EVALUATION OF CLINICAL AND RADIOGRAPHIC OUTCOMES OF CONCENTRATED GROWTH FACTOR (CGF) IN IMMEDIATE PLACEMENT AND PROVISIONALISATION OF MAXILLARY ANTERIOR SINGLE IMPLANTS

A Dissertation submitted in
partial fulfillment of the requirements
for the degree of

MASTER OF DENTAL SURGERY

BRANCH – II

PERIODONTOLOGY

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY
Chennai – 600 032

2017 - 2020

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This is to certify that **Dr.G.D.RAMKUMAR**, Post Graduate student (2017–2020) in the Department of Periodontology, Tamil Nadu Government Dental College and Hospital, Chennai – 600 003 has done this dissertation titled **"EVALUATION OF CLINICAL AND RADIOGRAPHIC OUTCOMES OF CONCENTRATED GROWTH FACTOR (CGF) IN IMMEDIATE PLACEMENT AND PROVISIONALISATION OF MAXILLARY ANTERIOR SINGLE IMPLANTS"** under my direct guidance and supervision in partial fulfillment of the regulations laid down by **The Tamil Nadu Dr. M.G.R. Medical University**, Chennai – 600 032 for **M.D.S.,** (Branch – II) **Periodontology** degree examination.

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NAME OF THE GUIDE	Dr. P.BHUVANESWARI, M.D.S.,
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I hereby declare that this dissertation titled **"EVALUATION OF CLINICAL AND RADIOGRAPHIC OUTCOMES OF CONCENTRATED GROWTH FACTOR (CGF) IN IMMEDIATE PLACEMENT AND PROVISIONALISATION OF MAXILLARY ANTERIOR SINGLE IMPLANTS"** is a bonafide and genuine research work carried out by me under the guidance of **Dr.P.BHUVANESWARI, M.D.S., Professor and Guide,** Department of Periodontology, Tamil Nadu Government Dental College and Hospital, Chennai - 600003.

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ABSTRACT

Background: Implant-based rehabilitation is a clinical challenge, especially in the esthetic aspect. The immediate placement of implants in the extraction sockets has been a highly advocated protocol since its introduction, especially in highly esthetic situations. A thorough understanding of the dimensional alterations in post extraction sockets favours the immediate implant placement protocol. The advantage of immediate implant placement with provisionalisation is its efficacy in optimizing esthetic success by preserving osseous and gingival tissues. Even with this protocol, some amount of crestal bone resorption and associated soft tissue changes are inevitable. The use of autologous biomaterials like platelet concentrates has been explored with this protocol for maximum preservation of esthetics. In this study, Concentrated growth factor (CGF) is used during immediate implant placement and provisionalisation and its role in obtaining peri-implant soft tissue esthetics is evaluated.

Aim: The aim of the study is to evaluate the clinical and radiographic outcomes of use of CGF during immediate placement and provisionalisation of maxillary anterior single implants.

Objectives: The objective of the study is to clinically assess the esthetic outcome by evaluation of soft tissues around the implants and radiographically assess the hard tissue changes around the implants.

Materials and methods: Ten patients were selected for single tooth replacement in maxillary anterior region with immediate implant placement and provisionalisation using Concentrated growth factor. Clinical evaluation was done at baseline, 3 months and 6 months. The clinical parameters include plaque scores, bleeding on probing (BOP), probing depth (PD), soft tissue levels and Pink esthetic score (PES) analysis. Radiological evaluation was done by cone beam CT pre operatively and at 6 months. Hard tissue parameters that were assessed include the height of labial, palatal, mesial and distal bones using CBCT.

Results: The survival rate of implants in the present study was 100%. In this study, the marginal bone level changes around implants, evaluated after 6 months using CBCT was statistically significant ($P < 0.05$), suggesting that use of CGF does not influence marginal bone remodelling. The evaluation of mid-facial mucosa, evaluated at baseline and after 6 months showed non-significant results (P value of 0.42), suggesting that soft tissue level was stable throughout the study period.

Conclusion: The present study conducted for a period of 6 months suggests that the use of CGF during immediate implant placement and provisionalisation has resulted in stable peri-implant esthetics, nevertheless, case selection and implant position holds the key for esthetic success. Further long term evaluation is required for better analysis.

Keywords: Immediate implant, Provisionalisation, Concentrated growth factor, Pink esthetic score

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LIST OF ABBREVIATIONS

CGF	Concentrated Growth Factor
BOP	Bleeding on Probing
PES	Pink Esthetic Score
WES	White Esthetic Score
CT	Computed Tomography
CBCT	Cone Beam Computed Tomography
mm	millimetre
ITI	International Team for Implantology
vs	versus
PICI	Peri Implant and Crown Index
ICAI	Implant Crown Aesthetic Index
BMP	Bone Morphogenetic Protein
PDGF	Platelet Derived Growth Factor
IGF	Insulin like Growth Factor
TGF	Transforming Growth Factor
FGF	Fibroblast Growth Factor
VEGF	Vascular Endothelial Growth Factor
PRF	Platelet Rich Fibrin
PRP	Platelet Rich Plasma

rpm	Rotations per minute
min	Minute
IOPA	Intra Oral Periapical Radiograph
UNC	University of North Carolina
PPD	Probing pocket depth
pt	Point
gm	gram
mg	milligram
Ncm	Newton per centimetre
SPSS	Statistical Package for Social Services
SD	Standard Deviation
ANOVA	Analysis of Variance
ISQ	Implant Stability Qoutient

Introduction

INTRODUCTION

The history of modern implant dentistry began with the introduction of titanium implants.[1] In the 1950s, ***Per-Ingvar Branemark***, during his study, discovered an intimate bone-to-implant apposition with titanium, the phenomenon he called as Osseointegration, for which he developed a specific protocol to predictably achieve it. One aspect of this protocol includes an unloaded healing period to achieve osseointegration and long term success.[2]

Modern implant dentistry for the past 25 years was based on the concept of osseointegration, and implant placement was predominantly performed in healed sites of fully edentulous patients.[3] In the 1980s, the application of dental implants started to be cautiously expanded into partially edentulous patients as well.[4]

In the case of single tooth replacement especially in esthetically demanding situations like maxillary anterior region, implant placement into healed sites has completely lost its dominance in recent times. A thorough understanding of dimensional ridge alterations in post extraction sites revealed that this approach frequently complicates therapy, and a post extraction healing period of at least 6 months prior to implant placement is not really attractive any more to patients or implantologists in daily practice.[5]

Chen et al in a review on comparing the clinical outcomes of immediate implant placement and delayed placement protocol reported that, survival rates in immediate implant placement when compared to delayed placement, immediate implant placement appears to be a predictable treatment option.[6] One of the most desirable features of immediate implant placement and provisionalisation is its efficacy in optimizing esthetic success by preserving the existing osseous and gingival architecture.[7]

Immediate loading plays an important role in conditioning the soft tissues during healing with the provisional prosthetic restoration and, on its own, is capable of shortening treatment time.[8] Achieving and maintaining optimal gingival esthetics around anterior single implants is a demanding task. In spite of the high success rates achieved with osseointegrated implants, gingival recession of up to 16% has been reported in anterior single implants.[9]

A thorough pre-surgical diagnosis, three dimensional positioning of implants and better management of soft tissues help in reducing the soft tissue complications associated with immediate implant placement and provisionalisation in maxillary anterior region .[10]

The use of autologous biomaterials like platelet concentrates has been explored in implant placement for its effect on soft tissue healing, regeneration and long term stability.[11] Growth factor-containing products have been shown to accelerate bone healing, increased bone implant contact and osseointegration. Clinically, good soft tissue coverage was obtained with use of platelet concentrates in immediate implants.

The current study evaluates the use of Concentrated Growth factor (CGF), a second generation platelet concentrate, during immediate implant placement by assessing clinical and radiological parameters.

Aim and objectives

AIM AND OBJECTIVES

Aim:

The aim of present study is to evaluate the clinical and radiographic outcomes of use of CGF during immediate placement and provisionalisation of maxillary anterior single implants.

Objectives:

The objective of present study is to

1. Clinically assess the esthetic outcome by evaluation of soft tissues around the implants.

2. Radiographically assess the hard tissue changes around the implants.

Review of Literature

REVIEW OF LITERATURE

Dimensional tissue alterations following tooth extraction

Bone alterations following tooth extraction

Schropp L et al (2003)[12] in a human study, reported that dimensional alterations cause reduction in ridge width of up to 50% during the first year following tooth loss in premolar and molar sites, where two-thirds of the total changes take place within the first 3 months post extraction.

Ten Heggeler JM et al (2011)[13] in a systematic review observed an alveolar bone loss of 2.6–4.5 mm in width and 0.4–3.9 mm in height of healed sockets.

Misawa M et al (2016)[14] in a study on humans observed that the extent of bone loss following extraction seems to depend on factors such as facial bone wall thickness, angulation of the tooth, and other differences in anatomy at the various tooth sites.

Chappuis et al (2013)[15] in a clinical cone beam computed tomographic study of 39 patients, observed a progressive bone resorption pattern in sites with a facial bone wall thickness of 1 mm or less, leading to a median vertical bone loss of 7.5 mm or 62% of the former facial bone height after 8 weeks of healing. In contrast, patients with a thick wall phenotype, showing a facial bone wall thickness of more than 1 mm, displayed only a median vertical bone loss of 1.1 mm or 9%.

Chen & Buser (2009)[16] while evaluating the clinical and esthetic outcomes of implants placed in post-extraction sites observed that bone modelling in single- tooth extraction sites seems to be localized to the central, mid-facial aspect of the socket wall at 8 weeks post-extraction period, while proximal areas are well supported by the periodontal ligament (PDL) of the neighbouring teeth and show no bone loss.

Morton D et al (2014)[17] in a consensus statement on esthetic outcomes in implant dentistry suggested that an immediate implant placement protocol can be

recommended in thick bone wall phenotypes and thick gingival biotypes, where the post-extraction bone modelling is expected to be minimal.

Araujo et al (2015)[18] observed that dimensional alterations inevitably occur following extraction, due to the resorption of the bundle bone, as it is a tooth-dependent structure, and also due to related factors such as a lack of functional stimulus and a lack of vascular blood supply due to the missing periodontal ligament and genetic information.

Soft tissue alterations following tooth extraction

Dimensional soft tissue changes after extraction have been examined in single tooth extraction sites**.** Overall, more than 50% of these changes occur very quickly, within 2 weeks of healing. The soft tissue thickness increases significantly depending on the underlying bone dimensions**.** In thick wall phenotypes, the alveolus provides a self-contained bony defect, which favours the ingrowth of progenitor cells from the bony socket walls and the surrounding bone marrow space. In such thick bone wall phenotypes, the soft tissue dimensions on the facial aspect remain unchanged during healing ***(Chappuis et al, 2015)***[19]**.**

This is in contrast to thin bone wall phenotypes, in which the soft tissue dimensions revealed a sevenfold spontaneous increase after healing which was termed "**spontaneous soft tissue thickening**". It may be hypothesized that the rapidly resorbing thin facial bone wall favours facial soft tissue ingrowth due to its high proliferative rate. Subsequently, these soft tissue cells occupy the majority of the available space in the crestal area of an extraction socket defect. A highly vascularised granulation tissue is formed and fibroblasts migrate into the wound ***(Gurtner et al, 2008)***[20]**.**

Flapless tooth extraction

Cardaropoli et al (2003)[21] reported tooth extraction is an invasive procedure, since it disrupts vascular structures and damages soft tissues and the associated periodontal ligament.

Fickl & Zuhr (2008)[22] in a volumetric analysis on beagle dogs observed that flapless tooth extraction has been shown to reduce the amount of bone loss in the early healing phase 4–8 weeks post extraction compared with full-thickness flap elevations.

Buser et al (2008)[23] ***and Hammerle et al (2004)***[24] recommended a flapless low-trauma tooth extraction approach in cases of immediate implant placement in sockets with thick facial bone wall phenotypes and also when using early implant placement protocols (Type 2 – soft tissue healing and Type 3 – partial bone healing) in order to avoid additional bone loss at the superficial bone wall.

Blanco et al (2008)[25] in a study on beagle dogs showed that the resorption of the buccal bone after immediate implant placement is reduced, but not statistically significant, when performed without raising a flap.

Clinical studies by ***Becker et al (2005)***[26] and ***Rocci et al (2003)***[27] suggest that flapless surgery prevents marginal bone loss.

A meta-analysis by ***Lin et al (2014)***[28] compared marginal bone loss and implant survival rate between flapless and flapped procedures. The authors found no statistically significant difference between the two, concluding that the flap design should be chosen for patient comfort, need for access and ridge augmentation, and experience level of the surgeon.

Classification of immediate implant site

Kan et al (2011)[29] classified sagittal root position of the failing tooth in the alveolar bone via cone-beam computed tomography and can be categorized as one of four different classes:

Class I	The root is positioned against the labial cortical plate.
Class II	The root is centered in the middle of the alveolar housing without engaging either labial or palatal cortical plates at the apical third of the root.
Class III	The root is positioned against the palatal cortical plate.
Class IV	At least two-thirds of the root is engaging both labial and palatal cortical plates.

Kan et al (2011)[29] suggested that it is important for clinicians to recognize cases that are favourable for immediate implant placement and provisionalisation (Class I sagittal root position), cases that are more technique-sensitive and entail additional attention (Class II and Class III sagittal root position) and cases that are contraindicated for immediate implant placement and provisionalisation, requiring augmentation of hard and/or soft tissue before implant placement (Class IV sagittal root position).

Classification of timing of implant placement

Wilson et al (1993)[30] used the following terms to describe the timing of implant placement in relation to soft tissue healing:

- **Immediate implant placement**
- **Recent implant placement**
- **Delayed implant placement**
- **Mature implant placement**

Mayfield et al (1999)[31] proposed a **classification based on timing of implant placement** as,

Immediate	0 weeks
Delayed	6 to 10 weeks
Late	6 months or more

Hammerle et al (2004)[32] proposed a **classification of implant placement** into four types:

Type I	In fresh extraction sockets
Type II	After soft tissue coverage (after soft tissue healing) (4 to 8 weeks)
Type III	After soft tissue coverage (after partial bone healing) (12 -16 weeks)
Type IV	Healed socket (>16 weeks)

Esposito et al (2007)[33] based on timing of implant placement introduced terminologies like

Immediate implant	In fresh extraction sockets
Immediate-delayed	< 8 weeks post extraction
Delayed	> 8 weeks post extraction

Immediate implant placement

The credit for the first evaluation of immediate implant placement goes to ***Professor Wilfried Schulte***[34] from the University of Tubingen in Germany, who introduced the so-called Tubinger Immediate Implant in 1978, which was a ceramic implant made of Al_2O_3.

The advantages of immediate implant placement are:

1. Decrease in the number of surgeries and of the overall treatment time[35, 36]
2. Ideal implant orientation[37, 38]
3. Bone preservation in the extraction area[39, 40, 41] and
4. Optimum esthetics of the soft tissues[38]

Systematic reviews by ***Esposito et al (2010)***[42] and ***Lang et al (2012)***[43] have shown that the survival rate of immediate implant placement (**type 1**) is similar to those with a delayed approach.

Caneva et al (2010)[44] in an experimental study in dogs observed that although a minimum of 1 mm of vertical bone loss can be expected after immediate implant placement, the use of wider implants that have contact with the buccal bone wall increases the vertical bone loss two times.

Romanos et al (2002 & 2003)[45, 46] in a histomorphometric analysis observed that Immediate implant loading may stimulate bone formation and thus may influence early stages of osseointegration.

Kan et al (2011)[47] suggested bone resorption following tooth extraction is not reduced by immediate implant placement per se but is influenced by the apico-coronal and bucco-palatal position of the implant.

Immediate implant placement with immediate provisionalisation

According to the ***Weber et al in Fourth ITI Consensus Report (2009)***[48], immediate loading is defined as a provisional prosthesis connected to the implant during the first week of healing; early loading 1-8 weeks of healing and conventional loading after 2 months.

Slagter et al (2014)[49] in a systematic review have shown improved esthetic conditions with immediate implant placement and provisionalisation in comparison with standard protocols.

The systematic reviews by ***Lang et al (2012)***[43] and ***Gallucci et al (2009)***[50] did not observe statistical differences with regards to survival rates of immediately loaded or conventionally loaded implants.

A randomized controlled trial by ***De Rouck et al (2009)***[51] demonstrated a preserving effect of immediate loading on buccal mucosa level. In the control group of the study in which provisional prosthesis was delayed, papillae shrinkage and buccal recession were higher than in the test group (immediate loading) at the 3 month follow up. At the 12 month re-examination, the two groups showed comparable results in papillary height. However, the differences in the position of the buccal mucosa persisted during the 1 year observation period and recession was two to three times higher in the delayed loading group (1.16 mm) when compared to the immediate loading group (0.41 mm).

Studies by ***Cosyn et al (2012)***[52], ***Canullo et al (2009)***[53]***,*** and ***Raes et al (2011)***[54] indicated a frequency of <10% of advanced recession in cases where the prosthesis was placed immediately.

Esposito et al (2009)[55] observed that immediately loaded implants presented with similar survival rates to implants loaded in a delayed protocol.

In a systematic review by ***Lang et al (2012)***[43] 2086 immediate implants were conventionally loaded and 822 were immediately loaded. The estimated annual failure rate of the conventional loading group was lower than that of the immediate loading group (0.75% vs 0.89%), but without statistically significant differences.

Slagter et al (2014)[49] in a systematic review stressed that delayed provisionalisation of immediate implants increased the odds ratio by 20 on marginal peri implant bone level change (>0.5 mm) and suggested that the use of an immediate provisional restoration may obtain better peri implant bone levels than immediate implants without a provisional restoration. This may be more critical when peri implant soft tissues are assessed.

De Rouck et al (2009)[51] in a one year single blind randomized clinical study observed that delayed restoration resulted in initial papilla loss taking up to one year to attain comparable height as for immediate restoration and mid-facial recession was systematically 2.5 -3 times higher following delayed restoration pointing to a 0.75 mm additional loss in comparison with immediate restoration after one year. The author concluded that single tooth immediate implants should be instantly provisionalised to obtain optimal mid-facial esthetics.

Canullo et al (2010)[56] in a multicentre randomized clinical trial evaluated the influence of restoration on marginal bone loss using immediate definitive abutments or provisional abutments later replaced by definitive abutments. Twenty five patients with 25 hopeless maxillary premolars participated. At the 3 year follow up, a survival rate of 100% in both groups was reported. In the provisional abutment group, peri implant bone resorption was 0.36 mm at 3 months, 0.43 mm at 18 months and 0.55 mm at 3 years. In the definitive abutment group, peri implant bone resorption was 0.35 mm, 0.33 mm and 0.34 mm at the same time intervals. Lower bone loss was significant in the

group with definitive abutments at 12 months (0.1 mm) and 3 years (0.2 mm). The author suggested that the use of definitive abutments after immediate implant placement might be a potential factor to minimize peri implant crestal bone resorption, but more clinical trials should be performed to better investigate this hypothesis.

A literature review by ***Weigl et al (2016)***[57] evaluated immediate implant placement and immediate restoration with a single crown in the anterior maxilla; it reported 626 implants with a success rate of 97.96% and a survival rate of 98.25% (medium follow-up: 31.2 months).

Galluci et al (2014)[58] provided recommendations regarding the timing of loading, the guidelines of the **International Team for Implantology (ITI)** group are as follows:

1. Torque of 20–45 N for immediate loading.
2. No systemic health contraindication.
3. More benefits than risks.

Del Fabbro et al (2015)[59] in a systematic review observed that immediate loading in post extraction sockets in esthetic area results in promising results.

Abrahamsson et al (1997)[60] and ***Rodriguez et al (2013)***[61] in an experimental animal study reported that multiple abutment disconnections and reconnections following implant placement may compromise the peri implant mucosal seal and may lead to increased marginal bone loss.

Soft tissue esthetics in immediate implants

A systematic review by ***Chen et al (2014)***[62] investigated the outcome of immediate and early placement of implants in the esthetic area and observed that

despite the great heterogeneity of the studies included, immediate implant placement provides good soft-tissue esthetic outcomes.

Evans et al (2008)[63] in a study on evaluating the esthetic outcomes of immediately placed implants observed that installation of implants into fresh extraction sockets has proved to be a reliable procedure. However, this procedure is associated with partial resorption of the buccal bone wall resulting in a compromised esthetic outcome.

In the randomized clinical trial by ***Bianchi and Sanfilippo (2004)***[64] which compared soft tissue behaviour around immediate implants with or without a connective tissue graft, there was total success for the first 3 years in the group of patients receiving a connective tissue graft (test group), whereas 80% of cases in the control group were considered successful.

Sanz et al (2014)[65] in a study placed implants in fresh extraction sockets in maxilla and reported 80% of all sites analyzed showed no recession after an observation period of 3 years.

Lang et al (2012)[43] provided data on the soft tissue level changes at 3, 6 and 12 months following immediate implants with immediate provisional restorations in relation to the preoperative status in the anterior maxilla. The review concluded that most of the soft tissue changes occurred in the first 3 months and that mesial and distal papilla decreased in size during the first year.

Kan et al (2003)[66] in one year prospective follow up study of patients with immediate placement and provisionalisation of maxillary anterior single implants observed that papillae may have the capacity to regrow over time following implant restoration, which seems to be independent of gingival biotype.

In another study by ***Kan et al (2007)***[67] the distribution of papillae fill during the first year following immediate implant placement and immediate restoration was investigated. In more than 90% of the implants they observed a papilla index score 2, where the papilla was greater than half the height of the proximal space, or 3 (the papilla fills the entire proximal space) at every examination visit. The number of papillae achieving score 3 continued to increase from implant placement and provisional insertion up to 6 months, gaining the papillae stability afterwards.

Cosyn et al (2012)[52] assessed the frequency of advanced recession (≥1 mm) and considered some potential risk factors in the esthetic outcome following immediate implant placement. They concluded that the advanced retraction frequency is <10% in cases with an intact buccal bone plate and thick biotype treated with flapless surgery and immediate prosthesis.

Cordaro et al (2009)[68] assessing the clinical outcome of implants placed in fresh extraction sockets observed that effect of gingival biotype on peri implant tissue response only seemed to be limited to facial gingival recession and did not influence interproximal papilla or proximal marginal bone levels.

Chen & Buser (2009)[69] in a systematic review assessing clinical outcomes with immediate, early and delayed implant placement concluded that recession of the facial mucosal margin was common with immediate placement (recession >1 mm was observed in 21.4% of sites); risk indicators included thin biotype, facial malposition of the implant and thin or damaged facial bone wall.

Jung et al (2013)[70] in a study showed that immediate implant placement into extraction sockets exhibiting periapical pathology can be a successful treatment modality in terms of clinical and esthetic parameters.

Evans & Chen (2008)[71] assessing the esthetic outcomes of immediately placed implants observed that the implants that were placed in a more palatal position presented with a mean recession of 0.6 mm in contrast to the 1.8 mm in sites where implants were placed towards the buccal crest.

Raes et al (2011)[72] in a one year case series study in humans, demonstrated significant less recession when immediate implants were placed with a flapless approach.

The systematic review by ***Lang et al (2012)***[43] analyzed six studies where grafting materials were not used, 16 studies where bone substitutes were applied and in 12 studies the principle of guided bone regeneration with bone substitutes was performed. In terms of survival rate, it seemed in grafting or non grafting, the buccal void does not affect implant survival.

Migliorati et al (2013)[73] evaluating the clinical and esthetic outcomes of soft tissue augmentation in post extraction implants suggested that the use of soft tissue grafting may improve facial soft tissue stability and esthetic outcomes.

Bianchi et al (2004)[74] observed that connective tissue grafting may provide stable peri implant soft tissues in the long term and with good esthetic outcomes, mainly on those cases with a thin gingival biotype.

Rieder et al (2016)[75] in randomized clinical trials evaluating the esthetic outcomes, confirmed that the Pink Esthetic Scores of post extraction, immediately loaded implants were superior to those of immediate implant placement and delayed provisional restorations, early implant placement with immediate loading or early implant placement with early loading, and significantly superior when compared with the group with early implant placement and immediate loading.

A case-series study by ***Raes et al (2011)***[76] evaluated soft tissue alterations in anterior maxilla that were rehabilitated with immediate implant placement and with conventional implant treatment. Immediate implant placement was performed with a flap or a flapless procedure. Sixteen patients were treated with immediate implant placement and 23 patients with conventional treatment. The immediate implant placement group showed only 7% recession, while in the control group the recession was approximately 43%. The authors concluded that specifically, the flapless approach had significantly less recession than the flap approach at the 26-week follow- up.

Hammerle et al (2012)[77] observed that in the esthetic area, with proper case selection, flapless surgery could be very useful in maintaining soft-tissue health and in obtaining good esthetics with peri-implant papilla preservation.

Furhauser et al (2014)[78] evaluated, in terms of three-dimensional accuracies and pink esthetic score, 27 patients rehabilitated with flapless single-tooth implants for delayed replacement of upper incisors showed that this is a predictable treatment modality in terms of esthetics (median pink esthetic score = 13) and accuracy.

The ***Osteology Consensus Group (2011)***[79] stated that the survival rate of post-extraction implants in the esthetic area is high but there is also a very high risk of mucosal recession.

Bone grafting in buccal gap space

Human studies by ***Artzi et al (2000)***[80]***; Carmagnola et al (2003)***[81]***; and Froum et al (2002)***[82] show that demineralized autologous graft, or other alloplastic grafts, left residual granules surrounded by connective tissue or by immature bone after 6– 9 months.

Artzi et al (2000)[80] tested deproteinized bovine bone in 15 post-extraction human alveoli, followed by biopsies after 9 months, and showed that using this approach the bone is preserved.

Nevins et al (2006)[83] in a study of the fate of buccal wall of extraction sockets of teeth evaluated deproteinized bovine bone using preoperative and postoperative computed tomography scans (30 and 90 days postoperatively) in order to assess the resorption of bundle bone. Authors found that bone resorption was reduced by 20% in areas where biomaterials were used.

Soft tissue grafts in implant esthetics

A systematic review by ***Lee et al (2015)***[84] evaluating the esthetic outcome of subepithelial connective tissue graft after immediate implant placement found that a combination of immediate loading of implant and connective tissue graft allows for better stability of the gingival margin and thickens the peri-implant soft tissues.

Pink esthetic score analysis

Furhauser and colleagues (2005)[85] developed the seven criteria **Pink Esthetic Score (PES)** to objectively evaluate the peri-implant soft tissue.

Gehrke et al (2008)[86] showed the PES was shown to have a good intra-examiner agreement.

Belser and colleagues (2009)[87] developed the Pink Esthetic Score based on 5 criteria such as

1. Mesial papilla,
2. Distal papilla,
3. Curvature of the facial mucosa,
4. Level of the facial mucosa, and

5. Root convexity/soft tissue colour and texture at the facial aspect of the implant site.

The authors combined a simplified 5 criteria PES with the WES to evaluate the anterior implant supported restorations.

Jiang Chen et al (2018)[88] explored the esthetics of natural teeth in the anterior maxilla using the Pink Esthetic Score/White Esthetic Score (PES/WES) index. The authors concluded that soft tissue margins, soft tissue contours and outline / volume of the crown were high risk parameters for the esthetic outcomes of implant reconstructions. Underlying factors such as age and gender contributed to the esthetics of natural teeth change.

Veber LB Azevedo (2018)[89] evaluated the PES/WES found in natural dentition in young adults. The authors concluded that PES/WES is valid, however rigorous, and its maximum score is not observed in healthy individuals (natural dentition).

Alessandro Lanza et al (2017)[90] verified the validity of PES/WES index for natural tooth-prosthetic rehabilitation of the anterior area and as a secondary objective, evaluated the long-term predictability of this clinical application. The authors concluded that rightness of the PES/WES index for the objective outcome assessment of the esthetic dimension of anterior single-tooth crown was confirmed. However, prospective clinical trials are needed to further validate and refine this index and its clinical use also for natural tooth prosthetic rehabilitation.

Roni Kolerman et al (2016)[91] in a case–control, retrospective study involving 34 patients treated with maxillary anterior single implants, immediately placed and restored. The clinical and esthetic results were analyzed using standard clinical examination and a comprehensive index, comprising pink esthetic and white esthetic

scores (PES/WES). The authors concluded that evaluation of soft and hard tissue augmentation in immediately restored, immediate implant procedures obtained stable hard and soft tissues. The combined GBR and CT graft procedure achieved favourable peri-implant soft tissue condition and esthetic results.

Francesco Guido Mangano (2016)[92] compared the esthetic outcome of single implants in extraction sockets and healed ridges of the anterior maxilla by means of the pink esthetic score/ white esthetic score (PES/WES) index. The authors concluded that both immediate and conventional single-implant treatment in the anterior maxilla can yield satisfactory aesthetic outcomes, when performed by experienced clinicians in well selected cases. Further studies are needed to confirm these results.

Nicholas Boardman et al (2015)[93] investigated objective and patient-centred aesthetic outcomes for single-tooth implants in the anterior maxilla by PES and WES. The authors concluded that satisfactory objective and patient-reported aesthetic outcomes were achieved with dental implants replacing missing single teeth in the anterior maxilla and assessment of esthetic outcome using PES was more predictable.

Sandro Tettamanti et al (2015)[94] compared three different esthetic indices (Peri-Implant and Crown Index [PICI], Implant Crown Aesthetic Index [ICAI], "Pink Esthetic Score/White Esthetic Score [PES/WES]) for the evaluation of single implant supported crowns. The authors concluded that in comparison with the ICAI, the PES/WES and PICI were more reproducible. Therefore, PES/WES and PICI seem to be more suitable as esthetic indices for single implant crowns.

Vaidya S et al (2015)[95] evaluated the influence exerted by different dental specialty backgrounds as well as the validity and reproducibility of the Pink Esthetic Score/White Esthetic Score (PES/WES) and the modified Implant Crown Aesthetic Index (mod-ICAI) on the assessment of esthetic aspects of maxillary implants

supported single-tooth prosthesis. The authors concluded that PES/WES and the modified ICAI scores can be reliable estimates of esthetic outcomes. The assessor degree of specialization affected the esthetic evaluation with both the PES/WES and the modified ICAI. Periodontists were identified to provide more favourable ratings than other specialties while prosthodontists were most critical in this study. With modified ICAI, more interobserver agreement within specialty resulted.

Markus Schlee et al (2014)[96] assessed the esthetic outcomes of implant based reconstructions after autologous and allogenic bone grafting, using PES analysis, and concluded that PES is a reliable method for assessing esthetic outcomes , but should be performed by the same individual.

Emerson Souza Cutrim et al (2012)[97] in a study used the Pink Esthetic Score (PES), which allows evaluation of gingival esthetics and soft tissues around implants in the anterior maxilla rehabilitated with cemented prostheses (CP) and screw-retained prostheses (SP). The study demonstrated that the PES proved to be an efficient index to assess peri-implant tissues, and that the type of crown retention does not influence the health and quality of the soft tissues around implants.

Concentrated growth factors in immediate implants

Concentrated growth factor (CGF) was defined by ***Sacco in 2006***[98].

Growth factors are bioactive proteins that control the wound healing process. The platelet-containing preparations derived from human blood contain many growth factors such as bone morphogenetic protein (BMP), platelet-derived growth factor (PDGF), insulin-like growth factor (IGF), vascular endothelial growth factor (VEGF), transforming growth factor-β1 (TGF-β1), and transforming growth factor-β2 (TGF-β2), which play a key role in bone healing ***(Anitua E et al, 1999***[99]***, 2004***[100]***, 2009***[101]***).*** These

growth factors attract the undifferentiated mesenchymal cells to the wound site, thus facilitating angiogenesis, chemotaxis, and cell proliferation ***(Oncu E et al, 2016)[102].***

A study by ***Sohn et al (2011)[103]*** has shown higher regeneration capacity and multipurpose use of CGF. The potential of CGF is because it contains growth factor-containing fibrin network; it contains fibroblast, platelet, leukocyte, and endothelial cell for angiogenesis and tissue remodelling; and it provides matrix for cell migration ***(Gassling et al, 2009)[104].***

Platelets, in particular, contain biologically active proteins at high concentrations and support healing, growth, and cell morphogenesis ***(Nurden et al, 2008)[105]***.

Growth factor-containing products have been shown to accelerate bone healing and osseointegration ***(Anitua E et al, 2004)[100].***

Growth factors indicate that they accelerate tissue healing when they function effectively. Studies in the literature have reported that thrombocytes secrete growth factors from α-granules and that these released growth factors promote collagen synthesis. Increased collagen synthesis is thought to play a role in increasing soft tissue resistance and in the initiation of callus formation in bone tissue ***(Lin & Zhang et al, 2009)[106].***

Regional CGF administration increases FGF-β or VEGF release, which plays an active role in angiogenesis, as well as enhancing neutrophil migration by performing integrin release. It has also been shown that CGF contains such growth factors and CD34-positive cells ***(Rodella et al, 2011)[107]***. It has been reported that CD34-positive cells in the CGF also provide angiogenesis, neovascularization, and vascular continuity ***(Majka et al, 2001)[108]***.

In an animal study, CGF, PRF, and PRP were placed separately in the defects formed in the rabbit skull in the study group; the defects were left empty in the control group. Histomorphometric analysis revealed statistically significant differences between control and study groups in the growth of new bone formation at 6 and 12 weeks. In the study group, the greatest bone formation was observed in the CGF-treated group but this difference was not statistically significant ***(Kim et al, 2014)[109].***

In a study by ***Takeda et al (2015)[110]*** performed on rats, it was observed that cell proliferation and osteoblastic differentiation in the cell culture from the CGF-treated group was significantly higher than in the other groups.

Kim et al (2002)[111] reported in a study that there was a statistically significant increase in bone implant contact with PRP administration in the vicinity of the implant.

W.K. Hafez et al (2015)[112] made a study to evaluate the efficacy of platelet rich fibrin as a membrane for coverage of immediate implants in the maxillary anterior region. After 6 months, the marginal bone was stable in 83% of cases. Clinically, good soft tissue coverage was obtained. Radiographically, the bone height showed a statistically significant decrease in the distal side while there was no statistically significant decrease at the mesial side. They concluded that platelet rich fibrin provided good soft tissue coverage over the immediate implants and it enhanced the bone stability.

CGF preparation

A standard, disposable, 10-ml non-anticoagulant tube and a matching centrifuge device (MEDIFUGE, Silfradentsrl, S. Sofia, Italy) were used. Intravenous blood samples from the patients were placed in centrifuge tubes without anticoagulants and accelerated for 30 seconds, centrifuged at 2700 rpm for 4 min, 2400 rpm for 4 min, 2700 rpm for 4 min, and 3000 rpm for 3 min, and decelerated for 36 seconds to stop.

All of these acceleration and deceleration processes are adjusted automatically due to the centrifugal device's feature. Three layers were observed in the tube: red blood cell layer at the bottom, platelet-deprived plasma layer (without cell) at the top, and fibrin gel with concentrated growth factor and platelet aggregation in the middle. First, the uppermost platelet-deprived fraction was removed with a sterile syringe. The layer in the form of a membrane containing the concentrated growth membrane was held with the aid of a hemostatic clamp, separated from the red blood cell layer by cutting with a pair of scissors and then pressed to form a membrane.

Materials and Methods

MATERIALS AND METHOD

STUDY POPULATION:

The study population was selected from the outpatient section of the Department of Periodontology, Tamil Nadu Government Dental College & Hospital, Chennai.

INCLUSION CRITERIA:

1. Motivated patients conscious of oral hygiene and willing to undergo restoration with dental implants.
2. Age above 18 years.
3. Either sex.
4. Systemically healthy individual.
5. Periodontally healthy individual.
6. Maxillary anterior teeth with extensive decay, not amenable for endodontic restoration and indicated for extraction.
7. Teeth with vertical root fracture.
8. Avulsed teeth
9. Retained deciduous teeth.
10. Teeth with external or internal resorption.
11. Presence of intact labial bone
12. Teeth with thick, flat gingival biotype.

EXCLUSION CRITERIA:

1. Poor general health that could complicate the outcome of the study and habits such as smoking and alcohol consumption.
2. Dental history of Para-functional habits and bruxism.
3. Existence of acute periapical infection.

4. Teeth with interproximal bone loss.

5. Patient under bisphosphonate medication.

6. Pregnant women.

7. Patients with wide/long gingival recession.

8. Absence of labial bone wall of the extraction socket.

9. Severe intermaxillary discrepancy.

10. Radiotherapy in the craniofacial region within the period of 12 months after radiation treatment.

STUDY DESIGN:

Ethical clearance was obtained from the Institutional Ethical Committee and throughout the course of the study, the ethical principles were meticulously followed. Patients who satisfied the inclusion criteria were selected randomly, with no discrimination on the basis of sex, caste, religion or socioeconomic status. After explaining the study procedure, written informed consent was obtained from all the patients selected for the study. A thorough medical and dental history followed by examination of the patients was done. A total of 10 patients were randomly selected for the study.

STUDY PROTOCOL:

1. Institutional Ethical Committee approval.

2. Medical history and informed consent.

3. Complete periodontal examination

4. Clinical photographs and study models.

5. Stent preparation

6. Intra-oral evaluation and periodontal examination using clinical parameters namely Plaque index, bleeding on probing, soft tissue level in relation to the affected tooth.

7. Radiographic evaluation (IOPA) of the affected tooth.

8. Pre- operative Cone beam CT evaluation to determine bone volume in relation to the affected tooth.

9. Phase I therapy.

10. Surgical procedure (Atraumatic extraction followed by immediate implant placement).

11. Concentrated growth factor preparation and placement

12. Provisional crown preparation and placement.

13. Post –operative care.

14. Clinical re-evaluation at the end of 3 and 6 months.

15. CBCT re-evaluation at the end of 6 months.

STENT PREPARATION:

Over the study models, occlusal stents were done using self-cure acrylic. The stent covered the incisal 1/3rd of the labial and palatal surfaces of the teeth. It involved two teeth on either side of the implant. Vertical grooves were prepared to guide the placement of the probe in the same plane and direction repeatedly during measurements to avoid any variation. The recordings were done using a 15 UNC periodontal probe.

CLINICAL ASSESSMENT:

The clinical parameters evaluated before and after implant placement includes:

1. Plaque index.
2. Bleeding on probing (BOP).

3. Probing pocket depth (PPD).
4. Soft tissue levels.
5. Pink esthetic score (PES).
6. CBCT evaluation.

SOFT TISSUE PARAMETERS:

1. **Plaque Index *(Sillness and Loe 1964)*[113]**

Examination of all teeth was done at four gingival areas in each tooth (disto-facial, facial, mesio-facial, palatal) and was scored as follows:

Criteria for Scoring:

Score 0: No plaque.

Score 1: A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may be seen only by running a probe across the tooth surface.

Score 2: Moderate accumulation of soft deposits within the gingival pocket, on the gingival margin and/or adjacent tooth surface, which can be seen by the naked eye.

Score 3: Abundance of soft matter within gingival pocket and /or on the gingival margin and adjacent tooth surface.

Calculation:

Plaque index score for a tooth: The scores from the four areas of the tooth are added and then divided by four.

$$\text{Plaque index per tooth} = \frac{\text{Total score per tooth}}{\text{Number of surfaces per tooth (4)}}$$

Plaque index score for the individual: The indices for each of the teeth are added and then divided by the total number of teeth examined.

$$\text{Plaque index per tooth} = \frac{\text{Total score of all examined teeth}}{\text{Total number of examined teeth}}$$

Interpretation:

Score 0	Excellent oral hygiene
0.1 to 0.9	Good oral hygiene
1.0 to 1.9	Fair oral hygiene
2.0 to 3.0	Poor oral hygiene

2. Probing depth:

Measurement was made to nearest 0.5mm at four sites per implant (mesial, mid-facial, distal and palatal) using a manual probe (CP 15 UNC) at 3 and 6 months post implant placement.

3. Bleeding on probing (*Ainamo and Bay* 1975[114]):

The probe was inserted slightly into the sulcus at four sites per implant (mesial, mid-facial, distal and mid-palatal) at an angle of about 45°. Any gingival unit that exhibited bleeding were recorded. The total number of bleeding sites at implant was thus recorded.

Criteria for Scoring:

Positive score (1) - Presence of bleeding within 30 seconds

Negative score (0) - Absence of bleeding

$$\%\text{ of bleeding sites} = \frac{\text{Total number of positive score x 100}}{\text{Total number of surfaces of all teeth}}$$

4. **Soft tissue dimensions were measured as follows:**

Papilla levels: The papilla levels were recorded using an acrylic stent provided with direction grooves. Papilla level (mesial and distal) was defined as the distance from the top of the groove to the tip of the papilla measured to the nearest 0.5mm using a manual probe (CP 15 UNC).

Mid-facial/mid-palatal mucosal level: The level of the peri-implant mucosa at the mid-facial aspect of the tooth/restoration (gingival zenith) was measured using the same acrylic stent provided with a central direction groove. The mid-facial level was defined as the distance from the top of the groove to the first contact with the peri-implant mucosa measured to the nearest 0.5 mm using a manual probe (CP 15 UNC). In a similar fashion mid-palatal mucosal level is measured.

5. **Pink esthetic score (PES) analysis (*Belser et al 2009*)[87]**

The Pink esthetic score assess the soft tissue by evaluating the following five variables at the facial aspect of the implant site:

1. Mesial papilla,
2. Distal papilla,
3. Curvature of the facial mucosa,
4. Level of the facial mucosa, and
5. Root convexity/ soft tissue colour and texture

Criteria for Scoring:

A score of 2, 1, or 0 is assigned to all five PES parameters

Mesial/distal papilla:

Score 2 - Complete presence of papilla

Score 1 - Incomplete presence of papilla

Score 0 - Absence of papilla

The curvature of the facial soft tissue line:

Score 2 - Being identical compared to natural control tooth

Score 1 - Slightly different compared to natural control tooth

Score 0 - Markedly different compared to natural control tooth.

The level of the facial peri-implant mucosa:

Score 2 – Identical to contralateral tooth

Score 1 - A slight (<1 mm) discrepancy to contralateral tooth

Score 0 – A major (>1 mm) discrepancy to contralateral tooth

Finally, the proposed index combines three additional specific soft tissue parameters as one variable: the presence, partial presence, or absence of a convex profile (in analogy to a root eminence) on the facial aspect and the related mucosal colour and surface texture.

Score 2 - All three parameters are more or less identical compared to the control tooth.

Score 1 - If two criteria are fulfilled.

Score 0 - None or only one parameter matches the control site.

The five described parameters (5 X 2) are summed up under optimum conditions, to a maximum score of 10; the threshold of clinical acceptability was set at 6.

6. CBCT Analysis:

Measuring pre-operative values:

A sagittal section of the affected tooth is obtained from the CBCT. The sagittal slice is positioned and selected in such a way that it lies in the centre /midway of the tooth when viewed in the axial view.

The height of the labial bone is measured from the most incisal part on the labial crest (point A) to a fixed reference point on the nasal floor/nasal spine (pt B).The height of the palatal bone is measured from pt. B to the most incisal point on the palatal crest (pt C). Thus the distance between pt A and pt B (AB) will represent the pre - operative height of labial bone and the distance between pt B and pt C (BC) represents the pre - operative height of the palatal bone. The relative positions of pt A and pt C are expected to change over a period of time in accordance with bone resorption or apposition whereas pt B is a stable fixed reference point that will not undergo any change.

The inter proximal bone levels mesially and distally are measured in a similar manner as described above. The most incisal point on the mesial bone is marked as point F and on distal bone is marked as point G. Point B on the nasal floor / nasal spine is used as the fixed reference point. The distance between pt F and pt B (FB) will represent the pre - operative height of mesial bone and the distance between pt G and pt B (GB) represents the pre - operative height of the palatal bone.

Measuring post-operative values:

The post-operative values are calculated after a period of 6 months after implant placement. A sagittal section of the implant is selected at a level coinciding with the pre-operative view in axial and sagittal sections. The post - operative height of the labial bone is measured from the most coronal point on the labial crest, pt D to pt B. The post-operative height of the palatal bone is measured from pt B to the most coronal aspect on the palatal plate (pt E). The post - operative height of the mesial bone is measured from the most coronal point on the mesial bone (pt H) to point B. The post-operative height of the distal bone is measured from pt B to the most coronal aspect on the distal bone (pt I).

Difference in height of labial bone = BA - BD

Difference in height of palatal bone = BC - BE

Difference in height of mesial bone = BF – BH

Difference in height of distal bone = BG - BI

ARMAMENTARIUM

For clinical examination:

- Mouth mirror
- Williams periodontal probe
- UNC probe
- Dental explorer
- Dental tweezers
- Kidney tray
- Cotton roll
- Sterilized disposable gloves
- Disposable facemask and headcap

For Phase I Therapy:

- Mouth Mirror
- Dental Explorer
- Scalers and Curettes
- Kidney Tray
- Cotton Rolls
- Disposable Gloves, facemask and head cap
- Disposable syringe
- Local Anaesthetic solution.

For surgical procedure:

- Mouth mirror
- William's periodontal probe
- UNC 15 probe
- Dental tweezers
- Surgical gloves
- Disposable mouth mask and head cap
- Local anaesthetic solution
- Periotome
- Extraction forceps
- Bard parker blade No. 15C and handle – straight and contra angled
- Periosteal elevator
- Area specific Gracey curettes and universal curette (Columbia 4R-4L)
- Straight and curved scissors
- Physiodispenser
- Implant surgical kit
- Surgical handpiece
- Saline and irrigation syringe
- Implant with abutment
- Dappen dish
- Alloplast bone graft (Perioglas, Novabone Products LLC.)

For CGF preparation:

- Sterile cotton and spirit
- Tourniquet
- 10 ml syringe

- Vacutainer test tubes
- Centrifuge device (Medifuge)

For provisional crown cementation:

- Preformed polycarbonate shell crowns
- Light curable composite resin.
- Flowable composite
- Light cure unit.
- Composite polishing kit

Surgical procedure:

After preoperative clinical assessment and case selection, written informed consent regarding planned treatment was obtained from all the patients. The patients were given antibiotics (Amoxicillin-1gm) and analgesic (Ibuprofen 400mg) one hour before the surgery preoperatively. Oral disinfection was done with 0.2% Chlorhexdine digluconate mouth wash. The patient's face was disinfected with 5% w/v povidone iodine solution. The oral cavity was prepared with 5% w/v povidone iodine solution and the patient is draped as per routine surgical procedure. Under local anaesthesia (2% lignocaine hydrochloride with adrenaline 1:80000), atraumatic extraction of the compromised tooth is done using periotome (Hu-Friedy PEREUR6) to avoid damage to the surrounding alveolar bone. Once the tooth was removed, the socket was carefully debrided with curette and irrigated with saline. The socket wall was examined with a blunt instrument for any fenestration or fracture.

Then the drilling sequence was carried out in a sequential manner. The osteotomy starts with 2mm round drill with copious irrigation. To avoid damage to the buccal cortical plate drill tip was positioned along the palatal wall of the extraction

socket, 4-5 mm coronal to the apical end of the socket. Osteotomy site was further enlarged to the desired diameter and the implant is placed achieving a primary stability of at least 35 Ncm. The implant shoulder was positioned palatal to the point of emergence of adjacent teeth and in the mesio-distal dimension; a distance of the implant shoulder to the neighbouring teeth of about 2mm was pursued. It is positioned 1mm subcrestally and 3-4mm below the outline of peri-implant mucosa. A straight abutment was screwed into the implant. In this study, root form tapered implant (Paltop Dynamic) was used which is specially designed for immediate loading.

CGF preparation:

A standard, disposable, 10-ml non-anticoagulant tube and a matching centrifuge device (MEDIFUGE, Silfradentsrl, S. Sofia, Italy) were used. Intravenous blood samples from the patients were placed in centrifuge tubes without anticoagulants and accelerated for 30 seconds, centrifuged at 2700 rpm for 4 min, 2400 rpm for 4 min, 2700 rpm for 4 min, and 3000 rpm for 3 min, and decelerated for 36 seconds to stop. All of these acceleration and deceleration processes are adjusted automatically due to the centrifugal device's feature. Three layers were observed in the tube: red blood cell layer at the bottom, platelet-deprived plasma layer (without cell) at the top, and fibrin gel with concentrated growth factor and platelet aggregation in the middle. First, the uppermost platelet-deprived fraction was removed with a sterile syringe. The layer in the form of a membrane containing the concentrated growth membrane was held with the aid of a hemostatic clamp, separated from the red blood cell layer by cutting with a pair of scissors and then pressed to form a membrane. The CGF membrane along with bone graft was placed in the buccal gap space between inner wall of extraction socket and implant surface.

Provisional crown preparation:

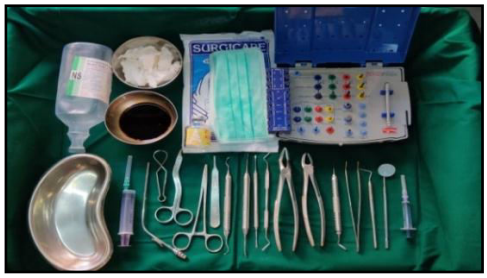
A provisional crown was prepared with light curable composite resin and prefabricated polycarbonate shell crowns. The crowns are prepared to provide adequate emergence profile in comparison to control tooth. The provisional crown is polished and connected to implant with screws. The access holes are finally closed with composite material. Care is taken that the provisional crown had no occlusal contact with the opposing teeth.

Post operative instructions:

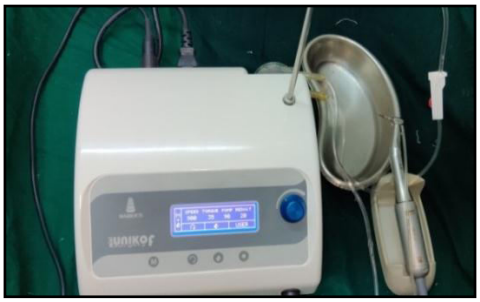
Patient was advised to eat soft foods. Postoperative instructions included avoidance of the surgical site while brushing and eating, the use of a 0.2% chlorhexidine mouthwash two times a day for 2 weeks, antibiotic therapy for 7 days (Amoxicillin 500 mg three times a day) and analgesic (Ibuprofen 400 mg three times a day). Definitive Prosthesis was done after 6 months. Re-evaluation of soft tissues was done at 3 and 6 months and hard tissue at 6 months.

Photographs

PHOTOGRAPH 1: SURGICAL ARMAMENTARIUM

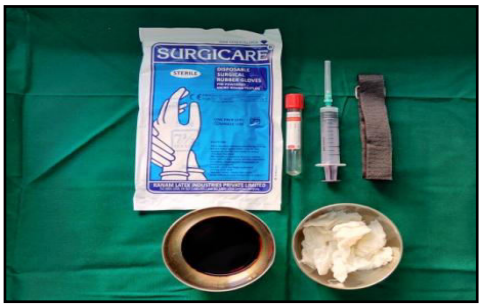


PHOTOGRAPH 2: PHYSIODISPENSER & SURGICAL HANDPIECE



PHOTOGRAPH 3: CENTRIFUGE FOR CGF PREPARATION (MEDIFUGE)

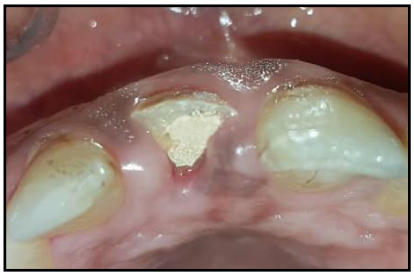
PHOTOGRAPH 4: ARMAMENTARIUM FOR CGF PREPARATION



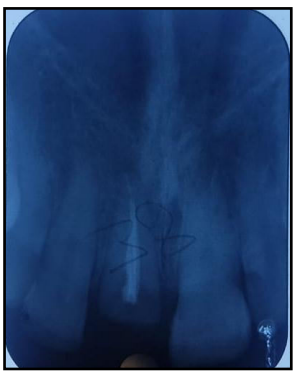
PHOTOGRAPH 5: IMPLANT (PALTOP DYNAMIC)

PHOTOGRAPH 6: ALLOPLAST GRAFT MATERIAL (PERIOGLAS)

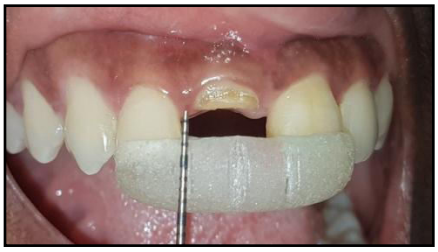
PHOTOGRAPH 7: PRE-OPERATIVE VIEW OF FRACTURED TOOTH 11



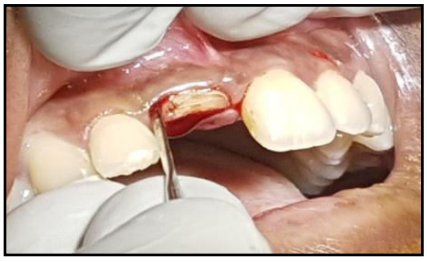
PHOTOGRAPH 8: PREOPERATIVE IOPA OF TOOTH 11



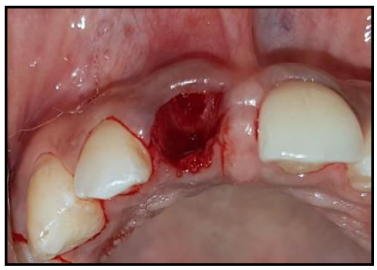
PHOTOGRAPH 9: PREOPERATIVE SOFT TISSUE MEASUREMENT WITH ACRYLIC STENT

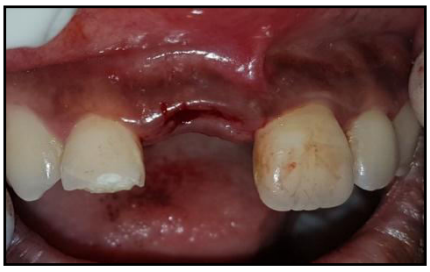


PHOTOGRAPH 10: ATRAUMATIC EXTRACTION WITH PERIOTOME

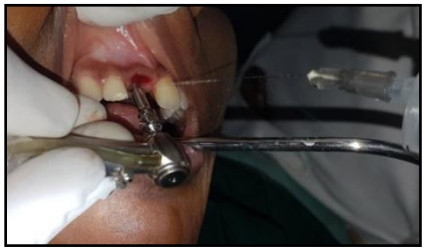


PHOTOGRAPH 11: SOCKET AFTER EXTRACTION

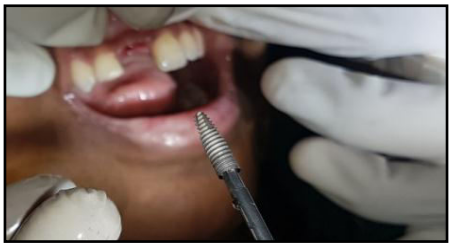




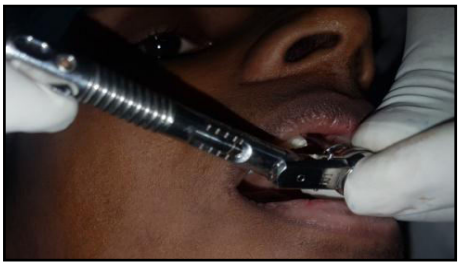
PHOTOGRAPH 12: OSTEOTOMY SITE PREPARATION WITH SEQUENTIAL DRILLS



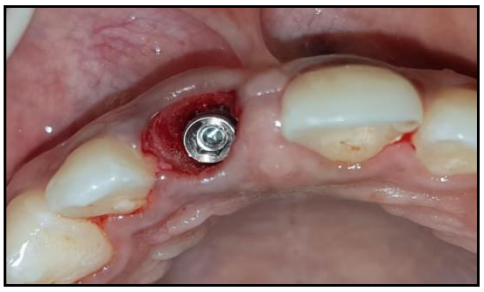
PHOTOGRAPH 13: IMPLANT PLACEMENT IN OSTEOTOMY SITE



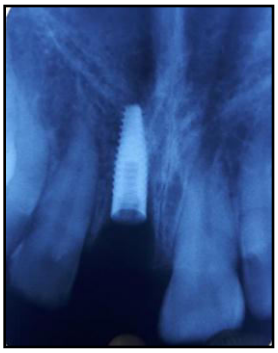
PHOTOGRAPH 14: PRIMARY STABILITY MEASUREMENT USING TORQUE WRENCH



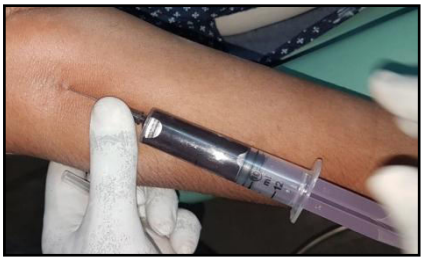
PHOTOGRAPH 15: OCCLUSAL VIEW OF IMPLANT IN POSITION



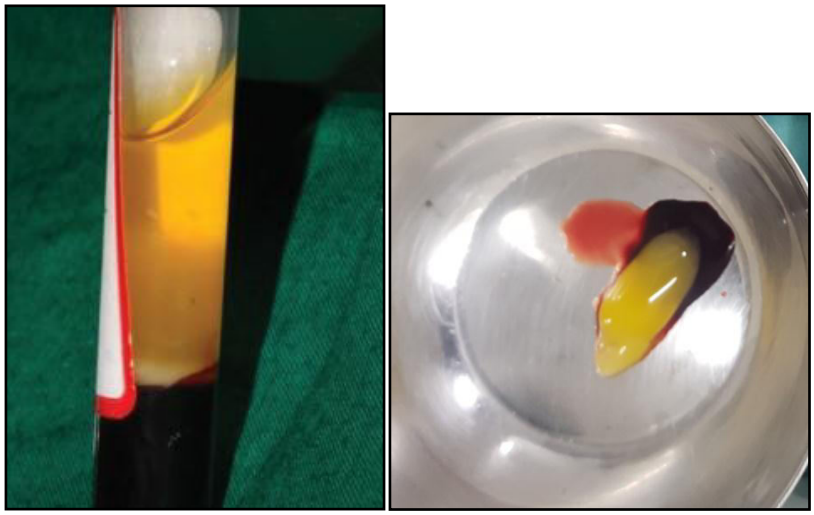
PHOTOGRAPH 16: IOPA AFTER IMPLANT PLACEMENT



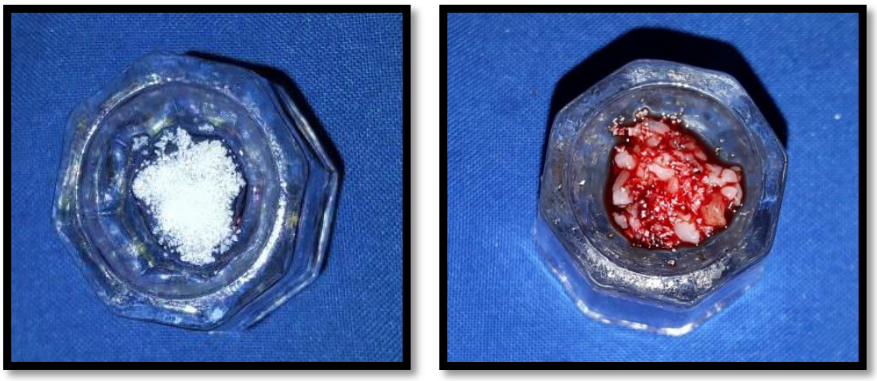
PHOTOGRAPH 17: BLOOD COLLECTION FOR CGF PREPARATION



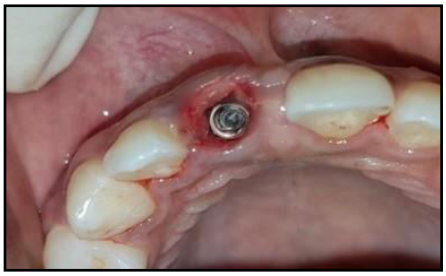
PHOTOGRAPH 18: CGF OBTAINED THROUGH CENTRIFUGATION



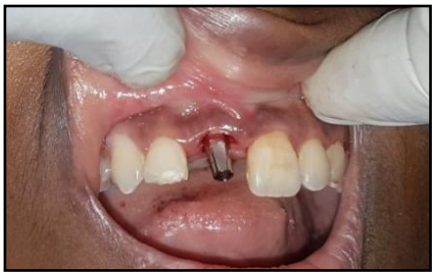
PHOTOGRAPH 19: PERIOGLAS GRAFT MATERIAL FOR PLACEMENT IN PERI-IMPLANT SPACE



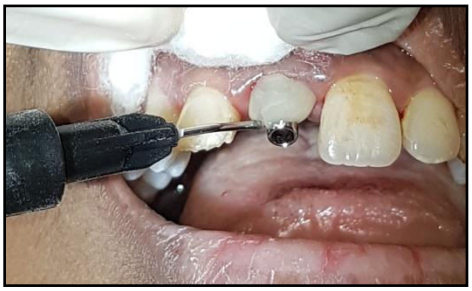
PHOTOGRAPH 20: CGF PLACED IN PERI-IMPLANT SPACE

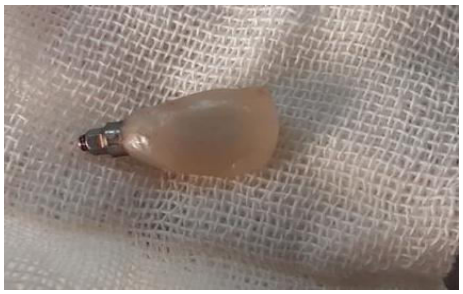


PHOTOGRAPH 21: ABUTMENT CONNECTED TO IMPLANT

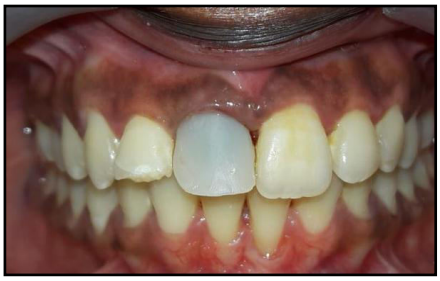


PHOTOGRAPH 22: PREPARATION OF PROVISIONAL CROWN USING COMPOSITE RESIN

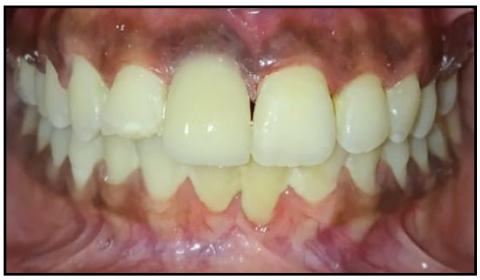




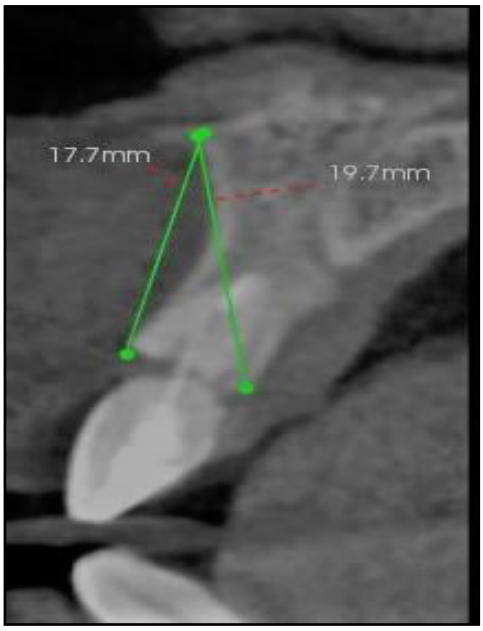
PHOTOGRAPH 23: IMMEDIATE PROVISIONAL CROWN



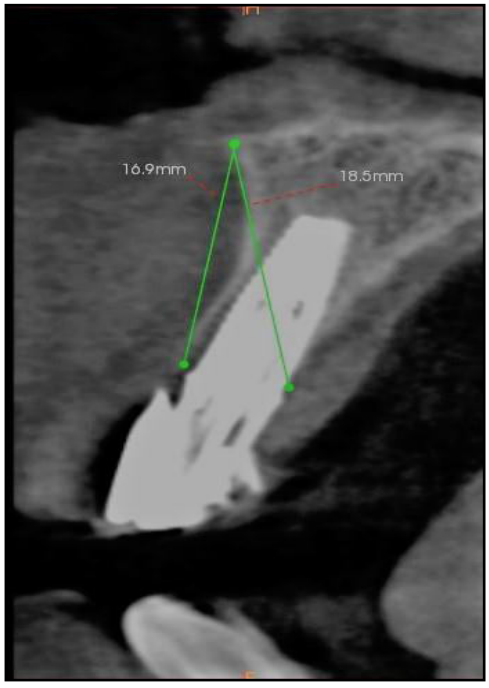
PHOTOGRAPH 24: DEFINITIVE PROSTHESIS AFTER 6 MONTHS



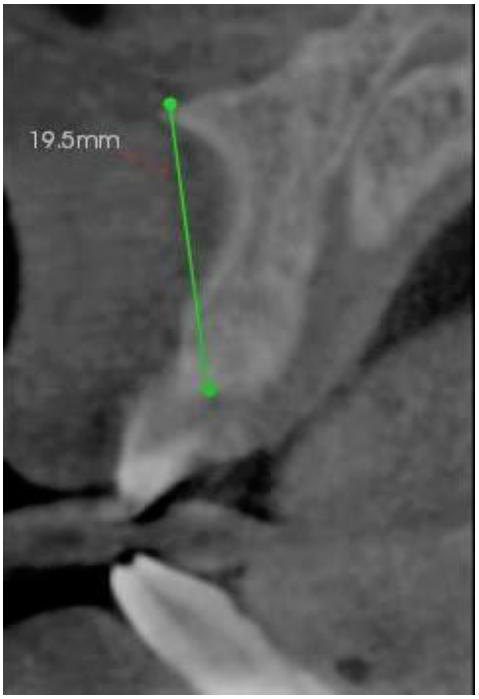
PHOTOGRAPH 25: PREOPERATIVE MEASUREMENT OF LABIAL & PALATAL BONE IN CBCT



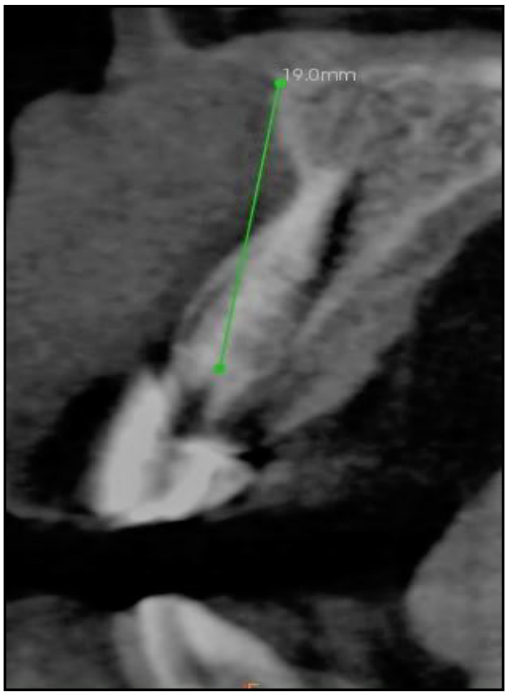
PHOTOGRAPH 26: POST OPERATIVE MEASUREMENT OF LABIAL & PALATAL BONE IN CBCT



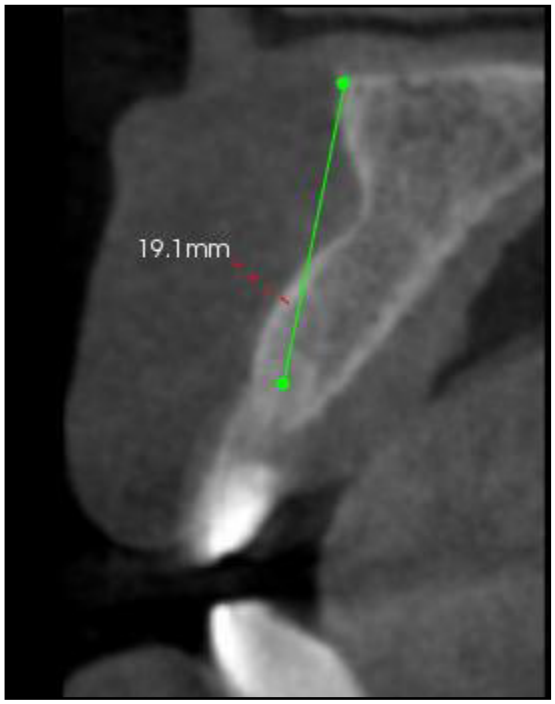
PHOTOGRAPH 27: PRE OPERATIVE MEASUREMENT OF MESIAL BONE IN CBCT



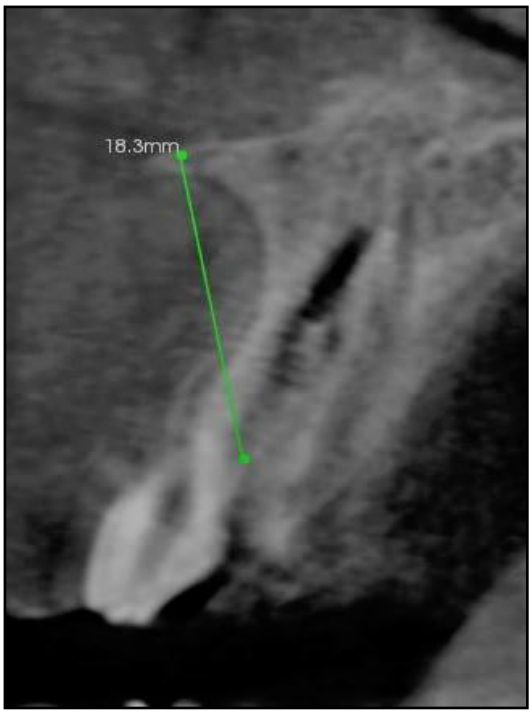
PHOTOGRAPH 28: POST OPERATIVE MEASUREMENT OF MESIAL BONE IN CBCT



PHOTOGRAPH 29: PRE OPERATIVE MEASUREMENT OF DISTAL BONE IN CBCT



PHOTOGRAPH 30: POST OPERATIVE MEASUREMENT OF DISTAL BONE IN CBCT



Statistical Analysis

STATISTICAL ANALYSIS

Statistical analysis was done by IBM SPSS (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.) Mean and SD were used to summarize the continuous data. Initially, the data was checked for normality using Shapiro Wilk test. The data was found to be normal, and thereby it was decided to use parametric tests for further comparisons.

For intra group comparison (within baseline, 3 months and 6 months post treatment data) a repeated measures ANOVA was used to find the significant difference. For changes in marginal bone levels and Probing pocket depth (pre-operative vs single post operative only) a paired t test was used. For analysis of qualitative data (PES scores), frequency and chi-square test was used to test the significance.

Results

RESULTS

The study evaluated 10 patients for a period of 6 months recording a detailed description of clinical and radiological parameters. All the 10 implants were osseointegrated. No early failures and complications were noted. The healing was uneventful. The patients showed good compliance and satisfaction as the tooth was replaced at the same day of surgery. The provisional restoration was esthetically pleasing for all the patients. The observations and results of various parameters are categorised in tables and figures.

PLAQUE INDEX:

The mean plaque index score at baseline were 0.84±0.06 which denotes a good oral hygiene. Oral prophylaxis were performed and oral hygiene instructions were given and reinforced during the follow up period. At 3 months the mean plaque scores were 0.59±0.09, at 6 months the mean plaque scores were 0.49±0.07. The plaque score at 3 months when compared to the baseline showed a mean difference of 0.25±0.05 with a p value of 0.001 which is significant and the plaque score at 6 months when compared to the baseline showed a mean difference of 0.35±0.04 with a significant p value of 0.00. This shows that the patients were motivated to improve their oral hygiene measures and they have maintained a good oral hygiene throughout the study (Table 3).

IMPLANT PROBING DEPTH:

The mean mesial implant probing depth at 3 months were 3.7±0.48 mm, and at 6 months were 3.1±0.31 mm. The mean distal implant probing depth at 3 months and 6 months were 3.5±0.52 mm and 3.0±0.47 mm respectively. The mean mid-facial implant probing depth at 3 months and 6 months were 2.6±0.51 mm and 2.0±0 mm respectively. The mean mid-palatal implant probing depth at 3 months were 2.8±0.42 mm, and at 6

months were 2.5±0.52mm. The mean pocket probing depth at 6 months when compared with 3 months at mesial, distal and mid-facial site showed a P value of 0.004, 0.038, and 0.002 respectively which were statistically significant. The mean palatal probing depths at 6 months when compared with 3 months showed a P value of and 0.17 which was not significant. The above results show that the pocket probing depths around implant were within normal healthy limits throughout the study (Table 5).

BLEEDING ON PROBING:

The mesial bleeding on probing at 3 months and at 6 months showed a P value of 0.17. The distal bleeding on probing at 3 months and at 6 months showed a P value of 0.06. The mid-facial bleeding on probing at 3 months and at 6 months showed a P value of 0.06. The palatal bleeding on probing at 3 months and at 6 months showed a P value of 0.06 (Table 7).

PINK ESTHETIC SCORE:

The mesial papilla was analysed at baseline, 3 months and 6 months and showed a P value of 0.78 which is non-significant (Table 9). The distal papilla was analysed at baseline, 3 months and 6 months and showed a non-significant P value of 0.82 (Table 9).

The curvature of facial mucosa was assessed at baseline, 3 months and 6 months and showed a P value of 0.84 which is non-significant (Table 10).

The level of facial mucosa was analysed at baseline, 3 months and 6 months and showed a P value of 0.87 which is non-significant (Table 11).

The root convexity/colour/texture of the facial mucosa were analysed at baseline, 3 months and 6 months showed a P value of 1.0 which is non-significant (Table 12).

The results show that the soft tissue was stable and the patient's esthetics was maintained throughout the study.

CHANGES IN BONE LEVELS:

The mean difference in the height of labial bone at 6 months when compared with baseline is 0.67 ± 0.49 mm with the significant P value of 0.001. The mean difference in the height of palatal bone at 6 months when compared with baseline is 0.76 ± 0.44 mm with a P value of 0.001 which is significant. The mean difference in the height of mesial bone at 6 months when compared with baseline is 0.96 ± 0.88 mm with a significant P value of 0.001. The mean difference in the height of distal bone at 6 months when compared with baseline is 0.85 ± 0.98 mm with a significant P value of 0.001 (Table 14).

CHANGES IN SOFT TISSUE DIMENSIONS

Mesial papilla:

The mean difference in the level of mesial papilla at 3 months when compared with baseline is -0.20 ± 0.16 mm with a P value of 0.23. At 6 months in comparison with the baseline values the mean difference is -0.40 ± 0.27 mm with a P value of 0.08 (Table 16).

Distal papilla:

The mean difference in the level of distal papilla at 3 months when compared with baseline is -0.30 ± 0.05 mm with a P value of 0.52. At 6 months in comparison with the baseline values the mean difference is -0.20 ± 0.11 mm with a non-significant P value of 0.52 (Table 16).

Mid facial mucosal level:

The mean difference in the level of mid facial mucosa at 3 months when compared with baseline is -0.20 ± 0.41 with a non-significant P value of 0.42. At 6 months in comparison with the baseline values the mean difference is -0.50 ± 0.34 with a P value of 0.08 which is non-significant (Table 16).

Palatal mucosa level:

The mean difference in the level of mid palatal mucosa at 3 months when compared with baseline is -0.50 ± 0.17 mm with a significant P value of 0.02. At 6 months in comparison with the baseline values, the mean difference is -0.70 ± 0.15 mm with P value of 0.009 (Table 16).

TABLE 3: CHANGES IN PLAQUE SCORES

Parameter	Time Point	Mean	Sd	P Value
Plaque Index	Baseline	0.84	.06	<0.001*
	3 Months	0.59	.09	
	6 Months	0.49	.07	

***Repeated Measures Anova**

TABLE 4: POCKET PROBING DEPTH

Probing Pocket Depth (Four Sites Per Implant)								
Implant	At 3 Months				At 6 Months			
	Mesial	Distal	Mid-Facial	Mid-Palatal	Mesial	Distal	Mid-Facial	Mid-Palatal
1	4	3	3	3	3	3	2	2
2	4	4	2	3	3	4	2	3
3	3	4	3	3	3	3	2	3
4	4	4	3	3	4	3	2	2
5	4	3	3	3	3	2	2	3
6	3	4	2	3	3	3	2	3
7	4	3	2	2	3	3	2	2
8	3	3	2	3	3	3	2	2
9	4	3	3	2	3	3	2	2
10	4	4	3	3	3	3	2	3

TABLE 1: MASTER CHART – IMPLANT AND PATIENT DETAILS

Patient	Age	Sex	Implant Position	Reason for Extraction	Implant diameter (in mm)	Implant Length (in mm)	Insertion Torque (Ncm)	Adjacent Area		Abutment Type
								Mesial	Distal	
1	43	M	13	Caries	3.75	11.5	40	T	T	Straight
2	27	F	11	Fracture	3.75	13	45	T	T	Straight
3	51	F	12	Caries	3.75	11.5	35	T	T	Straight
4	23	M	21	Fracture	3.25	13	35	T	T	Straight
5	44	F	13	Caries	4.2	13	45	T	T	Angled
6	35	M	22	Caries	3.75	13	35	T	T	Angled
7	45	M	11	Fracture	3.75	13	40	T	T	Straight
8	20	M	21	Fracture	3.75	13	40	T	T	Straight
9	31	M	12	Caries	3.75	13	35	T	T	Straight
10	20	M	11	Fracture	4.2	13	45	T	T	Straight

M-Male, F-Female, mm-millimetre, Ncm-Newton per centimetre, T-Tooth

TABLE 2: PLAQUE SCORES

Patient	Baseline	3 Months	6 Months
1	0.9	0.4	0.5
2	0.8	0.6	0.4
3	0.8	0.5	0.5
4	0.9	0.6	0.5
5	0.7	0.5	0.4
6	0.9	0.7	0.6
7	0.8	0.6	0.5
8	0.9	0.6	0.4
9	0.8	0.7	0.6
10	0.9	0.7	0.5

TABLE 5: CHANGES IN POCKET PROBING DEPTH

Parameter	Site	Time	N	Mean	SD	P Value
Periodontal Probing Depth	Mesial	3 Months	10	3.70	.48	0.004*
		6 Months	10	3.10	.31	
	Distal	3 Months	10	3.50	.52	0.038*
		6 Months	10	3.00	.47	
	Mid-Facial	3 Months	10	2.60	.51	0.002*
		6 Months	10	2.00	.00	
	Mid-Palatal	3 Months	10	2.80	.42	0.17*
		6 Months	10	2.50	.52	

***Paired T Test**

TABLE 6: BLEEDING ON PROBING

Bleeding On Probing (Four Sites Per Implant)								
Implant	At 3 Months				At 6 Months			
	Mesial	Distal	Mid-Facial	Mid-Palatal	Mesial	Distal	Mid-Facial	Mid-Palatal
1	1	0	0	0	0	0	0	0
2	0	1	0	0	1	0	0	0
3	1	1	0	0	0	1	0	0
4	1	0	0	1	1	0	0	0
5	1	1	1	0	0	1	0	0
6	1	1	0	0	0	0	0	0
7	0	1	0	1	0	0	0	0
8	1	0	1	0	1	0	0	0
9	0	0	1	0	0	0	0	0
10	0	1	0	1	0	0	0	0

TABLE 7: CHANGES IN BLEEDING ON PROBING

Parameter	Site	Time Duration (Frequency)				P Value
		3 Months		6 Months		
		Absent	Present	Absent	Present	
Bleeding On Probing	Mesial	4	6	7	3	0.17*
	Distal	4	6	8	2	0.06*
	Mid-Facial	7	3	10	0	0.06*
	Mid-Palatal	7	3	10	0	0.06*

***Chi-square test**

TABLE 8: PINK ESTHETIC SCORE

Pink Esthetic Score															
Implant	Baseline					At 3 Months					At 6 Months				
	Mesial Papilla	Distal Papilla	Curvature of Facial Mucosa	Level of facial mucosa	Root convexity /soft tissue contour & texture	Mesial Papilla	Distal Papilla	Curvature of facial mucosa	Level of facial mucosa	Root convexity /soft tissue contour & texture	Mesial	Distal	Curvature Of Facial Mucosa	Level of facial mucosa	Root convexity /soft tissue contour & texture
1	2	2	1	2	1	1	1	2	2	1	2	1	2	2	1
2	2	2	2	1	2	2	2	2	1	1	2	2	2	1	1
3	1	2	2	1	2	2	2	1	2	2	1	2	1	2	2
4	2	1	1	2	2	2	2	2	2	1	2	2	2	2	1
5	2	2	2	1	1	1	2	2	1	2	2	2	1	2	2
6	1	2	2	2	1	2	2	1	2	2	2	2	2	1	2
7	2	1	2	1	2	2	1	2	2	2	2	2	1	2	2
8	2	2	2	2	2	2	2	2	1	2	2	2	2	1	2
9	2	1	2	1	2	2	2	1	1	2	2	2	2	1	2
10	2	2	2	1	2	2	2	2	1	2	2	1	2	1	2

TABLE 9: PINK ESTHETIC SCORE – CHANGES IN PAPILLA

Site	Time Duration	Score (Frequency)		P Value
		Incomplete Presence	Complete Presence	
Mesial Papilla	Baseline	2	8	0.78*
	3 months	2	8	
	6 months	1	9	
Distal Papilla	Baseline	3	7	0.82*
	3 months	2	8	
	6 months	2	8	

***Chi-square test**

TABLE 10: PES – CHANGES IN CURVATURE OF FACIAL MUCOSA

Time Duration	Score (Frequency)			P Value
	Markedly Different	Minor Discrepancy (1)	No Discrepancy (2)	
Baseline	0	2	8	0.84*
3 months	0	3	7	
6 months	0	3	7	

***Chi-square test**

TABLE 11: PES – CHANGES IN LEVEL OF FACIAL MUCOSA

Time Duration	Score (Frequency)			P Value
	Major Discrepancy	Slight Discrepancy	Identical	
Baseline	0	6	4	0.87*
3 months	0	5	5	
6 months	0	5	5	

***Chi-square test**

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TABLE 12: PES – CHANGES IN ROOT CONVEXITY / TEXTURE/ COLOUR

Time Duration	Score (Frequency)			P Value
	Major Discrepancy	Slight Discrepancy	Identical	
Baseline	0	3	7	1.0*
3 months	0	3	7	
6 months	0	3	7	

***Chi-square test**

TABLE 13: CHANGES IN MARGINAL BONE LEVELS

Changes In Marginal Bone levels								
Implant	**Pre-operative**				**At 6 Months**			
	Height Of labial Bone	**Height of palatal bone**	**Height of mesial bone**	**Height of distal bone**	**Height Of labial Bone**	**Height of palatal bone**	**Height of mesial bone**	**Height of distal bone**
1	19.5	17.3	22.4	23.2	18.7	16.9	21.1	21.9
2	17.7	19.7	19.5	19.1	16.9	18.5	19.0	18.3
3	22.3	22.9	21.7	20.9	21.4	21.8	20.6	19.8
4	23.1	21.7	22.2	22.7	22.6	20.9	21.4	21.8
5	20.9	21.4	21.2	20.4	20.2	20.5	20.4	19.7
6	21.3	21.6	20.7	19.9	20.7	20.8	19.6	18.8
7	22.4	21.6	21.8	21.3	21.6	21.0	20.8	20.9
8	19.8	18.6	20.1	20.6	19.1	17.7	19.6	19.8
9	20.4	20.9	21.2	21.8	19.9	20.1	20.4	21.1
10	22.3	21.4	22.8	21.7	21.9	20.7	22.1	20.9

TABLE 14: ANALYSIS OF CHANGES IN MARGINAL BONE LEVELS

Site	**Bone height (Mean ± SD)**				**P value**
	Preoperative		**Post-operative**		
	Mean	**SD**	**Mean**	**SD**	
Labial bone	21.36	1.2	20.69	1.23	0.001*
Palatal bone	20.81	1.64	20.05	1.53	0.001*
Mesial bone	21.8	0.93	20.84	0.93	0.001*
Distal bone	21.43	1.02	20.58	1.007	0.001*

***Paired t test**

TABLE 15: CHANGES IN SOFT TISSUE DIMENSIONS

Changes in soft tissue dimensions												
Implant	**Baseline**				**At 3 months**				**At 6 months**			
	Mesial papilla	Distal papilla	Mid-facial	Mid-palatal	Mesial papilla	Distal papilla	Mid-facial	Mid-palatal	Mesial papilla	Distal papilla	Mid-facial	Mid-palatal
1	8	9	12	11	8	9	11	12	8	9	11	12
2	8	9	12	10	8	9	12	11	8	8	12	11
3	9	8	10	11	9	8	11	12	9	8	11	12
4	8	8	11	10	9	8	12	10	9	8	12	11
5	10	10	12	11	10	10	12	12	11	10	12	12
6	9	8	12	11	9	8	12	11	10	9	13	12
7	11	12	13	11	12	12	13	12	12	12	13	12
8	9	9	12	11	9	10	12	11	9	9	13	11
9	9	8	11	11	9	10	12	11	9	10	12	11
10	10	11	13	13	10	11	13	13	10	11	14	13

TABLE 16: ANALYSIS OF CHANGES IN SOFT TISSUE DIMENSIONS

Site	Time duration	Mean	SD	P value
Mesial papilla	**Baseline**	9.10	.99	0.13*
	3 months	9.30	1.15	
	6 months	9.50	1.26	
Distal papilla	**Baseline**	9.20	1.39	0.44*
	3 months	9.50	1.35	
	6 months	9.40	1.34	
Mid-facial papilla	**Baseline**	11.80	.91	0.13*
	3 months	12.00	.66	
	6 months	12.30	.94	
Mid-palatal papilla	**Baseline**	11.00	.81	0.008*
	3 months	11.50	.84	
	6 months	11.70	.67	

***Repeated measures ANOVA**

FIGURE 1: PLAQUE SCORE

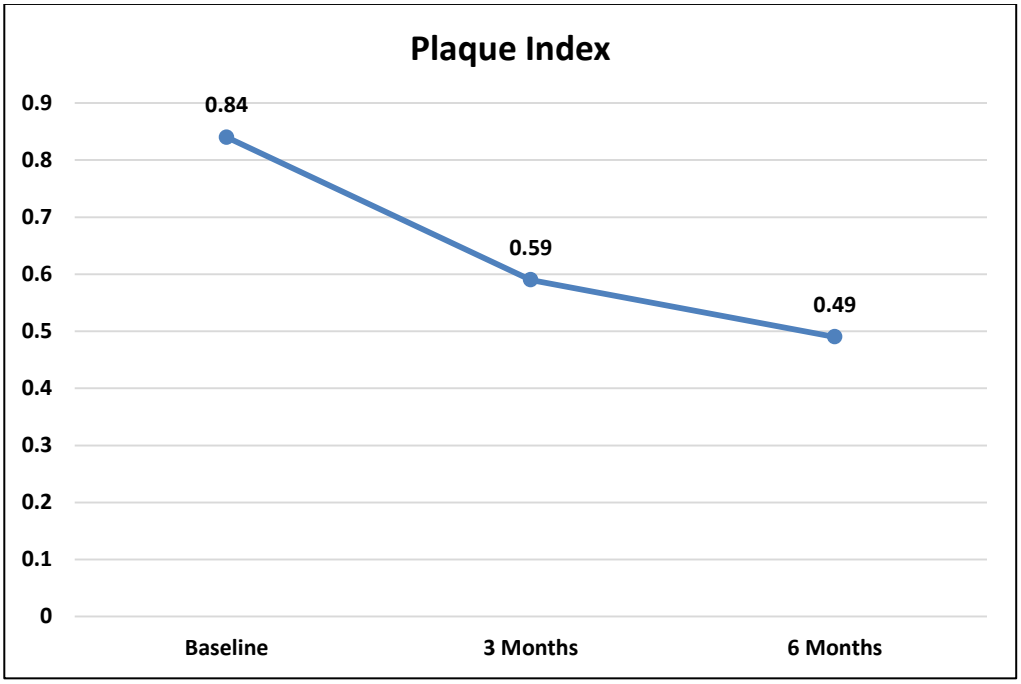


FIGURE 2: CHANGES IN BLEEDING ON PROBING

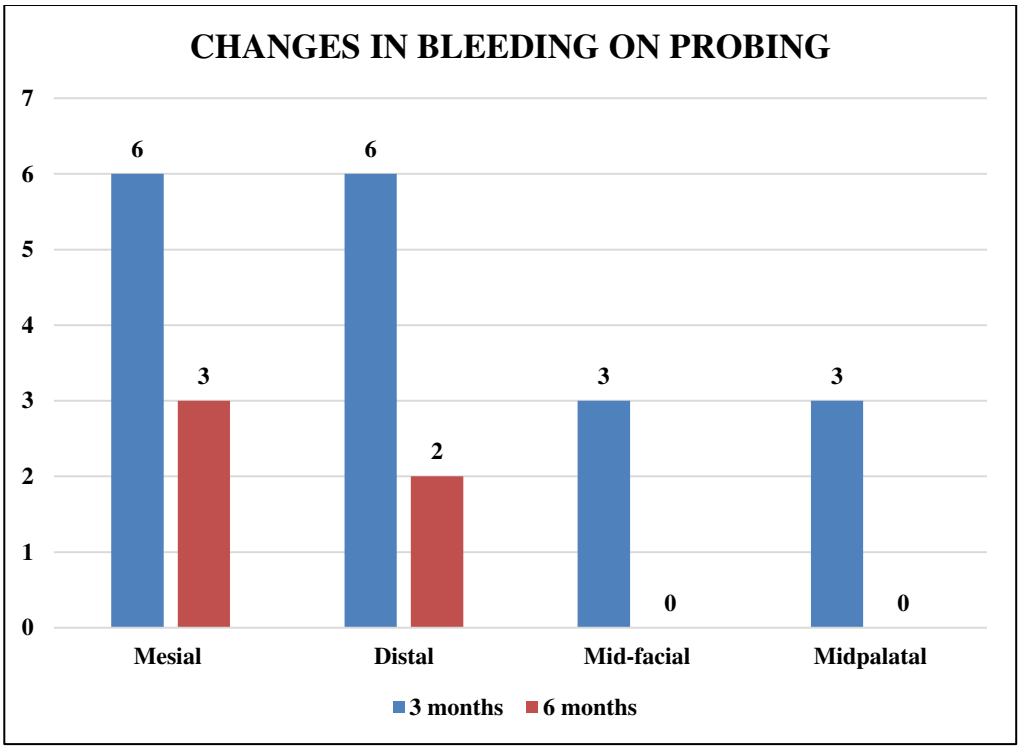


FIGURE 3: CHANGES IN POCKET PROBING DEPTH

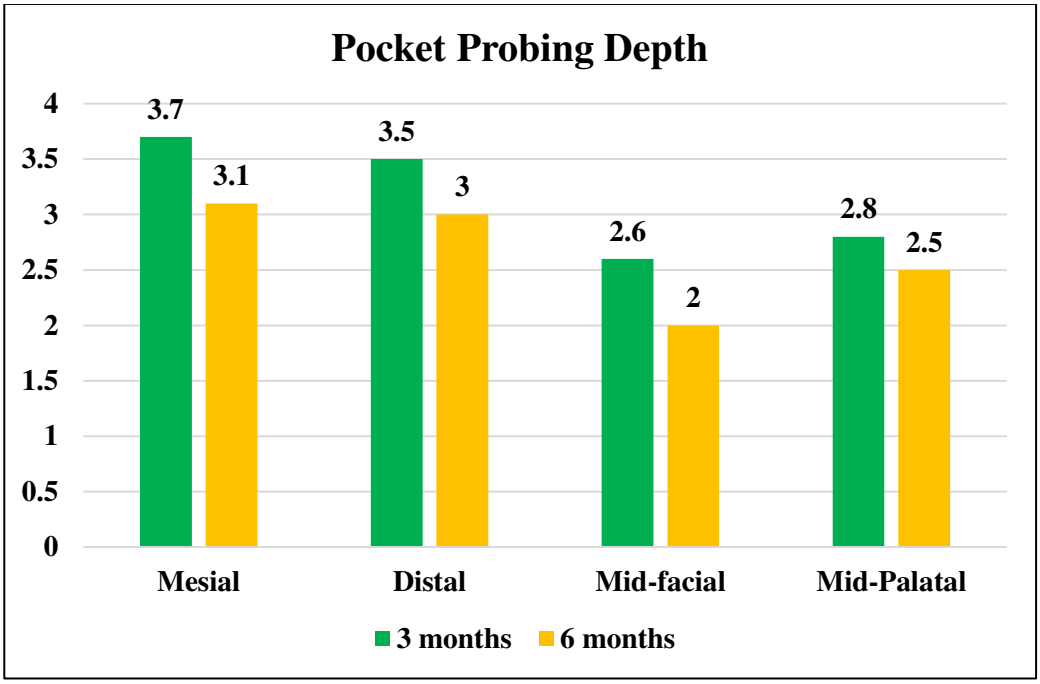


FIGURE 4: CHANGES IN SOFT TISSUE DIMENSIONS

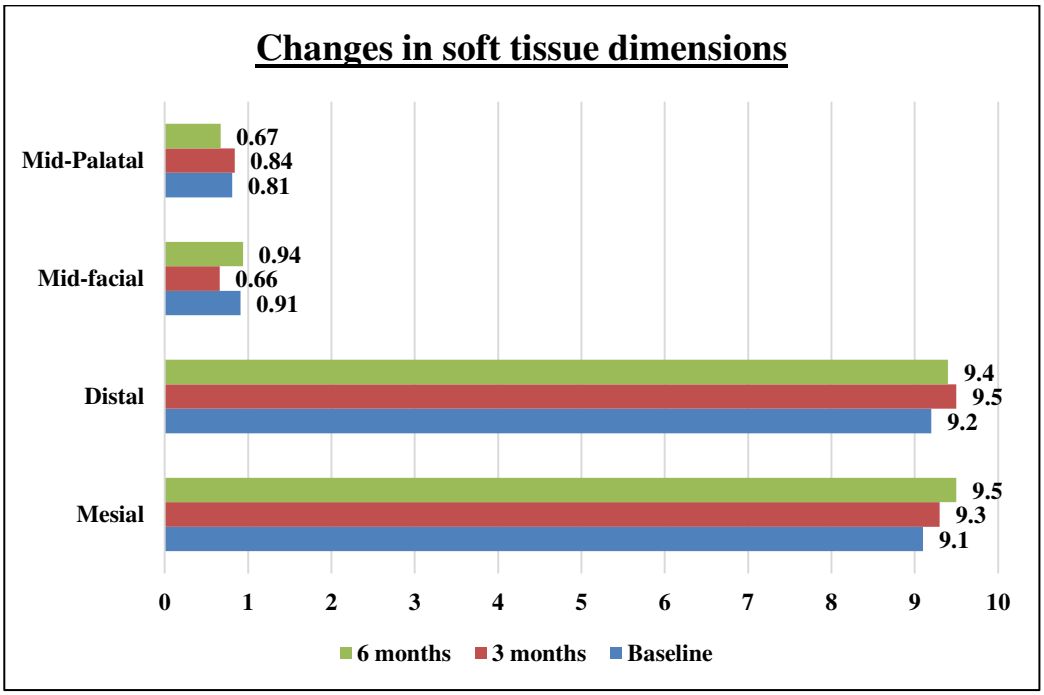


FIGURE 5: CHANGES IN MARGINAL BONE LEVELS

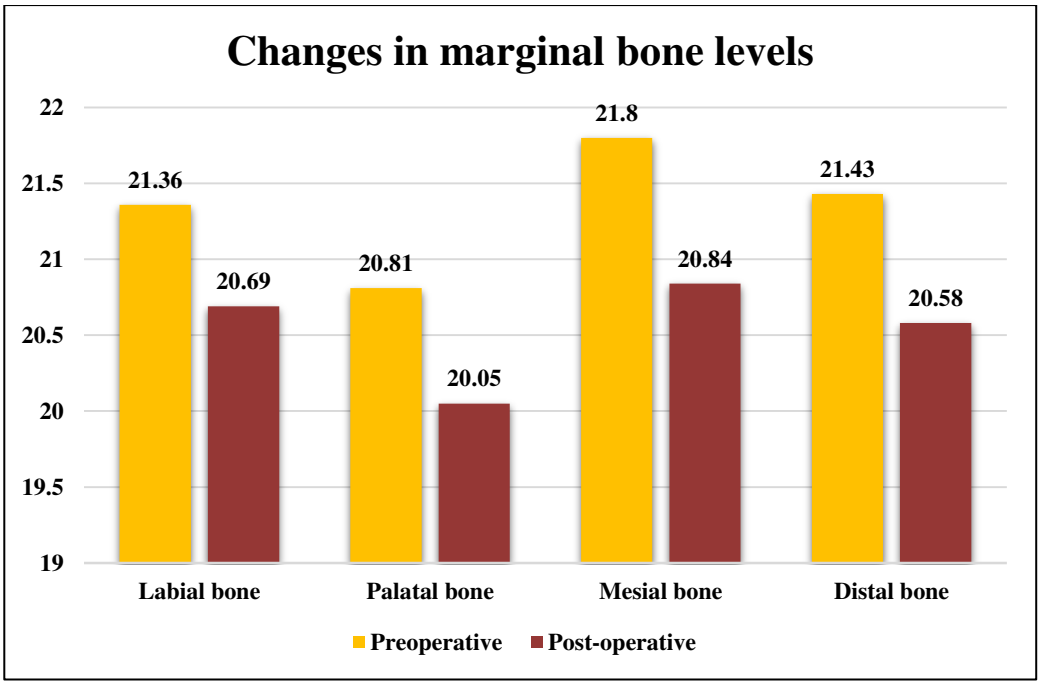


FIGURE 6: PES - CHANGES IN MSIAL PAPILLA

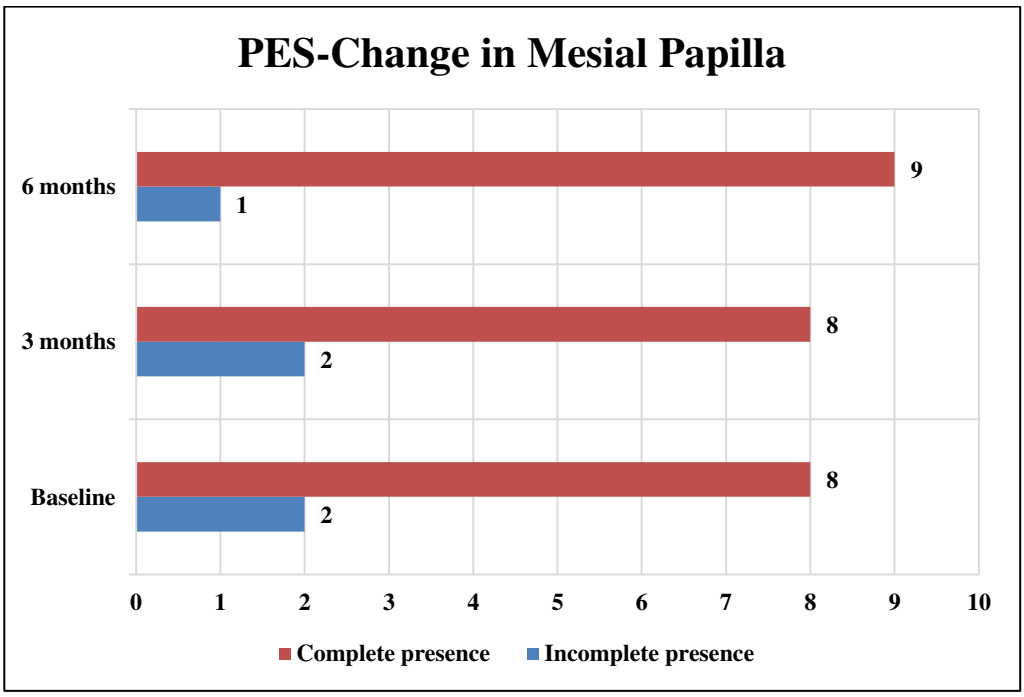


FIGURE 7: PES - CHANGES IN DISTAL PAPILLA

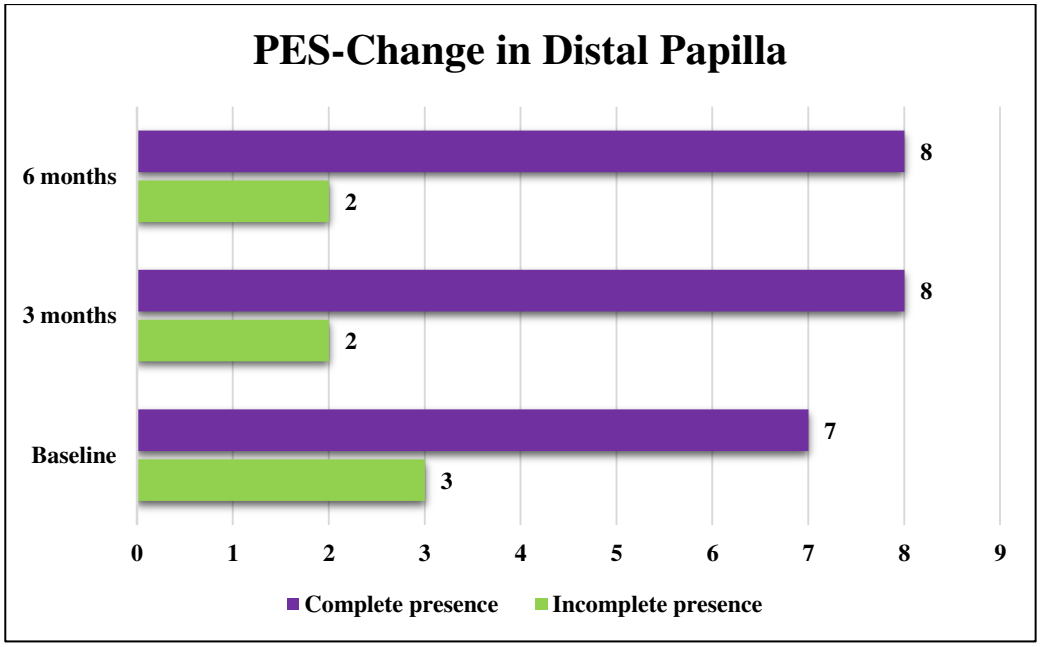


FIGURE 8: CHANGES IN CURVATURE OF FACIAL MUCOSA

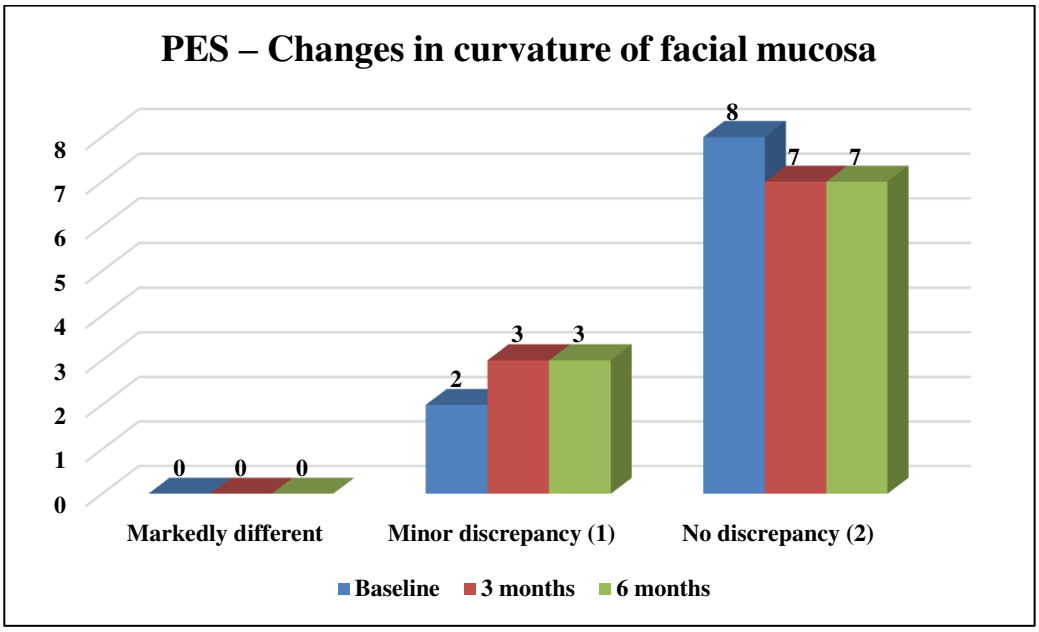


FIGURE 9: CHANGES IN LEVEL OF FACIAL MUCOSA

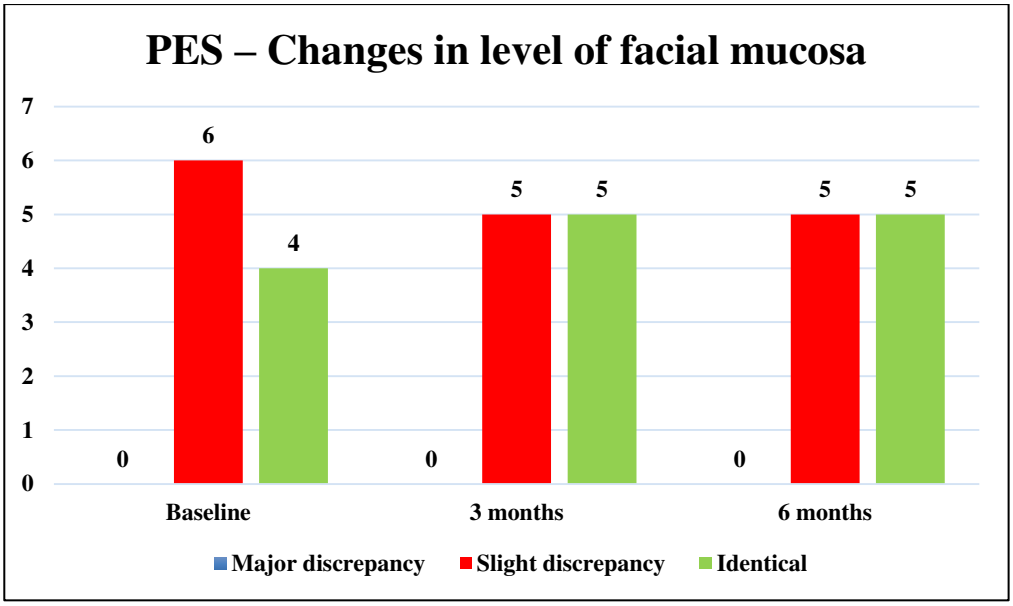
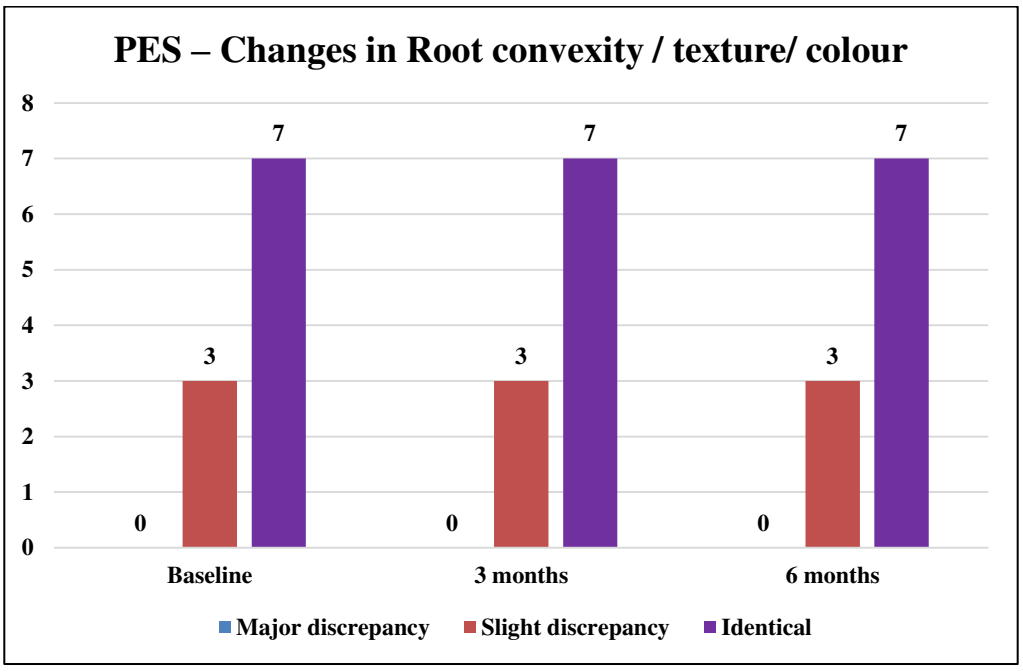


FIGURE 10: CHANGES IN ROOT CONVEXITY / TEXTURE / COLOUR



Discussion

DISCUSSION

The placement of immediate implants to replace a hopeless tooth in esthetically demanding situations like maxillary anterior region is an effective method and also preferred by both clinician and the patients. The reported advantages of immediate implant placement are not only reduced surgical time, cost effective treatment, and immediate esthetics, but also preservation of soft tissue morphology.

One of the most desirable features of immediate implant placement and provisionalisation is its efficacy in optimizing esthetic success by preserving the existing osseous and gingival architecture ***Kan et al (2000)[115].*** Achieving and maintaining optimal gingival esthetics around anterior single implants is a demanding task ***Kan et al (2001)[116].***

The use of autologous platelet concentrates in the immediate implant placement is beneficial in improving the outcome of the treatment for its inherent healing and regenerative properties.

Hence the study was done to evaluate the outcome of immediate implant with provisionalisation, using Concentrated growth factor (CGF), by assessing clinical and radiographic parameters.

The patients for the study were selected in accordance with the recommendations in consensus statement given by ***Morton et al, International Team for Implantology (ITI 2014)[117].*** The guidelines further highlight that with immediate implant placement, the risk of mucosal recession increases and hence a careful case selection should be ensured. The patients were selected with following specific criteria in addition to those who met the inclusion criteria as mentioned:

1. Intact socket walls.
2. Facial bone wall at least 1 mm in thickness.

3. Thick soft-tissue.
4. No acute infection at the site.
5. Availability of bone apical and palatal to the socket to provide primary stability.

Implant design configurations are an important criteria for success of immediate implant placement. ***Carlos Elias et al (2012)***, in their study concluded that screw type tapered implants have higher mechanical retention and primary stability. High primary stability is required for immediate provisionalisation.

Koticha et al (2012) investigated the effect of different thread designs on the final implant position in immediate implant placement and concluded that implants with V –shaped thread designs had better control on facio-lingual implant placement. In this study, a screw type tapered implant (Paltop Dynamic implants) specifically designed for immediate placement in extraction sockets and immediate loading was used.

Hammerle et al (2012)[118] in a consensus statement concluded that atraumatic flapless extraction could be very useful in maintaining soft-tissue health and in obtaining good esthetics with peri-implant papilla preservation. In accordance with this guidelines, in this study, flapless atraumatic extraction of involved tooth was performed using periotome.

International Team for Implantology (ITI 2014)[117] recommended that the implant should be placed in such a way as to maintain a gap of at least 2 mm between the implant and the internal surface of the facial bone wall. A gap of this dimension also provides a space for the formation of a blood clot which can subsequently reorganize into a provisional connective tissue matrix and support the formation of newly formed woven bone.

Evans et al (2008)[119] emphasized the importance of implant position to obtain stable esthetics and implant bed should be prepared into the sloping anatomy of palatal bone and facial malposition of the implant must be avoided by all means, since this is a common mistake with immediate implant placement and presents a risk factor for mucosal recession.

Chen et al (2016)[120] observed that corono-apically, the implant shoulder should be placed just apical to the mid-facial bone crest in order to compensate for approximately 0.5–1.0 mm of crestal bone resorption that may be anticipated following flapless extraction.

In this present study, the implants were placed following the above guidelines, maintaining a gap of at least 2 mm between implant and internal surface of facial bone wall and 0.5 – 1.0 mm apical to mid-facial bone crest.

Artzi et al (2000)[121] suggested the use of bone graft material in buccal gap space to increase bone implant contact (BIC). ***Nevins et al (2006)***[122] found that bone resorption was reduced by 20% in areas where biomaterials were used.

According to ***Blanco et al (2019)***[123] few preclinical models and no prospective trials support the use of bone grafts on the buccal gap after immediate implant placement. However, it can be suggested that with a thin gingival biotype and narrow buccal bone crest, the use of a graft can be recommended, in particular a slowly resorbed biomaterial.

In this present study, Perioglas (Novabone Products LLC), a synthetic bone graft particulate was used to fill the buccal gap space, since more than 2 mm of space was maintained.

Rodella et al (2011)[107] suggested the use CGF as barrier membrane to accelerate soft tissue healing or be mixed with bone graft to accelerate new bone formation in

extraction sockets with immediate implants. ***Pirpir et al (2017)***[124] suggested that Growth factor-containing products have been reported to increase implant stability and accelerate osseointegration and Concentrated growth factor (CGF) can be used for this purpose with the growth factors it contains.

In this present study, CGF was used along with bone graft in buccal gap space to accelerate the healing process and to obtain stable soft tissue esthetics .

According to the ***Fourth ITI Consensus Report (2009)***[48], immediate loading is defined as a provisional prosthesis connected to the implant during the first week of healing; early loading 1-8 weeks of healing and conventional loading after 2 months.

Slagter et al (2014)[49] in a systematic review have shown improved esthetic conditions with immediate implant placement and provisionalisation in comparison with standard protocols.

In this present study, provisional crowns are prepared with the use of prefabricated polycarbonate shell crowns and light curable composite filling materials on titanium abutments. The provisional crowns were checked for cervical gingival emergence to provide support to the labial soft tissue. The crowns were adjusted to clear all centric and eccentric functional contacts and polished to prevent accumulation of plaque. The provisional crowns are finally screw retained to implants.

The study population consisted of 10 patients (7 male and 3 female) evaluated for short term of about 6 months. One implant was placed in each patient in maxillary anterior region. All the implants healed without complications. The survival rate of implants in this study yielded 100%. This is in accordance in a systematic review by ***Lang et al (2012)***[125] on survival rate of immediate implants involving 46 prospective studies reported that 2-year survival rate of immediate implant protocol was 98.4%, and 4 year survival rate was 97.5%.

The mean plaque score of participants in this study at baseline were 0.84±0.06, at 3 months were 0.59±0.09, at 6 months were 0.49±0.07. During the study period, the plaque scores for all the patients remained low which indicate that the patients are motivated and maintaining good oral hygiene.

The mean pocket probing depth at 6 months when compared with 3 months at mesial, distal and mid-facial site showed a P value of 0.004, 0.038, and 0.002 respectively which were statistically significant. The mean palatal probing depths at 6 months when compared with 3 months showed a P value of and 0.17 which was not significant. The above results show that the pocket probing depths around implant were within normal healthy limits throughout the study.

The mid-facial, palatal and distal bleeding on probing at 3 months and 6 months showed a P value of 0.06. The mesial bleeding on probing at 3 months and 6 months showed a P value of 0.17. This results indicate that the peri-implant soft tissues were maintained in a healthy state. The above results correlates with the study of ***Cooper et al***[126] in ***2014*** who showed lower values of plaque and bleeding scores.

The esthetics around immediate implants were analysed using pink esthetic score using patient's photographs. The mesial papilla was analysed at baseline, 3 months and 6 months and showed a P value of 0.78 which is non-significant. The distal papilla was analysed at baseline, 3 months and 6 months and showed a non-significant P value of 0.82. The curvature of facial mucosa was assessed at baseline, 3 months and 6 months and showed a P value of 0.84 which is non-significant. The level of facial mucosa was analysed at baseline, 3 months and 6 months and showed a P value of 0.87 which is non-significant. The root convexity/colour/texture of the facial mucosa were analysed at baseline, 3 months and 6 months showed a P value of 1.0 which is non-significant. This results show that when evaluated using PES analysis, the soft tissue

was stable and the patient's esthetics was maintained throughout the study. ***Roni Kolerman et al (2016)***[91] in a study involving 34 patients treated with immediate implants, evaluated the esthetics using PES criteria. The authors concluded that evaluation of soft tissues in immediately restored, immediate implant procedures using PES, obtained stable soft tissues. Studies by ***Francesco Guido Mangano (2016)***[92]***, Nicholas Boardman et al (2015)***[93]***, and Sandro Tettamanti et al (2015)***[94] showed similar stable soft tissue esthetics in immediate placed and restored implants when analysed using PES criteria.

In this present study, when comparing the height of bone levels using CBCT, at baseline and at 6 months, this study reported the mean difference in the height of labial bone at 6 months when compared with baseline is 0.69 ± 0.49 mm with the significant P value of 0.001. The mean difference in the height of palatal bone at 6 months when compared with baseline is 0.76 ± 0.44 mm with a P value of 0.001 which is significant. The mean difference in the height of mesial bone at 6 months when compared with baseline is 0.96 ± 0.88 mm with a significant P value of 0.001. The mean difference in the height of distal bone at 6 months when compared with baseline is 0.85 ± 0.98 mm with a significant P value of 0.001.

Araujo et al (2015)[18] observed that dimensional alterations inevitably occur after extraction, due to the resorption of the bundle bone as a tooth-dependent structure, and also due to related factors such as a lack of functional stimulus and a lack of vascular blood supply due to the missing periodontal ligament and genetic information.

The dimensional changes occurring in alveolar crestal bone after tooth extraction and immediate implant placement have been evaluated in several clinical studies like, ***Vignoletti F et al (2014)***[127]***, Araujo MG et al (2009)***[28]***, Lang et al (2012)***[125]***. Araujo MG et al (2006)***[129] in a experimental study reported that, the vertical

of 0.02. At 6 months in comparison with the baseline values, the mean difference is -0.70 ± 0.15 mm with P value of 0.009. These results show that the stable mucosa around the implant was maintained throughout the study.

The present study correlates with the results of ***Renzo Guarneri et al (2015)*** [132] who concluded that the midfacial mucosa level did not alter significantly between the baseline and 5-year reassessment. ***Hafez et al (2015)***[133] used platelet rich fibrin as a membrane in 12 anterior immediate implants and obtained good soft tissue coverage with minimal recession.

On contrary ***Chen and Buser et al (2009)***[134] reported an increased risk for advanced midfacial recession >1 mm, and reported that the position of the implant shoulder in relation to the buccal bone plate was significantly associated with the occurrence of marginal recession. Studies by ***Cornelini et al (2005)***[135] and ***Jemt et al (1997)***[136] reported a limited risk, with mid-facial gingival recession between 0.55mm and 0.75 mm.

Canullo and Rasperini et al (2007)[137] in a prospective case study on 10 immediate implants, showed a mean change in mesial papillary height of 0.52 mm and distal papillary height of 0.32mm and change in mid-facial mucosa of 0.42mm.

Kan et al (2011)[138] in their prospective study observed major reductions in the soft tissue levels with a change in mid-facial mucosa of -1.13mm, change in mesial papilla of -0.22mm and of distal papilla with a value of -0.21mm.They observed the patients with thin biotype have undergone more reductions in the soft tissue dimensions than that of thick biotype.

The results of this present study correlated well with the available literature. The stable soft tissue contours in our study could be attributed to the use of CGF, in addition to the other contributing factors. The potential role of CGF in hard and soft tissue

dimensional changes of the buccal bone wall were 2.1± 0.4 mm apical to fixed landmark after 12 weeks of healing, and at the lingual wall only minor changes were observed.

Boticelli et al (2008[130] & 2006[131]) have reported that 3.14 mm vertical bone resorption in their study after 4 months of placing implants.

The results of our study correlated with the available literature. In respect to the available literature on marginal bone resorption after immediate implant placement, dimensional alterations inevitably occur post-extraction, due to the resorption of the bundle bone as a tooth-dependent structure and variations in changes of bone levels may be attributed to labial plate thickness, atraumatic extraction technique and positioning of implants. Though resorption cannot be completely avoided, the use of CGF in this study with the inherent regenerative capacity may be one of the factors that helped in less bone resorption.

On assessing the soft tissue dimensions, the following results were obtained. The mean difference in the level of mesial papilla at 3 months when compared with baseline is -0.20 ± 0.16 mm with a P value of 0.23. At 6 months in comparison with the baseline values the mean difference is -0.40 ± 0.27 mm with a P value of 0.08. The mean difference in the level of distal papilla at 3 months when compared with baseline is -0.30 ± 0.05 mm with a P value of 0.52. At 6 months in comparison with the baseline values the mean difference is -0.20 ± 0.11 mm with a non-significant P value of 0.52. The mean difference in the level of mid facial mucosa at 3 months when compared with baseline is -0.20 ± 0.41 with a non-significant P value of 0.42. At 6 months in comparison with the baseline values the mean difference is -0.50 ± 0.34 with a P value of 0.08 which is non-significant. The mean difference in the level of mid palatal mucosa at 3 months when compared with baseline is -0.50 ± 0.17 mm with a significant P value

regeneration has been well established in the literature ***(Anitua E et al 1999[99], 2004[100], 2009[101], Sohn et al 2011[103] , Nurden et al, 2008[105]).*** The use of CGF in immediate implant placement may help in achieving stable peri-implant tissues and better esthetics.

The present study of immediate implant placement with CGF offers many advantages for the patient as well as for the clinician. However, careful patient selection and treatment planning appear to be of critical importance in achieving a predictable treatment outcome. Evidently, further research is needed to monitor hard and soft tissue changes on a long-term basis.

Summary and Conclusion

SUMMARY AND CONCLUSION

In this present study conducted for a period of 6 months, immediate implant placement and provisionalisation was done in maxillary anterior region. The aim of this study was to evaluate the use of CGF during immediate implant placement and provisionalisation protocol. The soft tissue parameters like plaque score, bleeding on probing, implant probing depth, soft tissue level and Pink Esthetic Score (PES) were evaluated clinically. The hard tissue parameter like marginal bone levels were evaluated using CBCT. The following conclusions were drawn from the study:

1. Immediate implant placement protocol is predictable and has high survival rates.
2. The patient selection is very critical for immediate implant placement. Patients with intact labial plate with minimum of 1mm thickness and thick gingival biotype are better candidates for achieving esthetic success.
3. Flapless atraumatic extraction of tooth is recommended in immediate implant placement since it reduces the marginal bone loss and patient discomfort.
4. Proper positioning of implant in extracted socket should be ensured and gap of at least 2mm between implant and socket wall should be maintained.
5. A slow resorbable biomaterial should be placed in buccal gap space between implant and socket wall. The use of autologous biomaterials like CGF helps in rapid healing and has major impact on optimizing soft tissue esthetics.
6. The provisionalisation of immediate implants is suggested, since it positively influences esthetics and helps in maintaining the integrity of soft tissues.

Within the limits of present study, immediate implant placement with the use of CGF helps in maintaining soft tissue esthetics. Careful patient selection and treatment planning appears to be of paramount importance in achieving a successful clinical outcome. However, more studies with long term follow up are required.

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Annexures

Annexure 1: Information sheet English

PARTICIPANT INFORMATION SHEET

Title of the study:

Evaluation of clinical and radiographic outcomes of Concentrated Growth Factor (CGF) in Immediate placement and provisionalisation of maxillary anterior single implants.

Name of the Research Institution:

Tamil Nadu Government Dental College and Hospital, Chennai.

Purpose of the study:

We are conducting this study to replace your compromised tooth in the upper front jaw region with the implant using CGF, a blood component for better healing and bone formation. The temporary crown is given at the same day of surgery. The outcome of this treatment is evaluated for the period of 6 months.

Procedure:

Participants are selected according to their need to replace compromised tooth in the upper front teeth region. Complete medical history shall be taken. Examination of the oral cavity is done and necessary radiographs are taken. Complete scaling of your teeth done and oral hygiene instructions shall be given. Test dose of drug injection for producing numbness will be given to rule out any allergic reactions. You will be advised to take antibiotics one hour before surgery. On the day of surgery, under local drug injection, the compromised tooth will be removed carefully. The bone cavity will be cleaned well and shall be checked for any bony fracture.

With the special drills, the bone cavity will be prepared to receive the implant. Then the implant shall be placed inside the cavity and tightened.10 ml of your blood is collected and CGF is prepared and it shall be placed inside the cavity for better healing. The temporary crown shall be prepared and it will be placed at the same day. You are advised to eat soft foods and maintain good oral hygiene. The permanent crown shall be given after 6 months.

Risk of Participation:

Necessary precautions will be taken to avoid possible complications of the surgical procedure. However pain, swelling, infection resulting in failure of the treatment and rarely allergic reactions to titanium have been reported.

Benefits of Participation:

Replacement of compromised tooth is done at the same day of surgery at free of cost. The tooth replacement is fixed and can be easily maintained. It gives better esthetic solutions.

Confidentiality:

The identity of the patients participating in the research will be kept confidential throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Participants Rights:

Taking part in the study is voluntary. You are free to decide whether to participate in the study or to withdraw at any time. Your decision will not result in any loss of benefits to which you are otherwise entitled.

Compensation:

NIL

Contacts Details:

For queries, clarifications or doubts related to the study, the contact details are as mentioned below;

Primary investigator: XXXX

Name of the patient Signature/ Thumb impression

Name of the investigator Signature

Date:

Annexure 2: Informed consent form English

TAMIL NADU GOVT. DENTAL COLLEGE AND HOSPITAL, CHENNAI -3

DEPARTMENT OF PERIODONTOLOGY

Investigator: Dr.G.D.RAMKUMAR **Guide:** Dr.P.BHUVANESWARI, M.D.S.,

INFORMED CONSENT FORM

EVALUATION OF CLINICAL AND RADIOGRAPHIC OUTCOMES OF CONCENTRATED GROWTH FACTOR (CGF) IN IMMEDIATE PLACEMENT AND PROVISIONALISATION OF MAXILLARY ANTERIOR SINGLE IMPLANTS

Name: Mr/Ms _____

Address: _____ SEX : Male /Female

_____ AGE : Years

_____

I, _____, exercising my free power of choice, hereby give my consent to be included as my son or daughter participant in the study**.**

I agree to the following:

1. I have been informed to my satisfaction about the purpose of the study and study procedures. I agree to co-operate fully for complete examination.
2. I hereby give permission to use my medical records for research purpose.
3. I am told that the investigating doctor and the institution will keep my identity confidential.
4. I understand that I have rights to withdraw from the study and also that the investigator has the right to exclude me from the research at any point of time.

Name of Participants: Signature/ Thumb impression of

Investigator: Parent/Guardian

Date:

Annexure 5: Case proforma

DEPARTMENT OF PERIODONTOLOGY

TAMIL NADU GOVERNMENT DENTAL COLLEGE AND HOSPITAL

CHENNAI – 600003

EVALUATION OF CLINICAL AND RADIOGRAPHIC OUTCOMES OF CONCENTRATED GROWTH FACTOR (CGF) IN IMMEDIATE PLACEMENT AND PROVISIONALISATION OF MAXILLARY ANTERIOR SINGLE IMPLANTS

PROFORMA

OP No: Date:

Name: Age / Sex:

Address: Mobile No:

Occupation: Income:

Chief Complaint:

History of presenting illness:

Past Medical history:

Past Dental history:

INTRA ORAL EXAMINATION:

1. Mouth opening

2. Occlusion

3. Over jet

4. Over bite

CLINICAL EXAMINATION OF THE AFFECTED TOOTH:

Level of fracture / extent of caries

Gingival phenotype

Width of attached gingival

Position of the tooth in the arch

Clearance from opposing teeth

Signs of infection (pus discharge, sinus)

INVESTIGATIONS:

Blood investigations:

RADIOLOGICAL ASSESSMENT:

INTRA ORAL PERIAPICAL RADIOGRAPH:

Length of the root:

Root morphology:

Presence of periapical pathology:

Level of crestal bone (proximal):

CBCT ANALYSIS:

Labio lingual diameter of the tooth at crestal level:

Labio lingual diameter of the tooth at mid root level:

Distance between adjacent roots:

Distance from root apex to nasal floor / maxillary sinus:

Width of palatal bone at the level of root apex:

Thickness of labial plate:

DIAGNOSIS:

TREATMENT PLAN:

EMERGENCY / PRELIMINARY PHASE:

PHASE I:

Oral prophylaxis:

Study models:

PHASE II (SURGICAL):

IMPLANT EXAMINATION:

1.PLAQUE INDEX – SILLNESS AND LOE 1964

6																
3																
B																
	18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
	48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
B																
3																
6																

INDEX	BASELINE	3 MONTHS	6 MONTHS
Plaque Index (Sillness & Loe, 1964)			

2. CHANGES IN SOFT TISSUE DIMENSIONS

Description	Mesial Papilla (in mm)	Distal Papilla (in mm)	Mid Facial (in mm)	Mid Palatal (in mm)	Average
Baseline					
At 3 Months					
At 6 months					
Difference at 6 months					

3. PINK ESTHETIC SCORE (*Belser et al* 2009):

Description	Mesial papilla	Distal papilla	Curvature of facial mucosa	Level of facial mucosa	Root convexity / soft tissue colour & texture	Average
Baseline						
At 3 months						
At 6 months						
Difference at 6 months						

4. CHANGES IN MARGINAL BONE LEVELS:

Description	Height of labial bone (in mm)	Height of palatal bone (in mm)	Height of mesial bone (in mm)	Height of distal bone (in mm)
Pre operative				
At 6 months				
Difference				

5. BLEEDING ON PROBING (FOUR SITES PER IMPLANT):

Description	Mesial	Distal	Mid Facial	Palatal	Percentage Of Bleeding Sites
At 3 Months					
At 6 months					

6. POCKET PROBING DEPTH (FOUR SITES PER IMPLANT):

Description	Mesial	Distal	Mid Facial	Palatal	Average
At 3 Months					
At 6 months					
Difference at 6 months					

Signature of PG student Signature of the Guide

Date: