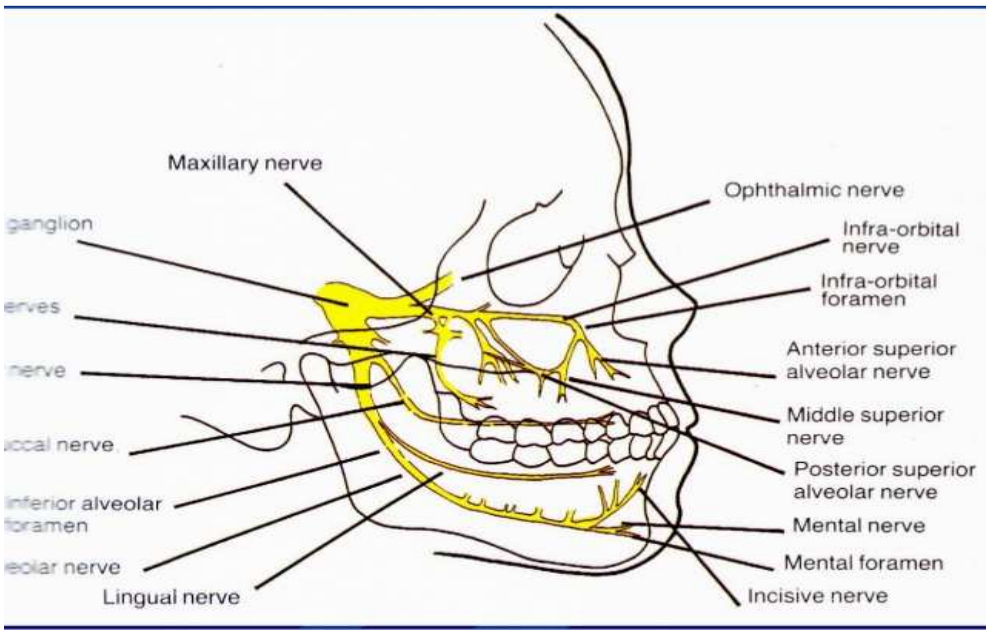
This nerve arises as a branch of the mandibular nerve (V3) in the infratemporal fossa. It appears at the inferior head of the lateral pterygoid muscle, courses downward, and enters the mandibular foramen on the medial aspect of the ramus. The inferior dental nerve runs as a one unit in the canal until it reaches the premolar region, where it divides into the mental and incisive nerves (Figure 10). The mental nerve exits the canal through the mental foramen. In an excessively resorbed ridge, the mental foramen, with its contents of mental nerve and

vessels, can be found on the crest of the ridge. So care should be taken while making the incision and reflecting the periosteum.[11]

The position of the inferior dental canal in vertical and buccolingual dimension is of paramount importance during site preparation for implants. The potential use of reconstruction techniques on computed tomographic scans and magnetic resonance imaging may increase clinicians' ability to locate the inferior dental canal precisely in the jawbone. Much less expensive techniques using panoramic cross-sectional tomographic imaging are also available. In some cases the inferior alveolar nerve may divide into two or three rami that occupy separate canals as the nerve travels in the mandible to supply the bone. Conventional radiographic techniques may be used to find these variations before operating in the implant site. The nerves in the bone, when in contact with an implant, may account for the rare but occasional observation of tenderness, even though the implant is rigid and appears healthy. In addition, the fibrous tissue around these nerves may cause an increase in the amount of fibrous tissue around an implant that is inserted in contact with these structures.

FIGURE – 10

NERVE SUPPLY TO THE MANDIBLE



BLOOD SUPPLY TO THE MANDIBLE

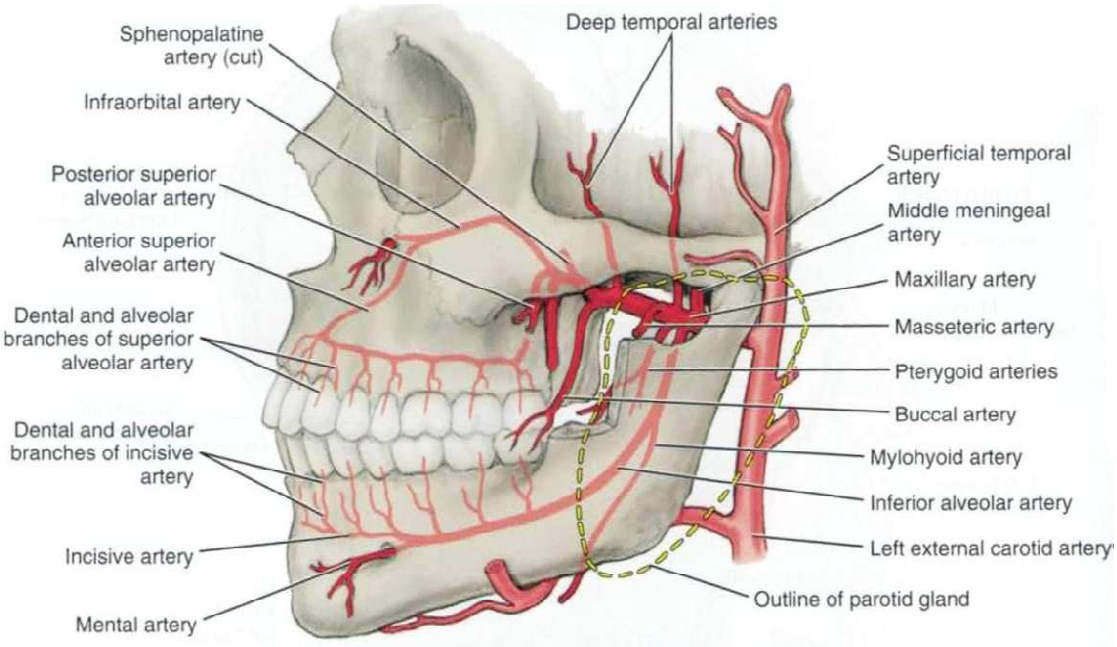
General concepts : The mandible and maxilla membrane bones and as such do not develop in the same manner as long bones. Most researchers agree that the circulation of blood within the body of the mandible and in the maxilla is centrifugal under normal condition. Endosteal and periosteal plexus exist that are connected with one another. In addition to these vascular networks, a periodontal plexus is found associated with the teeth. When teeth are present, intra osseous vessels send branches into alveolar processes (intra alveolar arteries), to the teeth (apical arteries), and to branches of the periodontal plexus. The intra alveolar arteries and periodontal plexus in turn connect with vessels of the periosteal plexus, as well as with vessels within soft tissues surrounding the bone. Once a tooth is removed, its periodontal plexus is lost. When abnormal circulatory conditions exist within the mandible or maxilla, such as occlusion of the nutrient artery, the blood supply to the bone is reversed so that the direction of flow is from the outside to the inside of the bone and is known as centripetal circulation.

MANDIBLE: The major artery supplying the blood to the mandible is the inferior alveolar artery (Figure - 11). The artery enters the medial aspect of ramus of the mandible and courses downward and forward within the mandibular canal to enter the body of the mandible. The artery branches in the premolar region to give rise to two terminal branches: the mental and incisive arteries. The incisive artery continues medially within the body to anastomose with the artery of the opposite side. This artery is often severed during the harvest of a monocortical symphyseal block of bone for grafting resorbed ridges. Crushing bone around the vessel or using bone wax easily controls the bleeding. The mental artery exits the body of the mandible through the mental foramen and supplies the region of the chin and anastomoses with the submental and inferior labial arteries. Near its origin the inferior alveolar artery gives off a lingual branch, which supplies blood to the oral mucosa.[11]

The coronoid process, the condylar process, and the angle of the mandible are supplied by arteries that provide blood to the muscles that attach to these sites. The condylar process is supplied by the vascular network of the TMJ joint capsule and the lateral pterygoid muscle. The vessels from the temporalis muscle supplies the coronoid process exclusively, and inferior alveolar artery supplies the angle of the mandible, as well as the muscles attached to the area. The vessels that supply the pterygomasseterric sling (i.e., the medial pterygoid and masster muscle) also supply the anterior portion of the ramus. Empirical findings from mandibular osteotomy procedures in human support many of these findings. Thus the repositioning of the inferior alveolar artery laterally, a procedures that may be needed in some cases before implant insertion, should not eliminate the blood supply to the bone in this region.

FIGURE – 11

BLOOD SUPPLY TO THE MANDIBLE



REVIEW OF LITERATURE

REVIEW OF LITERATURE

Ivan sondi et al(2004) showed that silver nanoparticles have excellent antibacterial activity against *E. coli.* This work integrated nanotechnology and bacteriology, leading to possible advances in the formulation of new types of bactericides. However, future studies on the biocidal influence of this nanomaterial on other Gram positive and Gram-negative bacteria are necessary in order to fully evaluate its possible use as a new bactericidal material.[13]

Simon Young et al (2005) emphasized how biomolecules released from gelatin controlled-release systems were able to retain their biological activity, allowing for their use in tissue engineering, therapeutic angiogenesis, gene therapy, and drug delivery applications[14].

Heidi L. Myshin et al (2005) explained the healing around dental implants is affected by the patient's health, soft- and hard-tissue contours, and the use and care of the prosthesis, as well as the manufacturer's implant-abutment designs, surgical augmentation and placement, and the design of the definitive prosthesis.[15]

Pekka LAINE et al (2005) showed that Ninety seven per cent of the bacterial cultures were positive, Streptococcus milleri being the most commonly identified aerobic and Fusobacterium nucleatum the most commonly anaerobic bacteria. the bacterial profile changes in relation to the healing time: immediately after implantation the bacteria are similar to those in acute odontogenic infection. Later they change to resemble the bacteria found in chronic periodontitis[16]

Michael S. Block et al, (2006) reviewed the literatures, reporting materials to be placed into extraction sites in preparation for placing dental implants. He also explained about various material and methods to graft the extraction site for future placement of dental implants .[17]

Dohan , Choukroun et al (2006) (part I) explained PRF belongs to a new generation of platelet concentrates , geared to simplified preparation without biochemical blood handling. He also described the conceptual and technical evolution from fibrin glues to platelet concentrates.[18]

Dohan , Choukroun et al (2006) (part II) explained PRF revealed that slow fibrin polymerization during PRF processing leads to the intrinsic incorporation of platelet cytokines and glycanic chains in the fibrin meshes. This result would imply that PRF would be able to progressively release cytokines during fibrin matrix remodelling. [19]

Dohan , Choukroun et al (2006) (part III) explained PRF is not only a platelet concentrate but also an immune node able to stimulate defence mechanisms, and the reduction of postoperative infections when PRF is used as surgical additive.[20]

Eduardo Anitua et al (2006) efficiency PRF lies in the local and continuous delivery of wide range of growth factors and proteins, mimicking the needs of the physiological wound healing and reparative tissue processes.[21]

Jun Tian et al (2007) showed that silver nanoparticles exerts positive effects through their antimicrobial properties , reduction in wound inflammation, and modulation of fibrogenic cytokines. Also explained the actions of silver and have provided a novel therapeutic direction for wound treatment in clinical practice .[22]

Cai LH (2008) demonstrated that GELATAMP colloidal silver gelatine sponge can prevent the occurrence of postsurgical complications .[23]

Lundquist *et al.*(2008) PRF provides sustained release and protection against proteolytic degradation of endogenous fibrogenic factors important for wound healing[24]

X.Chen et al (2008) concluded that silver nanoparticles may interact with proteins and enzymes with thiol groups within mammalian cells. These proteins and enzymes like glutathione, thioredoxin, SOD and thioredoxin peroxidase, are key components of the cell's

antioxidant defense mechanism. This mechanism is responsible to neutralize the oxidative stress of ROS largely generated by mitochondrial energy metabolism. Ag NP may deplete the antioxidant defense mechanism, which leads to ROS accumulation. Over accumulation of ROS can initiate an inflammatory response and perturbation and destruction of the mitochondria take place. Then apoptogenic factors like cytochrome C are released and programmed cell death is a final result.[25]

Mazor *et al* (2009) *In vivo* from a radiologic and histologic point of view at 6 months after surgery, the use of PRF as sole filling material during a simultaneous sinus lift and implantation stabilized a high volume of natural regenerated bone in subsinus cavity up to the tip of implants. Choukroun's PRF is a simple and inexpensive biomaterial and its systematic use during a sinus lift seems a relevant option, particularly for the protection of the Schneiderian membrane[24]

Sclafani *et al* (2009) reviewed a novel, simple method of preparing an autologous platelet derivative (Selphyl; Aesthetic Factors, Princeton, NJ) allows rapid and inexpensive generation of a PRF that can be used to enhance healing after facial procedures as well as to rejuvenate the face without tissue manipulation[24]

Su *et al* (2009) *in vitro* the PRF membrane should be used immediately after preparation, to maximize release of GF to surgical site. The remaining fluid can be recovered as an additional source of GF for grafting.[24]

Simonpieri *et al* (2009) *In vivo* PRF membranes are particularly helpful for periosteum healing and maturation. The thick peri-implant gingival tissue is as a result of several healing phases on a PRF membrane layer.[24]

Pye et al (2009) reviews dental implants and highlights factors leading to infection and potential implant failure. He also analysed the microbial composition of peri-implant infections. The microflora of dental peri-implantitis resembles that found in chronic

periodontitis, featuring predominantly anaerobic Gram-negative bacilli, in particular Porphyromonas gingivalis and Prevotella intermedia, anaerobic Gram-negative cocci such as Veillonella spp. and Spirochaetes including Treponema denticola[26]

Mahendra Rai (2009) et al reviewed and stated that the use of silver nanoparticles is also important, as several pathogenic bacteria have developed resistance against various antibiotics. Hence, silver nanoparticles have emerged up with diverse medical applications ranging from silver based dressings, silver coated medicinal devices, such as nanogels, nanolotions, etc.[27]

Virender K. Sharma et al (2009) reviewed an overview of silver nanoparticles (Ag NPs) preparation by green synthesis approaches that have advantages over conventional methods involving chemical agents associated with environmental toxicity.[28]

Chang *et al*(2010) *In vitro* PRF can stimulate osteoblasts proliferation. The activation of p-ERK and OPG expression by PRF suggests a potential role for new bone formation. The application of PRF may provide benefit for bone regeneration[24]

Nicolaas C. Geurs(2010) et al explained that the success of dental implants is dependent on the establishment of a soft-tissue barrier that is able to shelter the underlying osseous structures and the osseointegration surrounding the implant body. The esthetics of a dental implant prosthesis depend on the health and stability of the peri-implant mucosa. Understanding of soft-tissue healing and maintenance around dental implants is paramount for implant success[29]

Victoria Kostenko et al (2010) explained the application of silver dressings can also improve wound healing via antibiotic therapy since the interaction of silver released from the dressings significantly increases the susceptibility of bacterial cells within biofilms to the effects of antibiotics.[30]

Karla Chaloupka et al (2010) demonstrated that nano silver(NS) has useful anti-inflammatory effects and improves wound healing, which could be exploited in developing better dressings for wounds and burns. The key to its broad-acting and potent antibacterial activity is the multifaceted mechanism by which NS acts on microbes. This is utilized in antibacterial coatings on medical devices to reduce nosocomial infection rates.[31]

Gürbüzer *et al* (2010) *In vivo* case study with scintigraphic evaluation PRF might not lead to enhanced bone healing in soft tissue impacted mandibular third molar extraction sockets 4 weeks after surgery. PRF exhibits the potential characteristics of an autologous fibrin matrix. However, whether the presence of crystal-like particles on the outer surface of PRF alters bone healing should be investigated further. [24]

Sammartino *et al* (2011) *In vivo* use of L-PRF as a safe filling and hemostatic material is a reliable therapeutic option to avoid significant bleeding after dental extractions without suspension of continuous oral anticoagulant therapy in heart surgery patient.[24]

Roy *et al* (2011) *In vitro* and *in vivo* wound studies PRF matrix (PRFM) effectively induced endothelial cell proliferation and improved wound angiogenesis in chronic wounds, providing evidence of probable mechanisms of action of PRFM in healing of chronic ulcers[24]

Ruga *et al*(2011) showed in his prospective, *in vivo* study that combined action of PRF and piezoelectric surgery can be considered a safe and fine technique for third molar surgery and alveolar socket healing. [24]

Simon *et al*(2011) *showed the* advantages of PRFM alone includes less surgical time, elimination of techniques and potential healing difficulties associated with membranes, and less resorption during healing as compared to guided bone regeneration procedures.[24]

Simonpieri A *et al* (2011) *In vivo* The use of L-PRF as sole filling material during simultaneous sinus-lift and implantation seems to be a reliable surgical option promoting natural bone regeneration.[24]

Peck *et al*.(2011) successful usage of L-PRF in the alveolar ridge preservation (ARP) procedure, causing improvement of wound healing and stimulation of bone formation to facilitate implant placement in a compromised extraction socket[24]

Jiing-Huei Zhao et al (2011) clinical and histological findings suggest that filling a fresh extraction socket with PRF provides a viable therapeutic alternative for implant site preparation. Also he showed histological examination of the core taken from the socket revealed new bone formation. There was also no evidence of inflammatory infiltrates. The clinical and histological findings suggest that filling a fresh extraction socket with PRF provides a viable therapeutic alternative for implant site preparation.[32]

Omnia Hassan et al (2011) concluded that gelatamp containing colloidal silver with used concentration has better results in reducing postoperative infection and consequently pain following surgical removal of impacted mandibular third molar than gelfoam with systemic antibiotic.[7]

Bielecki *et al*.(2012) reviewed in the four families of platelet concentrates, two families contain significant concentrations of leukocytes: Leukocyte PRP (L-PRP) and L-PRF. The presence of leukocytes has a great impact on biology of these products, not only because of their immune and antibacterial properties, but also because they are turntables of the wound healing process and the local factor of regulation[24]

Simonpieri *et al*. (2012) reviewed that PRPs failed to prove strong strategic advantages that could justify their use in daily practice and use of most PRP techniques will probably be limited to some very specific applications where satisfactory results have been reached. Only a few simple, inexpensive, and efficient techniques such as L-PRF will continue to develop in oral and maxillofacial surgery in the next years[24]

Jankovic *et al* (2012) showed in his randomized controlled clinical study, use of a PRF membrane in gingival recession treatment provided acceptable clinical results, followed by enhanced wound healing and decreased subjective patient discomfort .[24]

Del Corso *et al* (2012) Case report Successful use of leukocyte-PRF during immediate postextractive implantation and loading for esthetic replacement of a fractured maxillary central incisor with promising results.[24]

Mendonça-Caridad *et al* (2012) The application of an autogenous platelet rich/fibrin rich composite matrix in tissue regeneration and wound healing has resulted in a favorable outcome with no complications or sequelae, in a series of ten patients with advanced frontal sinus disease over a long period of time.[24]

Anitua *et al* (2012) *explained* plasma rich in growth factors (PRGF) may present a role in reducing tissue inflammation after surgery, increasing new bone formation, and promoting vascularization of bone tissue. Peck *et al* (2012) showed L-PRF is a newly developed platelet concentrate that has successfully been used in a number of surgical procedures to optimize wound healing and was used to stimulate bone formation to facilitate ideal placement of implants.[24]

Clipet *et al* (2012) PRF conditioned medium induced gene expression in osteoblasts. Expression of osteopontin and osteocalcin and late osteogenic markers was observed and confirmed PRF is useful in stimulating tissue healing and bone regeneration.[24]

Vijayalakshmi *et al* (2012) described the application of PRF along with bone graft and guided tissue regeneration (GTR) membrane in the treatment of fenestration defect around an implant.[24]

Hakan Ozdemir (2012) PRF may offer the ease of use, simple handling, and enhanced delivery of growth factors during the bone augmentation procedures. When used in

conjunction with the titanium barriers, PRF use can increase the quality of the newly formed bone and enhance the rate of bone formation due to the concentration of growth factors.[24]

Marco Tatullo et al (2012) use of PRF reduce the healing time, favoring optimal bone regeneration around implant margins.[24]

Zaid H. Baqain et al (2012) showed that the early loss of dental implants was significantly associated with width of keratinised gingiva , the use polyglactin sutures, and the use of narrow implant. Multivariate logistic regression analysis established the significance of narrow keratinised gingiva and the use of polyglactin sutures , which we conclude are probably the strongest predictors of early failure of implants[33]

Bharali et al (2013) indicates that colloidal silver nanoparticles shows prominent antibacterial and chemotactic activity against Staphylococcus , Escherichia coli , Pseudomonas aeruginosa and Bacillus subtilis.[34]

Balaram Naik (2013) showed good promising results with use of the PRF. It has proved to have a good prospect for its use as healing aid in various aspects of the dentistry.[24]

Simonetta D'Ercole et al (2013) showed that that maintaining the screws for a period of 90 days caused an important increase in plaque quantity, with a dramatic change in plaque composition. Also founded that the microorganisms most commonly related to implant failure are rods and mobile forms of Gram-negative anaerobes (Prev. intermedia, Porph. gingivalis, A. actinomycetemcomitans, Tann. forsythia, Trep. denticola, Prev. nigrescens, Peptostreptococcus micros, V. parvula and F. nucleatum).[35]

Ozgur Baslarli et al (2014) showed that PRF has the potential characteristics of an autologous fibrin matrix and can accelerate the healing

David J. Barillo et al (2014) showed that ionized form of silver (Ag+1) has known antimicrobial properties. A number of wound dressings incorporating silver ion or silver compounds have recently been developed and marketed.[36]

Neethu Ninan et al (2014) used gelatin as a suitable matrix due to its natural abundance, biocompatibility, biodegradability and non-immunogenicity and prepared as scaffolds with antibacterial properties using gelatin as the polymer matrix.[37]

Sujata Mohanty et al (2014) found PRF membrane to be better owing to better workability and easier manipulation, better tear strength, better clinical healing, better epithelialization of wound on postoperative histopathological examination. More over, having an autogenous source, PRF is cost effective and carries no risk of allergic reactions.[38]

Elia Charbel Abboud et al (2014) compared patient-reported pain levels in patients previously randomized to receiving silver-nylon dressings vs. conventional gauze dressings in a study of surgical site infection in burn patients. Compared to gauze dressings, patients in the silver dressing group reported less pain between postoperative days 0 and 9. Silver-based dressings may reduce wound pain by providing an occlusive barrier or by undefined mechanism.[39]

Elia Charbel Abboud et al (2014) examined the incidence of SSI(surgical site infection) in high-risk groups and identify procedures where silver dressings, and other silver products, have been evaluated for the prevention of SSI. Silver dressings placed at the time of incision closure may represent the next step in the bundle approach to SSI prevention. Further study in the form of large prospective trials is needed to establish the widespread use of silver dressings across the surgical specialties for infection prevention.[40]

Anirban Chatterjee et al (2014) showed PRF bioactive membrane, which can enhance soft/hard tissue healing. He can also protect surgical sites, grafted materials from external aggressions. He also described the evolution of this second-generation platelet concentrate and its multiple uses in various surgical procedures.[41]

Suttapreyasri Srisurang et al (2014) explained that platelet rich fibrin (PRF) has the positive effect on both soft and hard tissue of extraction socket in an early phase of

healing by promoting faster healing of soft tissue covering the socket orifice in the first 2 weeks, enhancing bone healing, and preserving the marginal bone height and width as an evidence from the radiographic optical density and histomorphometric analysis at 12 weeks.[42]

David E. Marx(2014) explained biochemistry and physiology of silver , also reviewed with emphasis on the use of silver for wound care . Silver-ion based topical wound dressings can be designed to deliver predictably high and consistent levels of broad-spectrum antimicrobial therapy that is unlikely to induce resistance.[43]

Moraschini et al (2015) showed that PRF has the possibility of producing a dense fibrin-rich matrix, which has the ideal consistency for handling and suture, different from PRP, which is a gel.He also found PRF not only improving healing, but also positive gains in keratinized gingiva after soft tissue surgeries using PRF when compared with spontaneous healing control groups.[44]

Geewoo Nam et al (2015) stated that silver is capable of aiding the wound healing process due to its antibacterial activity. The broad spectrum activity of silver ions results in multiplicity of the bactericidal mechanism.[45]

Hafez et al (2015) showed that PRF membrane is successful in maintaining particulate autogenous bone graft and achieving primary coverage over immediately placed implants. It provides good esthetic results and labial soft tissue contours. PRF could serve as a resorbable membrane for guided tissue regeneration.[46]

Yuvika Rajkumar (2015) concluded that platelet-rich fibrin improves healing of both soft and hard tissues. Although osseous healing did not differ significantly between the groups, healing of soft tissue as judged by the pain score was significantly better in the experimental group.[47]

Nelson Duran et al (2015) discussed the release of silver nanoparticles and silver ions, cell membrane damage, DNA interaction, free radical generation, bacterial resistance

and the relationship of resistance to silver ions *versus* resistance to silver nanoparticles. The focus of the overview is to summarize the current knowledge in the field of antibacterial activity of silver nanoparticles. The possibility that pathogenic microbes may develop resistance to silver nanoparticles is also discussed.[48]

Ozkan ozgul et al (2015) PRF seems to be effective on postoperative horizontal swelling after third molar surgery. PRF could be used on a routine basis after third molar extraction surgery.[9]

Rui Figueiredo et al (2015) concluded that patients with submerged dental implant placement in the mandible and its healing are more prone to postoperative infections. This complication is relevant, because it is associated with a considerable and almost 80-fold increase in the risk of early implant failure.[49]

Orrett E. Ogle (2015) explained that success of a dental implant depends on the chemical, physical, mechanical, and topographic characteristics of its surface and explained about all types of material , shape and its texture [50].

Jonathan M. Tagliareni,, Earl Clarkson,(2015) explained basic concepts and techniques about various model dental implant systems and their sizes , shapes , and factors affecting primary stability and esthetic improvement.[51]

Ikiru Atsuta et al (2015) focused on improving the resistance to peri-implantitis and achieving appropriate soft tissue attachment following implant placement. The fragile seal between the implant surface and peri implant tissue is increasingly seen as a problem because this weakness translates to an increased risk of inflammation and leads to peri implantitis. He also stated that the epithelial seal around dental implants will be at least equal to or higher than that around the natural tooth, with an attendant decrease in the clinical occurrence of gingival recession or inflammation around implants.[52]

Aifang Han et al (2016) explained that bacterial adhesion and biofilm formation are the principle reasons that can cause peri-implantitis . The adhesion is a very complicated process which can be affected by many risk factors , such as the local factors of interaction between microorganisms and implant, systematic factors of oral environment, mechanism of bacterial adhesion and subsequent implant inflammation need to be further investigated. To solve the problem of bacterial adhesion , in particular on dental implant ,a multi-disciplinary collaboration is necessary.[53]

Faez Saleh Al-Hamed et al (2016) PRF could reduce alveolar osteitis, pain, and analgesic consumption following removal of impacted mandibular third molars.[54]

Andreas Anwandter et al (2016) stated that L-PRF showed similar outcome for ridge preservation procedures than the obtained with xenografts or allografts and even superior than with alloplastic grafts or natural healing. L-PRF might be effective at the same level as the rest of .osseous substitutes, but without having remaining graft particles and high cost.[55]

Yuliang Dong et al(2016) demonstrated that gelatine /Ag treatment could effectively reduce the infection caused by MRSA (methicillin resistant *Staphylococcus aureus*) and accelerate infected bone healing process. This material may help in the treatment of infected bone defects.[8, 56]

MATERIALS AND METHODS

MATERIALS AND METHODS

This study was conducted at Department of oral and maxillofacial surgery, ultra's best dental science college and hospital, Madurai from February 2015 to september 2016.

The institutional scientific review board and ethical committee approved the protocol of this clinical prospective study. The study population comprised of GELATAMP group and PRF group. Both the group has 5 patients each.

SAMPLE SELECTION

Five patients (10 implants) requiring bilateral lower molar tooth replacements were selected from pool of a patients reporting to the Best dental college for tooth replacement. The patients were selected using inclusion and exclusion criteria. All cases were selected in terms of ideal bone and soft tissue biotype. Then patients were assigned randomly to one of the two groups – GELATAMP (5 patients) or Autologous PRF (5 patients).

INCLUSION CRITERIA

- Patients willing for voluntary participation & have signed informed consent for the described procedure
- Patients with age group 20-50 years of either gender
- Systemically healthy subjects
- Partially edentulous jaw requiring single or multiple tooth replacement
- Implant site should have undergone extraction not less than 6 months.
- Patients with sufficient bone width (minimum 5mm) and height (minimum 8 mm)
- Patients with systemic diseases contraindicating any type of surgery.

EXCLUSION CRITERIA

- Patients receiving or who have received bisphosphonates.
- Patients with systemic diseases contraindicating any type of surgery
- Patients with active diseases of the implant bed (e.g., residual cysts) and

- Patients with bone atrophy requiring bone regeneration in both width and height.
- Patients showing unacceptable oral hygiene maintenance
- Patients with use of tobacco or tobacco related products
- Pregnant / Lactating patients
- Patients with any known allergies

PRESURGICAL ASSESSMENT:

The selected patients underwent complete blood analysis and oral prophylaxis. In both (PRF & GELATAMP) groups preoperative extra oral and intra oral photographs were taken to assess the soft tissue colour and measure the extra oral baseline value for swelling assessment. For all 5 patients the 3rd quadrant (left side molar area) were called as PRF side and 4th quadrant (right side molar area) were called as GELATAMP side. The preoperative OPG was taken to assess the size of the implant , quality and quantity of the bone where implant to be placed. All patients were measured clinically mesio-distal distance of edentulous space from the distal portion of the mesial tooth to the mesial portion of the distal tooth. The bucco-lingual width of the bone and mesio-distal distance of edentulous space was measured clinically using a Vernier calliper.

ARMAMATARIUM:

1) IMPLANT SURGICAL KIT .(Figure - 12)
2) ADIN TOUAREGTM-S IMPLANT SYSTEM. (Figure- 13)
3) VERNIER CALLIPER (figure -14)
4) IMPLANT CENTRE (SATELEC) HIGH PRECISION TORQUE CONTROL PHYSIODISPENSER (Figure -15)
5) SURGICAL HANDPIECE WITH 20:1 GEAR RATIO , TI-MAX, S-MAX SG20, NSK JAPAN.(Figure -16)
6) CENTRIFUGE MACHINE.(Figure -17)

7) BASIC MINOR SURGICAL INSTRUMENTS (Figure -18)

FIGURE - 12

FIGURE - 13

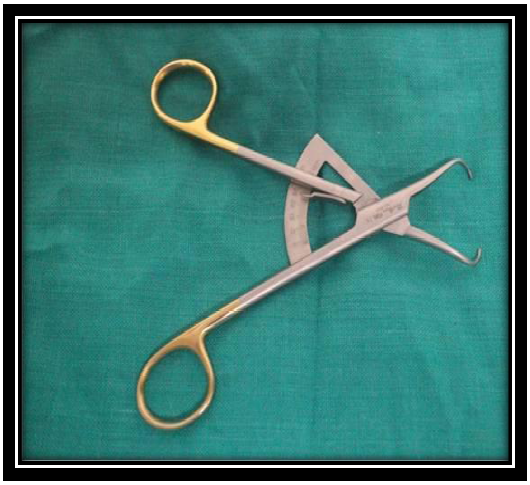


FIGURE – 14

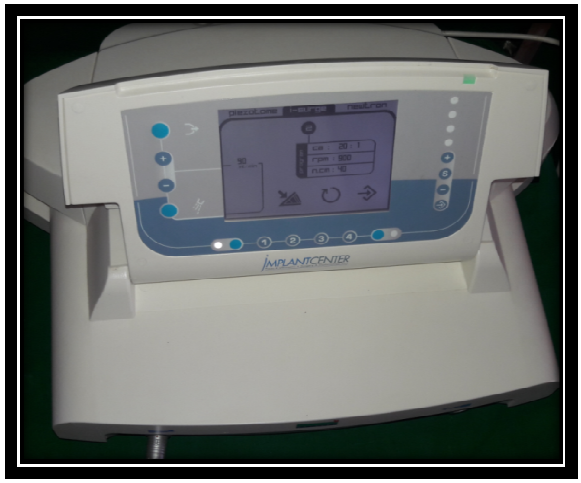


FIGURE - 15

FIGURE – 16

FIGURE – 17

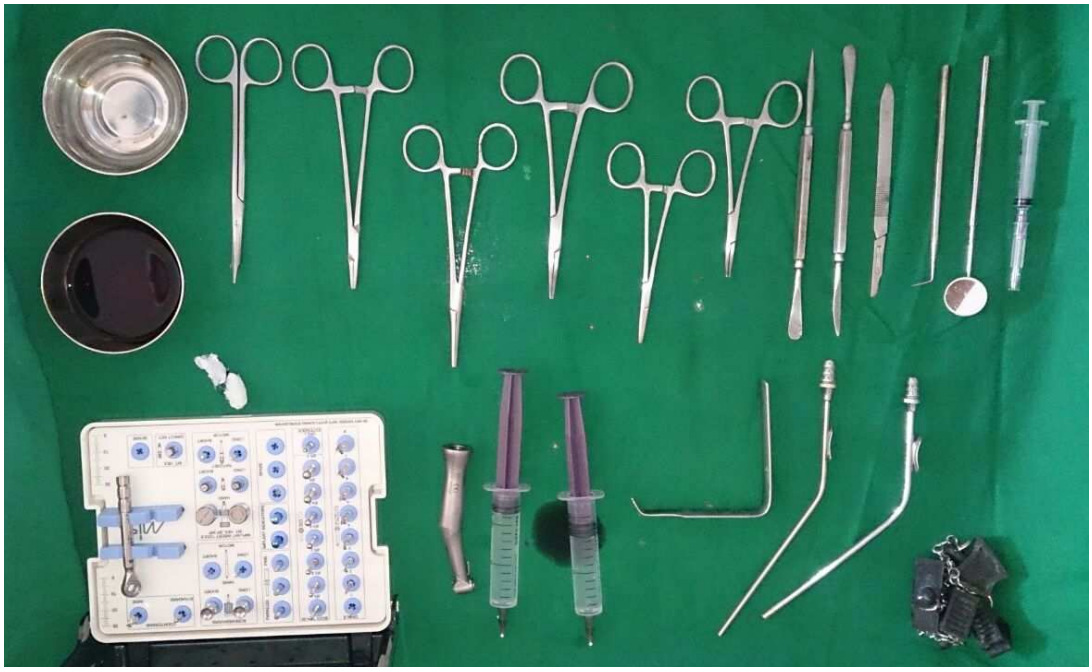


FIGURE - 18

SURGICAL PROCEDURE:

IMPLANT PLACEMENT PROEDURE:

PRF GROUP: (3RD QUADRANT)

The surgical field (left lower 1st molar site) was prepared and the implant site was anaesthetised with 2% lidocaine with 1:80000 epinephrine. In PRF group midcrestal incision was placed with sulcular extensions to adjacent teeth on either side with a Bard-Parker blade No.15 (Fig) and then a full thickness mucoperiosteal flap was raised. Initial entry was made with a No.5 round bur followed by pilot drill to the required depth. Then successive drills were made till the required diameter is achieved .The implant was then placed into the prepared site. At the same time the patient's blood was collected and sent to centrifugation unit for the preparation of autologous PRF at the rate of 3000 rpm for 12 minutes. After centrifugation Freshly prepared PRF gel was obtained and made it into small piece for the required size by light squeezing between two sterile gauze pieces, and it was augmented on the implant inserted site and covered the exposed bone along with the cover screw. The flaps

were repositioned and surgical site was closed with simple interrupted sutures (3-0 black silk, Ethicon US) .

PRF PREPARATION

Platelet rich fibrin (PRF) was prepared in accordance with the protocol developed by **Choukroun et al**. Just prior to surgery approximately 5-6ml of intravenous blood was drawn from the cubital fossa of the patient. Whole blood was collected in a 10-ml sterile glass tube without any anticoagulants and immediately centrifuged at 3000 rpm for 12 minutes.

Blood centrifugation resulted in separation of blood into a structured fibrin clot in the middle of the tube, just between the red corpuscles at the bottom and acellular plasma (Platelet-poor plasma) at the top. After removal of PPP, PRF was easily separated from red corpuscles base [preserving a small red blood cell (RBC) layer] using sterile tweezers and scissors.[57]

Because of the absence of an anticoagulant, blood begins to coagulate as soon as it comes in contact with the glass surface. Therefore, for successful preparation of PRF, speedy blood collection and immediate centrifugation before the clotting cascade is initiated, is absolutely essential. PRF can be obtained in the form of a membrane by squeezing out the fluids in the fibrin clot. [58]

GELATAMP GROUP (4TH QUADRANT)

The surgical field was prepared and the implant site was anaesthetised with 2% lidocaine with 1:80000 epinephrine.

In GELATAMP group, midcrestal incision was placed with sulcular extensions to adjacent teeth on either side with a BP blade No.15 (Fig) and then a full thickness mucoperiosteal flap was raised. Initial entry was made with a No.5 round bur followed by pilot drill to the required depth. Then successive drills were made till the required diameter is achieved. Once the osteotomy was finished the implant was then placed into the prepared

site. Now in this group, the implant inserted site was augmented and the cover screw was covered with GELATAMP. . The flaps were repositioned and surgical site was closed with simple interrupted sutures (3-0 black silk, Ethicon US) .

The Touareg™-S spiral implant system, ADIN DENTAL IMPLANT SYSTEM, ISRAEL were used in both the groups. The implants used were varied size from 3.5mm to 4.5mm and in length 10mm to 12mm. Patients in both the groups were given oral antibiotics and anti inflammatory, H2 receptor antognosits (amoxicillin 500 mg , Ibubrufen 400mg , ranitidine 150 mg) thrice daily for 5 days.

Patients in both the groups underwent two stage implant placement procedure. In the stage I surgery implants with cover screw were placed, and then left for 3 months for bone healing. In stage II surgery, in both groups tissue punch was used to expose the cover screw and the healing cap was placed for one week. The patient was then referred to department of prosthodontics for prosthetic rehabilitation.

POSTSURGICAL ASSESMENT

Intra oral and extra oral Clinical photographs were taken post operatively. Patients were recalled on post-operative 1st day, 3rd day and 7th day for intra oral soft tissue healing, pain and extra oral swelling assessment.

CLINICAL PARAMETERS

The parameters assessed were soft tissue healing potential using the standardised index by Landry, Turnbull and Howley ,[59] pain assessment by 10cm Visual analog scale , swelling assessment by modification of tape measuring method by Gabka and Matsumara on 1ts, 3rd, and 7th day after surgery were recorded

SOFT TISSUE HEALING ASSESSMENT

Soft tissue healing assessment was made by colour of gingival, bleeding on palpation, presence of granulation tissue, epithelisation of the margins and presence of suppuration .

Depends on the above mentioned factors the standardised soft tissue healing potential index was made by Laundry, Turnbull, and Howley.[59]

Scores Healing Index 1: Very Poor Has 2 or more of the following:

- Tissue color: >= 50% of gingiva red
- Response to palpation: bleeding
- granulation tissue: present
- incision margin: not epithelialized, with loss of epithelium beyond incision margin
- suppuration present

Healing Index 2: Poor

- tissue color: >= 50% of gingiva red
- response to palpation: bleeding
- granulation tissue: present
- incision margin: not epithelialized, with connective tissue exposed

Healing Index 3: Good

- Tissue color: >= 25% and < 50% of gingiva red
- Response to palpation: no bleeding
- Granulation tissue: none
- Incision margin: no connective tissue exposed

Healing Index 4: Very Good

- tissue color: < 25% of gingiva red
- response to palpation: no bleeding
- granulation tissue: none
- incision margin: no connective tissue exposed

Healing Index 5: Excellent

- tissue color: all tissues pink

- response to palpation: no bleeding
- granulation tissue: none
- incision margin: no connective tissue exposed

PAIN ASSESSMENT

The patients were requested to complete a sheet of table every evening for 1 week from 1st day to 7th day after surgery to report the level and severity of pain . The patient had to evaluate the pain on a 10cm visual analog scale (VAS) ranging from 0 (no pain) to 10(unbearable pain) (figure - 19)[60-62]

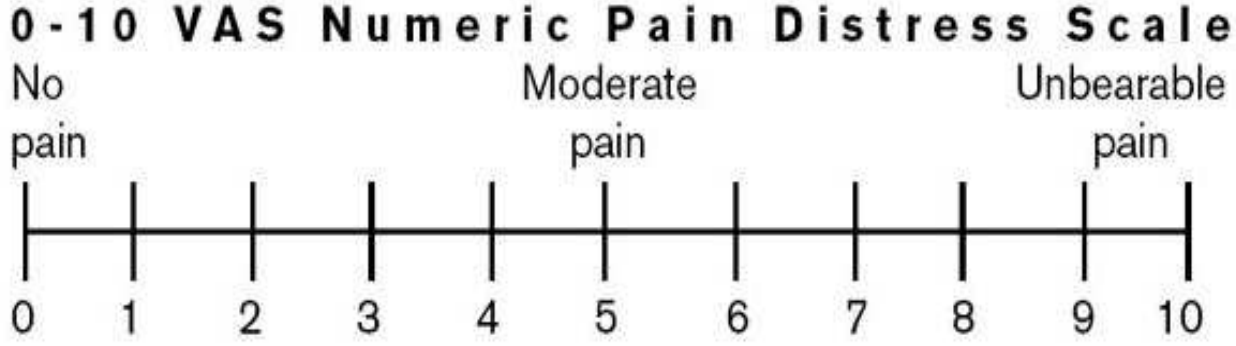


FIGURE – 19

SWELLING ASSESSMENT

The level of facial swelling was determined by a modification of tape measuring method described by Gabaka and Matsumara [63]. Three measurements were made between 5 reference points: tragus,soft tissue pogonion, lateral corner of the eye, angle of mandible, and outer corner of the mouth, preoperatively, and on second and seventh postoperative day(figure - 20). The difference between baseline and each postoperative day indicate the level of facial swelling for that day

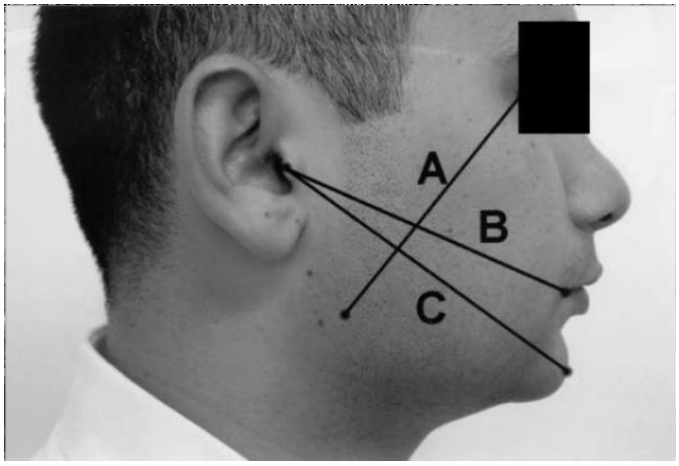


FIGURE – 20

FACIAL SWELLING MEASUREMENTS -- DETERMINATION

SWELLING ASSESSMENT

Swelling assessment by modification of Tape measuring method by Gabka and Matsumara.[63]

S1 – From Lateral canthus of the eye to angle of the mandible.

S2 - From Tragus to outer corner of the mouth.

S3 – From Tragus to Pogonion

(measurements in millimeters)

DATA ANALYSIS

The collected patient's data were tabulated and statistical analysis were performed. Microsoft Excel 2010 software to derive the mean and standard deviation and SPSS software version 21 was used for statistical analysis. Charts and graphic representations were obtained with the results. Descriptive statistics done by Measures of central tendency E.g. Mean and Measures of Dispersion E.g. Standard deviation was calculated for all the parameters. Inferential Statistics was done by 't' test to compare the mean difference between the two groups for difference in the Mean soft tissue healing score , swelling, VAS scores. P value of 5% was considered significant.

SURGICAL PICTURES AND ASSESSMENTS

SURGICAL PICTURES AND ASSESSMENTS

Pre-operative OPG

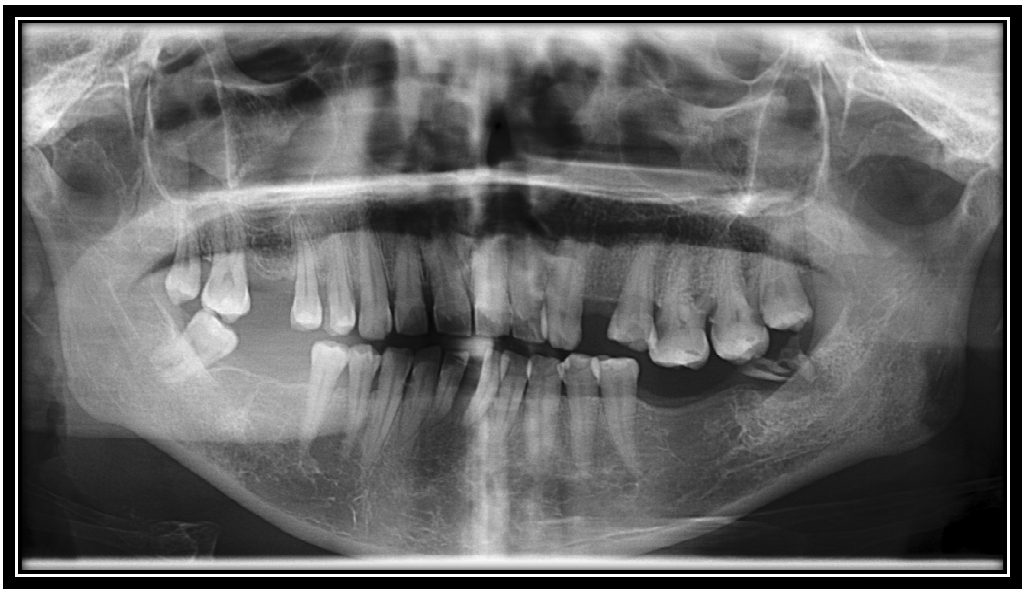


Figure21.1

Post – Operative OPG

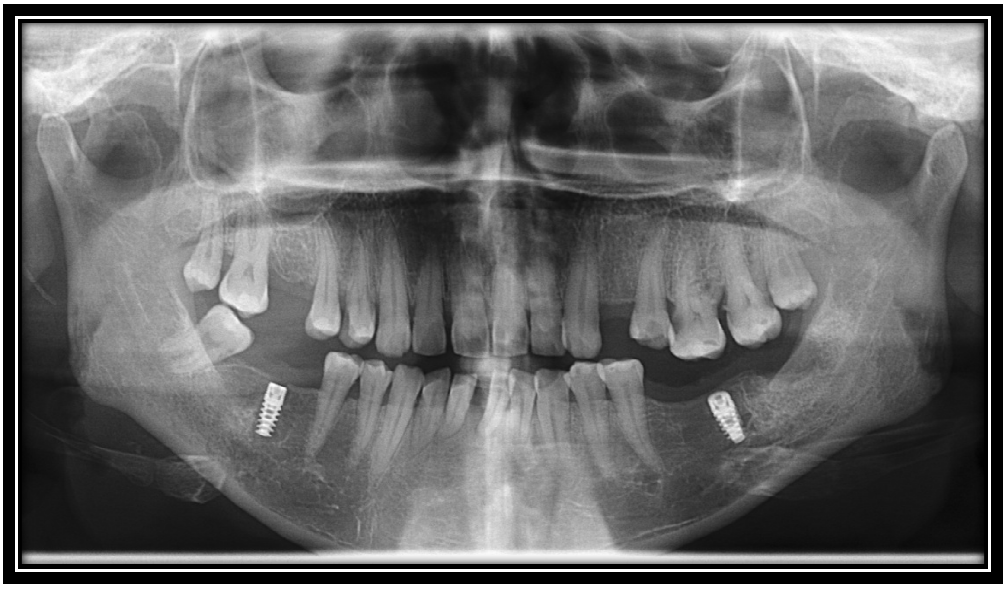


Figure 21.2

CLINICAL PICTURES

PRF Side

Implant Site

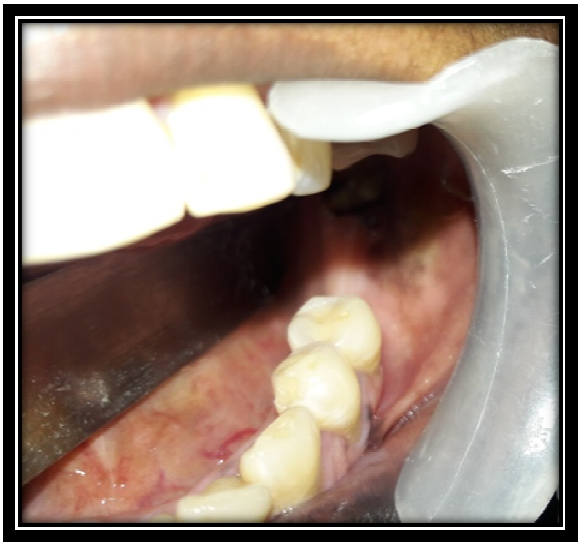


Figure 22.1

Site Exposure

Figure 22.2

Implant Placement

Figure 22.3

PRF

Figure 22.4

CLINICAL PICTURES

PRF SIDE

PRF Placement

Figure 22.5

Site Closure

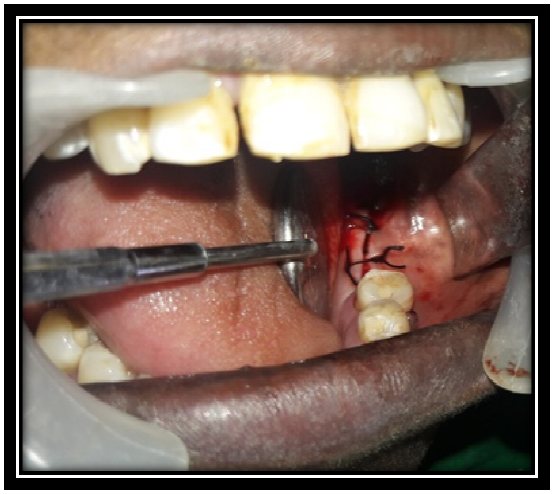


Figure 22.6

Abutment Placement

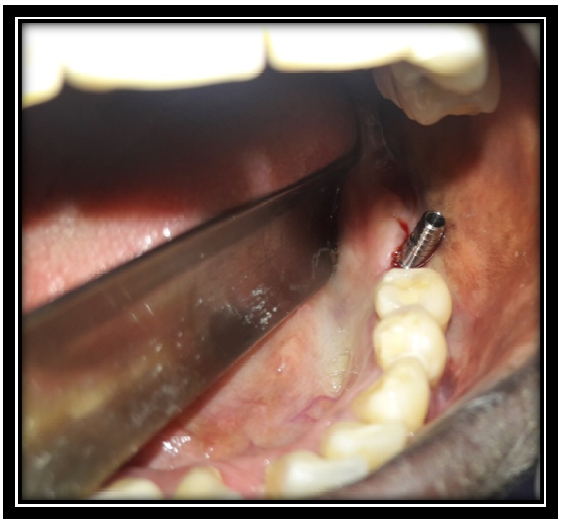


Figure 22.7

Prosthetic Rehabilitation

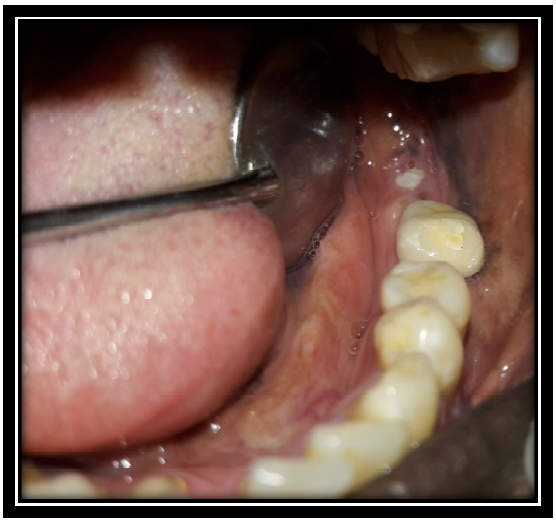


Figure 22.8

CLINICAL PICTURES

GELATAMP Side

Implant Site

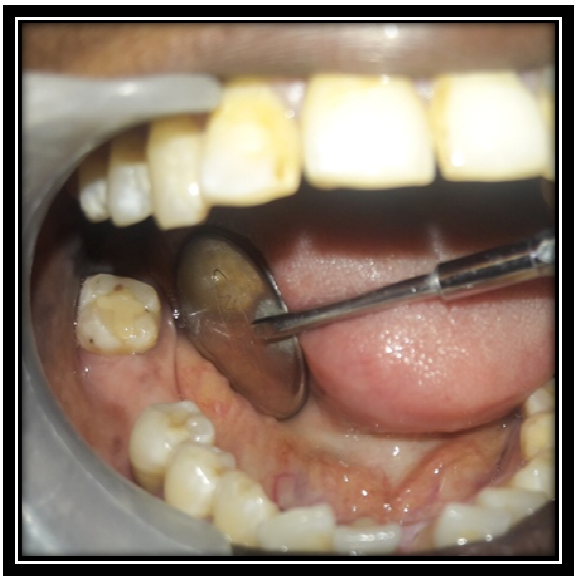


Figure 23.1

Site Exposure

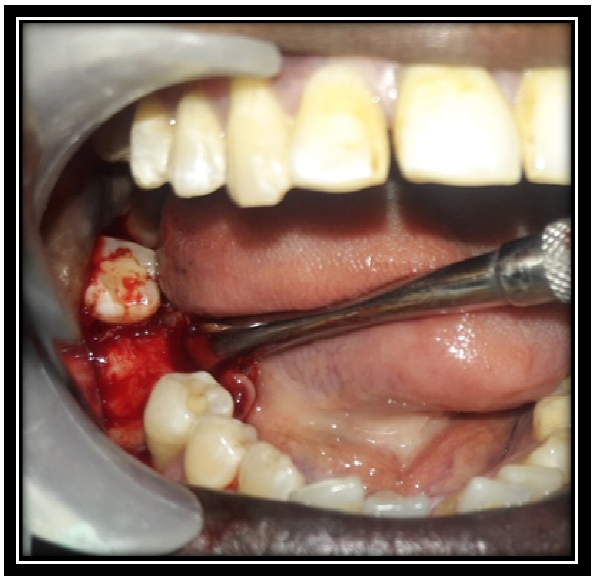


Figure 23.2

Implant Placement

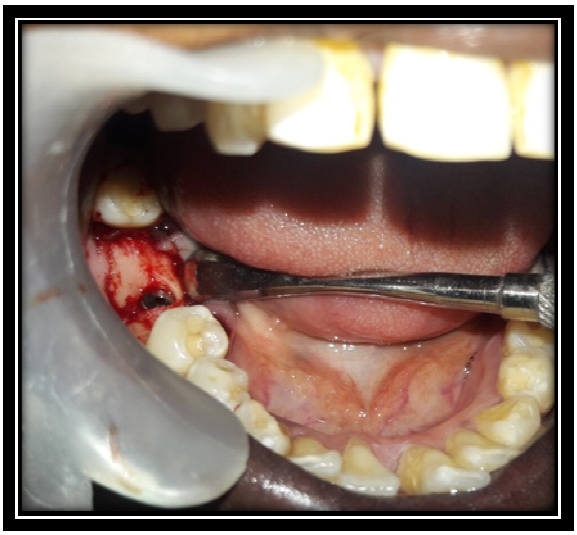


Figure 23.3

GELATAMP

Figure 23.4

CLINICAL PICTURES

GELATAMP Side

GELATAMP Placement

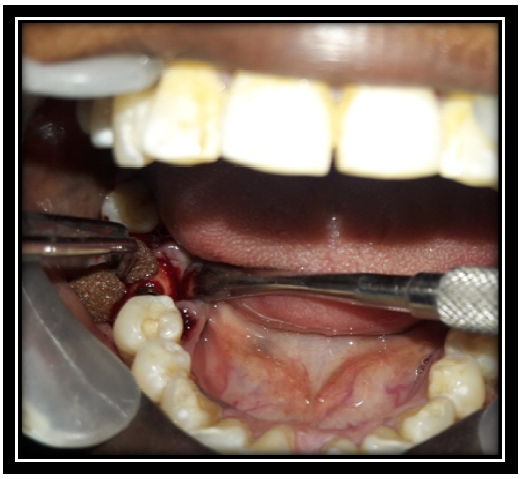


Figure 23.5

Site Closure

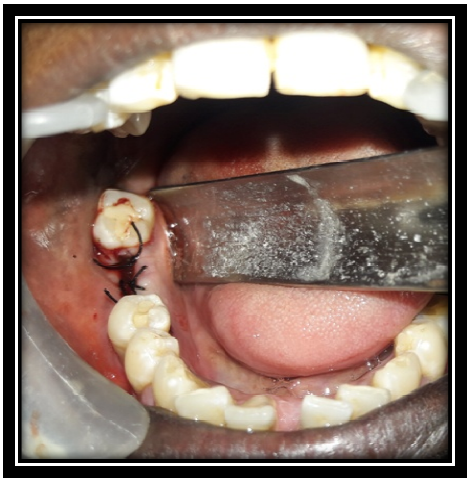


Figure 23.6

Abutment Placement

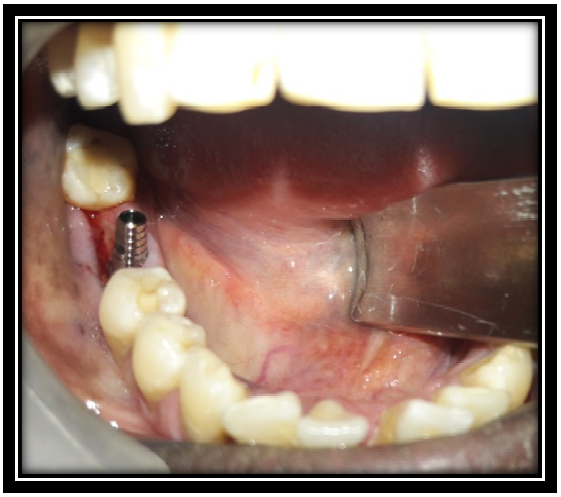


Figure 23.7

Prosthetic Rehabilitation

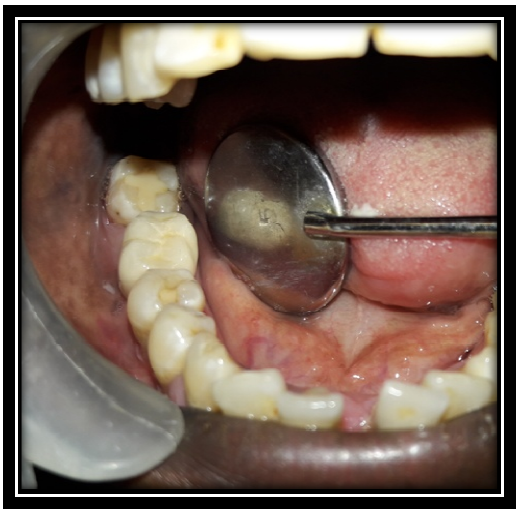


Figure 23.8

SOFT TISSUE HEALING ASSESSMENT

GELATAMP Side

1st Post Operative Day

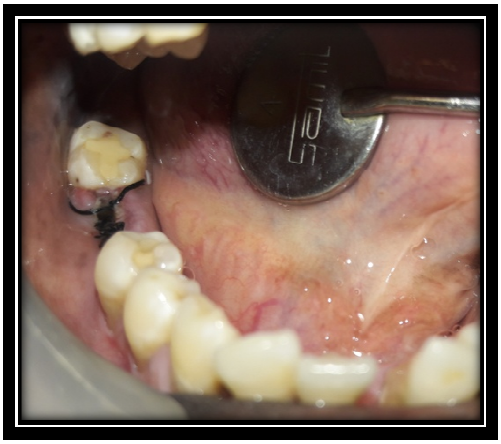


Figure 24.1

3rd Post Operative Day

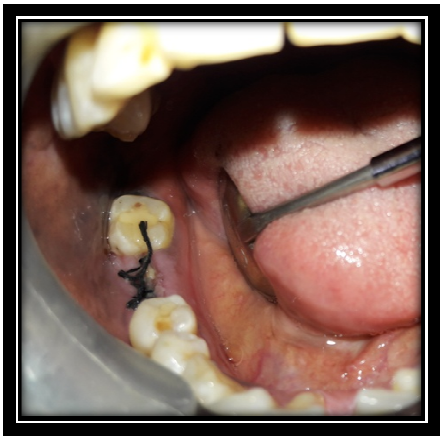


Figure 24.2

7th Post Operative Day

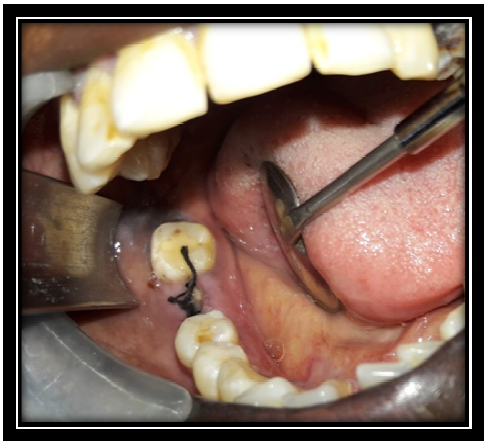


Figure 24.3

PRF Side

1st Post Operative Day

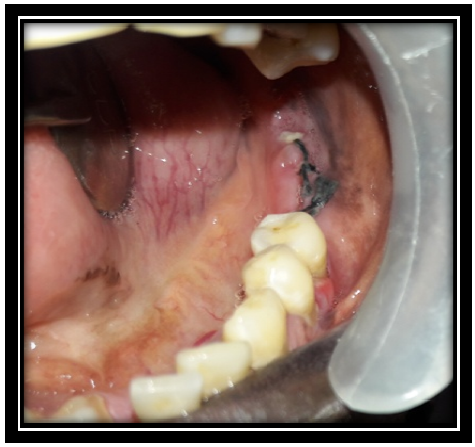


Figure 25.1

3rd Post Operative Day

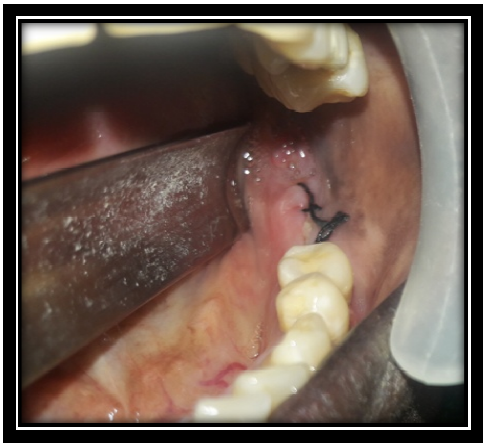


Figure 25.2

7th Post Operative Day

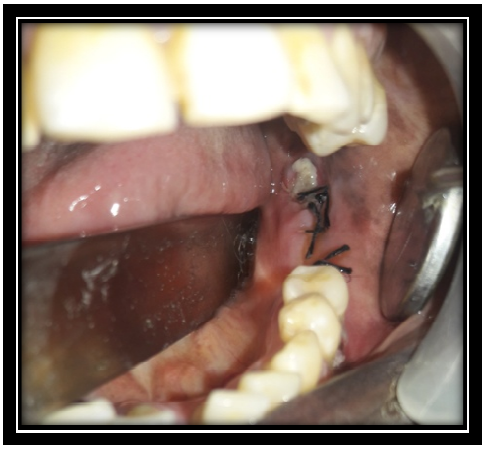


Figure 25.3

SWELLING ASSESSMENT

GELATAMP Side
1st Post Operative Day

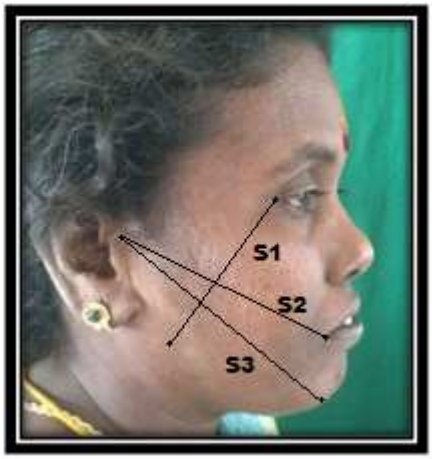


Figure 26.1

PRF Side
1st Post Operative Day

Figure 27.1

3rd Post Operative Day

Figure 26.2

3rd Post Operative Day

Figure 27.2

7th Post Operative Day

Figure 26.3

7th Post Operative Day

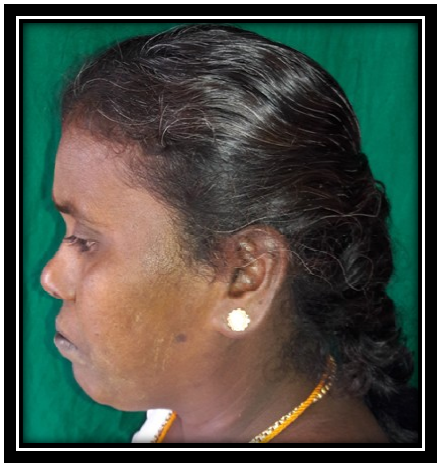


Figure 27.3

RESULT AND STATISTICAL ANALYSIS

RESULTS AND STATISTICAL ANALYSIS

The collected patient data were tabulated and statistical analysis was performed. Microsoft Excel 2010 software to derive the mean and standard deviation and SPSS software version 21 was used for statistical analysis. Charts and graphic representations were obtained with the results.

A total of 10 implants were placed in 5 patients by conventional flap surgery method . the patient's left side (3^{rd} quadrant) implant inserted sites were augmented with PRF and right side (4^{th} quadrant) implant inserted site were augmented with GELATAMP and surgical site closed with 3-0 black silk. The operation time ranged between 25 and 45 minutes and no unexpected postoperative complication such as nerve damage or infection was observed.

The study population includes 3 females and 2 males, the age groups between 25 to 42 yrs. The parameters assessed were soft tissue healing , pain, and post-operative swelling.

SOFT TISSUE HEALING

The soft tissue healing was assessed for all 5 patients (10 implant sites) on the both sides in 1^{st}, 3^{rd} , 7^{th} day postoperatively after implant placement . the healing potential was assessed by using the standardised index byLandry, Turnbull and Howley.

The mean soft tissue healing score was found to be 2.0 (SD±0.00) , 2.60 (SD±0.54), 3.2 (SD±0.447), in PRF group and 3.2 (SD±0.447), 4.4 (SD±0.548), 5.0 (SD±0.00), in the GELATAMP group on 1^{st}, 3^{rd} , and 7^{th} postoperative day respectively (Table- 3)

There was a statistical significance between two groups ($p=0.04$), ($p=0.01$) , ($p=0.01$) suggesting there was significant difference between the groups at the soft tissue healing assessment .

In PRF group mean soft tissue score was 2.00 on 1st, 2.6 on 3rd , 3.2 on 7th post operative day. In GELATAMP group 3.2 on 1st, 4.4 on 3rd , 5.0 on 7th postoperative day.(Table – 3.1 & 3.2)

PAIN ASSESSMENT BY VISUAL ANALOG SCALE (VAS):

Pain assessment by 10 cm VAS from the 1st , 3rd , 7th day after surgery was done for both the groups. During 1st ,3rd , and 7th day the VAS score of GELATAMP group is lesser than the PRF group (Table - 4).

SWELLING ASSESSMENT

The level of facial swelling was determined by a modification of tape measuring method described by Gabka and Matsumara.[63] The measurement before surgery was taken as the baseline value and then it was compared with the 1st , 3rd, and 7th day post-operative value.

The mean baseline value of S1 was 90.2mm in PRF group with 96.4mm in 1st postoperative day, 96.4mm in 3rd post operative day,and 92mm in the 7th postoperative day (Table - 5). In the GELATAMP group the mean baseline value of S1 was 91mm, 93.6 in 1st post operative, 91.8 in 3rd post operative and , 91 mm in 7th post-operative day (Table - 5).

The mean baseline value of S2 was 109.8 mm in PRF group with 114.6 mm in 1st postoperative day, 113.4 mm in 3rd post operative day,and 111.2 mm in the 7th postoperative day (Table – 6). In the GELATAMP group the mean baseline value of S2 was 110.2 mm, 113 in 1st post operative, 111.2 mm in 3rd post operative and , 110.2 mm in 7th post-operative day (Table -6).

The mean baseline value of S3 was 138.6 mm in PRF group with 143.8 mm in 1st postoperative day, 142 mm in 3rd post operative day, and 140 mm in the 7th postoperative day (Table - 7). In the GELATAMP group the mean baseline value of S3 was 138.4 mm,

141.2 in 1st post operative, 139.8 mm in 3rd post operative and , 138.4 mm in 7th post-operative day (Table – 7).

TABLE: 3

STATISTICAL VALUE OF SOFT TISSUE HEALING ASSESSMENT

Time Interval	Total (n)	(MEAN ±SD)	't' value	P value
Healing 1st Post Operative Day	5	(2.0±0.00) (3.2±0.44)	0.029	0.004
Healing 3rd Post Operative Day	5	(2.6±0.54) (4.4±0.54)	1.0	0.01
Healing 7th Post Operative Day	5	(3.2±0.44) (5.0±0.00)	0.029	0.01

TABLE – 3.1

SOFT TISSUE HEALING IN PRF GROUP

Sl. No	Post 1st day	Post 3rd day	Post 7th day
1	2	3	3
2	2	3	4
3	2	2	3
4	2	3	3
5	2	3	3
Mean	**2**	**2.6**	**3.2**

TABLE -3.2

SOFT TISSUE HEALING IN GELATAMP GROUP

Sl. No	Post 1st day	Post 3rd day	Post 7th day
1	3	4	5
2	3	5	5
3	4	5	5
4	3	4	5
5	3	4	5
Mean	**3.2**	**4.4**	**5**

TABLE - 4

STATISTICAL VALUE OF PAIN ASSESSMENT

Time Interval	Total (n)	(MEAN ±SD)	't' value	P value
Healing 1st Post Operative Day	5	(5.2±0.447) (2.4±0.548)	8.854	0.000
Healing 3rd Post Operative Day	5	(2.8±0.837) (1.0±0.008)	4.811	0.001
Healing 7th Post Operative Day	5	(1.2±0.447) (0.0±0.00)	0.029	0.000

TABLE - 4.1

VAS IN PRF GROUP

Sl. No	Post 1st day	Post 3rd day	Post 7th day
1	5	3	1
2	5	3	1
3	6	4	1
4	5	2	2
5	5	2	1
Mean	**5.2**	**2.8**	**1.2**

TABLE – 4.2

VAS IN GELATAMP GROUP

Sl. No	Post 1st day	Post 3rd day	Post 7th day
1	3	1	0
2	3	1	0
3	2	1	0
4	2	1	0
5	2	1	0
Mean	**2.4**	**1**	**0**

TABLE - 5

STATISTICAL VALUE OF SWELLING ASSESSMENT – S1

Time Interval	Total (n)	(MEAN ±SD)	't' value	P value
S1 -B	5	(90.2± 8.3) (91.0± 8.337)	0.953	0.883
S1 – 1st post operative day	5	(96.4± 8.5) (93.6± 8.9)	0.508	0.625
S1 - 3rd post operative day	5	(96.4±8.7) (91.8± 8.5)	0.473	0.649
S1 – 7th post operative day	5	(92 ± 8.1) (91 ± 8.337)	0.192	0.852

TABLE - 6

STATISTICAL VALUE OF SWELLING ASSESSMENT – S2

Time Interval	Total (n)	(MEAN ±SD)	't' value	P value
S2 -B	5	(109.8± 2.0) (110.2± 2.4)	0.909	0.789
S2 – 1st post operative day	5	(114.6± 1.9) (113± 2.4)	0.460	0.286
S2 - 3rd post operative day	5	(113.4± 2.0) (111.2± 2.5)	0.847	0.176
S2 – 7th post operative day	5	(111.2 ± 1.6) (110.2 ± 2.4)	0.750	0.475

TABLE -7

STATISTICAL VALUE OF SWELLING ASSESSMENT – S3

Time Interval	Total (n)	(MEAN ± SD)	't' value	P value
S3 -B	5	(138.6± 4.0) (138.4± 4.6)	0.720	0.944
S3 – 1st post operative day	5	(143.8± 3.9) (141.2± 4.5)	0.964	0.363
S3 - 3rd post operative day	5	(142± 4.1) (139.8± 4.2)	0.835	0.428
S3 – 7th post operative day	5	(140 ± 4.5) (138.4 ± 4.6)	0.617	0.554

STATISTICS:

STATISTICAL ANALYSIS

Descriptive statistics:

Measures of central tendency E.g. Mean and Measures of Dispersion Eg. Standard deviation was calculated for all the parameters.

Inferential Statistics:

To compare the mean difference between the two groups for difference in the Mean soft tissue healing , swelling, VAS scores, 't' test was used

P value of 5% was considered significant.

Significance level interpretation:

NS – Not significant

*** - Very highly significant

** - Highly significant

* - Significant

A total of 10 implants were followed for 7 days post surgically. Five of these patients were placed using PRF and 5 were placed using GELATAMP by conventional surgical procedure. The gender distribution of the patients was 60% female and 40% male. All the ten implants were placed in mandible (1^{st} molars and 2^{nd} molar site).

Statistically there was significant soft tissue healing between PRF and GELATAMP group when compared to PRF group in all the time intervals. The p value of 0.04 on 1^{st} post operative, 0.01 on 3^{rd} post operative, 0.01 on 7^{th} postoperative day. (Table – 3)

Pain assessment by Visual analog scale is statistically significant in all 3 interval postoperative days. The mean VAS score for 1st day was 5.2±0.44 in PRF group and 2.4±0.54 in GELATAMP group (p=0.000***). The mean VAS score for 3^{rd} day was 2.8±0.83 in PRF group and 1.0±0.008 in GELATAMP group (p=0.001**). The mean VAS score for 7^{th} day was 1.2±0.44 in PRF group and 0.0±0.00 in GELATAMP group(P=0.000***) (Table – 4)

There is no statistically significant value between PRF and GELATAMP group in post operative swelling assessment . The p value for S1 baseline , S1 1^{st} , S1 3^{rd} ,and S1 7^{th} postoperative day was 0.883, 0.625,0.649 and 0.852 respectively. The p value for S2 baseline, S2 1^{st} , S2 3^{rd} ,and S2 7^{th} postoperative day was 0.789, 0.286, 0.176 and 0.475 respectively . The p value for S3 baseline, S3 1^{st} , S3 3^{rd} ,and S3 7^{th} postoperative day was 0.944, 0.363, 0.428 and 0.554 respectively . (Table – 5,6 and 7)

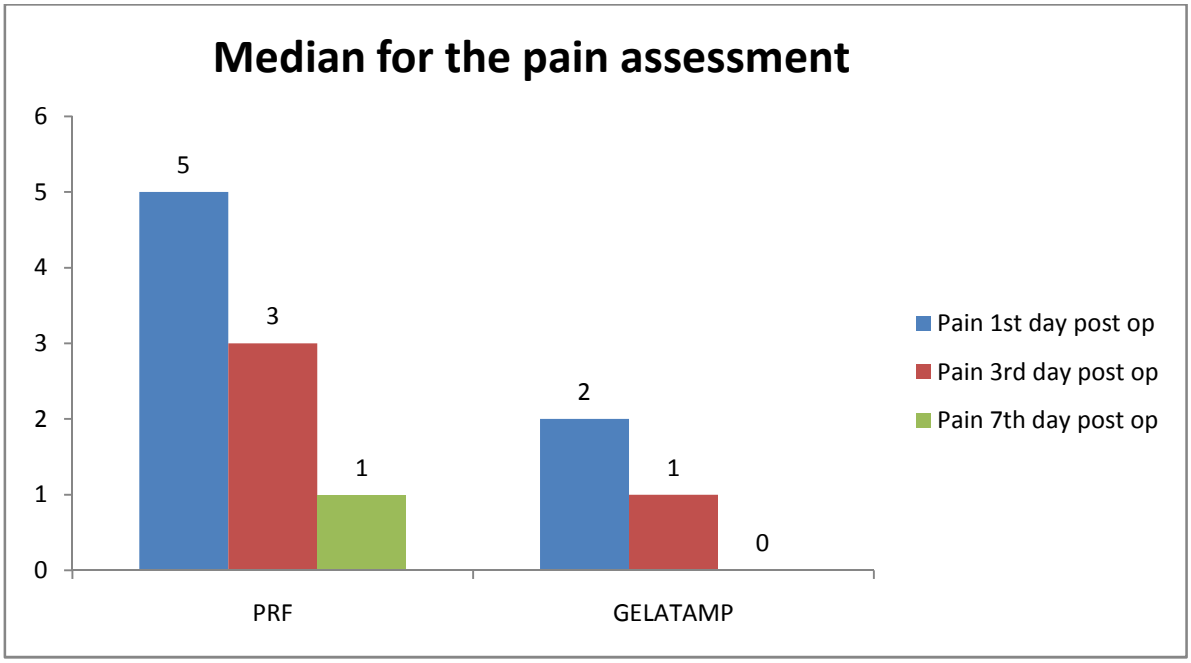


FIGURE – 28

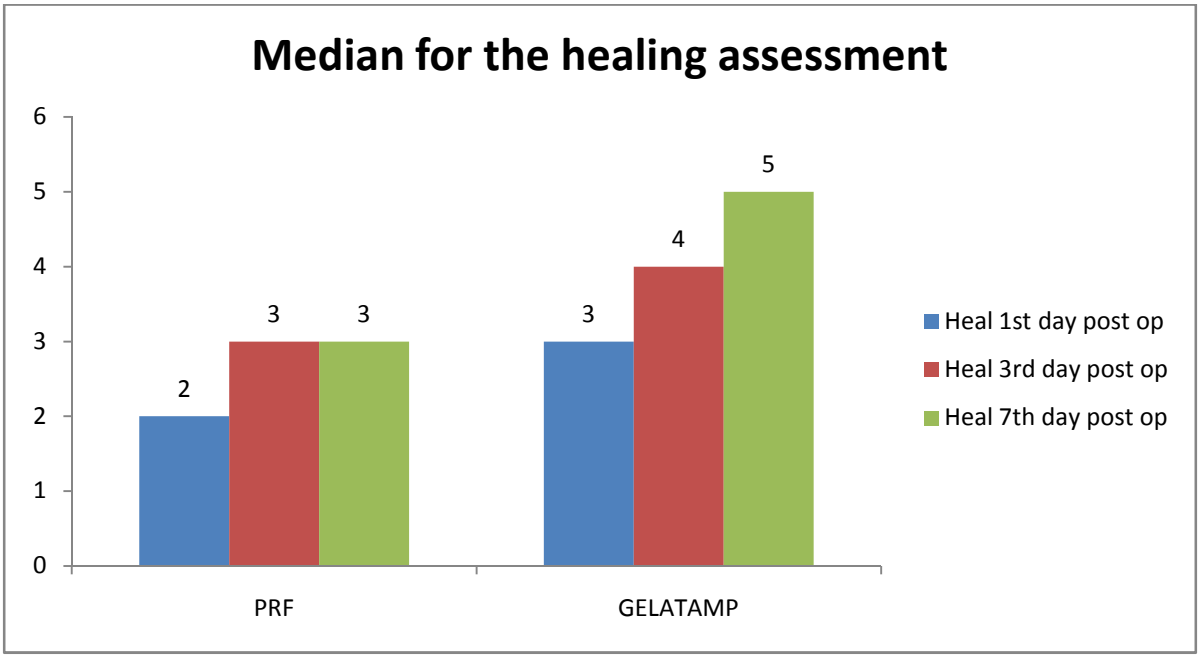


FIGURE - 29

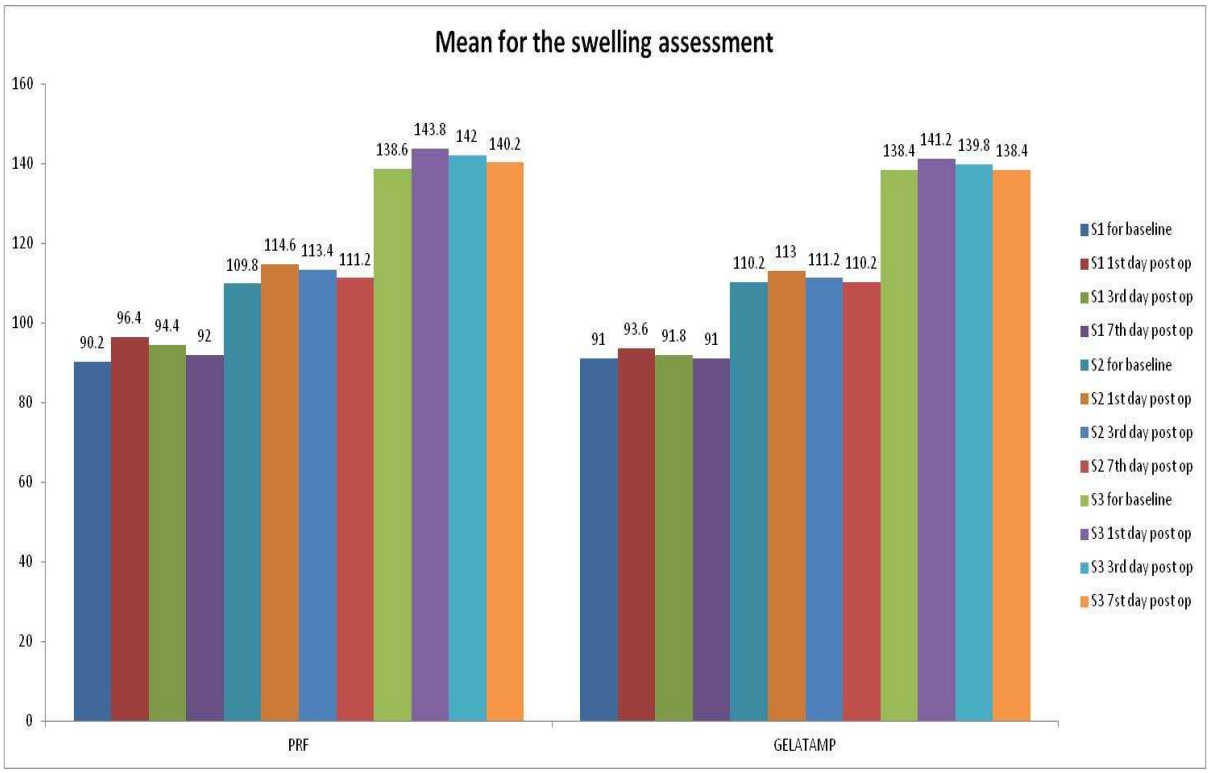

Mean for the swelling assessment
160
140
120
100
80
60
40
20
0
90.2
96.4
94.4
92
109.8
114.6
113.4
111.2
138.6
143.8
142
140.2
91
93.6
91.8
91
110.2
113
111.2
110.2
138.4
141.2
139.8
138.4
PRF
GELATAMP
S1 for baseline
S1 1st day post op
S1 3rd day post op
S1 7th day post op
S2 for baseline
S2 1st day post op
S2 3rd day post op
S2 7th day post op
S3 for baseline
S3 1st day post op
S3 3rd day post op
S3 7st day post op

FIGURE - 30

DISCUSSION

DISCUSSION

The removal of a tooth initiates the same sequence of inflammation, epithelialization, fibroplasia, and remodeling seen in prototypic skin or mucosal wounds. Extraction sockets heal by secondary intention, and many months must pass before a socket heals to the degree to which it becomes difficult to distinguish from the surrounding bone when viewed radiographically.[10]

When a tooth is removed, the remaining empty socket consists of cortical bone (the radiographic lamina dura) covered by torn periodontal ligaments, with a rim of oral epithelium (gingiva) left at thecoronal portion. The socket fills with blood, which coagulates and seals the socket from the oral environment. The inflammatory stage occurs during the first week of healing. White blood cells enter the socket to remove contaminating bacteria from the area and begin to break down any debris such as bone fragments that are left in the socket. Fibroplasia also begins during the first week, with the ingrowth of fibroblasts and capillaries. The epithelium migrates down the socket wall until it reaches a level at which it contacts epithelium from the other side of the socket or it encounters the bed of granulation tissue (i.e., tissue filled with numerous immature capillaries and fibroblasts) under the blood clot over which the epithelium can migrate. Finally, during the first week of healing, osteoclasts accumulate along the crestal bone.

The second week is marked by the large amount of granulation tissue that fills the socket. Osteoid deposition has begun along the alveolar bone lining the socket. In smaller sockets, the epithelium may have become fully intact by this point. The processes begun during the second week continue during the third and fourth weeks of healing, with epithelialization of most sockets complete at this time. The cortical bone continues to be resorbed from the crest and walls of the socket, and new trabecular bone is laid down across the socket. Not until 4 to 6 months after extraction is the cortical bone lining a socket usually

fully resorbed; this is recognized radiographically by a loss of a distinct lamina dura. As bone fills the socket, the epithelium moves toward the crest and eventually becomes level with adjacent crestal gingiva. The only visible remnant of the socket after 1 year is the rim of fibrous (scar) tissue that remains on the edentulous alveolar ridge.[10]

Management of partly or completely edentulous area has been revolutionized by dental implants. Implants are done as out patients, done in all age groups. Dental implant therapy has replaced most of the conventional methods of treating edentulous patients and has become a highly predictable and successive treatment modality.

MICROBIOLOGY OF ORAL CAVITY

There are more than 700 different types of microbe that can be isolated from the mouth but that greater than 50% of these cannot currently be grown in pure culture in the laboratory. A healthy gingival sulcus contains predominantly of gram-positive cocci and rods, principally Actinomyces naeslundii (14%), Actinomyces gerencseriae (11%), Streptococcus oralis (14%) and Pepto-streptococcus micros (5%). Gram-negative anaerobic rods account for 13% of the total cultivable organisms on average. six anerobic bacteria in teeth and implants sulci such as Gram-positive cocci, Gram-negative cocci, Prevotella, Porphyromonas gingivalis, Bacteroides fragilis and Fusobacterium.Gram-positive cocci and Gram-negative cocci had maximum and minimum percentage frequency in the two groups, respectively.[4]

IMPLANTS DESIGN AND COATING

The vast majority of dental implants have been placed in patients have a similar shape: a hollow supporting screw that receives, in a second time ,a supra-prosthetic device. There are numerous variations in the overall shape of the implants (e.g., a rounded or pointed apex; more or less spaced threads, cylindrical or conical body). The surface quality of an oral dental implant is one of the essential features for long term success . The manufacturers

have developed various specific processes to improve the rate of osseo-integration and the long-term biomechanical anchorage of the implant on the bone contact surface . Implants with a rough surface have a better osseo-integration than smooth surface .Roughness results in a better interlocking between the implant and bone surface on growth by increasing the developed surface at the micrometer scale. However, an excess of roughness, especially in the upper threads, can increase peri-implantitis as well as ionic leakage . It is generally accepted that a moderate roughness of 1—2 mm is the most suitable condition . Several methods have been pro-posed by the manufacturers to produce a rough surface on a dental implant.1. Titanium plasma-spraying,2 Particle blasting and acid etching, 3. Anodization of the implant surface. Several coating methods have been also proposed to modify the roughness and improve cell attachment . Hydroxyapatite can be deposed by plasma-spraying but the layer tends to delaminate, leading to implant failure later. These implants are nowadays abandoned. Similar problems were also encountered with coatings made of other orthophosphate calcium salts. Bio mimetic calcium phosphate have also been electro-deposited or created by immersion in synthetic body fluids (gel-sol technique) .[3]

In 1986 Albrektsson et al proposed certain criteria to assess success of implants. According to these criteria, bone loss of less than 0.2mm annually following the implant's first year of function is stated as being essential for long-term success.[64]

In 1990 Adell suggested that 2% of implants failed to achieve osseointegration following insertion . Using a meta-analysis, failure rates for Branemark dental implants were 7.7% (not including bone grafts) over five years. Interestingly, failure rates in completely edentulous patients were almost double than partially edentulous patients (3.8%). The long term success of a dental implant strongly depends on good adhesion of the surrounding tissue to the biomaterial. The interactions between bacteria and oral implant materials show microbial adhesion and aggregation

IMPLANT FAILURES

A multifactorial background for implant complications and failure has been extensively reviewed by Esposito and co-workers (1998). Major etiologic factors have been suggested:

1. **Infection:** Bacterial infection which leads to implant failures can occur at any time during implant treatment. (e.g) peri-implant mucositis, and peri-implantitis. Peri-implant mucositis is a term describing reversible inflammatory reactions in the soft tissue surrounding implants..
2. **Impaired healing:** It is believed that the magnitude of the surgical trauma (lack of irrigation and overheating), micromotion and some local and systemic characteristics of the host play a major role in implant failures related to impaired healing.[64]

Esposito and colleagues classified 4 categories of implant failure based on the osseointegration theory. [64,65]

1.Biological failure, 2. Mechanical failure 3. Iatrogenic failure 4. Adaption failure. Most common causes of dental implant failure at an early stage are surgical trauma , bacterial contamination, delayed wound healing (host-related), and early loading of the implants . Reports in the dental literature suggest that the incidence of early implant failure ranges from 0.7% to 2.0%.[66]

MICROBIOTA OF DENTAL IMPLANTS:

The primary etiologic factor for peri-implant mucositis is the oral biofilm. This initial challenge to the host defense mirrors the challenge that affects the natural dentition. Cortelli and colleagues (2013) found that the frequency of Porphymonas gingivalis was higher in cases of peri-implantitis than in cases of perimucositis and that the levels of P gingivalis and Aggregatibacter actinomycetemcomitans were similar in periodontitis and peri-implantitis .Fusiform bacterium and Streptococcus species were common in association with both

periimplantitis and periodontitis, whereas Parvimonas micra were seen only in association with peri-implantitis.[67]

A microbial biofilm is defined as a "complex, functional community of one or more species of microbes, encased in an exopolysaccharide matrix and attached to one another or to a solid surface. The process of bacterial adhesion to implant surface can be divided into two phases , (i) initial, instantaneous , and reversible physical phase (phase one) , and (ii) time-dependent and irreversible molecular and cellular phase (phase two) .

In brief , following initial attachment ,bacteria initiate to colonize and grow on the dental implant surface .Multilayered cellular clusters are formed by cell proliferation , intercellular adhesion. and production of an extracellular polymeric matrix. Subsequently, such a three-dimensional architecture developed into the well maturation stage .After that , some bacteria start to detach from the implant surface and dispersed into the body fluids, leading to the spreading of biofilm across another implant surfaces.It is obvious that the common aetiology of peri-implant pathogens remains same in the microbial colonization of implant surfaces.[6]

Simonetta D Ercole et al showed that in partially edentulous patients, the composition of the subgingival microbiota is similar to teeth and dental implants. Transmission of bacteria from residual pockets around neighboring teeth could be possible. The screws harbored more complex microbiota,(after 90 days) characterized by a lower percentage of coccoid cells and a higher percentage of rod cells. In teeth, these types of microbiota are considered as a more mature plaque.. The results of this study indicated that maintaining the screws for a period of 90 days caused an important increase in plaque quantity, with a dramatic change in plaque composition.[35]

According to a classic postulate of Koch- states that transfer of bacteria from one locus to another can cause the same disease in the other locus, whether this is between or within subjects. Medium of transfer of infection in oral cavity is saliva.[4]

The hollow spaces between implant and abutments may act as reservoir for commensal and pathogenic bacteria, especially anaerobic or microaerophilic species, acting as a potential source of tissue inflammation. According to Quirynen et al., (2002), gaps in the implant-abutment interface may act as a trap for bacteria, favoring the development of biofilm with varying composition and impact on periodontal tissues. Agregatibacter actinomycetemcomitans, Tannerella forsythia and Porphyromonas gingivalis, isolated frequently in these biofilms, are pathogens intimately related to the development and maintenance of periodontitis and peri-implantitis.[4]

A.D.Pye et al explained that implant failures are associated with a microbial flora traditionally associated with periodontitis. Staphylococci are present within the oral cavity and their isolation from peri-implant infection is significant as both Staphylococcus aureus and coagulase-negative staphylococci are mostly responsible for infections associated with metallic biomaterials. More recently, Staphylococcus aureus has been demonstrated to have the ability to adhere to titanium surfaces. This may be significant in the colonisation of dental implants and subsequent infections[26]

Ikiru Atsuta et al explained that peri implant junction is composed of three types of epithelium: peri implant epithelium (PIE), peri implant sulcular epithelium (PISE), and oral epithelium (OE) (Figure - 31. The PIE has a much lower functional sealing capacity than JE .This fragility of the seal means that probing often induces bleeding and permits the ingress of bacteria deep into the peri-implant tissues, accelerating the physical destruction of the epithelial and connective tissue.[52]

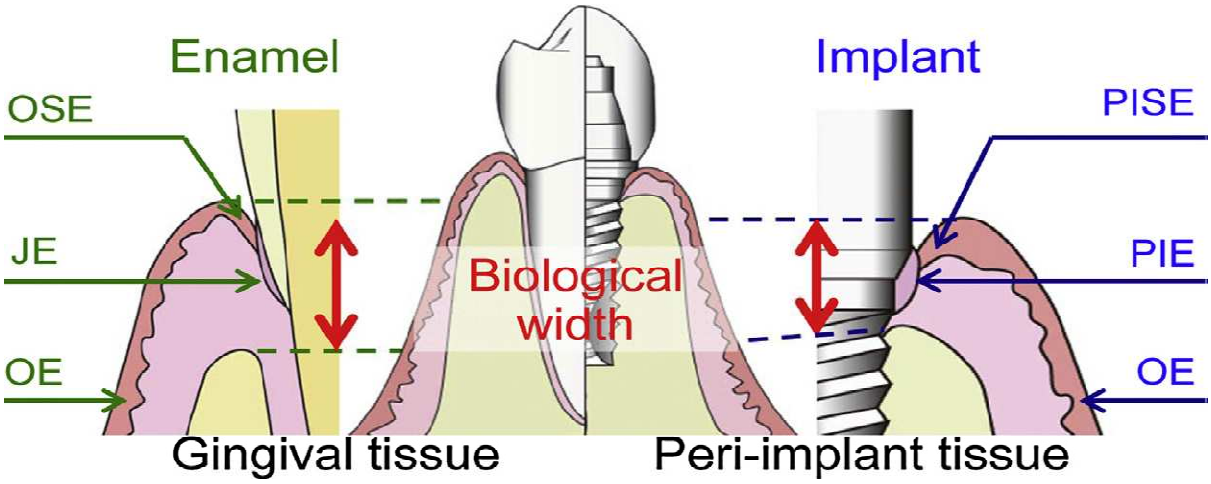


FIGURE – 31 – TYPES OF EPITHELIUM

C. do Nascimento et al stated that current implant systems cannot completely prevent microbial leakage and bacterial colonization of the inner part of the implant and its abutment. The penetration of oral microorganisms through the implant abutment interface may produce soft-tissue inflammation and constitute risk to the clinical success of the implants. Later revealed that pathogenic microorganisms are present in the implant and its related sites since the initial loading and persist over time. Since bi directional microleakage into and from implant-abutment interface have been associated to late implant failure.[68,69]

With the emergence of various pathogenic bacterial strains that possess a resistance towards more antibiotics, the medical field is in need of new classes of disinfection systems . Silver-containing systems, and notably silver nano particles (Ag NPs) and colloidal silver are to these days one of the most promising system to fill this role. Silver nanoparticles constitute a very promising approach for the development of new antimicrobial systems with out any resistance. Nanoparticulate objects can bring significant improvements in the antibacterial activity of the silver element, through specific effect such as an adsorption at bacterial surfaces.[70]

Silver is a naturally occurring element. Like other metals, the ionized form of silver (Ag+1) has known antimicrobial properties. A number of wound dressings and augmenting material incorporating silver ion or silver compounds have recently been developed and

marketed . Silver in its various forms has been used for over 200 years in the treatment of burn injury and silver nitrate solutions (5% -10% concentrations) were used as caustics or escharotics in the early 20th century . In 1965, Moyer et al. pioneered the use of 0.5% silver nitrate solution as a topical therapy for burn patients . Despite the availability of various newer topical antimicrobials, both 0.5% silver nitrate solution and 1% silver sulfadiazine cream continue to be used in contemporary burn wound care. 0.5% of Silver nitrate is highly effective against P. aeruginosa and may to be superior to chlorhedixine against more resistant strains of Streptococcus pyogenes and Staphylococcus aureus.[36]

Silver exhibits three oxidation states Ag [+1], Ag [+2] and Ag [+3] (pure metallic silver is Ag [0]). Of these, only the Ag [+1] state is sufficiently stable for use as an antibiotic as the other cations are highly reactive and short-lived. Silver compounds ionize in the presence of water and biologic fluids to release Ag (+1).[43]

There are four plausible mechanisms that have been postulated for the antimicrobial effects of silver.

1. Inhibition of life-sustaining enzymes by chemical interaction with silver ion. Silver ion is capable of blocking the electron transport system in bacteria. Ionic silver inhibit the enzymes of the respiratory chain at two specific areas . Silver ion interacts with thiol groups on enzymes, gets deactivated, which results in bacterial cell death.
2. Ionic silver kills bacterial cells is through interaction and rupture of the cell membrane or cell wall. binding of silver to a membrane can inhibit the passage of nutrients through the membrane, and/or interfere with normal concentration gradients between the cell and surrounding environment, leading to cell death.
3. The interaction of ionic silver with bacterial cell DNA , result in mutation of the DNA and ultimately in the death of a bacterial cell
4. Destruction of a bacterial cell by silver free-radicals.

Silver resistance is exceptionally rare and generally of no clinical significance . Clinicians should preferentially choose dressings that release high levels of ionic silver and demonstrate rapid bactericidal activity to minimize the risk of silver resistance.[43]

CLINICAL ASPECTS

In 2007 Jun Tian et al showed that deep partial-thickness wounds normally healed after 35.4 ± 1.29 days (mean ± SE). In animals treated with silver nanoparticles (ND), these healed in 26.5 ± 0.93 days, whereas wounds treated with silver sulfadiazine (SSD) needed 37.4 ± 3.43 days The rate of healing in the three groups was also compared. As with healing time, rate of healing was increased in animals treated with ND ($p<0.001$).[22]

They also compared the effect of ND towards bacterial colonization on wounds after induced thermal injury. Wound culture showed no microorganism growth up to 7 days after thermal injury in ND group. In contrast, bacterial growth was found in the SSD group 3 days after injury. This confirmed that silver nanoparticles have more effective antibacterial property . Also they compared ND with amoxicillin and metronidazole, two commonly used antibiotics. Wounds treated with ND completely healed in 25.2 ± 0.72 days after injury, whereas those treated with antibiotics required 28.6 ± 1.02 days ($p<0.01$). This finding suggests that various factors are also involved in the mechanism of action of silver nanoparticles.[22]

Maribel guzman et al demonstrated that the colloidal Ag NP s inhibited the growth and reduced the multiplication of the tested bacteria, including highly multidrug-resistant organisms such as methicillin resistant s. aureus, s. aureus, e. coli, and p. aeruginosa. A strong antibacterial activity was observed at very low total concentrations of silver (< 7 ppm). Also he tested the efficacy of nanocrystalline silver versus a control group receiving conventional silver sulfadiazine on 166 different burn wounds in 98 patients . Nanocrystalline

silver dressings significantly reduced the wound healing time by an average of 3.35 days and increased bacterial clearance from infected wounds.[71, 72]

Silver needs a substrate for sustained release. Various carrying materials are available for this purpose. Among these materials, Gelatin serve as a better carrying agent.

Gelatin is a natural polymer which is derived from collagen, and is commonly used for various pharmaceutical and medical applications because of its biodegradability and biocompatibility in normal environments. Simon young (2005) et al stated that controlled delivery of sensitive biomolecules from gelatin carriers, a diverse range of applications have been studied for gelatin carrier-mediated pharmaceutical drug delivery such as sustained antibiotic delivery and metal ions for bone infection repair and cancer chemotherapy. He also demonstrated that the versatility and utility of gelatin-based controlled-release systems in various applications by taking advantage of polyion complexation, a diverse array of charged biomolecules can be loaded into gelatin carriers while retaining their inherent biological activity.[14, 72].

A variety of bone augmentation materials for preservation of extraction socket are 1) bone fillers: bioactive glass with calcium sulfate (BG/CS), 2) freezedried bone allograft (FDBA), 3)magnesium-enriched hydroxyapatite, 4) organic corticancellous porcine bone xenograft (CPB), 5) calcium sulfate (CS); 6) collagen sponges: bioabsorbable polylactide-polyglycolide acid sponge (BAS), 7) absorbable gelatine sponge (GELATAMP) 8) recombinant human bone morphogenic protein-2 growth factor, 9) membranes: nonabsorbable expanded tetrafluroethylene membrane (NAM) and 10) bioabsorbable membrane made from glycolide and lactide polymers, 11) platelet concentrates(PRP, PRF)

Thawatchai Maneerung et al showed that impregnation, instead of coating or surfing the wound dressing with silver nanoparticle or nanocrystal improved the antibacterial activity of the wound dressing and reduced possibility of the normal human tissue damage. This action is probably due to the slow and continuous release of silver nanoparticles and then was slowly changed to silver ions under our physiological system and interact with microbial cells, thus silver ions will not be so high enough to cause the normal human cells damage and can increase the antimicrobial effect.[73]

Gelatin sponge is a biocompatible material which is used in the treatment of calvarial defects, in tooth socket extraction, and in iliac bone procurement to test bony healing. Gelatin sponge material has the characteristics of platelet adhesion induction and releases the content of the α-granules. Gelatin-based resorbable sponge has been placed as a carrier matrix for mesenchymal stem cells . Recently, several studies have been performed to test the effect of growth factors in extraction sockets using gelatin sponge as a scaffold material .[74]

CAI Yong -hai, LU Chang -shou.(2008) showed that the incidence rate of post operative complication of teeth extraction in experimental group(GELATAMP) was 7.72% , which was very lower than that of control(Non GELATAMP) group（24.43%）. There was significant difference in the incidence rates of complication between experimental group and control group（$P<0.005$). The incidence rate of bleeding, infection, pain, swelling and dry socket after teeth extraction in experimental group was lower than those of control group, and the difference between them was statistically significant（$P <0.05$)[23]

Wang YZ (2013) showed that the incidence of dry socket was 0.44% in group A(gelatamp implanted in alveolar socket), 2% in group B(gelatine sponge in alveolar socket) and 4.44% in group C (nothing implanted). There was significant difference in the incidence of dry socket between group A and group C ($P<0.01$). There was also significant difference between group B and group C($P<0.05$) and between group A and group B($P<0.05$).[75]

PRF is an autologous fibrin-based (membrane, matrix or scaffold), living biomaterial, derived and prepared from autogenous blood also referred to as an optimized blood clot. In brief, PRF is a natural (autologous) composite biomaterial, consisting of fibrin, platelets, more growth factors and various cell types including leukocytes and stem cells. The blood concentrate which is obtained after centrifugation has 3 distinct layers: 1. a red blood cell (RBC). base at the bottom, 2. a PRF clot in the middle, and 3. an acellular plasma (platelet-poor plasma [PPP]) supernatant layer at the top. The PRF clot is composed of two main parts observable with the naked eye: a upper fibrin yellow portion, constituting the main body, and a red portion located at the end of the clot (full of RBCs). Between these two areas, a whitish layer called the ‘‘buffy coat’’ can be seen. PRF can be used directly as a clot , as a membrane(after compression) or plug. Alternatively, the supernatant can be aspirated from the vacutube (i-PRF) and used in injectable form.

The key elements required to promote tissue healing, repair and regeneration are: the fibrin (using as a supporting matrix), the platelets (rich in growth factors), and cells (mostly the various populations of leukocytes, and stem cells for their antimicrobial , neo-vascularization and regenerative properties) which are all active component of PRF. Most importantly, the use of PRF enables local delivery of a fibrin matrix, cells, growth factors and proteins that provide unique biological properties and signs for promoting new blood vessel formation, and potentially accelerating wound healing and tissue regeneration, and also reducing morbidity due to its antimicrobial and antihaemorrhagic effects, with virtually no risk of rejection. The introduction of PRF as a autologous biomaterial has set in motion an exciting and promising era in the advancement of tissue healing and regeneration in the fields of dental implantology, periodontology, oral maxillofacial surgery and regenerative endodontics.[76]

Zhang et al evaluated the influence of PRF on bone regeneration in sinus augmentation. After a healing period of 6 months no statistical differences found between PRF and the control groups .According to a study by Choukroun et al. a cystic cavity filled with PRF would be totally healed in 2 months instead of the 6 to 12 months required for normal physiologic healing.

Kumar et al investigated the effect of platelet-rich fibrin (PRF) on postoperative pain, swelling, trismus, periodontal healing and concluded that trial group had less pain, swelling, and trismus. Also showed that increased and faster periodontal healing compared with control group. In another study by Singh et al concluded that use of PRF after bilateral mandibular 3rd molar removal resulted in reduced pain compared to control side.[47]

Ozkan et al showed the use of PRF in oral cavity has been implicated in different procedures such as extraction socket preservation, intrabony defects, sinus augmentation, and sinus lift procedures for implant placement, bone augmentation, denuded root coverage procedures, and healing in donor site with significant results In his study , PRF was used after 3rd molar removal , swelling and pain were evaluated. Statistically significant difference was found concerning first and third day horizontal measurements of PRF and control sides with more swelling at the control side ($p < 0.05$). These results are in accordance with Kumar et al.[I8,47]

Many research are available to show the effectiveness of GELATAMP and PRF aids in soft tissue healing , and reduction of post operative complications separately. But no study has compared the effectiveness of the above mentioned.

In our comparative study , Assessment of clinical parameters (pain, postoperative swelling, and soft tissue healing) are as follows :

Our study results were also statistical significance between two groups 1st postoperative ($p=0.04$), 3rd postoperative ($p=0.01$) , and 7th postoperative day ($p=0.01$)

suggesting there was significant difference between the groups at the soft tissue healing assessment.

Our results are similar to Elia Charbel Abboud (2014) in SSI (Surgical Site Infection) in colorectal surgery, neurological surgery, spinal surgery, and certain cardiovascular and orthopedic procedures. (p=0.03).[39] Omnia Hassan et al (2011) showed the statistically significant higher mean values than group A which showed the statistically significant lowest mean number of consumed tablets (where p-value was 0.004). The same was at the 2nd day(p-value 0.021) and at the 4th day (p-value 0.018).[7]

Liao R, Wang et al (2012) implanted Gelatamp in the extraction sockets of anterior teeth and performed early-implanting operations after 4 weeks. They described its advantages as easier wound closure, hemostasis effect, preventing infection and less soft tissue depression. Our findings indicated that Gelatamp may also promote bone healing in these cases.[8]

Yuliang dong et al (2016) investigated the efficiency of gelatine with / without colloidal silver on bone healing in infected cranial defect in animal model. 2 weeks after debridement, the gelatin group showed negligible amount of new bone formation in the defect area, while the defects of gelatin/Ag group had larger area occupied by bone tissue(p<o.o5).4 weeks after debridement, the defects of gelatin group remained almost unfilled, While new bone tissue had almost closed the defect of gelatin/Ag group.(p<0.005).[8]

Also in our study, statistically there was significant soft tissue healing between PRF and GELATAMP group in all the time intervals. The p value of 0.04 on 1st post operative, 0.01 on 3rd post operative , 0.01 on 7th postoperative day strongly suggesting that GELATAMP is the one of the best augmenting material in dental implant site for better soft tissue healing which aids in long term success of implants.

Pain has been referred to as “the fifth vital sign,” and the Joint Commission on the Accreditation of Health Care Organizations (JCAHO) now requires that pain be assessed and managed for all patients and those undergoing office-based surgical procedures.[62]

Fear of pain is one of the most commonly cited anxieties associated with dental treatment procedures. In particular, any oral surgical procedures under local anaesthetic injections including implant insertion, have been reported by patients to be among the most stressful and anxiety-provoking procedures in dentistry. Indeed, pain is a common complaint following dental implant surgery. Despite the importance of pain during oral surgery for the patient and the surgeon, there are few studies on the pain experienced following the placement of dental implants. Most studies fail to evaluate the intensity of pain and inflammation after surgery, and none have yet compared the patient’s perceived pain between GELATAMP and PRF groups. To evaluate the pain felt by patients, the current study used a VAS, which is the most widely used pain measurement instrument in many centres. The VAS is a simple, solid, sensitive, and reproducible tool for assessing pain in a given patient at different points in time.

Silver-containing dressings are mainstay of surgically incised wound. Along with its antimicrobial activity, there is anecdotal evidence that silver dressings may modulate or reduce wound pain. Pain is a subjective symptom and difficult to quantify, and most studies of silver-containing dressings evaluate pain as a secondary rather than a primary outcome. Among various studies from 2007 to 2013 there was a clinical significance that the silver dressing strongly reduced the postoperative pain for the following 8 days.[39]

Shirani and associates Compared to the standard of care at the time (fine mesh gauze), silver-nylon treated donor sites healed faster (9.3 vs. 12.4 days, $p < 0.05$). Silver-nylon sites were ‘pain-free’ while fine mesh gauze sites were ‘painful until completely healed .[39]

Omnia Hassan (2011) showed that reduced postoperative pain when gelatamp inserted in the alveolar socket after teeth extraction,and this is may be due to the antibacterial effects of colloidal silver within the gelatamp that reduces bacterial by products which can activate synthesis of biochemical mediators such as prostaglandins which involved in activation of pain and inflammatory processes.[7]

Faez Saleh Al-Hamed et al (2016) PRF patients significantly recorded less pain for the fifth, sixth and seventh postoperative days (P =0.041, 0.032 and 0.005 respectively), whereas no differences were observed for the second, third, and fourth postoperative days (P= 0.152, 0.078 and 0.057 respectively).[54]

In our comparative study the mean VAS score for 1st day was 5.2±0.44 in PRF group and 2.4±0.54 in GELATAMP group (p=0.000***). The mean VAS score for 3rd day was 2.8±0.83 in PRF group and 1.0±0.008 in GELATAMP group (p=0.001**). The mean VAS score for 7th day was 1.2±0.44 in PRF group and 0.0±0.00 in GELATAMP group(P=0.000***). The 'p' value was highly significant for the pain in VAS score (p=0.000). So , From our study, we can strongly recommend GELATAMP in surgical implant therapy for reduction of post operative complication especially pain.

In our present study the swelling assessment was done by the extent of facial swelling which was determined by a modification of tape measuring method described by Gabaka and Matsumara. Three measurements were made between 5 reference points: tragus, soft tissue pogonion, lateral corner of the eye, angle of mandible, and outer corner of the mouth, preoperatively, and on second and seventh postoperative day. The difference between baseline and each postoperative day indicate the level of facial swelling for that day. This swelling assessment was done

Ozkan ozgul et al were observed in first and third days horizontal measurements between PRF and control side ($p < 0.05$). And more swelling was seen at the control side.[9]

The results of this present study show that there is no statistical difference in the level of swelling between these two groups. To our knowledge there is no literature on swelling assessment in comparison between PRF and GELATAMP group. Even though there is no statistical significance, the 1st and 3rd postoperative day assessment value clearly shows there is more swelling in the PRF group from their baseline value when compared to the GELATAMP group. The p value for S1 baseline, S1 1st , S1 3rd ,and S1 7th postoperative day was 0.883, 0.625,0.649 and 0.852 respectively. The p value for S2 baseline , S2 1st , S2 3rd ,and S2 7th postoperative day was 0.789, 0.286, 0.176 and 0.475 respectively . The p value for S3 baseline , S3 1st , S3 3rd ,and S3 7th postoperative day was 0.944, 0.363, 0.428 and 0.554 respectively.

There is a learning curve associated with every surgical procedure, after which it becomes routine. Appropriate case selection, meticulous planning, systematic surgical protocols, and operator experience are required for success in dental implant surgical techniques. Our aim is to reduce the postoperative complications in implant placement procedure. For this purpose we augmented PRF and GELATAMP in implant site. In conclusion, this study has shown that GELATAMP augmented implant site showed significantly better soft tissue healing and also gives better pain control compare with the PRF site for implant placement when case selection is done carefully.

The limitation of this study is the small sample size. Randomized controlled trials with larger sample sizes, long time follow up, histological evaluation of the soft tissue over implant site , amount of keratinizaion, and radiological evaluation of marginal bone loss are required to confirm the findings of this study. Also, Within the limitations of this study, it can be concluded that GELATAMP site showed better soft tissue healing and better patient comfort when compared with PRF site provided proper patient selection is essential

SUMMARY AND CONCLUSION

SUMMARY AND CONCLUSION

Gelatamp containing colloidal silver has better results in reducing postoperative infection and consequently pain following surgical conventional dental implant placement.

There was a statistical significance between two groups (p=0.04), (p=0.01), (p=0.01) suggesting that there was better soft tissue healing in GELATAMP site compared to PRF site.

Pain assessment by Visual analog scale is also statistically significant and p=0.000, p=0.001, p=0.000 in 1st, 3rd, and 7th postoperative day respectively. There was less pain in GELATAMP side compare to PRF side.

Within the limitations of this study, it can be concluded that GELATAMP augmented dental implant site results in better soft tissue healing and also results in better patient comfort when compared with PRF augmented dental implant site.

While contemplating the use of GELATAMP in dental implant site based on this study gelatamp is recommended to be used in conventional implant placement therapy, as it has a good role for better soft tissue healing, reducing postoperative infection and pain.

BIBLIOGRAPHY

BIBLIOGRAPHY

1) Rajan Rajput, Zakariya Chouhan, Monica Sindhu, Sowmya Sundararajan, Ravi Raj Singh Chouhan , A Brief Chronological Review of Dental Implant History , International Dental Journal of Students Research 2016;4(3):105-107.
2) Jonathan M. Tagliareni , Earl Clarkson, Basic Concepts and Techniques of Dental Implants, Dent Clin N Am 2015; 59: 255–264.
3) Guillaume ,Dental Implants : A Review, Morphologie 2016;10:1-10.
4) Geetha Priya S., Auxilia Hemamalini Tilak , Incidence of Microbes on Dental Implants Journal of Pharmaceutical Research & Clinical Practice 2014; 4(1):67-78.
5) Miguel A. Vargas-Reus, Kaveh Memarzadeh, Jie Huang, Guogang G. Ren, Robert P. Allaker Antimicrobial activity of nanoparticulate metal oxides against peri-implantitis Pathogens, International Journal of Antimicrobial Agents 2012;40: 135– 139.
6) Ourania-Menti Goudouri, Eleana Kontonasaki, Ulrich Lohbauer, Aldo R. Boccaccini, Antibacterial properties of metal and metalloid ions in chronic periodontitis and peri-implantitis therapy, Acta Biomaterialia 2014
7) Omnia hassan, ebrahim abd allah, and atef fouda , evaluation of the role of gelatamp in comparison with gelatine sponge on postoperative complications following odontoctomy of impacted mandibular third molar, Egyptian Dental Journal 2011 ; vol. 57: 3653:3659,
8) Yuliang Dong, Weiqing Liu, Yiling Lei, Tingxi Wu, Shiwen Zhang, Yuchen Guo, Yuan Liu, Demeng Chen, Quan Yuan, YongyueWang , Effect of gelatin sponge with colloid silver on bone healing in infected cranial defects , Materials Science & Engineering 2016
9) Ozkan Ozgul, Fatma Senses, Nilay Er, Umut Tekin, Hakan Hıfzı Tuz, Alper Alkan, Ismail Doruk Kocyigit and Fethi Atil : Efficacy of platelet rich fibrin in the reduction of

the pain and swelling after impacted third molar surgery: Randomized multicenter split-mouth clinical trial , Head & Face Medicine 2015: 11:37

10) James R Hupp, Myron R Tucker ,Contemporary oral and maxillofacial surgery , 6th edition
11) Carl E.Mish ,Contemporary implant dentistry , 3rd edition
12) Newman , Caranza , clinical periodontology,
13) Ivan Sondi, Branka Salopek-Sondi , Silver nanoparticles as antimicrobial agent: a case study on E. coli as a model for Gram-negative bacteria , Journal of Colloid and Interface Science 2004 ;275: 177–182
14) Simon Young , Mark Wong , Yasuhiko Tabata , Antonios G. Mikos, Gelatin as a delivery vehicle for the controlled release of bioactive molecules, Journal of Controlled Release 2005; 109: 256– 274
15) Heidi L. Myshin, ,Jonathan P. Wiens, Factors affecting soft tissue around dental implants: A review of the literature, J Prosthet Dent 2005 ; 94 :440-4.
16) Pekka LAINE, Antero SALO, Risto KONTIO, Seija YLIJOKI, Christian LINDQVIST, Riitta SUURONEN, Failed dental implants – clinical, radiological and bacteriological findings in 17 patients, Journal of Cranio-Maxillofacial Surgery, 2005; 33:212–21
17) Michael S. Block, Walter C. Jackson, Techniques for Grafting the Extraction Site in Preparation for Dental Implant Placement, Atlas Oral Maxillofacial Surg Clin N Am , 2006; 14: 1–25
18) David M. Dohan, Joseph Choukroun, Antoine Diss, Steve L. Dohan, Anthony J. J. Dohan, Jaafar Mouhyi, and Bruno Gogly, Platelet-rich fibrin (PRF): A second-generation platelet concentrate. Part I: Technological concepts and evolution, Oral Surg Oral Med Oral Pathol Oral Radiol Endod , 2006 ;101:E37-44

19) David M. Dohan, Joseph Choukroun, Antoine Diss, Steve L. Dohan,d Anthony J. J. Dohan, Jaafar Mouhyi, and Bruno Gogly, Platelet-rich fibrin (PRF): A second-generation platelet concentrate. Part II Platelet-related biologic features ,Oral Surg Oral Med Oral Pathol Oral Radiol Endod, 2006; 101:E45-50

20) David M. Dohan, Joseph Choukroun, Antoine Diss, Steve L. Dohan, Anthony J. J. Dohan, Jaafar Mouhyi, and Bruno Gogly, Platelet-rich fibrin (PRF): A second-generation platelet concentrate. Part III: Leucocyte activation: A new feature for platelet concentrates, Oral Surg Oral Med Oral Pathol Oral Radiol Endod, 2006 ;101:E51-55

21) Eduardo Anitua, Mikel Sanchez, Alan T. Nurden, Paquita Nurden, Gorka Orive and Isabel Andia, New insights into and novel applications for platelet-rich fibrin therapies, Trends in Biotechnology, 2006; Vol.24 :No.5

22) Jun Tian , Kenneth K.Y. Wong, Topical delivery of silver Nanoparticles promote wound healing, chemMedChem, 2007;2:129-136

23) Cai YH , Lu CS, A Clinical study of gelatamp colloidal silver gelatine sponge on preventing the complication of teeth extraction, Hua Xi Kou Qiang, Yi Xue Za Zhi 2008;26(5):519 -21

24) Balaram Naik, P Karunakar, M Jayadev, V Rahul Marshal : Role of Platelet rich fibrin in wound healing: A critical review, Journal of Conservative Dentistry, 2013;16 : 4

25) X. Chen, H.J. Schluesener, Nanosilver: A nanoproduct in medical application, Toxicology Letters, 2008; 176 : 1–12

26) A.D. Pye , Lockhart , M.P. Dawson , C.A. Murray , A.J. Smith, A review of dental implants and infection, Journal of Hospital Infection, 2009; 72: 104e110

27) Mahendra Rai , Alka Yadav, Aniket Gade, Silver nanoparticles as a new generation of antimicrobial, Biotechnology Advances , 2009; 29 :76–83

28) Virender K. Sharma , Ria A. Yngard, Yekaterina Lin , Silver nanoparticles: Green synthesis and their antimicrobial activities, Advances in Colloid and Interface Science, 2009; 145: 83–96

29) Nicolaas C. Geurs, Philip J. Vassilopoulos, Michael S. Reddy, Soft Tissue Considerations in Implant Site Development, Oral Maxillofacial Surg Clin N Am, 2010; 22: 387–405

30) Victoria Kostenko et al , Application Of Silver Dressing Via Antibiotic Therapy 2010

31) Karla Chaloupka, Yogeshkumar Malam and Alexander M. Seifalian, Nanosilver as a new generation of nanoproduct in biomedical applications, Trends in Biotechnology, November 2010; Vol. 28: No. 1

32) Jiing-Huei Zhao , Chung-Hung Tsai , Yu-Chao Chang , Clinical and histologic evaluations of healing in an extraction socket filled with platelet-rich fibrin, Journal of Dental Sciences, 2011; 6, 116e122

33) Zaid H. Baqain , Wael Yousef Moqbel, Faleh ., Sawair, Early dental implant failure: risk factors, British Journal of Oral and Maxillofacial Surgery , 2012; 50: 239–243

34) Bharalia, Saikiab, S. Paulc, Konward, Colloidal silver nanoparticles/rhamnolipid (SNPRL) composite as novel chemotactic antibacterial agent, International Journal of Biological Macromolecules, 2013;61: 238– 242

35) Simonetta D'Ercole , Adriano Piattelli , Giuseppe Marzo , Antonio Scarano , Domenico Tripodi, Influence of bacterial colonization of the healing screws on peri-implant tissue, Journal of Dental Sciences, 2013; 8: 109e114

36) David J. Barillo , David E. Marx, Silver in medicine: A brief history BC 335 to present burns, 2 0 1 4 ; 40S: s3 – s8

37) Neethu Ninana,b, Muthunarayanan Muthiahc, Nur Aliza Bt.Yahayad, In-Kyu Parkc,Anne Elaina, Tin Wui Wongd, Sabu Thomasb, Yves Grohensa, Antibacterial and

wound healing analysis of gelatin/zeolite scaffolds , Colloids and Surfaces B: Biointerfaces , 2014;115: 244–252

38) Sujata Mohanty , Himani Pathak , Jitender Dabas, Platelet rich fibrin: A new covering material for oral mucosal defects, journal of oral biology and cranio facial research

39) Elia Charbel Abboud , Timothy B. Legare , Judson C. Settle , Amir M. Boubekri , David J. Barillo , Jorge E. Marcet , Jaime E. Sanchez : Do silver-based wound dressings reduce pain? A prospective study and review of the literature ,2014; burns40 : 40–s47

40) Elia Charbel Abboud , Judson C. Settle , Timothy B. Legare , Jorge Marcet , Dave J. Barillo , Silver-based dressings for the reduction of surgical site infection: Review of current experience and recommendation for future studies, 2014; Burns 40s : s30–s39.

41) Anirban Chatterjee, Prerna Agarwal , Shobha Krishna Subbaiah, Platelet rich fibrin: an autologous bioactive membrane, apollo medicine, 2014; 11: 24e26

42) Suttapreyasri Srisurang, Buasod Kantheera, Leepong Narit, Pripatnanont Prisana, Socket preservation using platelet-rich fibrin in conjunction with epithelialized palatal free graft in minipigs, Journal of Oral and Maxillofacial Surgery, Medicine, and Pathology, 2014; 108–117

43) David E. Marx, David J. Barillo, Silver in medicine: The basic science,2014; burns40s: s9 – s18

44) V. Moraschini, E. S. P. Barboza, Effect of autologous platelet concentrates for alveolar socket preservation: a systematic review, Int. J. Oral Maxillofac. Surg. 2015

45) Gee woo nam , sabarinathan rangasamy, baskaran purushothaman, the application of bactericidal silver nanoparticles in wound treatment, Nanomaterial and nanotechnology :2015 :5:23

46) W.K. Hafez , S.A. Seif , H. Shawky , M.M. Hakam, Platelet rich fibrin as a membrane for coverage of immediate implants, Case-series study on eight patients, Tanta Dental Journal 2015; 1-8

47) Yuvika Raj Kumara, Sujata Mohantya, Mahesh Vermab, Raunaq Reet Kaurb,1,Priyanka Bhatiac, Varun Raj Kumarc, Zainab Chaudharyaa, Platelet-rich fibrin: the benefits , British Journal of Oral and Maxillofacial Surgery 2015

48) Nelson Durán, Marcela Durán , Marcelo Bispo De Jesus, Amedea B. Seabra, Wagner J. Fávaro And Gerson Nakazato : Silver Nanoparticles: A New View On Mechanistic Aspects On Antimicrobial Activity : Nanomedicine: Nanotechnology, Biology, And Medicine 2015,

49) Rui Figueiredo, Octavi Camps-Font, EduardValmaseda-Castell_on, andCosmeGay-Escoda, Risk Factors for Postoperative Infections After Dental Implant Placement: A Case-Control Study, J Oral Maxillofac Surg, 2015; 1-7:

50) Orrett E. Ogle, Implant Surface Material, Design, and Osseointegration, Dent Clin N Am - 2015

51) Jonathan M. Tagliareni , Earl Clarkson, Basic Concepts and Techniques of Dental Implants, Dent Clin N Am, 2015; 59: 255–264

52) Ikiru Atsuta , Yasunori Ayukawa , Ryosuke Kondo , Wakana Oshiro , Yuri Matsuura , Akihiro Furuhashi , Yoshihiro Tsukiyama , Kiyoshi Koyano, Soft tissue sealing around dental implants based on histological interpretation, journal of prosthodontic research 2015

53) Aifang Han , JamesK.H.Tsoi , FláviaPiresRodrigues , JulianG.Leprince , William M.Palin, Bacterial adhesion mechanisms on dental implant surfaces and their influencing factors, International Journal of Adhesion & Adhesives :2016

54) Faez Saleh Al-Hamed , Mohamed Abdel-Monem Tawfik, Ehab Abdelfadil, Clinical effects of platelet-rich fibrin (PRF) following surgical extraction of lower third molar : The Saudi Journal for Dental Research, 2016: 1-8

55) Andreas Anwandter Stephanie Bohmann Mauricio Nally Ana B. Castro Marc Quirynen , Dimensional changes of the post extraction alveolar ridge, preserved with Leukocyte- and Platelet Rich Fibrin, A Clinical Pilot Study: Journal of Dentistry 2016;1-6

56) Yuliang Dong, Weiqing Liu, Yiling Lei, Tingxi Wu, Shiwen Zhang, Yuchen Guo, Yuan Liu, Demeng Chen, Quan Yuan, YongyueWang : Effect of gelatin sponge with colloid silver on bone healing in infected cranial defects : Materials Science & Engineering 2016; 1-9

57) Pallavi S Badade, Swapna A Mahale, Alisha A Panjwani, Prutha D Vaidya, Ayushya D Warang, Antimicrobial effect of platelet‐rich plasma and platelet‐rich fibrin, Indian J Dent Res 2016;27:300-4.

58) Anilkumar K,Geetha A, Umasudhakar, Ramakrishnan T, Vijayalakshmi R5, Pameela E , Platelet-rich-fi brin: A novel root coverage approach Journal of Indian Society of Periodontology , 2009 ; Vol 13, Issue 1,

59) Hemalatha. R, Gemimaa Hemagaran, Effectiveness of Honey and Aloe Vera on Post Extraction Healing, IOSR Journal of Dental and Medical Sciences , 2015; Volume 14: Issue 5 Ver. IV : PP 123-128

60) Gillian A. Hawker, Samra Mian, Tetyana Kendzerska, And Melissa French, Measures Of Adult Pain, Arthritis Care & Research, 2011; Vol. 63: No. S11, , Pp S240–S252

61) Gillian Z. Heller, Maurizio Manuguerra, Roberta Chow, How to analyze the Visual Analogue Scale: Myths, truths and clinical relevance , Scandinavian Journal of Pain, 2016 ; 13 : 67–75

62) Martin McCarthy , Chih-Hung Chang, A Simon Pickard, Anita Giobbie-Hurder, Visual Analog Scales for Assessing Surgical Pain, J Am Coll Surg, 2005 ; 201:245–252

63) Yakup U Stu N, Zgu R Erdog An, Emin Esen, And Ebru Deniz Karsli, Comparison Of The Effects Of 2 Doses Of Methylprednisolone On Pain, Swelling, And Trismus After Third Molar Surgery, Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2003;96:535

64) Hadi SA, Ashfaq, Bey , Khan, Biological factors responsible for failure of osseointegration in oral implants, Biology and Medicine, 2011 ;3 (2) Special Issue: 164-170, 2011

65) Esposito M, Hirsch J-M, Lekholm U, Thomsen P: Biological factors contributing to failures of osseointegrated oral implants. (I) Success criteria and epidemiology. Eur J Oral Sci 1998; 106: 527–551.

66) Mohanad Al-Sabbagh, Ishita Bhavsar : Key Local and Surgical Factors Related to Implant Failure , Dent Clin N Am - 2014

67) Dolphus R. Dawson, Samuel Jasper, Key Systemic and Environmental Risk Factors for Implant Failure , Dent Clin N Am 2014

68) C. do Nascimento, Barbosa, Issa, E. Watanabe, Albuquerque Junior: Bacterial leakage along the implant–abutment interface of pre machined or cast components, Int. J. Oral Maxillofac. Surg. 2008; 37: 177–180.

69) Cássio do Nascimento, Murillo Sucena Pita, Microbiome of titanium and zirconia dental implants abutments, dental materials,2015;

70) Benjamin Le Ouay, Francesco Stellacci, Antibacterial activity of silvernanoparticles: A surface science insight, Nano Today ,2015;

71) Maribel Guzman, Jean Dille, Stéphane Godet, Synthesis and antibacterial activity of silver nanoparticles against gram-positive and gram-negative bacteria, Nanomedicine: Nanotechnology, Biology, and Medicine , 2012; 12: 37–45

72) Guang Yang , Jianjian Xie, Feng Hong, Zhangjun Cao, Xuexia , Antimicrobial activity of silver nanoparticle impregnated bacterial cellulose membrane: Effect of fermentation carbon sources of bacterial cellulose, Carbohydrate Polymers ,2012; 87: 839– 845

73) Thawatchai Maneerung, Seiichi Tokura, Ratana Rujiravanit, Impregnation of silver nanoparticles into bacterial cellulose for antimicrobial wound dressing, Carbohydrate Polymers, 2008; 72: 43–51

74) Jun Beom Park , Ridge Preservation Following Tooth Extraction Using An Absorbable Gelatine Sponge, 2015; OHDM –Volume 14-No.5:

75) Wang YZ ,Guan QL, Li YX, Guo JL , Jiang L,Use of "gelatamp" colloidal silver gelatin sponge to prevent dry socket after extracting mandibular impacted teeth, Shanghai KOU Qiang Yi Xue, 2013 feb:22(1):108-10

76) Johan Hartshore , Howard Gluckman , International Dentistry – African Edition Vol 6 No 5(14-24)

ANNEXURE

BEST DENTAL SCIENCE COLLEGE
ULTRA TRUST
69/1A, Ultra Nagar, Madurai - Chennai Highway,
Madurai - 625 104. Ph : 0452 2423290 / 91

Trust Regd.office : 4/235, College Road, Thasildhar Nagar, Madurai - 625020. Ph : 2534593, 2534701 Fax : 91-452-2539828

ANNEXURE-I

Ref:UT:BDSC:IRB-EC/2014 Date:18.11.2014

From

Institutional Review Board-Ethical committee,
Best dental science college,
Madurai.

To

The Controller of Examinations,
The Tamil Nadu DR.MGR Medical University,
No. 69, Anna salai,
Guindy,
Chennai-600 032

Sir/Madam

The Dissertation topic titled "COMPARATIVE EVALUATION OF SOFT TISSUE HEALING IN DENTAL IMPLANT SITE AUGMENTED WITH PRF AND GELATAMP" submitted by DR.L.BALAMURUGAN postgraduate student has been approved by Institutional Review Board of Best Dental Science College on 18.11.2014.

DR.K.S PREM KUMAR.M.D.S.,
VICE PRINCIPAL
MEMBER SECRETARY
INSTITUITONAL REVIEW BOARD-ETHICAL COMMITTEE
BEST DENTAL SCIENCE COLLEGE
MADURAI

DR.PURUSHOTHAM MANVI.,M.D.S.,
PRINCIPAL
BEST DENTAL SCIENCE COLLEGE
MADURAI

Patient Information and Consent for Surgical Placement of Dental Implants and augmentation of implant site with PRF and GELATAMP:

An explanation of your need for dental implant(s), their purpose and benefits, the surgeries related to their placement and exposure, and the possible complications, as well as alternatives to their use, were discussed with you in consultation. We obtained your verbal consent to undergo the implant surgical treatment and augmentation of implant site with PRF and GELATAMP planned for you. Please read this document, which restates issues, we discussed and provide the appropriate signatures on the last page. Please ask for clarification of anything you do not understand.

Name of Patient: OP NUMBER:

Diagnosis:

After careful oral examination, a review of radiographs, and study of my dental condition, Dr._____has advised me that my missing tooth or teeth might be replaced with artificial teeth supported by an implant or implants.

Recommended Treatment: In order to treat my condition, my dentist has recommended the use of root form implants. I understand that the procedure for root form implants involves placing implant fixtures into the jawbone along with placement of PRF and GELATAMP in implant site. This procedure has two phases, surgical phase (placing the implants and augmentation of implant site with PRF and GELATAMP & later exposing them), followed by a prosthetic restorative phase (getting the replacement teeth attached to the implant). The Implant Clinic in department of oral surgery, Ultra's Best Dental Science college does only the surgical phase. My prosthetic phase would have been done by department of prosthodontics.

Overview of Surgical Procedures:

Most patients need two surgical procedures to place the implant(s). The first surgical procedure consists of placing a titanium implant fixture into the jaw bone and augmenting PRF and GELATAMP over implant site. The second surgical procedure usually occurs three to six months after the initial surgery and involves uncovering the implant fixture and placement of the healing abutment on the fixtures.

Surgical Placement Phase of Procedure:

I understand that a local anesthetic will be administered to me as part of the treatment. My gum tissue will be opened to expose the bone. Implants will be placed by tapping or threading the fixture into small holes that have been drilled into my jawbone. The implants will have to be snugly fitted and held tightly in place and the implant site will be augmented with PRF and/ or GELATAMP.

The gum and soft tissue will be stitched closed over or around the implants. A periodontal bandage or dressing may be placed. Healing will be allowed to proceed for a period of three to six months. I understand that during this healing phase I will be without teeth.

I further understand that if clinical conditions turn out to be unfavorable for the use of this implant system, or prevent the placement of implants at all, my surgeon will make a professional judgment on the management of the situation. The procedures also may involve a supplemental bone graft or other types of graft materials to build up the ridge of my jaw and thereby help in the placement, closure, security, and ultimate success of my implants. This may require additional fees to those already quoted for the surgical placement .

Second Surgical Procedure:

For implants requiring a second surgical procedure, the overlying tissues will be opened at the appropriate time and the stability of the implant will be verified. If the implant appears stable, an attachment will be connected to the implant(s). Plans and procedures to create an implant crown (by department of prosthodontics) can begin after your gum tissue has healed.

Post-Operative Complications:

Some problems that may occur: pain around the abutment fixture, infection, phobia or change of mind by the patient. In addition, some tingling and loss of sensation in the area may occur when the implants are placed in the back of the lower jaw. In rare situations, this altered or loss of sensation may be permanent.

Prognosis

While prognosis is favorable at this time, the results cannot be guaranteed since unforeseen changes in the bone and soft tissue may occur which may require removal of the implant fixture. If an implant fixture does not join properly with the bone, it will be necessary to remove the implant in question. No problems are usually foreseen as a result of this removal. If on the remote possibility, the entire group of implant fixtures should fail to integrate into the bone, a new attempt can be made at a later date.

Prosthetic Restorative Phase of Procedure:

I understand that at this point, I will be referred to department of prosthodontics for completion of this aspect of my care. I further understand that additional fees will be charged by the concerned department for completion of this restorative phase of my care. During this phase, an implant prosthetic device or crown will be attached to the implant. This phase is just as important as the surgical placement phase for the long-term success of my oral health.

Expected Benefits:

The purpose of the dental implants is to allow me to have more functional artificial teeth. The implants provide support, anchorage, and retention for these teeth.

Principal Risks and Complications:

I understand that some patients do not respond successfully to dental implants, and, in such cases, the implant may be lost. Implant surgery may not be successful in providing artificial teeth. Because each patient's condition is unique, long-term success cannot not be predicted.

These complications include, but are not limited to (1) Implant loss (2) post-surgical infection, (3) bleeding, swelling and pain, (4) facial discoloration, (5) transient but on occasion permanent numbness of the lip, tongue, teeth, chin or gum, (6) jaw joint injury or associated muscle spasm, (7) transient but on occasion permanent increased tooth looseness, (8) tooth sensitivity to hot, cold, sweet or acidic foods, (9) shrinkage of the gum tissue upon healing resulting in elongation of some teeth and greater spaces between some teeth, (10) cracking or bruising of the corners of the mouth, (11) restricted ability to open the mouth for several days or weeks, (12) impact on speech, (13) allergic reactions, (14) injury to teeth, (15) bone fractures, (16) nasal sinus penetrations, (17) delayed healing and (18) accidental

swallowing of foreign matter. The exact duration of any complications cannot be determined and they may be irreversible.

I understand that the design and structure of the prosthetic appliance can be a substantial factor in the success of failure of an implant. I further understand that alterations made on the artificial appliance or the implant can lead to loss of the appliance or implant. I understand and I am advised that the connection between the implant and the tissue may fail and that it may become necessary to remove the implant. This most often occurs in the preliminary phase, during the initial integration of the implant to the bone or at any time thereafter.

Alternative to Suggested Treatment:

I understand that alternative treatments for missing teeth include no treatment, new removable prosthesis, fixed prosthesis and other procedures, can be provided depending on the circumstances.

Necessary Follow-Up Care and Self-Care:

I understand that it is important for me to continue treatment with my dentist. Implants, natural teeth and artificial teeth must be maintained daily in a clean, hygienic manner. Implants and appliances must also be examined periodically and may need to be adjusted. I will need to come for appointments following the procedure so that my healing may be monitored and so that my doctor can evaluate and report on the outcome of the surgery upon completion of healing. I understand that it is important to follow the specific prescriptions and instructions given by my dentist.

No Warranty or Guarantee:

Even though dental implants have a high rate of success, I hereby acknowledge that no guarantee, warranty or assurance has been given to me that the proposed treatment will be successful. Due to individual patient differences certainty of success cannot be predicted. There exists the risk of failure, relapse, additional treatment, or worsening of my present condition, including the possible loss or devitalization of certain teeth, despite the best care

Publications of Records:

I authorize photos, slides, x-rays or any other viewing of my care and treatment during or after its completion to be used for the education and research in dentistry and for reimbursement purposes. My identity will not be revealed to the general public without my permission.

PATIENT CONSENT

I have been fully informed of the nature of dental implant surgery, the procedure to be utilized, the risks and benefits of the surgery, the alternative treatments available and the necessity for follow-up care and self-care. I have had an opportunity to ask any questions I may have in connection with the treatment and to discuss my concerns with my dentist. After thorough deliberation, I hereby consent to the performance of dental implant surgery as presented to me during consultation and in the treatment plan presentation as described in this document along with the associated fees.

I also consent to the use of an alternative implant system or method if clinical conditions are found to be unfavorable for the use of the implant system that has been described to me. If clinical conditions prevent the placement of implants, I defer to Dr's._____ judgment on the surgical management of that situation. I also give my permission to receive supplemental bone grafts or to other types of grafts to build up the ridge of my jaw and thereby to assist in the placement, closure and security of my implants.

I understand that the fee(s) for my dental implant(s) and surgery does not include the fee for the restorative work (crowns or dentures).

I understand that estimated fee(s) relates only to procedures for dental implant(s) and surgeries. If I need additional treatment, (such as Endodontics, Periodontics, Prosthodontics, etc), the fees related to treatments in other departments are not included in the fee estimated in the treatment plan proposed at this time.

I certify that I have read and fully understand this document.

I hereby give the consent to perform the necessary treatment.

Patient Signature_____

Date_____

Patient Printed Name:_____

I have discussed the nature and purpose of the above therapeutic/diagnosis procedure, and the associated risks, consequences and available alternatives, with the person signing above, and I am satisfied that he/she understands them.

Treating Dentist Signature_____

Date_____

Patient Signature K Pandi

Date 04/05/2016

Patient Printed Name: K. Pandiammal.

I have discussed the nature and purpose of the above therapeutic/diagnosis procedure, and the associated risks, consequences and available alternatives, with the person signing above, and I am satisfied that he/she understands them.

Treating Dentist Signature L Parthasarathy

Date 04/05/2016

<u>ஆராய்ச்சி ஒப்புதல் படிவம்</u>

செயற்கை வேர் (இம்ப்ளாண்ட்) பதியம் செய்து அதனுடன் பிளேட்லெட் ரிச் ஃபைரின் மற்றும் ஜெலடெம்ப் வைத்து நிரந்தர செயற்கை பல் பொருத்தும் முறைகள் குறித்த ஒப்பீட்டு ஆய்வு.

நோயாளியின் பெயர் : தேதி :

வயது / பாலினம் : உள், புற நோயாளி எண் :
ஆராய்ச்சி சேர்க்கை எண் :

என்னுடைய சுய நினைவுடனும் மற்றும் முழுசுதந்திரத்துடனும் இந்த மருத்துவ ஆராய்ச்சியில் சேர்ந்துகொள்ள ஒப்புதல் அளிக்கிறேன். கீழ்க்கானும் நிபந்தனைகளுக்கு நான் ஒப்புக் கொள்கிறேன்.

இந்த சிகிச்சையின் போது என் கீழ்தாடையில் செயற்கை வேர் (இம்ப்ளாண்ட்) பொருத்தப்பட்டு அதனுடன் பிளேட்லெட் ரிச் ஃபைரின் மற்றும் ஜெலடெம்ப் வைத்து செயற்கை நிரந்தர பல் பொருத்தப்படுகிறது என்பதை நான் நன்றாக அறிவேன்.

புறநோயாளிப் பிரவின் செய்யப்படும் இந்த சிகிச்சையின் போது என் தாடை, உதடு, கண்ணம் ஆகியவை தற்காலிகமாக மறத்து போவதற்காக ஊசி மருந்துகள் அளிக்கப்படும். (LOCAL ANESTHESIA) என்பதையும், தாடை எலும்பில் சிறிய துளைகள் இடப்பட்டு அவற்றில் டைடானியம் (Titanium) உலோகத்தினால் செய்யப்பட்ட செயற்கை வேர்கள் பொருத்தப்பட்டு, அதன்பின் அந்த இடத்தில் பிளேட்லெட் ரிச் ஃபைரின் மற்றும் ஜெலடெம்ப் வைத்து பின்பு தையல் போடப்படும் என்பதையும் அறிவேன். இந்த சிகிச்சையின் போது நீண்ட நாட்கள் உதடுகள் மறத்துப் போகவும் (Paraesthesia), தாடை எலும்பு முறிவு (Fracture of Jaw bone) ஒவ்வாமை (Allergy) , குறுகிய கால இரத்த போக்கு போன்றவை ஏற்பட வாய்ப்பு உண்டு என்பதையும் நன்கு அறிவேன். சில சமயங்களில் பொருத்தப்பட்ட இம்ப்ளாண்ட் எலும்புடன் இணையாமல் கழன்றும் வரலம் என்பதையும் அறிவேன்.

எனது உடல்நிலை பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறான நோய்க்குறிகள் தென் பட்டாலோ அதனை உடனடியாக பல் மருத்துவரிடம் தெரிவிக்க சம்மதிக்கிறேன்.

எனது மருத்துவ குறிப்பேடுகளை இந்த ஆராய்ச்சியில் பயன்படுத்திக் கொள்ள சம்மதிக்கிறேன். இந்த ஆராய்ச்சி மையமும், மருத்துவமனையும், பல் மருத்துவகல்லூரியும், ஆராய்ச்சியாளரும் என்னுடைய விவரங்கள் அனைத்தும்

இரகசியமாக வைப்பதாக அறிகிறேன். மேலும் இந்த ஆராய்ச்சிகளுக்காக தேவைப்படும் இரத்த பரிசோதனை, எக்ஸ்ரே, மற்றும் புகைப்படங்கள் எடுக்க ஆராய்ச்சியாளருக்கு முழு அனுமதி அளிக்கிறேன்.

இம்ப்ளாண்ட் பொருத்தப்பட்டு பின்பு புகை பிடித்தாலோ, வாய், ஈறு மற்றும் பல் சுத்தமாக பராமரிக்காமல் இருந்தாலோ சிகிச்சையின் முடிவுகள் பாதிக்கப்படலாம் என்பதையும் நன்கு அறிவேன்.

நோயாளியின் பெயர் கையொப்பம் தேதி

ஆராய்ச்சியாளர் பெயர் கையொப்பம் தேதி

ULTRA'S BEST DENTAL SCIENCE COLLEGE, MADURAI

DEPARTMENT OF ORAL & MAXILLOFACIAL SURGERY

THESIS (IMPLANT) CASE SHEET PROFORMA

Patient's Name :

O.P No :

Age / Gender :

Address/Phone NO :

Habits :

Date of Operation :

Chief Complaint :

H/O Present illness :

Medical History :

Dental History :

CLINICAL EXAMINATION

Oral Hygiene :

Periodontal Condition :

State of Occlusion :

Missing Teeth :

Site of Implant :

Number of Missing Teeth

8 7 6 5 4 3 2 1	**1 2 3 4 5 6 7 8**
8 7 6 5 4 3 2 1	**1 2 3 4 5 6 7 8**

Width of Ridge :

Inter–maxillary Space :

Artificial appliances :

Investigation :

Radiological Investigation :

O.P.G ……...:

Periapical……..….:

a. Distance from the crest of the ridge to Inferior Alveolar Canal :

b. Width of the ridge :

c. Distance from the Adjacent Teeth :

d. Condition of Bone :

Blood Investigation:

a. Hb % :
b. TC, DC :
c. BT, CT :
d. Blood Group & Rh Typing :
e. Blood Sugar (R) :

Preoperative Assessment:

a. Type of Implant :
b. Site of Implant :
c. Number of Implant :
d. Length of Implant :
e. Width of Implant :

Type of Material augmented	**Quadrant / Side**	**Implant Site**
1. PRF	3rd Quadrant/ Left Side	
2. GELATAMP	4th Quadrant/ Right Side	

Operative Notes :

Follow up :

Gingival Former :

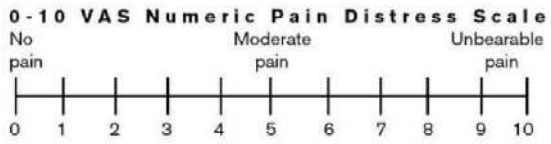
Prosthetic Work :

ASSESSMENT OF PARAMETERS

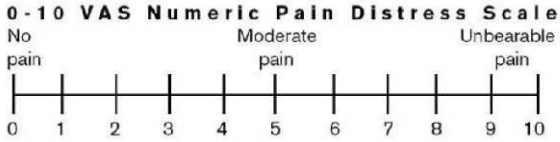
1. PAIN ASSESSMENT :

3rd QUADRANT

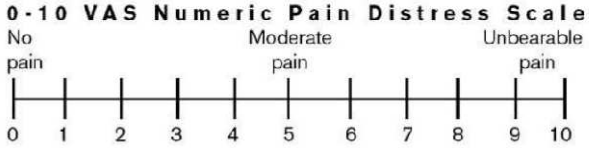
1st Post Operative Day



3rd Post Operative Day

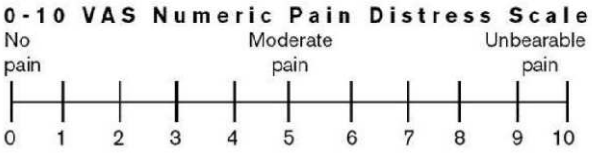


7th Post Operative Day

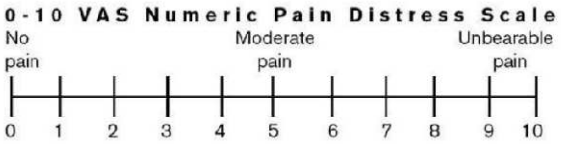


4th QUADRANT

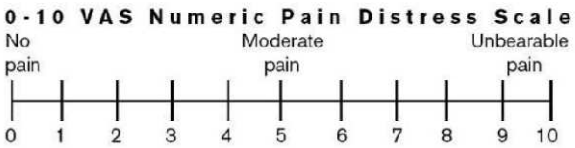
1st Post Operative Day



3rd Post Operative Day



7th Post Operative Day



2. SWELLING ASSESSMENT

Swelling assessment by modification of Tape measuring method by Gabka and Matsumara.

S1 – From Lateral canthus of the eye to angle of the mandible.

S2 - From Tragus to outer corner of the mouth

S3 – From Tragus to Pogonion.

3rd QUADRANT (PRF SIDE)

Measurement Points	Baseline Values	1st P.O Day	3rd P.O Day	7th P.O Day
S1				
S2				
S3				

4th QUADRANT (GELATAMP SIDE)

Measurement Points	Baseline Values	1st P.O Day	3rd P.O Day	7th P.O Day
S1				
S2				
S3				

3. POST OPERATIVE HEALING:

Healing potential was assessed by Healing Index of Landry, Turnball and Howley.

Healing Index 1: Very Poor

Has 2 or more of the following:

1. Tissue color: >= 50% of gingiva red
2. Response to palpation: bleeding
3. granulation tissue: present
4. incision margin: not epithelialized, with loss of epithelium beyond incision margin
5. suppuration present

Healing Index 2: Poor

1. tissue color: >= 50% of gingiva red
2. response to palpation: bleeding
3. granulation tissue: present
4. incision margin: not epithelialized, with connective tissue exposed

Healing Index 3: Good

1. tissue color: >= 25% and < 50% of gingiva red

2. response to palpation: no bleeding

Healing Index 4: Very Good

1. tissue color: < 25% of gingiva red
2. response to palpation: no bleeding
3. granulation tissue: none
4. incision margin: no connective tissue exposed

Healing Index 5: Excellent

1. tissue color: all tissues pink
2. response to palpation: no bleeding
3. granulation tissue: none
4. incision margin: no connective tissue exposed7

Healing Index :

	1st P.O Day	**3rd P.O Day**	**7th P.O Day**
3rd QUADRANT (PRF)			
4th QUADRANT (GELATAMP)			

Name of the Operator

Dr.L.Balamurugan **Signature of the Guide**