COMPARATIVE EVALUATION OF SOFT AND HARD TISSUE CHANGES FOLLOWING ENDOSSEOUS IMPLANT PLACEMENT USING FLAP AND FLAPLESS TECHNIQUES IN THE POSTERIOR EDENTULOUS AREAS OF THE MANDIBLE

Dissertation submitted to

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

In partial fulfillment for the Degree of

MASTER OF DENTAL SURGERY

BRANCH II

PERIODONTOLOGY

APRIL 2016

THE TAMILNADU Dr.MGR MEDICAL UNIVERSITY CHENNAI

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation titled **"COMPARATIVE EVALUATION OF SOFT AND HARD TISSUE CHANGES FOLLOWING ENDOSSEOUS IMPLANT PLACEMENT USING FLAP AND FLAPLESS TECHNIQUES IN THE POSTERIOR EDENTULOUS AREAS OF THE MANDIBLE"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. B. SHIVAKUMAR, M.D.S.,** Professor, Department of Periodontology, Ragas Dental College and Hospital, Chennai.

K. Divya

Dr. DIVYA . K
Post Graduate Student
Department of Periodontology
Ragas Dental College and Hospital,
Chennai

Date: 7th Jan 2016
Place: Chennai

CERTIFICATE

This is to certify that this dissertation titled **"COMPARATIVE EVALUATION OF SOFT AND HARD TISSUE CHANGES FOLLOWING ENDOSSEOUS IMPLANT PLACEMENT USING FLAP AND FLAPLESS TECHNIQUES IN THE POSTERIOR EDENTULOUS AREAS OF THE MANDIBLE"** is a bonafide record of work done by **Dr. Divya . K** under my guidance during the study period of 2013-2016.

This dissertation is submitted to **THE TAMILNADU Dr. MGR MEDICAL UNIVERSITY** in partial fulfilment for the degree of **MASTER OF DENTAL SURGERY, BRANCH II- PERIODONTOLOGY.** It has not been submitted (partial or full) for the award of any other degree or diploma.

7.1.2016

RAGAS DENTAL COLLEGE Chennai

Dr. T.S.S Kumar, MDS.,
Professor and Head
Department of Periodontology
Ragas Dental College & Hospital
Chennai.

Dr. T.S.S. KUMAR. M.D.S.,
Professor and Head,
Department of Periodontics and Implant Dentistry
Ragas Dental College and Hospital
Chennai - 600 119.

Dr. B. Shivakumar, MDS.,
Professor and Guide
Department of Periodontology
Ragas Dental College & Hospital
Chennai.

Department of Periodontics,
Ragas Dental College & Hospital,
2/102, ECR, Chennai-119

Dr. S. Ramachandran, MDS.,
Principal
Ragas Dental College & Hospital, Chennai.

PRINCIPAL
RAGAS DENTAL COLLEGE AND HOSPITAL
UTHANDI, CHENNAI - 600 119.

Acknowledgment

ACKNOWLEDGEMENT

I would like to express my gratitude to all the people who were instrumental in the completion of this thesis.

I take this opportunity to sincerely thank ***Dr. S. Ramachandran, MDS, Principal,*** *Ragas Dental College and Hospital, for his support and guidance during my postgraduate course at Ragas Dental College, Chennai.*

I would like to express my sincere thanks to my respected and beloved professor, ***Dr. T.S.S. Kumar, MDS, Professor and Head,*** *Department of Periodontics, Ragas Dental College and Hospital, Chennai, for his valuable guidance, support and encouragement during my postgraduate course. I consider myself highly fortunate to have been under his guidance and to have imbibed values of humility, honesty and kindness that would hold me in good stead throughout my life.*

I would like to express my sincere thanks to my beloved professor and guide ***Dr. B. Shiva Kumar, MDS, Professor,*** *Department of Periodontics, Ragas Dental College and Hospital, Chennai, for his valuable advice, guidance and encouragement during my postgraduate course, and inspiring me to develop a passion for the subject. I am deeply grateful for his continuous support and valuable advice which has been a vital part of my postgraduate course and for my future career.*

My sincere gratitude goes to ***Dr. K.V. Arun****,* ***MDS, Professor,*** *Department of Periodontics, Ragas Dental College and Hospital, Chennai, a great teacher who has inspired many including me to develop a passion for the subject. I shall forever remain indebted to him for his over whelming help and valuable advice without which I would have never accomplished this particular research.*

I am extremely thankful to ***Dr. G. Sivaram, MDS, Professor,*** *who helped me in designing and carrying out my study. I am indebted to him for his patience, and valuable guidance throughout the study. . I am deeply grateful for his continuous support and valuable advice which has been a vital part of my postgraduate course.*

I extend my sincere thanks to ***Dr. Ramya Arun, Reader, Dr. Swarna Alamelu****,* ***Reader*** *and* ***Dr. Santosh Devanaadhan, Reader*** *for their continuous guidance and constant encouragement throughout my study period.*

I extend my heartfelt thanks to ***Dr Radhabharathi, Senior Lecturer, Dr. Deepavalli, Senior Lecturer*** *and* ***Dr. Akbar, Senior Lecturer*** *Department of Periodontics, Ragas Dental College, for their support and encouragement.*

During one's postgraduate tenure, one learns a lot from colleagues, and I have been lucky to have some of the best. I would like to specially thank my batchmates ***Dr. Juala Catherine, Dr. Laxman Boyapati, Dr. Malarkodi, Dr. Nikhita David*** *and* ***Dr. Shreemogana*** *for their extensive help and support*

throughout my postgraduate course. I extend my thanks to my seniors and juniors especially ***Dr. Swetha, Dr. Raghu, Dr. Swaranakantha, Dr. Guhanathan*** *and* ***Dr. Keerthiha*** *for all the help extended.*

I would like to thank ***Dr. Vinay Pitchika*** *and* ***Dr. Junaid*** *for all the help extended in the statistical analysis. I would also like to thank* ***Mr. Thavamani*** *and* ***Miss. Sudha*** *for the timely help.*

I extend my thanks to ***Mrs. Parvathi,*** *who has been a source of encouragement and support all through the post graduate course, and* ***Mr. Chellapan, Mrs. Rosamma, Miss. Kokila*** *and* ***Miss. Sheela*** *for their timely help during the tenure and* ***Mrs. Deepa*** *and* ***Mrs. Laila ,*** *Staff Nurses, Department of Oral & Maxillofacial surgery for their help in the implant theatre.*

I would like to thank all my ***Patients*** *for their kind cooperation.*

I would like to especially thank my ***parents*** *for their love, understanding, support and encouragement throughout these years. They have been a constant source of inspiration and motivated me to achieve higher goals. . I am greatly indebted to them for all the sacrifices they have made to see me succeed in my past, present and all my future endeavors. I owe it all to their unconditional love and support.*

I thank my ***sister Deepa*** *for her continuous encouragement and support throughout my life. I would like to express my sincere gratitude to my*

*Grandmother, Aunts **Mrs Gita** and **Mrs Tara** and **family*** for all their prayers and support. *I would also like to thank my wonderful friends, **Vidya, Shradha, Kamini, Sneha**, **Mandeep** and **Rahul** who have stood by me through thick and thin.*

*Above all, I am thankful to **God** almighty, to have given me the strength to pursue this course and also to have given all these wonderful people in my life.*

LIST OF ABBREVIATIONS

BIC	Bone implant contact
VAS	Visual Analogue Scale
PD	Probing Depth
KM	Keratinized Mucosa
CBH	Crestal bone height
WSRT	Wilcoxon Signed Rank Test
CSR	Cumulative Success Rate

ABSTRACT

BACKGROUND:

Implant supported restorations have long been used as a successful modality for replacing missing teeth. There are two well established methods of implant placement. The traditional approach to implant surgery involves raising a mucoperiosteal flap and the alternative approach does not involve reflecting a flap, each having its own merits and demerits. The purpose of the present study was to compare and evaluate the soft and hard tissue changes around endosseous implants placed using flap and flapless surgery in mandibular posterior edentulous sites over a period of time (6 months).

MATERIALS AND METHODS:

A total of 20 systemically healthy patients with a single edentulous site in the posterior mandible were enrolled in this study and endosseous implants were placed. A total of 20 implants were placed (10 in flap group and 10 in flapless group). The peri-implant probing depth was assessed at 3 and 6months. Radiographic assessment was done for changes in the marginal bone levels at the mesial and distal side of the implant for a period of six months with measurements made at 0-3months, 3-6 months and 0-6 months. Patient centered outcomes were assessed by using the Visual Analogue Scale (VAS). All these parameters were statistically analyzed using Wilcoxon Signed Rank

Test and Independent sample t-test and were considered to be significant if the *p* value was ≤ 0.05.

RESULTS:

Twenty patients were enrolled in the present study, 10 in the Flap group and 10 in the flapless group and endosseous implants were placed. 18 subjects were followed up throughout the study period and two patients were excluded from the study.

- ✓ On intra group comparison, the mean peri-implant PD in the flap group on the buccal and lingual aspect at 6 months was significantly higher than the mean peri-implant PD at 3 months. The mean peri-implant PD in the flapless group on the buccal and lingual aspect at 6 months did not show a significant change.
- ✓ On intergroup comparison, no significant difference was seen in the mean peri-implant PD between the flap and flapless groups at 3months on both the buccal and lingual aspects.
- ✓ On intergroup comparison, no significant difference was seen in the mean peri-implant PD between the flap and flapless groups at 6 months on the buccal aspect while a statistically significant difference was noted on the lingual aspect.

- ✓ The difference in mean crestal bone levels between flap and flapless groups in the time period of 0-3 months were marginal but statistically significant with the flapless group showing lesser resorption.
- ✓ No significant difference was seen in the mean crestal bone levels between flap and flapless groups in the time period of 3-6 months.
- ✓ The difference in the mean crestal bone levels between flap and flapless groups in the time period of 0-6 months were marginal but statistically significant with the flapless group showing lesser resorption.
- ✓ The mean VAS Score on Day 0 in the flap and flapless group was statistically significant. The flapless group showed significantly lesser post-operative pain when compared to the flap group.

CONCLUSION:

The flapless technique of endosseous implant placement yielded improved soft and hard tissue and patient centered outcomes in comparison with conventional flap technique of implantation.

Key words:

Endosseous implants, flap and flapless method, peri-implant probing, crestal bone loss

CONTENTS

S .No.	INDEX	Page No.
1.	**INTRODUCTION**	1
2.	**AIMS AND OBJECTIVES**	4
3.	**REVIEW OF LITERATURE**	5
4.	**MATERIALS & METHODS**	32
5.	**RESULTS**	49
6.	**DISCUSSION**	55
7.	**SUMMARY & CONCLUSION**	65
8.	**BIBLIOGRAPHY**	68
9.	**ANNEXURE**	-

LIST OF TABLES

TABLE NO.	TITLE
1	Edentulous site - implant dimensions
2	Mean peri-implant probing depth at three and six months
3	Radiographic difference of marginal bone levels on mesial and distal aspects of implants
4	Comparison of mean peri-implant Probing depth at 6 months on buccal aspect in flap and flapless group - Statistical Analysis
5	Comparison of mean peri-implant Probing depth at 6 months on lingual aspect in flap and flapless group - Statistical Analysis
6	Comparison of mean peri-implant Probing depth at 3 months on buccal and lingual aspect in flap and flapless group - Statistical Analysis
7	Comparison of mean per-implant Probing depth at 6 months on buccal and lingual aspect in flap and flapless group - Statistical Analysis
8	Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 0-3 months
9	Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 3-6 months
10	Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 0-6 months
11	VAS Scores at different time intervals
12	VAS Scores - Statistical Analysis

LIST OF GRAPHS

GRAPHS NO.	TITLE
1	Comparison of mean peri-implant PD at 3 and 6 months on buccal aspect in flap and flapless groups
2	Comparison of mean peri-implant PD at 3 and 6 months on lingual aspect in flap and flapless groups
3	Comparison of mean peri-implant PD at 3 months on buccal and lingual aspect in flap and flapless group
4	Comparison of mean peri-implant PD at 6 months on buccal and lingual aspect in the flap and flapless group
5	Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 0-3months
6	Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 3-6months
7	Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 0-6months
8	Mean VAS Scores on Day 0 and Day 3

Introduction

INTRODUCTION

An ideal functional dentition is vital for well being and quality of life. Edentulism is a common problem affecting majority of the population worldwide and has a bearing on the overall health as well as the health of the remaining natural teeth. Kennedy's Class III is the most common class of edentulism in both dental arches[9]. Fixed treatment options for partial edentulism includes fixed partial dentures, resin bonded restorations and implants. Dental implants have emerged as a viable treatment alternative to replace missing teeth. The primary goal of Implant therapy is to restore normal contour, function, comfort, esthetics, phonetics and overall health and well being without affecting the existing natural dentition.

A high degree of success was achieved with implants in partly edentulous jaws[85,52]. The single-tooth implant has become a predictable treatment option[50]. Several clinical trials have proven the long term success of using dental implants to replace missing teeth[2,3,31]. The survival rates of endosseous implants have been shown to be as high as 85-90% for implant supported fixed prosthesis and > 90% for implants replacing single missing tooth and for implant supported removable prosthesis.

Several authors have put forth the ideal characteristics of a successful osseointegrated implant based on the crestal bone loss < 1.5mm, absence of mobility, peri-implant probing depth <5mm, absence of BOP, absence of recurrent peri-implant infection and suppuration and absence of radiolucency

around the implant[8,60]. Several factors are found to influence the overall success of an implant. The primary factor however is the quantity and quality of bone at the edentulous site which is one of the main risk factors for implant failure[41]. The surgical protocol adopted while placing the implant, flap or flapless surgery is found to influence the crestal bone changes over a period of time at the implant site.

The traditional implant placement protocol involves the exposure of the alveolar ridge by means of a full thickness mucoperiosteal flap. The elevation of a mucoperiosteal flap is especially beneficial in sites with limited bone quantity as it allows the surgeon to visually assess the bone quality and morphology at the treatment site. It can also reduce the risk of bone fenestrations or perforations[68] and is found to produce a better emergence profile as the soft tissues can be manipulated to the required contour[49]. Dental implants placed after reflecting mucoperiosteal flaps invariably present with some bone resorption. During the initial phase of healing, bone resorption of varying degrees almost always occurs in the crestal region of the alveolar bone[72]. Extent of alveolar bone height reduction resulting from this resorption is related to the bone thickness at the specific site[92].

In the flapless procedure, the dental implant is placed through the mucosal tissues without reflecting a flap. The periosteum is left intact on the buccal and lingual aspects of the alveolar ridge and maintains a better blood supply to the site, thereby reducing the likelihood of resorption[6]. Other

potential advantages of the flapless technique include a reduction in the intra-operative bleeding and surgical time along with preservation of hard and soft tissues, rapid post surgical healing and fewer post operative complications[75,11,82]. The shortcomings of the technique include the inability to visualize the true topography of the underlying alveolar bone which can pose a threat to several important anatomical landmarks and also increase the risk for unwanted perforations that could compromise esthetics and lead to loss of implant[29]. Alveolar bone should have sufficient width and height for implant placement using a flapless technique[13,14,20].

Changes in the crestal bone level can be influenced by a number of factors such as the surgical trauma, implant design, loading protocol etc[44,42,59,91,38]. Several authors have compared the influence of flap and flapless techniques on the crestal bone level[26,54,87]. Healthy soft tissue surrounding a dental implant is essential for its health, function, and esthetics[58]. Clinical importance of the Biological or soft tissue seal around the implant has been identified as a dominant factor to determine the long-term success of peri-implant health[47,94] .

The present clinical study was undertaken to analyze the effect of peri-implant soft and hard tissue changes and patient centered outcomes around endosseous implants placed using flap and flapless surgical techniques over a period of time.

Aims and Objectives

AIMS AND OBJECTIVES

AIM:

To compare and evaluate the soft and hard tissue changes around endosseous implants placed using flap and flapless surgery in mandibular posterior edentulous sites over a period of time (6 months).

OBJECTIVES :

1. To compare and evaluate the peri-implant soft tissue changes around endosseous implants placed using flap and flapless surgery at different time intervals.
2. To compare and evaluate the crestal bone level changes around endosseous implants placed using flap and flapless surgery at different time intervals.
3. To evaluate the patient centered outcomes using VAS to compare both flap and flapless surgical techniques used for endosseous implant placement.

Review of Literature

REVIEW OF LITERATURE

EFFECTS OF EDENTULISM, PREVALENCE AND MODES OF REPLACEMENT

Davis DM et al (2001) [28] investigated the reactions to tooth loss in a partially dentate group of 100 people using a questionnaire-based method. The authors concluded that tooth loss has been found to have an emotional impact affecting one's self-confidence, food habits, esthetics, and function, personal and social life.

Enoki K et al (1992) [32] have concluded from their study that partial edentulism has a significant emotional and psychological impact on ones confidence and might lead to social inhibitions due to the changes in appearance that follow tooth loss .

AL-Dwairi ZN (2006)[9] investigated the frequency of different classes of patterns of partial edentulism and concluded that Kennedy's class III is the most common class of edentulism in both dental arches.

Hebel K et al (2000)[39] analyzed the disadvantages associated with fixed replacement options such as conventional fixed partial denture and resin bonded restorations. They concluded that a single-tooth implant is the restoration of choice, providing a highly esthetic, functional, long-term result when placed in ideal situations.

Ekelund JA et al (2003)[31] studied the clinical and radiographic performance of mandibular fixed prostheses supported by osseointegrated implants over more than 20 years. Clinical and radiographic data were collected at several examinations over the 20-year observation period. During the last 5 years, a majority of the implants with several exposed implant threads could be maintained without any complications, and the frequency of implants showing signs of ongoing peri-implantitis was less than 3%.The authors conclude that dental implants can be used successfully to replace missing teeth.

CUMULATIVE SUCCESS RATES OF IMPLANTS

There is lack of a set of universally accepted success criteria for implants. **Ong**[66] in his systematic review gives a cumulative success rate to define implant success based on clinical and radiographic criteria given by various authors. Based on his review, implant success is defined as follows.

1. Crestal bone loss lower than 1.5mm during the first year after loading and 0.2 mm anually thereafter **(Albrektsson et al).**
2. Absence of mobility **(Buser et al).**
3. Absence of persistent subjective complaints (**Buser et al).**
4. Absence of radiolucency around the implant **(Buser et al).**
5. Probing Pocket Depth around the implant <5mm **(Mombelli and Lang).**
6. Absence of Bleeding on Probing **(Mombelli and Lang).**

7. Absence of recurrent peri-implant infection and suppuration **(Buser et al).**

Becker W et al (1999)[16] conducted a long term evaluation of 282 implants placed in the maxillary and mandibular molar region. Seventy implants were inserted in maxillae and 212 in mandibles. They concluded that implants placed into molar positions indicated favorable clinical outcomes with CSR of 91.5% in mandibular implants and 82.9% in maxillary implants.

Lindquist LW et al (1996)[56] conducted a prospective 15-year follow-up study of mandibular fixed prostheses supported by osseointegrated implants. A total of 273 implants were placed in 47 edentulous patients and followed up. The CSR of the implants was 98.9% both after 10 and 15 years. The marginal bone loss around the implants was on average 0.5mm during the first post surgical year and thereafter about 0.05mm annually. More bone was lost around the anterior implants than around the posterior ones. They concluded that the long-term results of the mandibular implant treatment were extremely successful.

Nevins M and Langer B (1992)[62] conducted a long term study over a period of 7 years wherein a total of 1203 implants were placed in 200 partially edentulous posterior mandibular sites and 193 partially edentulous posterior maxillary sites. At the end of the study period a success rate of 95.5% was recorded for mandibular implants and 95.2% for the maxillary implants. They

concluded that osseointegrated endosseous implants used to replace posterior edentulous sites were efficacious and yielded high success rates.

SUCCESS RATES OF IMPLANTS PLACED USING FLAP AND FLAPLESS TECHNIQUES

Rousseau P (2010)[77] conducted a retrospective study in order to compare the flapless method (FL) of implant placement with the traditional flap method (TM) with regards to changes in bone level, overall safety and success rates. The primary criteria for successful implants were the absence of mobility, radiolucency, pain and infection. At the first visit, the success rate for the FL group was 98.3% (171/174 implants) and 98.5% (200/203 implants) in the TF group. There was no statistically significant difference in the success rates between the groups. The author concluded that the flapless approach is a highly predictable procedure and had good success rates.

Campelo LD and Camara JRD (2002)[20] conducted a 10 year retrospective analysis of implants placed using the flapless approach. The recall visits were after 3 months, 6 months, 1 year and then once every year. The prosthesis was removed, implant mobility assessed, periodontal probing done and periapical radiographs were taken at the recall visits. The CSR after 10 years varied from 74.1% for implants placed in 1990s to 100% at 2000. It was concluded that the flapless method of implant placement was a highly predictable procedure provided patient selection and surgical protocol followed are appropriate.

Bashutski JD et al (2013)[12] conducted a randomized controlled trial to compare the traditional flap and the flapless protocol for implant placement. Radiographic and clinical measurements were assessed at baseline 3,6,9 and 15 months. The Clinical parameters which were evaluated are Plaque index (PI), Gingival index (GI), Papillary index (PPI), marginal tissue levels, biotype, width of Keratinized tissue and soft tissue thickness. The results of the study showed an implant success rate of 92% in both groups. The PPI was found to increase with time in both groups, however the flapless group had a significantly greater change in PPI from crown placement to 6 and 9 months ($P < 0.01$). The crestal bone levels in the flapless group were more coronal in relation to the implant platform while the flap group had more apical bone levels throughout the duration of the study. No differences were noted amongst all the other parameters. The authors conclude that both flapless as well as conventional flap protocols for implant placement resulted in high success rates. The flapless method seemed to provide better short -term esthetic results but no long term advantages have been reported.

SURVIVAL RATES OF IMPLANTS PLACED WITH FLAP AND FLAPLESS TECHNIQUES

An implant is considered to be surviving if they continue to support a load bearing restoration and is free from any irresolvable clinical complaints such as chronic pain, implant mobility, peri-implant radiolucency and progressive bone loss **(Evian et al, 2004).**

Lin GH et al (2014) [54] studied the effect of the flapless technique on implant survival rates (SRs) compared with the conventional flap approach. A total of 12 human clinical trials were selected to be a part of the systematic review. The average survival rate is 97.0% for the flapless procedure and 98.6% for the flap procedure. They concluded that the implant survival rates of flapless intervention was comparable with the flap surgery approach.

De Bruyn et al (2011) [29] conducted a study to compare single implants installed with a flap (F) or flapless (FL) surgery with respect to survival and marginal bone preservation after at least 3 years. A total of 53 implants were placed in 49 patients and a delayed loading protocol was adopted. Radiographs were recorded at baseline, 1 and 3 years of function. The overall survival rate was 100% and the overall mean bone loss after an average of 38 months was 1.35 mm. Both groups showed increasing bone loss during the first year and reduced after that. They concluded that **single** implants yield an excellent prognosis with stable bone levels irrespective of the surgical technique, and that flapless surgery was a viable alternative to more extensively planned guided surgery. Proper case selection and clinical experience are considered prerequisites for a predictable treatment outcome.

Brodala N (2009) [19] evaluated the effect of flapless surgery on dental implant outcomes. Only clinical (human) studies with five or more subjects were included in this review. The prospective cohort studies demonstrated approximately 98.6% survival rate, suggesting clinical efficacy, while the

retrospective studies or case series demonstrated 95.9% survival rate, suggesting effective treatment. It was concluded that Flapless surgery was a highly predictable and plausible treatment modality for implant placement, demonstrating both efficacy and clinical effectiveness.

Rocci et al (2003)[75] conducted a retrospective 3-year clinical study. A total of 97 Brånemark implants were inserted in 46 patients using flapless surgery. A cumulative survival rate of 91% was recorded after 3 years. Hence flapless surgery was a highly predictable form of implant placement.

IMPLANT DESIGN, MACRO AND MICRO GEOMETRY

Esposito M et al (2007)[33] have chosen around 40 RCT's and compared different osseointegrated implants with different materials, shapes and surface properties having a follow up of at least 1 year. It was concluded that no particular type of dental implant has superior long-term success based on the shape, material and surface modifications and no clinically significant differences were noted while comparing use of cylindrical and tapered implants.

Petrie C.S. and **Williams J.L. (2005)**[71] analyzed and compared systematically the relative and interactive effects of implant diameter, length and taper on calculated crestal bone strains. They concluded that a wide and relatively long untapered implant was favorable to minimize the peri-implant

strain in the crestal alveolar bone. Narrow, short implants with taper in the crestal region should be avoided especially in low density bone.

Shalabi et al (2006) [80] in a systematic review investigated the effects of implant surface roughness on bone response and implant fixation. Enhanced bone-to-implant contact was seen with increasing surface roughness. They concluded that there existed a positive correlation between surface roughness and bone-to-implant contact and pushout strength.

Wennerberg A and **Albrektsson T (2009)** [90] analyzed the effects of titanium surface topography on bone integration in a systematic review comprising 100 papers. The bone response to differently configurated surfaces was mainly evaluated by histomorphometry (bone-to-implant contact), removal torque and pushout/ pullout tests. They concluded that no major advantages or disadvantages were seen when blasted implants were compared with machined implants and etched surfaces with machined implants. However, blasted + etched surfaces were found to be strongly integrated in bone than machined surfaces. Titanium Plasma sprayed surfaces demonstrated less strong bone response than the blasted + etched surfaces.

Ortega-Oller I et al (2014)[67] analyzed the influence of implant diameter on its survival. 16 studies were chosen and separated into two groups, implants of diameter <3.3 mm (group 1) implants of diameter > 3.3 mm (group 2). This meta-analysis concluded that narrower implants

(<3.3 mm) had significantly lower survival rates of 75% when compared with wider implants (>3.3 mm) which showed a survival rate of 87%.

Levine RA et al (2002)[53] conducted a retrospective analysis of six hundred and seventy-five posterior single-tooth implants. A cumulative survival rate of 99.1% was obtained for all sites. The survival rates for individual sites were as follows: 98.4% mandibular molars, 100% maxillary molars, 100% mandibular premolars, and 100% maxillary premolars.

SURGICAL TECHNIQUE

IMPLANT PLACEMENT BY FLAP SURGERY

The traditional implant placement protocol involves the exposure of the alveolar ridge by means of a full thickness mucoperiosteal flap, following which implants are placed and then the flap is re-approximated using sutures[78,45]. The elevation of a mucoperiosteal flap is especially beneficial in sites with limited bone quantity as it allows the surgeon to visually assess the bone quality and morphology at the treatment site.

Ozan O et al (2007)[68] have postulated that implant placement by conventional flap surgery can reduce the risk of bone fenestrations or perforations as adequate visibility and accessibility is obtained on raising the flap.

Kinsel RP and **Lamb RE (2000)**[49] studied the development of gingival esthetics in the edentulous patients restored with implant supported

fixed prosthesis. It is found that implantation by elevating a flap can produce a better emergence profile as the soft tissues can be manipulated to the required contour.

Dental implants placed after reflecting mucoperiosteal flaps invariably present with some bone resorption.

Nobuto et al (2005)[64] performed mucoperiosteal flap surgery on 12 adult dogs. They investigated the bone remodeling in the healing process after mucoperiosteal flap surgery and concluded that flap reflection always resulted in bone resorption and changes of the crestal bone level and was closely related to the microcirculation.

Van der Zee et al (2004) [84] reported postsurgical tissue loss following flap reflection in the two-stage procedure of implant placement, implying that flap surgery for implant placement may negatively influence implant esthetic outcomes especially in the maxillary anterior region.

Yaffe et al (1994)[93] studied the remodeling process after mucoperiosteal flap surgery in the mandible in 60 Wistar rats. Regional accelerated phenomenon (RAP) was observed within 10 days post treatment with striking resorption of the alveolar bone. They concluded that the resorption was more prominent when a mucoperiosteal flap was performed and that there was a higher risk of bone dehiscence following flap surgery when the bone was thin.

Ramfjord SP and **Costich ER (1968)**[72] studied the healing of the alveolar process after exposure of the periosteum. They conclude that during the initial phase of healing, bone resorption of varying degrees almost always occurs in the crestal region of the alveolar bone[13].

Wood DL et al (1978)[92] conducted a clinical study on nine patients to evaluate the difference in response of the marginal radicular alveolar bone to the full thickness flap and the partial thickness flap. All patients who were surgically re-evaluated lost crestal radicular bone, after both the full thickness and the partial thickness flap. Extent of alveolar bone height reduction resulting from this resorption is related to the bone thickness at the specific site[14].

Roman GG (2001)[76] conducted a study on the influence of flap design on the peri-implant interproximal crestal bone loss around single tooth implants. The study compared 2 flap designs: 1. A widely mobilized flap design that included the papilla and 2. A limited flap design that preserved the papilla. The site selection was such that the flap design was wide on one side either mesially or distally and limited on the other. The interproximal bone loss was evaluated using digital periapical radiographs immediately after surgery, at the time of crown placement and 1 year post restoration. The interproximal crestal bone loss was found to be lesser with the limited flap design and was also statistically significant.

FLAPLESS SURGERY

In the flapless procedure, the dental implant is placed through the mucosal tissues without reflecting a flap. A small amount of tissue over the crest of the edentulous ridge is removed and this is sufficient to expose the underlying bone to facilitate implant placement. As no soft tissue flap is reflected, no sutures are required and it potentially reduces post operative discomfort and swelling[46].

Al-Ansari BH, Morris RR (1998)[6] have postulated that leaving the periosteum intact on the buccal and lingual aspects of the alveolar ridge maintains a better blood supply to the site, thereby reducing the likelihood of resorption.

Kim JI et al (2008) [48] compared the vascularity of the peri-implant mucosa using flap and flapless surgeries in canine models. Bilateral, edentulated, and flat alveolar ridges were created in the mandible of six mongrel dogs and implants were placed by either flap or flapless procedure on either side. After a healing period of 3 months, biopsies were obtained, and exposed to morphometric measurements. The supracrestal connective tissue lateral to the implant was more richly vascularized in the flapless group when compared to the flap group. The authors concluded that the flapless procedure may increase the vascularity of the peri-implant mucosa.

Lazić Z et al (2015) [51] compared the effect of mini - incision flapless versus flap technique of implant placement on the peri-implant vasculature in pigs using immunohistochemical analysis. They concluded that the flapless surgical implant placement using mini-incision provides better vascularization of peri-implant mucosa compared with flap surgery.

Other potential advantages of the flapless technique include a reduction in the intra-operative bleeding and surgical time along with preservation of hard and soft tissues, rapid post surgical healing and fewer post operative complications[75,11,82].

Becker *et al* (2006)[15] evaluated implants placed using flapless and flap surgery in canine models. They suggested that implants placed without flap reflection remained stable and exhibited clinically relevant osseointegration that was similar to implants placed with flapped procedures.

De Bruyn H et al (2011)[29] In the flapless technique the inability to visualize the true topography of the underlying alveolar bone can pose a threat to several important anatomical landmarks and also increase the risk for unwanted perforations that could compromise esthetics and lead to loss of implant eventually.

Sclar AG (2007)[78] reviewed the advantages, disadvantages, indications and contraindications for flapless implant surgery. The prerequisites for using tissue punch in the flapless approach were clearly

outlined in comparison to conventional flap surgery and other minimally invasive techniques. A 2.5-3 mm wide zone of attached gingiva was considered ideal and important for maintenance of the implant site. Further the use of high frequency radiosurgery was advocated to maintain a relatively bloodless surgical field and also enhance visibility.

EVALUATION OF SOFT TISSUE PARAMETERS

You TM et al (2009)[95] compared the morphogenesis of peri-implant mucosa with flap and flapless implant surgeries by using a canine mandible model. The peri-implant mucosa was evaluated by using clinical, radiographic and histometric parameters. The parameters included gingival index, bleeding on probing, probing pocket depth, marginal bone loss and the vertical dimension of the peri-implant tissues. The assessed parameters were found to be significantly greater in the flap group than in the flapless group ($P < 0.05$). The authors concluded that the height of the junctional epithelium, gingival inflammation, marginal bone loss around the non submerged implants may be reduced when adopting the flapless method of implant placement.

Tsoukaki M et al (2013)[83] conducted a study to compare the placement of flapped vs. flapless dental implants using clinical, radiographic, microbiological, and immunological parameters. Clinical recordings, sulcular fluid sampling, microbiological analysis, and digital subtraction radiography were used to compare the two surgical approaches. The peri-implant sulcus depth was significantly greater in flapped implants at both 6 and

12 postsurgical weeks. Flapped implants showed crestal bone loss, whereas in contrast, no bone resorption was detected around flapless implants. Matrix metalloproteinase-8 values were found to be higher in the flap group after placement. In the flapless group, the presence of Porphyromonas gingivalis was significantly higher at the 2nd postoperative week whereas the counts of Tannerella forsythia were more at the 1st, 2nd and 12th postoperative weeks, which could indicate an early formation and maturation of the peri-implant sulcus. The authors conclude that Flapless implant placement yielded improved clinical, radiographic, and immunological outcomes compared with flapped implantation.

Al-Ansari and Morris (1998)[6] evaluated the healing and clinical integration of implants placed using flapless method. The surgical site was prepared without elevating a flap and evaluated periodically for 2 years. The results of the study showed normal healing pattern in the first week post placement, a probing depth < 2mm circumferentially around all healing caps at 3 months and also in the recall visits. The implants were clinically stable and free of any signs of mobility or infection. Radiolucency was absent. The authors concluded that the flapless method of implant placement provided several advantages over the conventional 2 step flap procedure.

Oh TJ et al (2006)[65] studied the effect of flapless implant surgery on the soft tissue profile around implants. Twenty-four patients were assigned to either immediate loading group (IL) or delayed loading group (DL). An

endosseous implant was placed in each patient by flapless surgery. Clinical measurements such as the papillary index (PPI), marginal levels of the soft tissue (ML), probing depths (PDs), modified bleeding index (mBI), modified plaque index (mPI), and the width of the keratinized mucosa (WKM) were recorded at baseline, 2, 4, and 6 months. The authors concluded that flapless implant surgery provides esthetic soft tissue results irrespective of the loading protocol followed and no significant changes were seen in all the other parameters.

Ravindran DM et al (2010)[73] assessed the efficacy of flapless implant surgery on the soft tissue profile and compared the clinical outcomes of flapless implant therapy on immediate loading (IL) implants and delayed loading (DL) implants. The soft tissue parameters evaluated were the modified plaque index (*mPI*), modified bleeding index (*mBI*), papillary index (*PPI*), marginal level of soft tissue (*ML*) and width of keratinized mucosa (*WKM*). No statistically significant difference was noted in the soft tissue parameters in the delayed and immediately loaded implant groups. The authors concluded that that flapless implant surgery using either immediately loading implants or delayed loading implants showed enhanced implant esthetics.

Vlahovic Z et al (2015)[86] compared the effect of flapless and flap technique of implant placement on the degree of inflammation of the peri-implant soft tissue through histopathological analysis in porcine models. A high degree of inflammation was recorded in the flap group from

day 7 to day 21. The flapless group did not show such a high degree of inflammation throughout the study period. The authors concluded that flapless surgical technique decreases peri-implant soft tissue inflammatory reaction when compared to flap surgery.

RADIOGRAPHIC EVALUATION OF HARD TISSUE CHANGES

Ozan O et al (2007)[68] conducted a randomized controlled clinical study to compare the survival rates of early loaded implants placed using flapless and flapped surgical techniques. The bone density in the implant sites was determined using computerized tomography (CT). The mean bone density value of each implant recipient site was recorded in Hounsfield units (HU). Overall implant survival rate was 98·3% average at 9 months. The highest average bone density value (801 ± 239 HU) was found in the anterior mandible, followed by 673 ± 449 HU for the posterior maxilla, 669 ±346 HU for the anterior maxilla and 538 ± 271 HU for the posterior mandible.

Herman JS et al (2001)[40] compared the crestal bone changes around titanium implants using linear radiographs and histometric measurements. The first bone to implant contact was determined on standardized periapical radiographs and was compared to similar analyses made from non decalcified histology. Both techniques provided the same information. From the data obtained, the authors conclude that standardized periapical radiography can evaluate crestal bone levels around implants accurately in a high percentage of cases.

Penarrocha et al (2004)[69] evaluated the one year post loading periimplant bone resorption around implants using radiographs. The mean loss in alveolar bone height determined by panoramic radiography was found to be 1.36mm, 0.76mm by intraoral periapical radiographs and 0.95mm by digital radiography. The authors concluded that conventional periapical radiographs and digital radiographs provided greater accuracy in assessing periimplant bone loss in comparison with orthopantomography.

INFLUENCE OF FLAP AND FLAPLESS TECHNIQUE ON CRESTAL BONE LEVEL

Jeong S et al (2007)[45] examined the effect of flapless implant surgery on crestal bone loss and osseointegration in canine mandible models. Bilateral, edentulous flat mandibular alveolar ridges were created. Two implants were placed on each side by either flap or flapless technique. Micro computerised tomography was performed after a healing period of 8 weeks and the bone height at the peri-implant site was measured. It was found that the mean osseointegration and peri-implant bone height was greater in the flapless sites. The authors concluded that flapless surgery could achieve better results that conventional flap surgery in implant placement.

Job S et al (2008)[46] compared the changes in the crestal bone height around implants placed with conventional flap surgery and flapless surgery. A total of ten implants were placed in six patients. The change in crestal bone height was measured on standardized digital periapical radiographs at 0, 1 and

3 months. The reduction of crestal bone height around implants placed using flap surgery (0.4mm) was statistically significant while the reduction of crestal bone height around implants placed with flapless surgery (0.6mm) was not statistically significant. Amongst the two groups, the flapless technique of implant placement showed lesser crestal bone reduction.

Becker et al (2006)[15] evaluated implants placed using flapless and flapped surgery in canines. The BIC was evaluated using histometric analysis and the primary stability with resonance frequency analyzer. The results of the histologic evaluation showed high bone - implant contact without any evidence of gingival tissue or foreign body inclusions. No significant differences in the marginal bone levels between the surgical protocols was noted. The authors conclude that Flapless implant placement is as biologically successful as implants placed using the convenional mucoperiosteal flap reflection.

Wadhwa B et al (2015)[88] compared the effect of flapless and flap techniques of implant placement on the CBH around implants. Radiographic assessment of CBH was carried out using standardized intraoral periapical radiograph of the site at baseline, 3 months, 9 months and 15 months after implant placement. The authors concluded that both techniques showed a reduction in CBH with time but the flapless technique showed a lesser reduction. Therefore, the flapless method can be considered as a better

technique for implant placement, especially where adequate width and height of bone are present.

Chrcanovic BR et al (2014)[26] conducted a meta-analysis of previously published clinical studies to investigate whether there are any positive effects of flapless implant insertion surgery postoperative infection, and marginal bone loss in comparison with the more traditional open flap technique. A total of 23 studies were compared and they concluded that there were no significant effects of flapless technique on the occurrence of postoperative infection or on the marginal bone loss.

Ricci et al (2004)[74] evaluated clinical outcomes of implants loaded for 60 months in a retrospective study. A total of 112 implants in 51 patients were assessed. The results showed a survival rate of 100%, crestal bone loss >3mm in 28.6% cases, Bleeding on probing in 15.5% cases and probing depth > 5mm in 4.5% cases. The authors concluded that with strict plaque control and stringent supportive therapy, the crestal bone loss around two stage implant systems may be minimal.

Froum SJ et al (2011)[37] conducted a RCT to compare the survival of a one-piece anodically oxidized surface implant placed by flapless or flap protocol. Bone loss measurements on radiographs and changes in clinical probing depths 1 year post–definitive restoration placement were recorded and compared. They concluded that the implants placed had high survival rates

(100%) and stable marginal bone and probing depth levels whether a flapless or flap protocol was used for implant insertion.

Lin GH et al (2014)[54] studied the effect of the flapless technique on marginal bone levels (MBLs) compared with the conventional flap approach. A total of 12 human clinical trials were included in the systematic review. They concluded that the radiographic marginal bone loss of flapless intervention was comparable with the flap surgery approach.

Vohra, F et al (2015) [87] compared the crestal bone loss (CBL) around dental implants placed using flapped and flapless surgical techniques. A total of 10 articles were selected and analyzed in a systematic review. They concluded that CBL around dental implants placed in healed sites using flapped and flapless techniques is comparable.

EFFECT OF LOADING PROTOCOL:

According to *Branemark (1983),* implants placed in bone should be left unloaded for a period of 4-6 months.

The rationale behind the delayed loading protocol is:

- Premature loading may lead to fibrous tissue encapsulation instead of direct bone apposition *(Albrektsson et al. 1986).*
- The necrotic bone at the implant bed border is not capable of load-bearing and must be first replaced by new bone *(Brånemark 1983).*

- Rapid remodeling of the dead bone layer compromises the strength of the osseous tissue supporting the bone–implant interface *(Roberts et al. 1984).*
- Integrity of the periosteal margin may be threatened by undermining remodeling of adjacent bone during the late healing period *(Roberts et al. 1989).*

The Third ITI consensus conference defined the implant loading protocols as follows **Cochran et al (2004)[27].**

- *Immediate loading:*

  A restoration is placed in occlusion with the opposing dentition within 48 hours of implant placement.

- *Early loading:*

  A restoration in contact with the opposing dentition and placed at least 48 hours after placement of implant and not later than 3 months afterwards.

- *Conventional loading:*

  The prosthesis is attached in a second procedure after a healing period of 3 to 6 months.

- *Delayed loading:*

  The prosthesis is attached in a second procedure that takes place sometime later than the conventional healing period of 3 to 6 months.

- *Immediate restoration:*

  A restoration inserted within 48 hours of implant placement but not in occlusion with the opposing dentition.

Cannizzaro G (2008)[22] compared the efficacy of immediate functionally loaded implants placed with a flapless procedure (test group) versus implants placed with flap surgery and conventional load-free healing (control group). The implant stability quotient (ISQ value- Osstell) was significantly higher at baseline in the flapless group. When the baseline data in the first, second and third years were compared within each group, the mean Osstell values for the flapless group did not increase but the Periotest values showed a significant increase. The author concludes that implants can be successfully placed using the flapless protocol and also loaded immediately. There is no compromise on the success rate and has the added advantage of lesser patient discomfort and decreased overall treatment time.

Ericssion et al in a clinical and radiographical study evaluated the survival outcome of single tooth replacement implants with immediate loading and compared it with conventional 2- stage loading protocol. In the immediate loading group 2 out of 14 implants failed within 5 months of placement. In the conventional loading group none of the implants failed after 12 months. Radiographic assessment after 12 months showed mean bone loss of 0.1 mm in both the study groups.

Cannizzaro G et al (2011)[22] evaluated the efficacy of flapless versus open flap implant placement in partially edentulous patients who were subjected to immediate loading. Seventy-six implants were placed by flapless technique and sixty seven after flap elevation. There were no statistically significant differences for prosthetic and implant failures, complications, ISQ values and marginal bone levels between groups. However, flapless implant placement required significantly less operation time, induced less postoperative pain, swelling, analgesic consumption and was found to be more preferred by patients. Mean ISQ values of both groups significantly decreased over time. They concluded that implants can be successfully placed by the flapless method and loaded immediately, also reducing the treatment time and patient discomfort.

Degidi M and **Piatteli A (2005)**[30] conducted a clinical study to evaluate immediate functionally loaded and immediate non functionally loaded implants to traditional healing periods with a follow up of upto 24 months for various parameters such as mobility, peri-implant radiolucency, crestal bone loss , pain, infection etc. A total of 702 implants were placed of which 253 were immediate functionally loaded, 135 implants were immediate non functionally loaded and 314 were controls. In each of the 3 groups, 2 implants failed. Successful osseointegration was noted in all the other implants. They concluded that both immediate functional loading and

immediate non functional loading protocol are predictable techniques with good success.

Penarrocha et al (2002)[69] recommended that full osseointegration should occur before dental implants are loaded, to guarantee the greatest success.

PATIENT CENTERED OUTCOMES

Implant dentistry is rapidly evolving with considerable emphasis on predictable treatment planning with maximum patient comfort and minimal patient morbidity. Patient self-assessment indicated that implant placement is a mild to moderately painful and anxiety provoking procedure (**Eli et al. 2003, Hashem et al. 2006).** In the present clinical study, the Visual Analogue Scale (VAS) was used to compare the pain levels post implant placement using both flapless and flap techniques.

Fortin et al (2006)[36] compared the pain experienced after implant placement with the conventional flap and flapless procedure. Visual analogue scale was used to evaluate the pain experienced and also the number of analgesics taken post operatively from the day of surgery for 6 days was noted. The results showed that pain decreased faster with flapless procedure and the number of patients who felt no pain was higher with the flapless procedure.

Lindeboom JA, Van Wijk AJ (2010)[55] conducted a clinical study to compare the patient outcome variables using flapless and conventional flapped implant placement techniques. All implants were placed as two-phase implants. No significant difference was noted between conditions on dental anxiety (s-DAI), emotional impact (IES-R), anxiety, procedure duration or technical difficulty, although the flapless group did score consistently higher. The flap group reported less impact on quality of life and included more patients who reported no feeling of pain during placement. The authors concluded that the differences found in the patient outcome variables suggest that patients in the flapless implant group had to endure more pain than the patients in the flap group.

Cannizaro G et al (2011)[21] evaluated the efficacy of open flap versus flapless implant placement in partially edentulous patients. There was no statistically significant differences for prosthetic and implant failures, complications, ISQ values and marginal bone levels between the groups. The flapless group required significantly lesser operation time (17 minutes less) and also induced less postoperative pain, swelling, analgesic consumption and was more preferred by patients. The authors concluded that implants can be placed using both the flapless and the conventional flap protocols successfully and also loaded immediately with a reduction in the treatment time and patient discomfort.

Arisan et al (2010)[11] compared the surgical and post-operative outcomes of a computer-aided implant surgery performed by bone- and mucosa-supported stereolithographic guides (SLA) against the standard technique. 3 groups were considered, the standard flap group (control), bone supported group (BSG) and mucosa supported SLA (flapless groups). Surgical duration (min), number of analgesics (tablets) as well as haemorrhage, difficulty in mouth opening (or trismus) and other incidences were recorded. Pain and swelling was assessed using the visual analog scale (VAS). The mean surgery duration and the number of analgesics consumed in the Flapless group were lower than those in the control and BSG groups. The Flapless group also reported a lower pain score, less haemorrhage and fewer instances of trismus too when compared to the standard and BSG groups.

Nkenke E et al (2007) [63] compared the patient centered outcomes post implant placement using flapless and flap approach. Patients were asked to rate pain and discomfort on a Visual Analogue Scale. The authors concluded that flapless implant placement reduces patient morbidity and showed significant post-operative pain reduction.

Materials and Methods

MATERIALS AND METHODS

PATIENT SELECTION:

Twenty patients selected from the Out patient, Department of Periodontics, Ragas Dental College, Chennai participated in this clinical study for endosseous implant placement. Participants in the present clinical trial presented with single edentulous site in the posterior mandibular region and required replacement of the same with a fixed prosthesis without affecting the adjacent natural teeth.

INCLUSION CRITERIA:

- Age group between 20 to 60 years in both genders.
- Single edentulous space in the mandibular posterior region with adequate ridge dimension for implant placement.
- Optimal bone quantity and quality at the edentulous site.
- Interocclusal clearance of minimum 7 mm.
- Presence of adequate KM at the edentulous site.
- Absence of pathological migration / periapical pathology adjacent to the edentulous site.
- Patients who are motivated, highly compliant, with good oral hygiene practice.

- The plaque and bleeding index in the present study group was less than 20% at all times of the study period.

EXCLUSION CRITERIA:

- Presence of active periodontal disease.
- Patients with any systemic disease and medications that will interfere with treatment outcome.
- Patients with known risk factors and risk modifiers which can influence the overall outcome of treatment were excluded from the study.
- Pregnant and lactating women.

STUDY DESIGN:

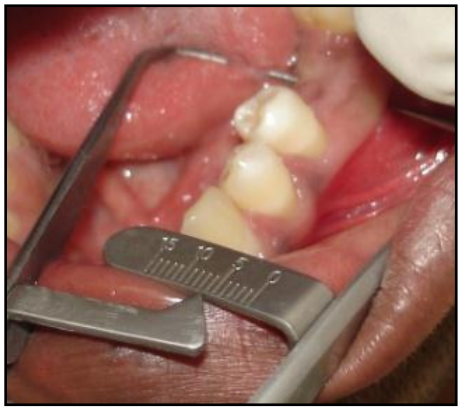
In the present clinical trial, a total of 20 patients (12 M, 8 F) were selected and randomly allocated by toss of a coin to either the flap group or the flapless group. A total of 20 implants were placed, 10 implants in the flapless group and 10 implants in the flap group.

PRE SURGICAL PROTOCOL:

PRE TREATMENT RECORDS:

1. Detailed medical and dental history
2. Periodontal charting
3. Diagnostic casts and models
4. Intra-oral periapical radiographs
5. Clinical photographs
6. Blood Investigations – including Hb%, Total count, Differential count, Bleeding time, Clotting time, Blood glucose level were done to evaluate the fitness of the patient for endosseous implant placement
7. Obtaining written consent from the patient:

   Patients who were enrolled in this study were given adequate instructions on oral hygiene maintenance and its importance on the success of implant therapy. The college Institutional Review board approved this study and an informed written consent was obtained from all the patients in their own language before commencement of the procedure.
8. Radiographs and Bone mapping: Intra-oral periapical radiographs were used to evaluate pre and post operative bone level changes. Radiographs and bone mapping aided in determining the size of the implants.



Bone mapping

9. Pre- surgical oral prophylaxis**:**

   All the subjects in the present clinical study maintained good oral hygiene and were under maintenance therapy. Oral prophylaxis was done 15 days before the planned implant surgery.

CLINICAL PARAMETERS:

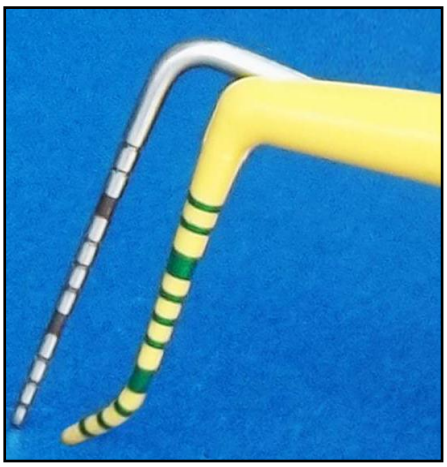
All clinical data regarding soft and hard tissue dimensions were recorded by one independent dental examiner.

SOFT TISSUE MEASUREMENTS:

PERI-IMPLANT PROBING DEPTH:

The peri-implant probing depth is measured using a non-rigid, graduated flexible plastic probe at 6 surfaces of the implant (mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual, distolingual) at three and six

months. The mean probing depth on the buccal and lingual aspect was calculated (one recording on the buccal aspect and one on the lingual aspect).



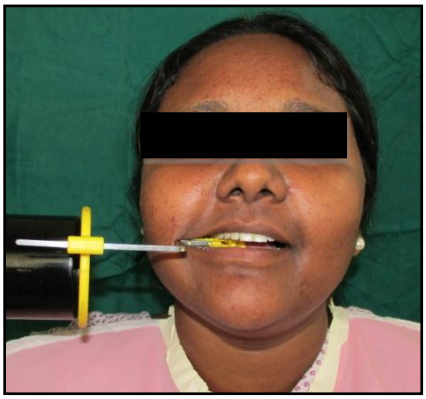
Williams Periodontal probe and Graduated flexible plastic periodontal probe

HARD TISSUE MEASUREMENTS:

RADIOGRAPHIC EVALUATION OF CRESTAL BONE HEIGHT

A series of intra oral periapical radiographs (IOPA) were obtained at the baseline (pre-operative), 3 and 6 months post loading. IOPA's were taken using Long Cone Paralleling technique with PID (Position indicating device, or X-ray cone) to improve the accuracy and reproducibility over different time periods. All the standardized intraoral periapical radiographs were converted into a digital image using an HP image scanner and computer analysis was performed with Image processing software (Image J Analysis) to analyze the radiographic dimensional changes at the crest of the alveolar bone.

The apex of the implant was taken as the fixed reference point to measure the crestal bone height. The distance from the apex of the implant to the crest of bone (on the mesial and distal aspects) where it contacts the implant (BIC- Bone implant contact) was measured using Image J Analysis software. These measurements were calculated on the radiographs taken between baseline (0) - 3months, 3-6months and 0- 6 months and comparison of the same between flap and flapless techniques were evaluated. The dimensional changes were nullified by caliberating the radiographic implant length to the original implant length.



VAS SCALE MEASUREMENTS:

The patients were given instructions on charting of the VAS. Patients were asked to chart their perceptions on pain, swelling and bleeding over the first-week healing period, on days 0 (at night prior to sleeping), 3, 5 and 7 using a VAS with equal units from 0 to 10 (on a line of 10 cm), with 0 designated as no bleeding/ swelling/pain to 10 for severe excruciating pain/ swelling / bleeding.

ARMAMENTARIUM

1. Mouth mirror. (No: 5)
2. William's periodontal probe with marking of 10mm
3. Flexible plastic periodontal probe with marking of 10mm
4. Tweezers
5. Dappen dish
6. Stainless steel bowl
7. Kidney tray
8. Normal physiological saline 500ml bottles (0.9%w/v)
9. Disposable syringes - 2ml, 10ml
10. Stainless steel scale
11. Lignocaine hydrochloride with 1:80000 adrenaline (2%)
12. Bard Parker handle No.3 with Bard Parker Blade No.15
13. Periosteal elevator
14. Bone curette
15. Universal curette
16. Adsons tissue holding forceps
17. Curved Goldman fox scissors
18. Needle holder
19. Suture cutting scissors

20. 3-0 Black braided silk sutures

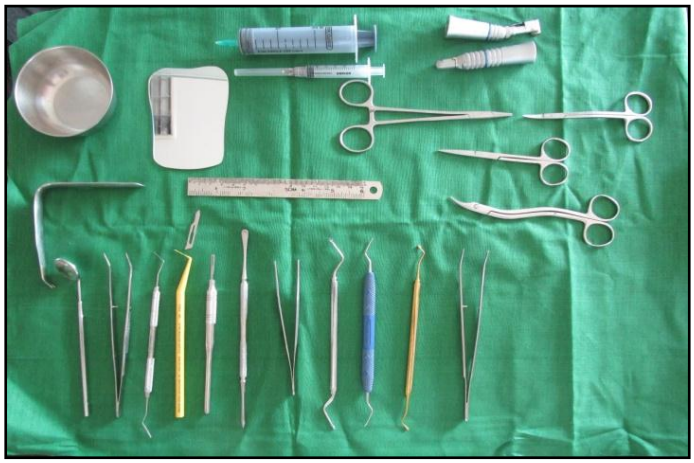
21. 1:16 reduction gear hand piece and physiodispenser

22. Surgical kit and implant drivers

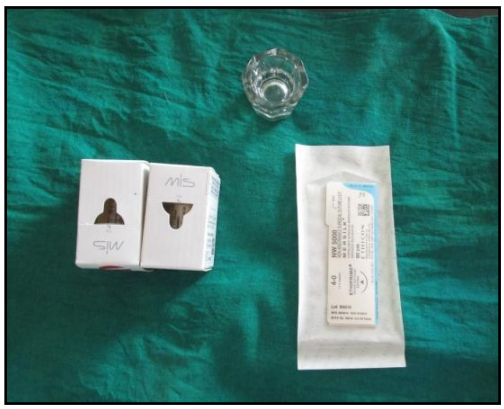
23. Implants (MIS and S1)

24. Healing collars (Height - 2mm)

25. Restorative components



Armamentarium



Implant

Implant Kit

IMPLANT SURGERY:

Standard pre surgical protocol was followed for all patients. The surgical sites were anaesthetized using sub periosteal infiltration using 2% Lignocaine with 1: 80000 adrenaline. Nerve block was avoided to prevent any iatrogenic injury to anatomical landmarks. After the administration of local anaesthesia, the numbness of the site was checked with the blunt end of the periosteal elevator to ensure adequate anesthesia.

FLAPLESS GROUP:

A circular bit of tissue was removed using a tissue punch of 2mm diameter. Osteotomy was performed through cortical bone using a round bur. Incremental drilling with progressively larger drill sizes were used to achieve the desired length and diameter of the osteotomy site. A recommended drill speed of 700-1000rpm was maintained for all drills with a constant supply of copious amount of normal saline. The depth gauge was used intermittently to ensure the required depth. Once the required depth has been achieved, the implant is mounted on a carrier and is then slowly motor driven to its final position. Care was taken to make sure that the implant collar flushes with the crest of the existing alveolar ridge. According to the implant diameter, a healing collar of 2mm height was placed over the implant platform.

FLAP GROUP:

In the flap group, the implant was placed after making a midcrestal incision and raising a full thickness mucoperiosteal flap. Osteotomy was performed through cortical bone using a round bur. Incremental drilling with progressively larger drill sizes were used to achieve the desired length and diameter of the osteotomy site. A recommended drill speed of 700-1000rpm was maintained for all drills with a constant supply of copious amount of normal saline. The depth gauge was used intermittently to ensure the required depth. Once the required depth has been achieved, the implant is mounted on a carrier and is then slowly motor driven to its final position. Care was taken to make sure that the implant collar flushes with the crest of the existing alveolar ridge. Instead of the healing collar, a cover screw was placed over the implant. Tension free primary closure was obtained using 3-0 black braided silk sutures.

Post surgical instructions:

All patients were prescribed broad spectrum antibiotics (Amoxicillin 500mg, thrice daily for 5 days) and anti-inflammatory analgesics (Ibuprofen 400mg or Paracetomol 500mg, thrice daily for 5 days). Immediate post operative assessment was done 24 hours following surgery and the patients were recalled after a week for review. The sutures were removed after 7 days in the flap group. The area was thoroughly irrigated with saline. The site was examined for any infection or presence of wound dehiscence and oral hygiene

instructions were reinforced. All patients were reviewed at one month, three and six months. Patients who underwent endosseous implant placement were followed up and evaluated for plaque and gingival status and oral prophylaxis was performed when required over the study period.

LOADING OF IMPLANT:

A conventional loading protocol was adopted for all the implants placed irrespective of the method of surgical placement. Second stage surgery was done after 3 months of placement in the flap group. Mid crestal incision was placed and flap was reflected to expose the implant collar. Cover screw was removed and a healing collar of height 2mm was placed and the flap was sutured around the healing collar. Healing collar was removed after a period of 15 days and tissue maturation of the gingival cuff examined. No signs of inflammation were noted and the healing collar was removed and a transfer coping was fixed to the implant. An impression was made with elastomeric impression material and the transfer coping was transferred to the impression. An implant analog was attached to the coping and the casts were poured. Then a suitable abutment was attached to the analog and prepared to obtain adequate clearance. A metal ceramic restoration was fabricated over the abutment and the prosthesis was cemented.

In the flapless group, the existing healing collar was removed and the gingival cuff formation was examined. No signs of inflammation were noted. A transfer coping was fixed to the implant. An impression was made with

elastomeric impression material and the transfer coping was transferred to the impression. An implant analog was attached to the coping and the casts were poured. Then a suitable abutment was attached to the analog and prepared to obtain adequate clearance. A metal ceramic restoration was fabricated over the abutment and the prosthesis was cemented.

Patients were reviewed after three and six months and clinical and radiographic parameters were evaluated.

RAGAS DENTAL COLLEGE & HOSPITAL

2/102, EAST COAST ROAD, UTHANDI, CHENNAI-119

Phone: (044) - 2453003-6

DEPARTMENT OF PERIODONTOLOGY

CASE SHEET - ENDOSSEOUS IMPLANTS

Pt Name : **Date :**

Age / Sex: **Op No :**

Address : **Occupation:**

Contact No :

Chief Complaint :

History of Present Illness :

Past Dental History :

Past Medical History :

Family History :

Habits :

CLINICAL EXAMINATION

Missing Tooth :

Oral hygiene: Good / Fair / Poor

PARAMETERS

CLINICAL ASSESMENT	SITE	MB	MB	DB	ML	ML	DL
PERI –IMPLANT PROBING DEPTH							

RADIOGRAPHIC ASSESMENT	SITE	BASE LINE	3 MONTHS	6 MONTHS
CRESTAL BONE LEVEL IN mm	MESIAL			
	DISTAL			

INVESTIGATIONS:

Laboratory:

Blood Glucose:

Hb:

BT:

CT:

Others:

Pre-treatment Evaluation :

B. Radiographic :

Available bone height :

Relation of anatomical Structures :

Pre-treatment Procedure:

Bone Mapping :

Soft tissue thickness :

Bone width 2mm from the crest:

Bone width 4mm from the crest:

Bone width 6mm from the crest:

TREATMENT PLAN:

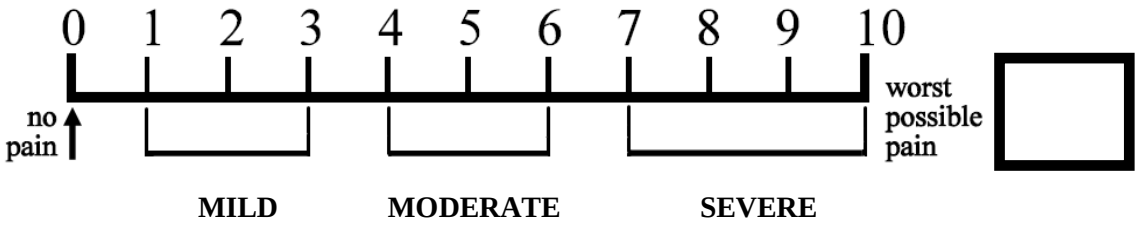
Total no: of implants:

Site of implant placement:

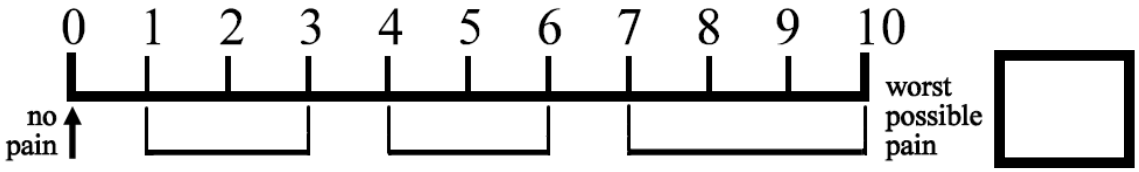
Size and dimension of the implant to be placed:

Any other procedure:

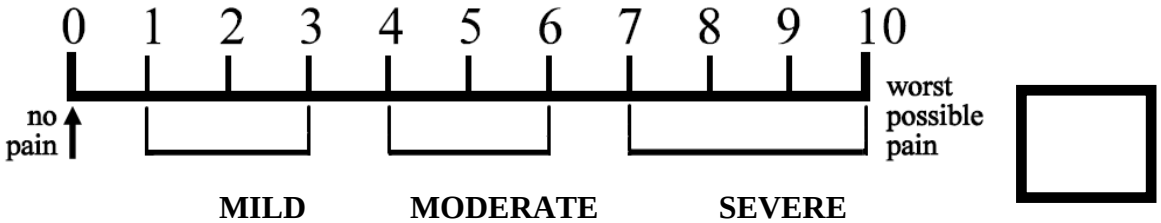
24 HOURS POST OPERATIVE RECORDING OF VISUAL ANALOGUE SCALE



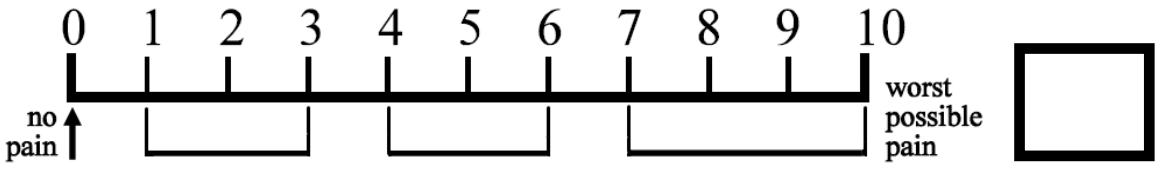
3 DAYS POST OPERATIVE RECORDING OF VISUAL ANALOGUE SCALE



5 DAYS POST OPERATIVE RECORDING OF VISUAL ANALOGUE SCALE



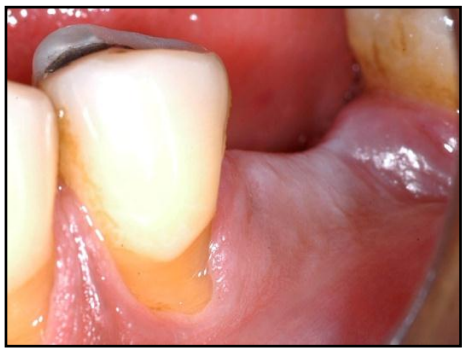
7 DAYS POST OPERATIVE RECORDING OF VISUAL ANALOGUE SCALE



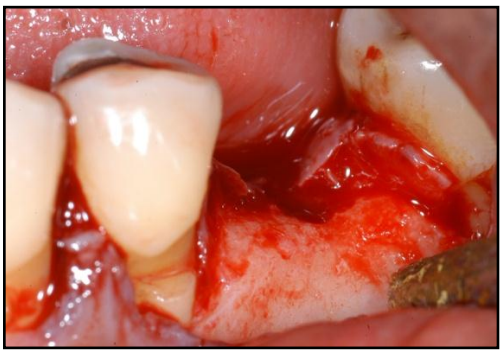
Photographs

IMPLANT PLACEMENT i.r.t 36 BY CONVENTIONAL FLAP SURGERY

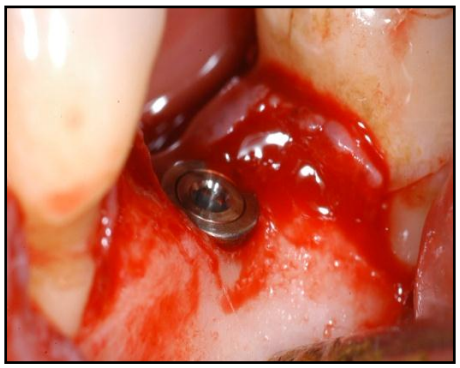
PRE-OPERATIVE



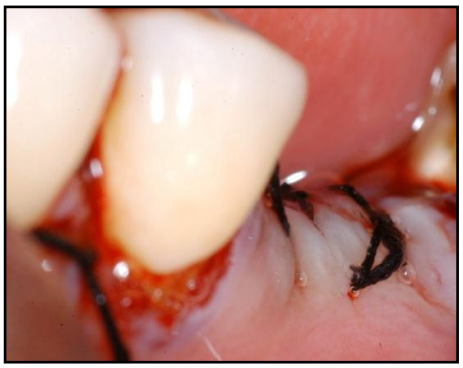
FLAP ELEVATION



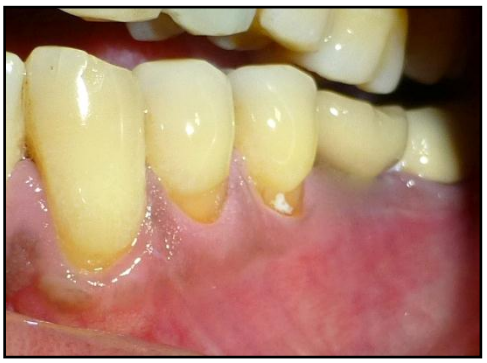
IMPLANT PLACEMENT



SUTURING

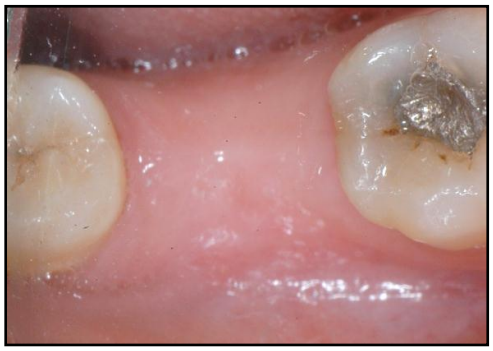


RESTORED 36

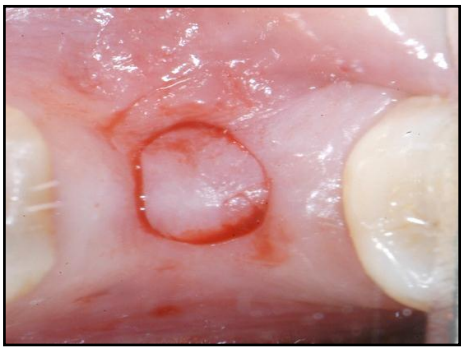


IMPLANT PLACEMENT i.r.t 37 BY FLAPLESS SURGERY

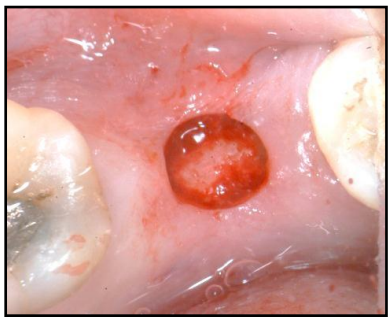
PRE-OPERATIVE



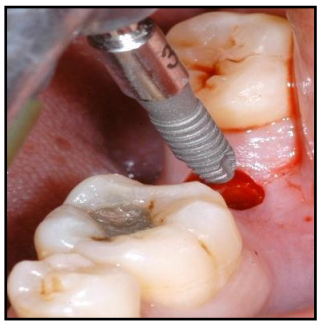
TISSUE PUNCH MADE USING MUCOTOME



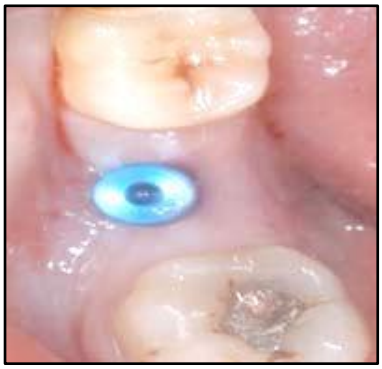
UNDERLYING BONE EXPOSED



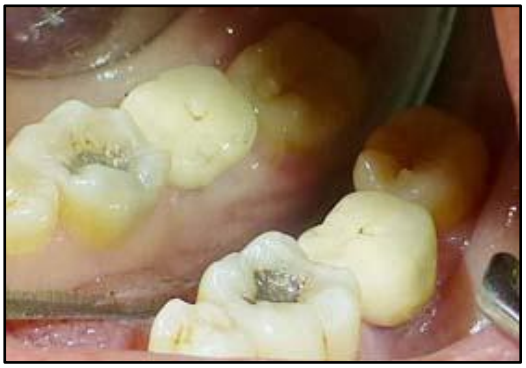
IMPLANT PLACEMENT



HEALING COLLAR PLACED

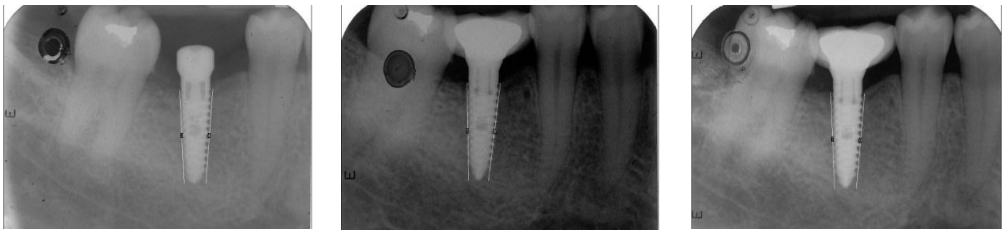


RESTORED 37



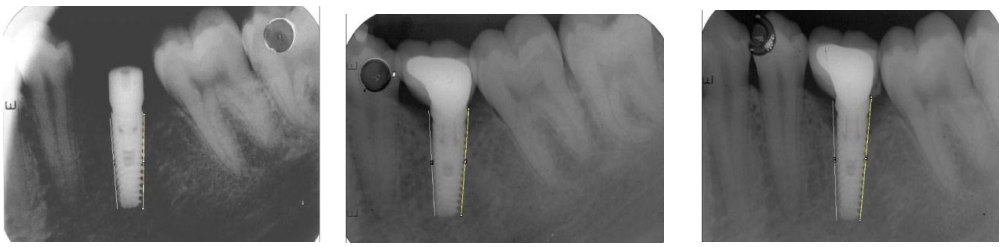
RADIOGRAPHIC EVALUATION - FLAP GROUP
(MESIAL AND DISTAL)

PLACEMENT **3 MONTHS** **6 MONTHS**



RADIOGRAPHIC EVALUATION - FLAPLESS GROUP
(MESIAL AND DISTAL)

PLACEMENT **3 MONTHS** **6 MONTHS**



Results

RESULTS

The present clinical study was undertaken to compare the soft and hard tissue changes around endosseous implants placed in edentulous sites in the posterior mandible using both flap and flapless techniques. The peri-implant probing depth was evaluated at 3 and 6 months. Radiographical assessment included evaluation of the crestal bone changes on mesial and distal side of implant at time intervals of 0–3 months, 3-6 months and 0-6 months. The patient centered outcomes in the two groups were also evaluated using VAS.

Twenty patients were enrolled in the present study (10 in the Flap group and 10 in the flapless group). Patients were randomly assigned to either group and endosseous implants were placed. 18 subjects were followed up throughout the study period. One implant was explanted at 1 month post placement in flap group because of active suppuration at the implant site. One subject in the flapless group did not report during the study period after three months for loading and further management and hence was excluded from the study.

Soft tissue parameters were evaluated at 3 and 6 months, hard tissue parameters were measured at 0-3months, 3-6months and 0-6 months and the VAS was recorded on day 0, day 3, day 5 and day 7 post surgery.

STATISTICAL ANALYSIS

The data was entered into an access database (Microsoft Office, Access 2010®, Reddmond, MA., USA). All analyses were performed using the statistical programme R, version 3.2.1 (R Core Team, 2015). The soft and hard tissue parameters and patient centered outcomes were statistically analysed using Wilcoxon Signed Rank Test and Independent sample t-test. Mean and Standard deviations were estimated from the samples of each study group. Mean values were compared between the groups. *p* value $\leq$ 0.05 was considered as the level of significance.

SOFT TISSUE PARAMETERS:

PERI-IMPLANT PROBING DEPTH:

The mean peri-implant probing depth was calculated on the buccal and lingual aspects in both the flap and flapless groups.

Comparison of mean peri-implant Probing depth at 3 and 6 months on buccal aspect in flap and flapless group

In the present study, the mean peri-implant PD on the buccal aspect in the flap group at 3 months was 1.4mm ± 0.5 and at 6 months was 2.0mm ± 0.7. On statistical analysis, it is found that the mean peri-implant PD on the buccal aspect at 6 months was significantly higher than the mean peri-implant PD at 3 months (*p* value = 0.04). The mean peri-implant PD on the buccal aspect in the flapless group at 3 months was 1.6mm ± 0.5 and at

6 months was 1.4mm ± 0.5. On statistical analysis, it is found that the mean peri-implant PD at 6 months was not significantly higher than the mean peri-implant PD at 3 months (*p* value = 0.99).

Comparison of mean peri-implant Probing depth at 3 and 6 months on lingual aspect in flap and flapless group

The mean peri-implant PD on the lingual aspect in the flap group at 3 months was 1.3mm ± 0.5 and at 6 months was 2.0mm ± 0.7. On statistical analysis, it is found that the mean peri-implant PD at 6 months was significantly higher than the mean peri-implant PD at 3 months (*p* value = 0.02). The mean peri-implant PD on the lingual aspect in the flapless group at 3 months was 1.3mm ± 0.5 and at 6 months was 1.1mm ± 0.3. On statistical analysis, it is found that the mean peri-implant PD at 6 months was not significantly higher than the mean peri-implant PD at 3 months (*p* value = 0.35).

Comparison of mean peri-implant Probing depth at 3 months on buccal and lingual aspect in flap and flapless group

The mean peri-implant PD at 3 months on the buccal aspect in the flap group was 1.44mm ±0.53 while in the flapless group it was 1.56mm ±0.53.The mean peri-implant PD at 3 months on the lingual aspect in the flap group was 1.33mm ±0.50 while in the flapless group it was 1.33mm ±0.50. On statistical analysis, no significant difference was seen in the mean peri-implant

PD between the flap and flapless groups at 3 months on both the buccal and lingual aspects

Comparison of mean peri-implant Probing depth at 6 months on buccal and lingual aspect in flap and flapless group

The mean peri-implant PD at 6 months on the buccal aspect in the flap group was 2.0mm ±0.71 while in the flapless group it was 1.44mm ±0.53.The mean peri-implant PD at 6 months on the lingual aspect in the flap group was 2.0mm ±0.71 while in the flapless group it was 1.11mm ±0.33. On statistical analysis, no significant difference was seen in the mean peri-implant PD between the flap and flapless groups at 6 months on the buccal aspect while a statistically significant difference was noted on the lingual aspect (*p* value = 0.004)

EVALUATION OF HARD TISSUE PARAMETERS

Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 0-3 months

The mean crestal bone level on the mesial aspect in the flap group at 0-3 months was 0.536mm ± 0.20 and in the flapless group it was 0.330mm ± 0.22. The mean crestal bone level on the distal aspect in the flap group at 0-3 months was 0.608mm ± 0.22 and in the flapless group it was 0.324mm ± 0.26. The difference in crestal bone levels between flap and

flapless groups were marginal but the observed difference was statistically significant ($p \leq 0.05$)

Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 3-6 months

The mean crestal bone level on the mesial aspect in the flap group at 3-6 months was 0.431mm ± 0.13 and in the flapless group it was 0.307mm ± 0.15. The mean crestal bone level on the distal aspect in the flap group at 3 – 6 months was 0.383mm ± 0.16 and in the flapless group it was 0.340mm ± 0.18. No significant difference was noted

Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 0-6 months

The mean crestal bone level on the mesial aspect in the flap group at 0-6 months was 0.967mm ± 0.26 and in the flapless group it was 0.636mm ± 0.17. The mean crestal bone level on the distal aspect in the flap group at 0-6 months was 0.948mm ± 0.32 and in the flapless group it was 0.663mm ± 0.17. The difference in crestal bone levels between flap and flapless groups were marginal but the observed difference was statistically significant ($p \leq 0.05$)

EVALUATION OF PATIENT CENTERED OUTCOMES:

VISUAL ANALOGUE SCALE (VAS) SCORES:

The mean VAS score on Day 0 and Day 3 in the flapless and flap groups were compared. On Day 0, the mean VAS score in the flap group was 3.11 ± 1.16 while in the flapless group it was 1.33 ± 0.50. On day 3, the mean VAS score in the flap group was 0.667 ± 0.50 while in the flapless group it was 0.33 ± 0.50. When these values were subjected to statistical analysis, a significant difference was noted with p value ≤ 0.05 on Day 0. The patients perceived lesser pain in the flapless group.

Tables and Graphs

TABLE 1: EDENTULOUS SITE - IMPLANT DIMENSIONS

S NO	SITE OF ENDOSSEOUS IMPLANT PLACEMENT	IMPLANT DIMENSION (mm)
FLAP GROUP		
1	Mandibular left first molar	3.75 x 13
2	Mandibular left second molar	3.75 x 11.5
3	Mandibular left first molar	3.25 x 12
4	Mandibular right first molar	3.75 x 11.5
5	Mandibular left first molar	4 x 10
6	Mandibular right first molar	3.75 x 11.5
7	Mandibular left first molar	3.25 x 12
8	Mandibular left first molar	3.75 x 11.5
9	Mandibular left first molar	3.75 x 13
10	Mandibular right first molar	3.25 x 12
FLAPLESS GROUP		
1	Mandibular left first molar	4.2 x 13
2	Mandibular right second molar	4 x 12
3	Mandibular left second molar	3.25 x 12
4	Mandibular left first molar	4.2 x 11.5
5	Mandibular right first molar	3.75 x 13
6	Mandibular left second molar	4.2 x 11.5
7	Mandibular left first molar	3.75 x 13
8	Mandibular left first molar	4.2 x 11.5
9	Mandibular left first molar	3.75 x 13
10	Mandibular left first molar	3.75 x 11.5

TABLE 2: MEAN PERI-IMPLANT PROBING DEPTH AT THREE AND SIX MONTHS

S.NO	MEAN PROBING DEPTH AT 3 MONTHS (mm)		MEAN PROBING DEPTH AT 6 MONTHS (mm)	
FLAP GROUP	**BUCCAL**	**LINGUAL**	**BUCCAL**	**LINGUAL**
1.	1	1	2	2
2.	2	2	2	3
3.	1	1	2	2
4.	2	2	3	3
5.	2	1	2	2
6.	2	1	3	2
7.	1	2	1	2
8.	1	1	1	1
9.	1	1	2	1
FLAPLESS GROUP				
1.	1	2	1	2
2.	2	1	2	1
3.	1	1	1	1
4.	2	2	2	1
5.	2	2	2	1
6.	2	1	2	1
7.	2	1	1	1
8.	1	1	1	1
9.	1	1	1	1

TABLE 3: RADIOGRAPHIC DIFFERENCE OF MARGINAL BONE LEVELS ON MESIAL AND DISTAL ASPECTS OF IMPLANTS

S.NO	**0 - 3MONTHS (mm)**		**3-6 MONTHS (mm)**		**0-6 MONTHS (mm)**	
FLAP GROUP	M	D	M	D	M	D
1	0.485	0.467	0.548	0.160	1.033	0.627
2	0.541	0.987	0.673	0.430	1.214	1.417
3	0.477	0.782	0.405	0.344	0.882	1.126
4	1.038	0.837	0.439	0.426	1.477	1.263
5	0.538	0.333	0.376	0.420	0.914	0.753
6	0.485	0.474	0.262	0.701	0.747	1.175
7	0.437	0.658	0.521	0.33	0.958	0.988
8	0.487	0.479	0.388	0.175	0.875	0.654
9	0.338	0.459	0.268	0.459	0.606	0.533
FLAPLESS GROUP						
1	0.107	0.025	0.552	0.524	0.659	0.549
2	0.017	0.124	0.387	0.519	0.404	0.643
3	0.554	0.680	0.179	0.173	0.733	0.853
4	0.236	0.037	0.291	0.538	0.527	0.575
5	0.422	0.318	0.154	0.120	0.576	0.438
6	0.432	0.358	0.301	0.173	0.733	0.531
7	0.633	0.766	0.355	0.202	0.988	0.968
8	0.438	0.327	0.094	0.301	0.532	0.628
9	0.128	0.279	0.446	0.507	0.574	0.786

TABLE 4: Comparison of mean peri-implant Probing depth at 6 months on buccal aspect in flap and flapless group - Statistical Analysis

S. No.	Surface	Flap group 6 months	Flapless group 6 months	Statistical test	*p*-value
		Mean (sd)	Mean (sd)		
1	Buccal	2 (0.7)	1.4 (0.5)	WSRT	0.04*

* Statistically significant; $p \leq 0.05$

TABLE 5: Comparison of mean peri-implant Probing depth at 6 months on lingual aspect in flap and flapless group - Statistical Analysis

S. No.	Surface	Flap group 6 months	Flapless group 6 months	Statistical test	*p*-value
		Mean (sd)	Mean (sd)		
1	Lingual	2 (0.7)	1.1 (0.3)	WSRT	0.03*

* Statistically significant; $p \leq 0.05$

TABLE 6: Comparison of mean peri-implant Probing depth at 3 months on buccal and lingual aspect in flap and flapless group - Statistical Analysis

	Groups	N	Mean	Std. Deviation	*p*-value
Buccal	Flap Group	9	1.4444	.52705	0.661
	Flapless Group	9	1.5556	.52705	.
Lingual	Flap Group	9	1.3333	.50000	1.000
	Flapless Group	9	1.3333	.50000	

TABLE 7 : Comparison of mean per-implant Probing depth at 6 months on buccal and lingual aspect in flap and flapless group - Statistical Analysis

	Groups	N	Mean	Std. Deviation	*p*-value
Buccal	Flap Group	9	2.0000	.70711	0.077
	Flapless Group	9	1.4444	.52705	
Lingual	Flap Group	9	2.0000	.70711	0.004*****
	Flapless Group	9	1.1111	.33333	.

* Statistically significant , $p \leq 0.05$

TABLE 8: Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 0-3 months

	Groups	N	Mean	Std. Deviation	*p*-value
Mesial	Flap Group	9	.5362	.19752	0.050*****
	Flapless Group	9	.3297	.21502	
Distal	Flap Group	9	.6084	.21828	0.023*****
	Flapless Group	9	.3238	.25911	

* Statistically significant, $p \leq 0.05$

TABLE 9: Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 3-6 months

	Groups	N	Mean	Std. Deviation	*p*-value
Mesial	Flap Group	9	.4311	.13280	0.078
	Flapless Group	9	.3066	.14727	
Distal	Flap Group	9	.3828	.16188	0.600
	Flapless Group	9	.3397	.17949	

TABLE 10: Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 0-6 months

	Groups	N	Mean	Std. Deviation	*p*-value
Mesial	Flap Group	9	.9673	.25563	0.005*****
	Flapless Group	9	.6362	.16853	
Distal	Flap Group	9	.9484	.31696	0.031*****
	Flapless Group	9	.6634	.17127	

* Statistically significant, $p \leq 0.05$

TABLE 11: VAS Scores at different time intervals

S.NO	VAS SCORE			
	Day 0	**Day 3**	**Day 5**	**Day 7**
FLAP GROUP				
1.	4	1	0	0
2.	3	0	0	0
3.	3	1	0	0
4.	5	1	0	0
5.	3	0	0	0
6.	1	0	0	0
7.	4	1	0	0
8.	3	1	0	0
9.	2	1	0	0

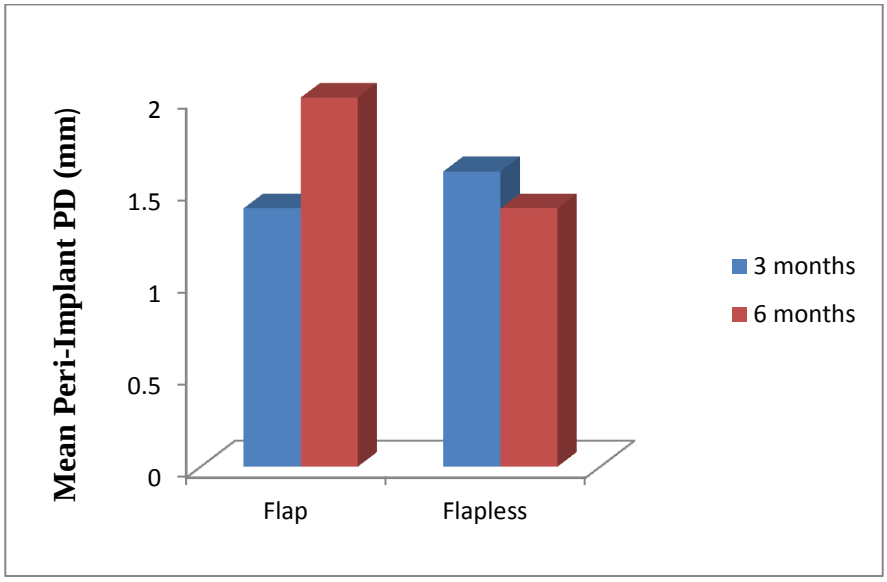
S.NO	VAS SCORE			
	Day 0	**Day 3**	**Day 5**	**Day 7**
FLAPLESS GROUP				
1.	1	0	0	0
2.	1	0	0	0
3.	2	1	0	0
4.	1	0	0	0
5.	1	0	0	0
6.	2	1	0	0
7.	1	0	0	0
8.	1	0	0	0
9.	2	1	0	0

TABLE 12: VAS SCORES - Statistical Analysis

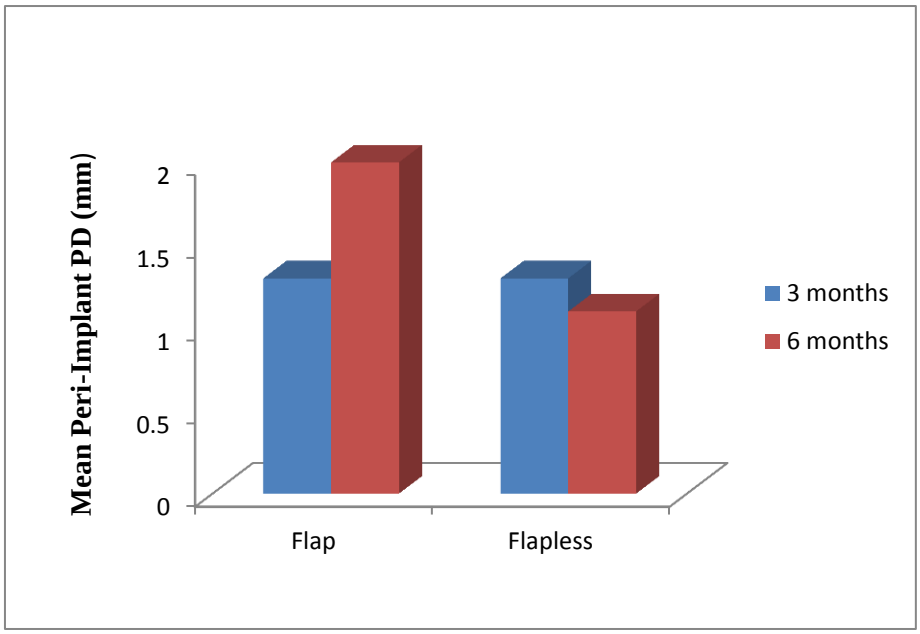
	Group	N	Mean	Std. Deviation	p value
Day 0	Flap	9	3.111	1.167	0.001*
	Flapless	9	1.333	0.500	
Day 3	Flap	9	0.667	0.500	0.180
	Flapless	9	0.333	0.500	

* Statistically significant, $p \leq 0.05$

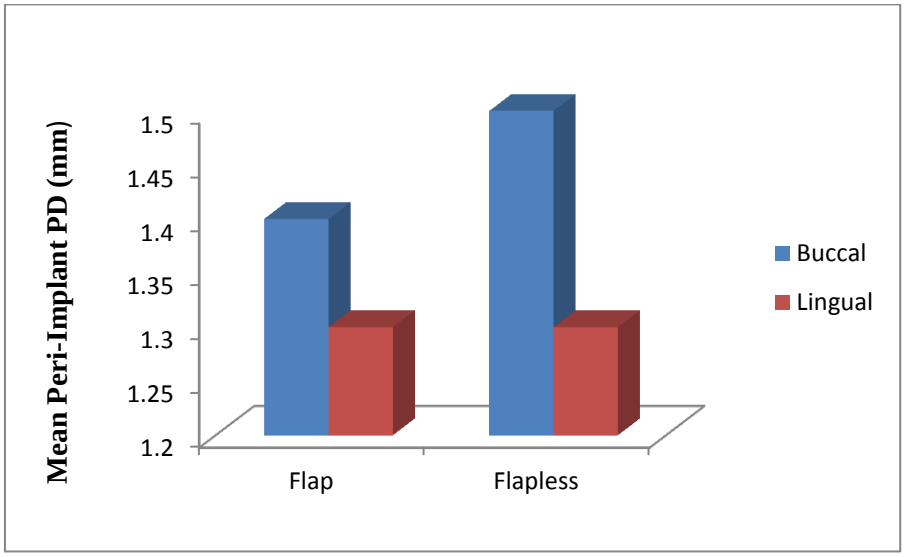
GRAPH 1: Comparison of mean peri-implant PD at 3 and 6 months on buccal aspect in flap and flapless groups



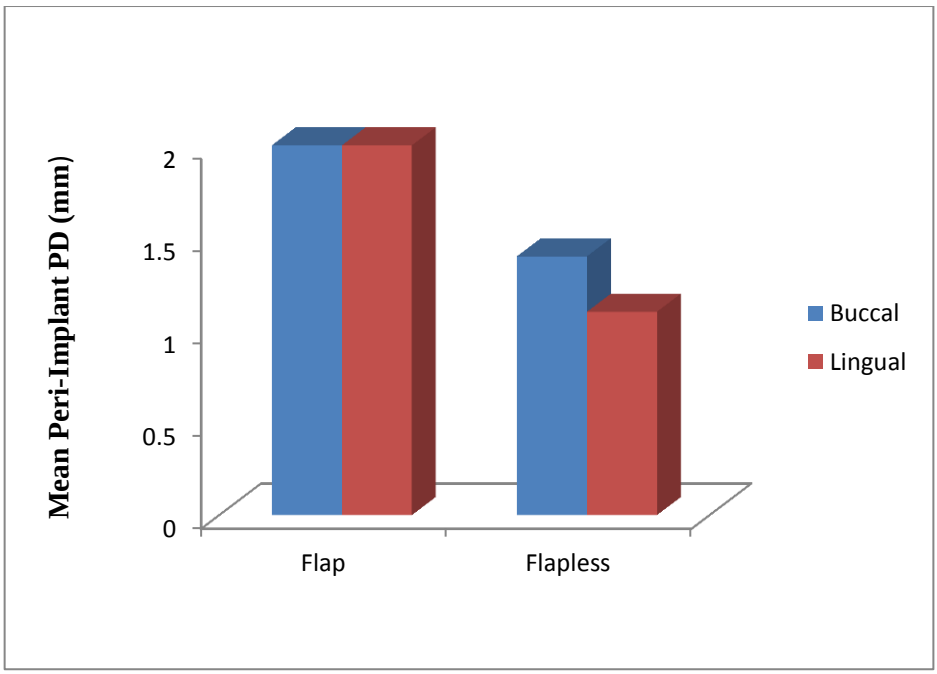
GRAPH 2: Comparison of mean peri-implant PD at 3 and 6 months on lingual aspect in flap and flapless groups



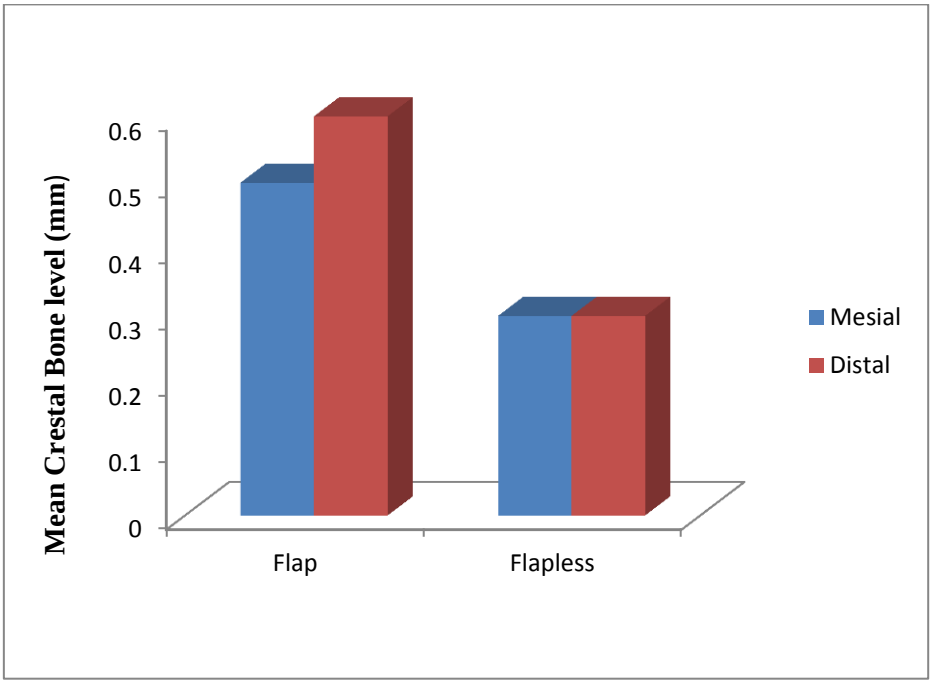
GRAPH 3: Comparison of mean peri-implant PD at 3 months on buccal and lingual aspect in flap and flapless group



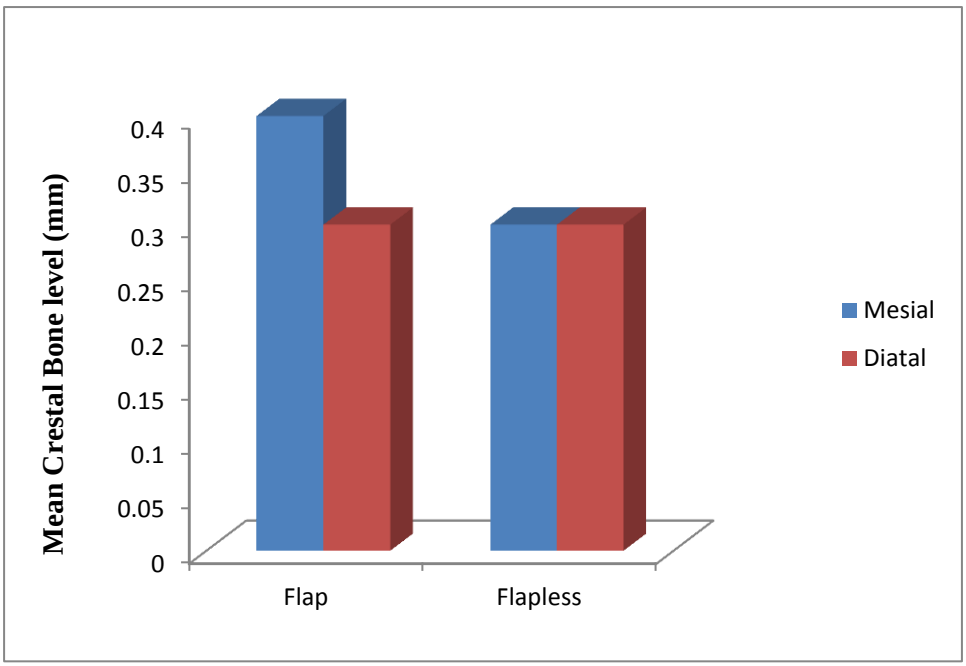
GRAPH 4: Comparison of mean peri-implant PD at 6 months on buccal and lingual aspect in the flap and flapless group



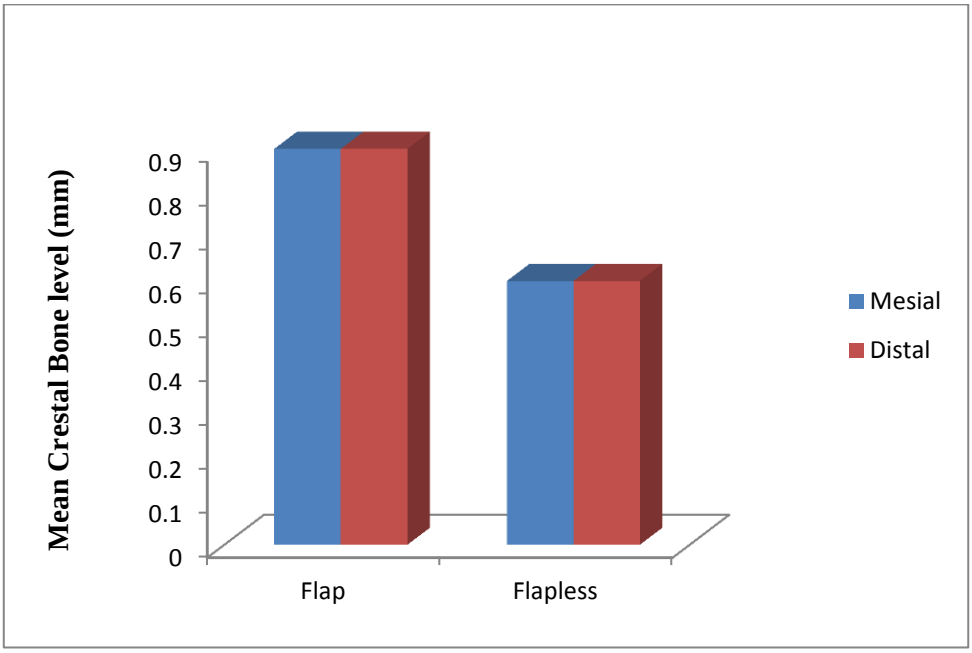
GRAPH 5: Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 0-3 months



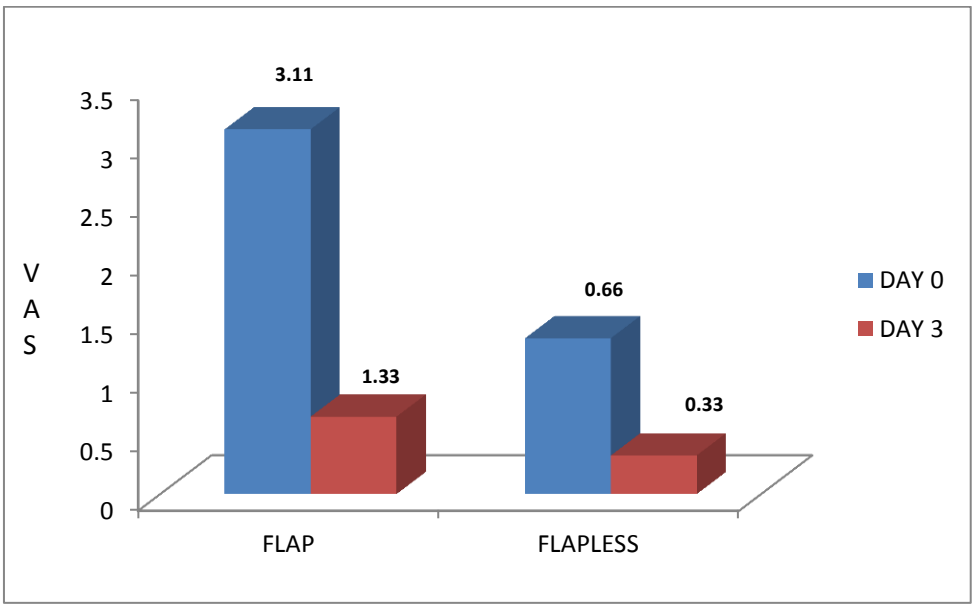
GRAPH 6: Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 3-6 months



GRAPH 7: Comparison of mean crestal bone levels on the mesial and distal aspects in the flap and flapless groups at 0-6 months



Graph 8: Mean VAS Scores on Day 0 and Day 3



Discussion

DISCUSSION

Over the last few decades, the utilization of bone - anchored dental implants has become an established treatment method in the replacement of missing teeth[35]. On comparison with tooth supported fixed dental prosthesis, implant supported restorations provide a better solution as intact tooth structure and supporting tissues can be preserved. Implant supported prostheses have been in vogue for several decades. Ever since the first titanium implant was placed by Branemark in 1965, this mode of treatment has evolved into a treatment of choice for replacing missing teeth.

The standard protocol for placing dental implants has been a two-stage approach. The implant is inserted into the bone and it heals without loading for 3 months in the mandible or for 6 months in the maxilla. In the second stage, the implant is exposed and then loaded with a prosthesis.[3,4] The load-free healing period was suggested to be crucial for implant integration,[57] with the rationale that osseointegration must take place before the implant is loaded in order to minimize the risk of failure.[34,43]

IMPORTANCE OF PERIPHERAL SEAL AND PERI-IMPLANT PROBING

The health and vitality of an osseointegrated implant depends on the surrounding supporting tissues, which not only anchor the implant to the bone but also have the important function of providing a protective seal. For dental

implants, it is vital that an initial soft tissue seal is achieved as this helps to stabilize and preserve the peri-implant tissues during the restorative stages following placement. This biologic soft-tissue seal with the implant is critical to ensure the long-term prognosis of dental implants.[23] Bacterial invasion of the transmucosal region leads to the progressive destruction of the peri-implant tissues and their subsequent failure (Mombelli, 1999), indicating that effective protection of the peri-implant mucosa is mandatory (Pontoriero et al., 1994; Tonetti & Schmid, 1994) .

Warrer et al[89] demonstrated that implants surrounded by non-keratinized mucosa may exhibit more crestal bone loss and mucosal recession, when compared to implants surrounded by a keratinized mucosa, under similar levels of plaque accumulation. Similar observation was also demonstrated by Strub et al.[81] Mucosal inflammation and plaque accumulation were significantly higher around implants with KM < 2 mm (Chung et al. 2006). It has also been shown that increased width of KM is associated with lower alveolar bone loss (Bouri et al. 2008).

Peri-implant probing provides an assessment of different parameters such as bleeding on probing and suppuration from the sulcus and peri-implant tissues.[5] Clinical probing depth is higher around implants versus teeth, as the probe tip ends apically to the junctional epithelium into the connective tissue close to the bone crest.[60] The soft tissue cuff around an implant in a canine model has been shown to be about 3-3.5mm regardless of system and the

connective tissue attachment of 1-1.5mm.[1] Therefore, generally successful implants allow the probe to penetrate approximately 3mm.[61]

In the present study, the mean peri-implant PD on the buccal aspect in the flap group at 3 months was 1.4mm ± 0.5 and at 6 months was 2.0mm ± 0.7. On statistical analysis, it is found that the mean peri-implant PD at 6 months was significantly higher than the mean peri-implant PD at 3 months (*p* value = 0.04). The mean peri-implant PD on the buccal aspect in the flapless group at 3 months was 1.6mm ± 0.5 and at 6 months was 1.4mm ± 0.5. On statistical analysis, it was found that the mean peri-implant PD at 6 months was not significantly higher than the mean peri-implant PD at 3 months (*p* value = 0.99) (Table 4). From this it can be inferred that there was a significant change in the mean peri-implant PD in the flap group at 6 months while the flapless group did not show a significant change.

In the present study, the mean peri-implant PD on the lingual aspect in the flap group at 3 months was 1.3mm ± 0.5 and at 6 months was 2.0mm ± 0.7. On statistical analysis, it was found that the mean peri-implant PD at 6 months was significantly higher than the mean peri-implant PD at 3 months (*p* value = 0.02). The mean peri-implant PD on the lingual aspect in the flapless group at 3 months was 1.3mm ± 0.5 and at 6 months was 1.1mm ± 0.3. On statistical analysis, it was found that the mean peri-implant PD at 6 months was not significantly higher than the mean peri-implant PD at 3 months (*p* value = 0.35) (Table 5). From this it can be inferred that there was

a significant change in the mean peri-implant PD in the flap group at 6 months while the flapless group does not show a significant change.

These results comply with the finding that the initial maturation and stabilization of the peri-implant mucosa occurs within the first 6 weeks after implantation[17.] Thereby the flapless group showed more stable peri-implant PD over the time period and it was also lesser when compared to the flap group. The results of this study were found to be consistent with that of authors such as **Tsoukaki et al**[83] and **You et al.**[95]

The mean peri-implant PD at 3 months on the buccal aspect in the flap group was 1.44mm ±0.53 while in the flapless group it was 1.56mm ±0.53. The mean peri-implant PD at 3 months on the lingual aspect in the flap group was 1.33mm ±0.50 while in the flapless group it was 1.33mm ±0.50. On statistical analysis, no significant difference was seen in the mean peri-implant PD between the flap and flapless groups at 3 months on both the buccal and lingual aspects (Table 6).

The mean peri-implant PD at 6 months on the buccal aspect in the flap group was 2.0mm ±0.71 while in the flapless group it was 1.44mm ±0.53.The mean peri-implant PD at 6 months on the lingual aspect in the flap group was 2.0mm ±0.71 while in the flapless group it was 1.11mm ±0.33. On statistical analysis, no significant difference was seen in the mean peri-implant PD between the flap and flapless groups at 6 months on the buccal aspect while a

statistically significant difference was noted on the lingual aspect (*p* value = 0.004) (Table 7).

The results in table 7 could be reflective of the marginal tissue discrepancy between the buccal and lingual aspects on flap elevation. The statistical significance noted on the lingual aspect was however within the limits of healthy peri-implant probing.[61]

SURGICAL TECHNIQUES FOR PLACEMENT

Direct vision of the crestal bone is always of immense help in deciding the location and angulation of the implants. The elevation of a mucoperiosteal flap provides the operator with better accessibility and visibility of the surgical site. Elevating a flap is considered more advantageous when the esthetic appearance of the soft tissue is critical as the soft tissues can be manipulated and placed in the desirable position.[20] It can also reduce the risk of bone fenestrations or perforations.[68] Following implantation, during the initial phase of healing, bone resorption of varying degrees almost always occurs in the crestal area of the alveolar bone.

An alternative technique for implant placement is one without raising the flap. Flapless surgery can be done either by removing a circular bit of soft tissue or directly drilling through the soft tissue.[20,24] Since the mucoperiosteal flap is not elevated, it results in lesser intra-operative bleeding, post-operative swelling and discomfort.[36] Since the periosteum is not reflected, it maintains

better blood supply to the site reducing the amount of bone resorption.[24] In addition flapless surgery maintains the soft tissue architecture and decreases duration of surgery.

CRESTAL BONE LEVEL CHANGES

Many authors have compared the alveolar bone level changes around implants placed using flap and flapless techniques. It has been concluded in several systematic reviews and meta-analysis that marginal bone loss seen around implants placed using flapless intervention was comparable with the flap surgery approach.[26,54,87] ***Cecchinato et al***[25] evaluated bone level alterations around implants placed with flap surgery and a bone loss ranging from 0.06 to 0.57mm was observed over a period of 24 months.

However, some authors have shown that flapless implant placement yielded improved clinical, radiographic, and immunological outcomes compared with flapped implantation.[83]

The mean crestal bone level on the mesial aspect in the flap group at 0-3 months was 0.536mm ± 0.20 and in the flapless group it was 0.330mm ± 0.22. The mean crestal bone level on the distal aspect in the flap group at 0-3months was 0.608mm ± 0.22 and in the flapless group it was 0.324mm ± 0.26. The difference in crestal bone levels between flap and flapless groups were marginal but the observed difference was statistically significant ($p \leq 0.05$) (Table 8).

The mean crestal bone level on the mesial aspect in the flap group at 3-6 months was 0.431mm ± 0.13 and in the flapless group it was 0.307mm ± 0.15. The mean crestal bone level on the distal aspect in the flap group at 3 – 6 months was 0.383mm ± 0.16 and in the flapless group it was 0.340mm ± 0.18. No significant difference was noted (Table 9).

The mean crestal bone level on the mesial aspect in the flap group at 0-6 months was 0.967mm ± 0.26 and in the flapless group it was 0.636mm ± 0.17. The mean crestal bone level on the distal aspect in the flap group at 0-6 months was 0.948mm ± 0.32 and in the flapless group it was 0.663mm ± 0.17. The difference in crestal bone levels between flap and flapless groups were marginal but the observed difference was statistically significant ($p < 0.05$) (Table 10).

The crestal bone level as measured in this study can be used as a reasonably sensitive indictaor of changes that occur in the crest of the alveolar bone following implant placement. Hence it is found that the flapless technique results in lesser crestal bone resorption compared to flap technique. This result is in accordance to the finding that leaving the periosteum intact on the buccal and lingual aspects of the alveolar ridge in the flapless technique helps maintains a better blood supply to the site, thereby reducing the likelihood of resorption.[6] However it is to be noted that margin of difference in the bone levels in both groups is very small to be clinically significant. According to Albrektsson's criteria for a successful implant the crestal bone

loss should be lower than 1.5mm during the first year after loading and 0.2 mm annually thereafter. From the present study it is inferred that though both groups showed minimal bone loss during the study period, all the implants were osseointegrated and functionally stable after loading.

Therefore, the change in crestal bone height is inevitable in both flap and flapless techniques.

VAS SCORES

VAS scores appear to be valid tools that were used to assess dental pain perception.[79] The present study also investigated the implantation associated pain from the patients' perspective using a VAS questionnaire. The pain reports were on the lower end of the pain scale for both surgical approaches. However, patients in the flap group had a mean pain score of 3.11 ± 1.16 on Day 0 and 0.667 ± 0.50 on Day 3 while the flapless group had a mean score of 1.33 ± 0.50 on Day 0 and 0.33 ± 0.50 on Day 3. The results on Day 0 were found to be statistically significant (p = 0.001). Thus it can be concluded that the patients in the flap group experienced statistically significant more pain compared with the flapless group on Day 0. The pain pattern in the flapped group showed a statistically significant increase on Day 0 followed by a remarkable decrease on Day 3, 5 and 7, whereas in the flapless group the pain gradually decreased during the first postsurgical week.

Al-Khabbaz et al [10] also reported significantly higher mean pain scores on the first day after implantation probably because of the local postsurgical inflammatory reaction. ***Campelo and Camara*** [20] have concluded from their retrospective study on flapless implants that patients did not need any pain management and the procedure was characterized as totally painless. Similar findings were shown in studies by ***Fortin et al*** [36] ***and Nkenke E et al***[63] who compared pain levels between flapped and flapless implants.

LIMITATIONS OF THE STUDY

Some of the limitations of the present clinical study which might have a significant impact on the results obtained include:

1) Small sample size.

2) Relatively short observation period.

3) Only radiographic assessment of osseointergration was carried out.

4) Two dimensional radiography (intra-oral periapical radiographs) was used to assess the hard tissue changes.

FUTURISTIC RESEARCH OPTIONS:

The patients who participated in the present study should be followed up over a longer time period to determine the survival and success rate of the implants and to assess the stability of the soft and hard tissues post loading. Further longitudinal studies with a larger sample size are needed to confirm

the results. Advanced radiographic aids and histomorphometric analysis should be employed to assess the changes in the hard tissue parameters over a period of time. Primary stability and osseointegration should be assessed using sophisticated measuring devices to validate the results. Immunological and microbiological parameters can also be assessed to gain a better perspective of the peri-implant changes and assess the annual bone loss in both the groups after loading and also assess the longevity of the implant.

Summary and Conclusion

SUMMARY AND CONCLUSION

The aim of the study was to compare and evaluate the soft and hard tissue changes around endosseous implants placed using flap and flapless surgery in mandibular posterior edentulous sites over a period of time (6 months).

20 patients were selected from the out-patient, Department of Periodontics of Ragas Dental College and Hospital, Chennai for endosseous implant placement. A total of 20 implants were placed, 10 by flap method and 10 by flapless method. Clinical and radiographic assessment was done at baseline, 3 months and 6 months. Patient centered outcomes were recorded by means of VAS. In the present study out of 20 subjects, 18 subjects were followed up throughout the study period. One implant was explanted at 1 month post placement in flap group because of active suppuration at the implant site. One subject in the flapless group did not report during the study period after three months for loading and further management and hence was excluded from the study.

Within the limits of the present study the following conclusions were drawn after analysis of the results:

- ✓ On intra group comparison, the mean peri-implant PD in the flap group on the buccal and lingual aspect at 6 months was significantly higher than the mean peri-implant PD at 3 months. The mean peri-implant PD

in the flapless group on the buccal and lingual aspect at 6 months did not show a significant change.

- ✓ On intergroup comparison, no significant difference was seen in the mean peri-implant PD between the flap and flapless groups at 3 months on both the buccal and lingual aspects.
- ✓ On intergroup comparison, no significant difference was seen in the mean peri-implant PD between the flap and flapless groups at 6 months on the buccal aspect while a statistically significant difference was noted on the lingual aspect.
- ✓ The difference in mean crestal bone levels between flap and flapless groups in the time period of 0-3 months were marginal but statistically significant with the flapless group showing lesser resorption.
- ✓ No significant difference was seen in the mean crestal bone levels between flap and flapless groups in the time period of 3-6 months.
- ✓ The difference in the mean crestal bone levels between flap and flapless groups in the time period of 0-6 months were marginal but statistically significant with the flapless group showing lesser resorption.
- ✓ The mean VAS Score on Day 0 in the flap and flapless group was statistically significant. The flapless group showed significantly lesser pain when compared to the flap group.

In conclusion, the flapless technique of endosseous implant placement yielded improved soft and hard tissue and patient centered outcomes in comparison with conventional flap technique of implantation.

Bibliography

BIBLIOGRAPHY

1. **Abrahamsson I, Berglundh T, Wennströmm J, Lindhe J**. The periimplant hard and soft tissue characteristics at different implant systems. A comparative study in the dog. Clin Oral Implants Res 1996;7:212-219.
2. **Adell R, Eriksson B, Lekholm U, Branemark PI, Jemt T.** Long-term follow-up study of osseointegrated implants in the treatment of totally edentulous jaws. Int J Oral Maxillofac Implants 1990; 5:347-59.
3. **Adell R, Lekholm U, Rockler B, Branemark PI.** A 15-year study of osseointegrated implants in the treatment of the edentulous jaw. Int J Oral Surg1981; 10:387-416.
4. **Aires I, Berger J.** Simultaneous immediate placement and immediate loading of implants in the maxilla: A case presentation. J Calif Dent Assoc 2002;30:227–232.
5. **Akagawa Y, Takata T, Matsumoto T.** Correlation between clinical and histological evaluations of the peri-implant gingiva around the single-crystal sapphire endosseous implant. *J Oral Rehabil*. 1989;16(6):581-587
6. **Al-Ansari BH, Morris RR.** Placement of dental implants without flap surgery. A clinical report. Int J Oral Maxillofac Implants 1998;13; 861-865.

7. **Albrektsson T, Branemark PI, Hansson HA.** Osseointegrated titanium implants. Requirements for ensuring a long-lasting, direct bone-to-implant anchorage in man. *Acta Orthop Scand* 1981;52: 155-170.
8. **Albrektsson T, Zarb G, Worthington P, Eriksson AR.** The long-term efficacy of currently used dental implants: A review and proposed criteria of success. Int J Oral Maxillofac Implants. 1986;1:11–25.
9. **AL-Dwairi ZN.** Partial edentulism and removable denture construction: a frequency study in Jordanians. Eur J Prosthodon Restor Dent. 2006;14 (1):13-17.
10. **Al-Khabbaz, A.K., Griffin, T.J. & Al-Shammari, K.F.** Assessment of pain associated with the surgical placement of dental implants. Journal of Periodontology. 2007, 78: 239–246.
11. **Arisan V, Karabuda CZ, Ozdemir T.** Implant surgery using bone- and mucosa-supported stereolithographic guides in totally edentulous jaws: surgical and post-operative outcomes of computer-aided Vs. standard techniques. Clin Oral Implants Res 2010; 21: 980–988.
12. **Bashutski JD, Wang HL, Rudek I, Moreno I, Koticha T, Oh TJ.** The effect of flapless surgery on single tooth implants in the esthetic zone : a randomized clinical trial. J Periodontol.2013 ;84:1747-1754.
13. **Becker W, Becker BE, Alsuwyed A, Al-Mubarak S.** Long-term evaluation of 282 implants in maxillary and mandibular molar

positions: a prospective study. Journal of periodontology. 1999 Aug 1;70(8):896-901.

14. **Becker W, Goldstein M, Becker BE, Sennerby L, Kois D, Hujoel P.** Minimally invasive flapless implant surgery: A prospective multicenter study. Clin Implant Dent Relat Res 2005;7(suppl 1): S21–27.
15. **Becker W, Goldstein M, Becker BE, Sennerby L, Kois D, Hujoel P.** Minimally invasive flapless implant placement: Follow-up results from a multicenter study. J Periodontol 2009;80(2):347–352.
16. **Becker W, Wikesjö UM, Sennerby L, Qahash M, Hujoel P, Goldstein M.** Histologic Evaluation of Implants Following Flapless and Flapped Surgery: A Study in Canines. J Periodontol 2006;77: 1717-22.
17. **Berglundh, T., Abrahamsson, I., Welander, M., Lang, N.P. & Lindhe, J.** Morphogenesis of the peri-implant mucosa: an experimental study in dogs. Clinical Oral Implants Research 2007 ; 18: 1–8.
18. **Branemark PI, Hansson BO, Adell R**. Osseointegrated implants in the treatment of the edentulous jaw. Experience from a 10-year period. *Scand J Plast Reconstr Surg Suppl* 1977;16:1-132.
19. **Brodala N.** flapless surgery & its effect on dental implant outcomes. Int J Oral Maxillofacial Implants 2009;24:118- 125.

20. **Campelo LD, Camara JR**. Flapless implant surgery: A 10-year clinical retrospective analysis. Int J Oral Maxillofac Implants 2002;17(2):271–276.
21. **Cannizaro G, Felice P, Leone M, Checchi V, Esposito M.** Flapless versus open flap implant surgery in partially edentulous patients subjected to immediate loading: 1 year results from a split-mouth randomized controlled trial. Eur J Oral Implantol.2011 Autumn;4(3):177-88.
22. **Cannizzaro G, Leone M, Consolo U, Ferri V, Esposito M.** Immediate functonal loading of implants placed with flapless surgery versus conventional implants in partially edentulous patients : A 3 - year randomized controlled clinical trial . Int J Oral Maxillofac Implants 2008;23:867-75.
23. **Carmichael R, Apse P, Zarb G, McCulloch C.** Biological, microbiological and clinical aspects of the pre-implant mucosa. In: Albrektsson T, Zarb G, eds. The Bra˚nemark Osseointergrated Implant. Chicago: Quintessence; 1989:39-78.
24. **Casap N, Tarazi E, Wexler A, Sonnefield U.** Intraoperative computerized navigation for flapless implant surgery and immediate loading in edentulous mandible. Int J Oral Maxillofac Implants 2005;20:92-98.

25. **Cecchinato D, Olsson C, Lindhe J.** Submerged or non-submerged healing of endosseous implants to be used in the rehabilitation of partially dentate patients. J Clin Periodontology 2004;31:299-308.
26. **Chrcanovic BR, Albrektsson T, Wennerberg A**. Flapless versus Conventional Flapped Dental Implant Surgery: A Meta-Analysis. PLoS ONE 2014; 9(6):e100624.
27. **Cochran DL, Morton D, Weber HP.** Consensus statements and recommended clinical procedures regarding loading protocols for endosseous dental implants. The International journal of oral & maxillofacial implants. 2004;19 Suppl:109–113.
28. **Davis DM, Fiske J, Scott B, Radford DR.** The emotional effects of tooth loss in a group of partially dentate people: a quantitative study. Eur J Prosthodont Restor Dent 2001 Jun;9(2):53-57.
29. **De Bruyn, H., Atashkadeh, M., Cosyn, J. and van de Velde, T**. Clinical Outcome and Bone Preservation of Single TiUnite™ Implants Installed with Flapless or Flap Surgery. Clinical Implant Dentistry and Related Research 2011; 13: 175–183.
30. **Degidi M, Piattelli A.** Comparative analysis study of 702 dental implants subjected to immediate functional loading and immediate nonfunctional loading to traditional healing periods with a follow-up of up to 24 months. The Journal of Prosthetic Dentistry. 2005 Aug 31;94(2):203.

31. **Ekelund JA, Lindquist LW, Carlsson GE, Jemt T.** Implant treatment in the edentulous mandible: a prospective study on Branemark system implants over more than 20 years. Int J Prosthodont 2003; 16:602-8.
32. **Enoki K, Ikebe K, Hazeyama T, Ishida K, Matsuda K.I, Maeda Y.** Incidence of partial denture usage and Kennedy classification. JPD. 1992;67(5):664-7.
33. **Esposito M, Murray-Curtis L, Grusovin MG, Coulthard P, Worthington HV.** Interventions for replacing missing teeth: different types of dental implants. The Cochrane Library. 2007 Jan 1.
34. **Esposito M, Worthington HV, Coulthard P.** Interventions for replacing missing teeth: Different times for loading dental implants. Cochrane Database Syst Rev 2003;1:CD003878.
35. **Fischer K, Sternberg T.** Three year data from a randomized controlled study of early loading of single- stage dental implants supporting maxillary full arch prostheses. Int J Oral Maxillofac Implants 2006;21:245-52.
36. **Fortin T, Bosson JL, Isidori M, Blanchet E.** Effect of flapless surgery on pain experienced in implant placement using an image guided system. Int J Oral Maxillofac Implants 2006; 21:298-304.
37. **Froum SJ, Romanos G, Natour M, Neri D.** Survival rate of onepiece dental implants placed with a flapless or flap protocol — A

randomized, controlled study: 12-month results. Int J Periodontics Restorative Dent 2011;31:591-601.

38. **Gotfredsen K, Berglundh T, Lindhe J.** Bone reactions to titanium implants with different surface characteristics subjected to static load. A study in the dog (II). Clin Oral Implants Res. 2001; 12: 196-201.
39. **Hebel K, Gajjar R, Hofstede T.** Single-tooth replacement: bridge vs. implant-supported restoration. Journal (Canadian Dental Association). 2000 Sep;66(8):435-8.
40. **Hermann JS, Schoolfield JD, Nummikoski PV, Buser D, Schenk RK**. Crestal bone changes around titanium implants: A methodologic study comparing linear radiographic with histometric measurements . Int J Oral Maxillofac Implants 2001; 16:475-85.
41. **Herrmann, I., Lekholm, U., Holm, S. & Kultje, C.** Evaluation of patient and implant characteristics as potential prognostic factors for oral implant failures. International Journal of Oral & Maxillofacial Implants 2005; 20: 220–230.
42. **Hoshaw SJ, Brunski JB, Cochran GVB.** Mechanical loading of Branemark implants affects interfacial modeling and remodeling. Int J Oral Maxillofac Implants. 1994; 9: 345-360.
43. **Hruska A, Borelli P, Bordanaro AC, Marzaduri E, Hruska KL.** Immediate loading implants: A clinical report of 1301 implants. J Oral Implantol 2002;28:200–209.

44. **Iyer S, Weiss C, Mehta A.** Effects of drill speed on heat production and the rate and quality of bone formation in dental implant osteotomies. Part I: Relationship between drill speed and heat production. Int J Prosthodont 1997;10:411–414.

45. **Jeong S, Choi B, Li J, Kim H, Ko C.** Flapless implant surgery, an experimental study. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2007;104:24-8.

46. **Job S, Bhat V, Naidu EM.** In vivo evaluation of crestal bone heights following implant placement with 'flapless' and 'flap' techniques in sites of immediately loaded implants. Indian J Dent Res. 2008 Oct-Dec;19(4) : 320-5.

47. **Kawahara H, Kawahara D, Hashimoto K, Takashima Y, Ong J. L.** Morphologic studies on the biologic seal of titanium dental implants. Report I. *In vitro* study on the epithelialization mechanism around the dental implant. Int. J. Oral Maxillofac. Implants 1998 ; 13, 457–464.

48. **Kim JI, Choi BH, Li J, Xuan F, Jeong SM.** Blood vessels of the peri-implant mucosa: a comparison between flap and flapless procedures. Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology. 2009 Apr 30;107(4):508-12.

49. **Kinsel RP, Lamb RE.** Development of gingival esthetics in the edentulous patient with immediately loaded, single stage, implant

supported fixed prosthesis: A clinical report. Int J Oral Maxillofac Implants 2000; 15: 711-21.

50. **Laney WR, Jemt T, Harris D, Henry PJ, Krogh PH, Polizzi, G.** Osseointegrated implants for single-tooth replacement: progress report from a multicenter prospective study after 3 years. *Int J Oral Maxillofac Implants* 1994; 9:49-54.
51. **Lazić Z, Golubović M, Marković A, Šćepanović M, Mišić T, Vlahović Z.** Immunohistochemical analysis of blood vessels in peri-implant mucosa: a comparison between mini-incision flapless and flap surgeries in domestic pigs. Clin. Oral Impl. Res. 26, 2015, 775–779.
52. **Lekholm U, Gunne J, Henry P, Higuchi K, Linden U, Bergstrom C.** Survival of the Branemark implant in partially edentulous jaws: a 10-year prospective multicenter study. *Int J Oral Maxillofac Implants* 1999; 14:639-45.
53. **Levine RA, Clem D, Beagle J, Ganeles J, Johnson P, Solnit G.** Multicenter retrospective analysis of the solid-screw ITI implant forposterior single-tooth replacements. Int J Oral Maxillofac Implants. 2002; 17: 550–556.
54. **Lin GH, Chan HL, Bashutski JD, Oh TJ, Wang HL.** The effect of flapless surgery on implant survival and marginal bone level: a systematic review and meta-analysis. *J Periodontol* 2014;85:e91-103.
55. **Lindeboom JA, Van Wijk AJ.** A comparison of two implant techniques on patient-based outcome measures: A report of flapless vs.

conventional flapped implant placement. Clin Oral Implants Res 2010;21: 366-370.

56. **Lindquist, L. W., Carlsson, G. E. and Jemt, T.** A prospective 15-year follow-up study of mandibular fixed prostheses supported by osseointegrated implants. Clinical results and marginal bone loss ; Clinical Oral Implants Research 1996; 7: 329–336.
57. **Lorenzoni M, Pertl C, Zhang K, Wimmer G, Wegscheider WA.** Immediate loading of single tooth implants in the anterior maxilla. Preliminary results after one year. Clin Oral Implants Res 2003;14:180–187.
58. **McKinney R, James RA.** Tissues surrounding dental implants. In Misch CE, Contemporary implant dentistry, St Louis, Mosby 1993:369-86.
59. **Misch CE, Bidez MW, Sharawy M.** A bioengineered implant for a predetermined bone cellular response to loading forces. A literature review. J Periodontol. 2001; 72: 1276-1286.
60. **Mombelli A, Lang NP.** Clinical parameters for evaluation of dental implants. *Periodontol 2000*. 1994;4:81-86.
61. **Mombelli A, Lang NP.** The diagnosis and treatment of periimplantitis. Periodontol 2000, 1998; 17:63-76.
62. **Nevins M, Langer B.** The successful application of osseointegrated implants to the posterior jaw: a long-term retrospective study. The

International journal of oral & maxillofacial implants. 1992 Dec;8(4):428-32.

63. **Nkenke E, Eitner S, Radespiel-Tröger M, Vairaktaris E, Neukam FW, Fenner M.** Patient-centred outcomes comparing transmucosal implant placement with an open approach in the maxilla: a prospective, non-randomized pilot study. Clin Oral Implants Res. 2007;18:197-203.
64. **Nobuto, T., Suwa, F., Kono, T., Taguchi, Y., Takahashi, T., Kanemura, N., Terada, S. & Imai, H.** Microvascular response in the periosteum following mucoperiosteal flap surgery in dogs: Angiogenesis and bone resorption and formation. Journal of Periodontology 2005;76, 1346 - 1353.
65. **Oh TJ, Shotwell JL, Billy EJ, Wang HL.** Effect of flapless implant surgery on soft tissue profile: A randomized controlled clinical trial. J Periodontol 2006;77:874-882.
66. **Ong CTT, Ivanovski S, Needleman IG, Retzepi M, Moles DR, Tonetti MS, Donos N.** Systematic review of implant outcomes in treated periodontitis subjects. Journal of Clinical Periodontology. 2008 May;35(5):438–462.
67. **Ortega-Oller I, Suárez F, Galindo-Moreno P, Torrecillas-Martínez L, Monje A, Catena A, Wang HL.** The influence of implant diameter on its survival: a meta-analysis based on prospective clinical trials. Journal of periodontology. 2014 Apr;85(4):569-80.

68. **Ozan O, Turkyilmaz I, Yilmaz B**. A preliminary report of patients treated with early loaded implants using computerized tomography-guided surgical stents: flapless versus conventional flapped surgery. J Oral Rehabil 2007;34:835–840.
69. **Penarrocha M, Guarinos J, Sanchis JM, Balaguer J.** A retrospective study (1994-1999) of 441 ITI(r) implants in 114 patients followed-up during an average of 2.3 years. Med Oral 2002;7:144-155.
70. **Penarrocha M, Palomar M, Sanchis JM, Guarinos J, Balaguer J.** Radiologic study of marginal bone loss around 108 implants and its relation to smoking, implant location and morphology. Int J Oral Maxillofac Implants 2004;19:861-67.
71. **Petrie CS, Williams JL.** Comparative evaluation of implant designs: influence of diameter, length, and taper on strains in the alveolar crest. Clinical oral implants research. 2005 Aug 1;16(4):486-94.
72. **Ramfjord SP, Costich ER.** Healing after exposure of periosteum on the alveolar process. J Periodontol 1968;38:199–207.
73. **Ravindran DM, Sudhakar U, Ramakrishnan T, Ambalavanan N.** The efficacy of flapless implant surgery on soft-tissue profile comparing immediate loading implants to delayed loading implants: A comparative clinical study. J Indian Soc Periodontol 2010 Oct;14(4):245-51.

74. **Ricci G, Aimetti M, Stablum W, Guasti A.** Crestal bone resorption 5 years after implant loading . Int J Oral Maxillofac Implants 2004; 19:597-602.

75. **Rocci A, Martignoni M, Gottlow J.** Immediate loading in the maxilla using flapless surgery, implants placed in predetermined positions, and prefabricated provisional restorations: A restrospective 3-year clinical study. Clin Implant Dent Relat Res 2003;5(suppl 1): 29–36.

76. **Roman GG.** Influence of flap design on peri-implant interproximal crestal bone loss around single tooth implants. Int J Oral Maxillofac Implants 2001;16:61-67.

77. **Rousseau P.** Flapless and traditional dental implant surgery : an open, retrospective comparative study. J Oral Maxillofac Surg. 2010 Sep;68(9):2299-306.

78. **Sclar AG.** Guidelines for flapless surgery. Int J Oral Maxillofac Implants 2007;65:20-32.

79. **Seymour, R., Charlton, J. & Phillips, M.** An evaluation of dental pain using visual analogue scales and the McGill pain questionnaire. Journal of Oral and Maxillofacial Surgery 1983; 41,643–648.

80. **Shalabi MM, Gortemaker A, Van't Hof MA, Jansen JA, Creugers NH.** Implant surface roughness and bone healing: a systematic review. Journal of dental research. 2006 Jun 1;85(6):496-500.

81. **Strub JR, Gaberthuel TW, Grunder U.** The role of attached gingiva in the health of peri-implant tissue in dogs, Clinical findings. Int J Periodontics Restorative Dent 1991; 11: 317-33.

82. **Sunitha RV, Sapthagiri E**. Flapless implant surgery: a 2-year follow-up study of 40 implants. Oral Surg Oral Med Oral Pathol Oral Radiol 2013;116: e237–e243.

83. **Tsoukaki M, Kalpidis CDR, Sakellari D, Tsalikis L, Mikrogiorgis G, Konstantinidis.** A. Clinical, radiographic, microbiological and immunological outcomes of flapped vs. flapless dental implants: a prospective randomized controlled clinical trial. Clin.Oral Impl. Res. 2013 Sep;24(9):969-76.

84. **Van der Zee E, Oosterveld P, Van Waas MA.** Effect of GBR and fixture installation on gingival and bone levels at adjacent teeth. Clin Oral Implants Res 2004;15:62-5.

85. **Van Steenberghe D**. A retrospective multicenter evaluation of the survival rate of osseointegrated fixtures supporting fixed partial edentulism. *J Prosthet Dent* 1989; 61:217-23.

86. **Vlahovic Z, Markovic A, Golubovic M, Scepanovic M, Kalanovic M, Djinic.** A.Histopathological comparative analysis of peri-implant soft tissue response after dental implant placement with flap and flapless surgical technique. Experimental study in pigs. Clin. Oral Impl. Res. 26, 2015, 1309–1314.

87. **Vohra, F., Al-Kheraif, A. A., Almas, K., & Javed, F.** Comparison of Crestal Bone Loss Around Dental Implants Placed in Healed Sites Using Flapped and Flapless Techniques: A Systematic Review. *Journal of periodontology*,2015;*86*(2),185-191.

88. **Wadhwa B, Jain V, Bhutia O, Bhalla AS, Pruthi G.** Flapless versus open flap techniques of implant placement: A 15-month follow-up study. Indian J Dent Res 2015;26:372-7.

89. **Warrer K, Buser D, Lang NP, Karring T.** Plaque-induced peri-implantitis in the presence or absence of keratinized mucosa. An experimental study in monkeys. Clin Oral Implants Res 1995; 6: 131-8.

90. **Wennerberg A, Albrektsson T.** Effects of titanium surface topography on bone integration: a systematic review. Clinical oral implants research. 2009 Sep 1;20(s4):172-84.

91. **Wiskott HWA, Belser UC.** Lack of integration of smooth titanium surfaces: A working hypothesis based on strains generated in the surrounding bone. Clin Oral Implants Res. 1999; 10: 429-444.

92. **Wood DL, Hoag PM, Donnenfeld OW, Rosenfeld LD.** Alveolar crest reduction following full and partial thickness flaps. J Periodontol 1972; 42:141–144.

93. **Yaffe A, Fine N, Binderman I.** Regional accelerated phenomenon in the mandible following mucoperiosteal flap surgery. Journal of periodontology. 1994 Jan;65(1):79-83.

94. **Yeung S. C.** Biological basis for soft tissue management in implant dentistry. Aust. Dent. J.2008 ; 53(Suppl. 1) S39–S42

95. **You TM, Choi BH, Li J, Xuan F, Jeong SM, Jang SO.** Morphogenesis of the peri-implant mucosa: a comparison between flap and flapless procedures in the canine mandible. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2009 Jan;107(1):66-70.

Annexures

ANNEXURE I

CONSENT FORM

I ……S/o, d/o, w/o……..aged about …… …….years…….residing at…… …… …do solemnly state as follows.

I have been explained about the nature and purpose of the study in which I have been asked to participate.

I give my consent after knowing full consequence of the dissertation/thesis/study and I undertake to cooperate with the doctor for the study.

I have been given the opportunity to ask questions about the procedure.

I also authorize the Doctor to proceed with the study and I will cooperate with the doctor.

I have also agreed to come for regular follow up for a period of atleast one year.

I am also aware that I am free to withdraw the consent given at any time during the study in writing.

The doctor has explained the procedure to me and I have understood the same and signed my consent in (English / Tamil / Hindi / Telugu.....).

SIGNATURE OF THE PG STUDENT **SIGNATURE OF THE PATIENT**

SIGNATURE OF THE GUIDE: **SIGNATURE OF THE HOD**

ANNEXURE II

RAGAS DENTAL COLLEGE & HOSPITAL
(Unit of Ragas Educational Society)
Recognized by the Dental Council of India, New Delhi
Affiliated to The Tamilnadu Dr. M.G.R. Medical University, Chennai
2/102, East Coast Road, Uthandi, Chennai - 600 119. INDIA.
Tele : (044) 24530002, 24530003 - 06. Principal (Dir) 24530001 Fax : (044) 24530009

TO WHOM SO EVER IT MAY CONCERN

Date: 04-01-2016
Place: Chennai

From
The Institutional Review Board,
Ragas Dental College & Hospital,
Uthandi,
Chennai – 600119.

The thesis topic '**COMPARATIVE EVALUATION OF SOFT AND HARD TISSUE CHANGES FOLLOWING ENDOSSEOUS IMPLANT PLACEMENT USING FLAP AND FLAPLESS TECHNIQUES IN THE POSTERIOR EDENTULOUS AREAS OF THE MANDIBLE**submitted by**Dr. DIVYA . K**, has been approved by the institutional review board of Ragas Dental College & Hospital on 5th may, 2014.

(Dr. S. RAMACHANDRAN M.D.S.)
Secretary, Institutional Review Board,
Head of the Institution,
Ragas Dental College & Hospital,
Uthandi,
Chennai - 600119

PRINCIPAL
RAGAS DENTAL COLLEGE AND HOSPITAL
UTHANDI, CHENNAI - 600 119.