EVALUATION OF SOFT AND HARD TISSUE RESPONSES TO TWO DIFFERENT TYPES OF ABUTMENTS: A 1- YEAR PROSPECTIVE CLINICO-RADIOGRAPHIC FOLLOW UP STUDY

Dissertation

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In

PROSTHODONTICS, CROWN & BRIDGE AND IMPLANTOLOGY

By

Dr. TARUNA CHOUDHARY

Under the guidance of

Dr. Virag Srivastava

Reader

PROSTHODONTICS, CROWN & BRIDGE AND IMPLANTOLOGY

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

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Date: 5th July, 2021

Place: Lucknow

Taruna Choudhary

Dr. Taruna Choudhary

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This is to certify that the dissertation entitled **"EVALUATION OF SOFT AND HARD TISSUE RESPONSES TO TWO DIFFERENT TYPES OF ABUTMENTS: A 1- YEAR PROSPECTIVE CLINICO-RADIOGRAPHIC FOLLOW UP STUDY"** is a bonafide work done by **Dr.Taruna Choudhary**, under my direct supervision and guidance in partial fulfilment of the requirement for the degree of MDS in Department of Prosthodontics, Crown & Bridge and Implantology.

Virag Srivastava

Date: 5th July, 2021

Dr. Virag Srivastava
Reader
Department of Prosthodontics,
Crown & Bridge and Implantology.
BBDCODS, BBDU
Lucknow

ENDORSEMENT BY THE HOD / HEAD OF THE INSTITUTION

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Dr. Amrit Tandan
Professor & Head
Department of Prosthodontics
Crown & Bridge and Implantology
BBDCODS, BBDU
Lucknow

Dr. B. RAJKUMAR
Principal
Professor & Head
Department of Conservative
Dentistry & Endodontics
BBDCODS, BBDU
Lucknow

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Date: 5th July, 2021

Place: Lucknow

Taruna Choudhary

Dr. Taruna Choudhary

This Thesis Is Dedicated To My

Parents For Their Endless Love,

Support And Encouragement.

MR.SANJEEV CHOUDHARY

&

MRS. POONAM CHOUDHARY

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-Dr. Taruna Choudhary

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S.NO	ABBREVIATIONS	FULL FORM
1.	Bio-HPP	Biocompatible - High Performance Polymer
2.	PEEK	Poly Ether Ether Ketone
3.	CBL	Crestal Bone Loss
4.	MBL	Marginal Bone loss
5.	mPlI	Modified Plaque Index
6.	mBI	Modified Bleeding Index
7.	UNC	University of North Carolina
8	GIC	Glass Ionomer Cement
9	IOPA	Intra Oral Peri Apical

S.NO	Symbol	Description
1.	ǂ	NSK Surgic AP, Japan
2.	£	NSK, Japan
3.	©	©Planmeca Prostyle intraoral X-ray machine
4.	∂	Planmeca Pm 2002 Cc Proline
5.	₳	Dentsply India
6.	₸	X-ray Mesh Gauge, Dentech Corporation, Japan
7.	Δ	Osstell, A W&H Company
8.	€	Shofu
9.	ʊ	Marathon
10.	#	Adin Implant Pvt. Ltd
11.	α	Algitex
12.	Θ	Denstone, Pankaj Enterprises
13.	⁋	Nummit spray, ICPA health products Ltd. India
14.	﷼	Dentonum Forte ™
15.	∞	Dispo Van 3 ml

16.	*	Betadine
17.	ɣ	NS. Otsuaka Pharmaceutical India PVT. LTD.
18.	ϕ	Ethicon, Johnson & Johnson Ltd. India
19.	√	Elite P & P
20.	≠	Kalrock, Kalabhai Karlson Private Ltd, Mumbai, India
21.	ʕ	Coltene
22.	Ψ	GC
23.	ɕ	M-Seal P.T.F.F. Thread seal tape
24.	ȣ	Kodak @ Ekta speedfilm
25.	F	API
26.	%	Life Sheild
27.	ᵜ	GDC
28.	※	Hu-Friedy

ABSTRACT

BACKGROUND: Endosseous implants are routinely used for prosthetic rehabilitation of missing teeth. Presently, the prosthetic materials used for restoration have a high Young's modulus, thus transmitting the occlusal forces to the bone without any cushioning effect which is provided by PDL fibers in natural teeth but is absent in case of implants. Also, the peri-implant soft tissue health is of great significance for implant's long-term success which is facilitated by materials resistant to plaque accumulation. BioHPP (modified PEEK) has elasticity similar to bone, and is claimed to have properties like high polishability, inertness and less water-sorption.

AIM: The present study was conducted to evaluate the crestal bone loss and peri-implant soft tissue health in implants restored with Bio-HPP abutments as compared to conventional prefabricated titanium abutments.

METHODS:A total of 30 implant sites were divided in two equal groups. Group I implants were restored with titanium abutments and PFM crown whereas group II was restored with composite veneered Bio-HPP abutment. Crestal bone loss was evaluated radiographically in both groups and the soft tissue health was assessed with the help of mPlI and mBI at the time of prosthesis placement, 1 month, 3 month and 1 year later.

RESULTS: The difference in mean crestal bone loss in both the groups did not differ significantly ($P > 0.05$). However, net mean crestal bone loss percentage calculated between both the groups out of which group II shows 25% less bone loss as compared to group I. The difference in mPlI and mBI was also not statistically significant. ($P > 0.05$)

CONCLUSION: Within the limitations of the study, it can be concluded that BioHPP causes less crestal bone loss as compared to titanium abutment. There is no such clinically significant response of soft tissue surrounding implant.

INTRODUCTION

Revolutionary advancement in implant dentistry was achieved through clinical replacement of lost natural teeth by osseointegrated implants, which has proved to be successful treatment modality for years now. Remarkable advancements of dental restorative material, strategies and techniques along with scientifically proven approaches, that are predictably effective for long term management of tooth loss, provides dental patients with esthetically and functionally excellent options.

Partially or completely edentulous patients through implant retained crowns and prosthesis, no longer has to endure compromised function and reduced confidence that traditional removable partial or full denture wearers commonly experienced. Multidisciplinary approach in dental implantology, through careful treatment planning, meticulous surgical technique and precise prosthetic restoration, fosters to achieve success in different clinical scenarios in dental implant therapy.

The concept of osseointegration laid the foundation for modern dental implantology as we know it today. Dr. Per Ingvar Brnemark, a Swedish academic, discovered osseointegration by accident in the early 1950s while experimenting with titanium implant chambers in rabbit bone to analyse blood flow.[6]

Predictable Survival of endosseous implants is highly dependent on the integration between the implant surface and the oral tissue which includes both hard and the soft tissues. The initial sign of tissue breakdown at the implant- tissue interface is generally seen at the crestal region.

Inflammation of the peri-implant mucosa after osseointegration with simultaneous progressive marginal bone loss is called peri-implantitis. Among other proposed clinical signs,the operator usually evaluates the success of dental implants by studying the radiographic image of each implant to determine signs of marginal bone loss.[67] Peri-implant bone loss is frequently preceded by inflammation of the peri-implant soft tissue and is thought to be plaque induced. This usually gives rise to a crater-like bone loss around the implant.

Two main factors are thought to be responsible for the occurrence of peri-implantitis: bacterial infection [plaque theory] and mechanical overload [loading theory].The frequency of peri Implant bone loss has been reported to be in the range of 1%to19%.[2]

INTRODUCTION

Natural teeth, traditional dental prostheses, and dental implants all depend on bone for support. While the mechanisms of such support differ, the monitoring of bone level maintenance provides valuable information about the longevity of teeth and their replacements. Bone level maintenance is considered as an important factor in implant Prosthodontics. Currently used implant success criteria include measurements of bone levels and this radiographic criterion constitutes an integral part of routine clinical evaluation.[68]

Two periods have been defined within the normal parameters of peri-implant bone loss(1)A healing and remodelling period beginning at prosthesis delivery and lasting about 1 year, during which bone losses of 0.4 to 1.6mmmaybe recorded and (2)A follow-up period after the first year,in which marginal bone loss of 0.005 to 0.15mm per year can be observed.The mean bone loss for Branemark osseointegrated implantsis found to be 1.5mm for the first year,followed by a mean bone loss of 0.1mm per year.[6]

Thus, success of osseointegrated implants is determined by the crestal bone preservation around the implant. Enhanced crestal bone loss around dental implants during the initial healing and loading period leads to increased stress concentration in and around the crestal region during or after prosthetic loading. This has been demonstrated by several study results.

Because the periodontal ligament is lost when an implant is placed, the occlusal load is transmitted directly to the bone without any damping effect. There appears to be a threshold level that, if exceeded, will cause osteoclastic activity in the bone, potentially leading to implant failure.[9]

Such complications can be decreased by using a material which have a lower modulus of elasticity, and will give cushioning or damping effect to the occlusal load.

According to some researchers, a more resilient superstructure material, such as gold, resins, composites, and other materials, would be useful in reducing stresses around the implant due to the materials' elastic deformation behaviours.[10-12]On the contrary, there have been studies that claim to have changed the way people think. The stress levels were unaffected by the superstructure material.[14-16]

INTRODUCTION

According to published research, the surface characteristics of the abutment influence the healing of peri-implant tissue in a positive way, lowering the risk of post-operative infections significantly.[19]

PEEK (Poly ether ether ketone) is the lastest invention in dentistry and previously also have been used in medical field in orthopaedic department for joint replacement surgery and claimed to have better properties as compared to existing material.

PEEK is a thermoplastic material which withstand high temperature and semi crystalline in nature with high melting temperature range. It is known to have better physical and mechanical properties. One such property is its elastic modulus that isclose to that of cancellous bone, which helps in even distribution of stress from the implant to the surrounding bone. However, PEEK has only been used in temporisation in implant abutments as its tensile strength is inadequate for use as a final abutment.[25]

As a result, ceramic fillers were added to PEEK in an attempt to improve its physical properties. PEEK has been modified to Bio-HPP where bio refers to its biocompatible properties and HPP denotes for High Performance Polymer.

Bio Hpp is reinforced with approximately 20% ceramic particles to withstand extreme forces, allowing it to be used as a prosthetic framework.Its modulus of elasticity is comparable to that of bone and PEEK. The ceramic filler present is of grain size 0.3 to 0.5µm grain size (Bredent). Its bio-inertness and low surface roughness of 0.018 m RA (Jena Uni) aid in better peri-implant tissue healing.[21,23]

The purpose of this study was to assess crestal bone loss and soft tissue health(Modified Plaque and Bleeding Index)around implant using Bio-HPP abutments with composite veneered crowns and titanium abutments with pfm crowns. The changes will be evaluated radiographically and clinically in the peri-implant bone at the time of prosthesis placement, at interval of 1month, 3 month and after 1 year. The radiographic findings will be correlated with clinical findings.The criteria both subjective and objective will be used to evaluate the success of the implant process. The necessary statistical analysis will be performed to obtain results.

AIM AND OBJECTIVES

AIM:

To evaluate effect of BioHPP, PEEK and Titanium abutments on bone crestal level and peri-implant soft tissue health.

OBJECTIVES:

1. To evaluate the Crestal bone level, modified plaque index (mPlI), and modified Bleeding Index (mBI) at the time of prosthesis placement of using Bio-HPP and Titanium abutments in separate groups.

2. To evaluate the Crestal bone level, modified plaque index (mPlI), and modified Bleeding Index (mBI)1 month, 3 month and 1 year after prosthesis placement of both groups.

3. To find the difference in the mean changes in crestal bone level, modified plaque index (mPlI), and modified Bleeding Index (mBI) 1 month, 3 month and 1 year after prosthesis placement of both groups.

Structured review of scientific publications in English literature related to dissertation topic **"EVALUATION OF SOFT AND HARD TISSUE RESPONSES TO TWO DIFFERENT TYPES OF ABUTMENTS: A 1- YEAR PROSPECTIVE CLINICO-RADIOGRAPHIC FOLLOW UP STUDY"** was done.

Albrektsson T et al (1986)[26] proposed six criteria which are applicable for defining the clinical success of endosseous dental implants and these criteria are suggested for use in clinical examination on implants.

1. The individual unattached implant should be immobile when it is tested clinically.

2. No evidence of peri-implant radiolucency should be present which should be assessed on a radiograph which is undistorted.

3. The mean vertical bone loss around the implant should be less than 0.2mm per year after the first year of prosthetic rehabilitation of implant.

4. No persistent pain, discomfort or infection should be caused by the implant.

5. By these criteria, success rate of 85% (5-years observation period) and 80% (10 years period) are minimum levels for success.

Alberktsson et al (1988)[1] conducted a follow up study over a period of 5 to 8 years. They reported that in the mandible out of the 334 implants examined, there was a success rate of 99.1%. In the maxilla out of 106 implants examined, a success rate of 84.9% in irradiated and grafted mandibles, none was lost in up to five years whereas 3 out of 16 implants in grafted and 12 out of 71 implants in irradiated maxilla failed.

Rossen V et al (1990)[27] calculated by means of three dimensional (3-D) finite element analysis, the stress distribution in bone around implant with and without stress absorbing elements. In this study, two loading situations (1) Purely implant

supported prosthesis (not connected to tooth), (2) loading an tooth- implant supported prosthesis were analysed to ascertain with finite element analyses which of the concepts mentioned, presents with the most uniform stress-distribution in bone when a stress-absorbing element (SAE) is used. The results of this study suggest that: A stress-absorbing element (a material which can be describes as analogous with periodontium- i.e.a material which has modulus of elasticity lower /similar to bone) in a freestanding implant may function as a damping element (reduce the maximum stress by damping the occlusal force; i.e. stress absorption) but not as a stress-distributor.

Brosh T, Persovki Z, Binderman I (1995)[28] conducted a study of the following four biomechanical parameters: peak force, vertical displacement, interface stiffness and strain energy to assess the bone-implant interface properties. It was suggested in this study that the interface stiffness, which was believed to be a significant factor for success of implant, increased in three months during healing phase in dogs. These three months is comparable to four to six month when healing period in human mandibles is considered. Four months were appropriate for lamellar bone formation after implant surgery and the restorative treatment can be proceeded with if presence of such bone can be seen.

Fritz ME (1999)[2] published a research article on two stage implant systems. He stated in this article that two-stage dental implants are successful with confidence interval of 90%. It also appeared that the implants placed in mandible are more successful as compared to maxillary implants.

Bahat O (2000)[3] evaluated Branemark System implants placed in posterior maxillae that have been restored with fixed partial ceramometal restorations and followed for 12 years after loading. The cumulative success rate of 94.4% \and 93.4 after 5 to 6 years and 10 years respectively was observed. The study concluded that surgical techniques are chiefly vital to the success of osseointegrated implants placed in the posterior segment of maxilla. With careful planning and execution, a success rate of approximately 95% in a period of 5 years can be achieved.

Bouri A et al (2008)[29] conducted a cross-sectional study which basically determined a correlation between the width of keratinized mucosa and the health of

soft tissue health around implant. The results validated considerably higher mean gingival index score, plaque index score and radiographic marginal bone loss for implants which had a narrow zone (< 2 mm) of keratinized mucosa. Thus, it was concluded that the higher width of keratinized mucosa around implants is directly associated with lower mean marginal bone loss around implant.

BONE CRESTAL LEVEL

Smith and Zarb (1989)[30]stated in their article named "Criteria for success of osseointegrated endosseous implants" that bone support around implant is an important criterion for success determination. Based on the findingson submerged implants. This study also reported annual marginal bone loss of 0.2mm around implant after 1 year post prosthetic rehabilitation which supports the finding by Albrektsson.

Also, to the 5 criteria for success given by Albrektsson, one more criteria was added, which states that the implant design should not impede upon crown prosthesis placement with a satisfactory appearance to the dentist as well as the patient.

Behneke et al (1997)[62]conducted 3-year longitudinal study on hard and soft tissue reactions to ITI screw implants. 320 implants were consecutively placed in 109 patients.Study focused on implant success and clinical proof and the patients were observed in a prospective longitudinal manner. Hard and soft tissue reactions were examined through radiologic and clinical parameters which were established at specific time intervals.Clinical parameters and the measured bone resorption were analysed and correlated.75of patients were edentulous, and 16% had distal extensions or additional edentulous spaces. Nine percent of the implants were for single-tooth replacement. In follow-up, a total of 10 patients with 29 implants dropped out, and 6 implants were lost as a result of failed osseointegration. 98.1% cumulative implant survival rate was found and the cumulative implant success rate, using strict criteria for success, was 97.1% after 3 years. The mean bone loss between implant placement and prosthetic restoration was calculated and found to

be0.8 mm. Mean annual bone resorption of approximately 0.1 mm was between prosthetic treatment and the 3-year examination was observed. The periodontal parameters indicated a healthy soft tissue response when values were calculated. A definite relationship between the crevicular fluid volume and bone resorption was analysed through the statistical analysis and correaltion. The results of the study stated that ITI screw implants, with the nonsubmerged healing characteristic, can serve as a reliable foundation for implant-supported restorations.

Giano Ricci et al (2004)[64] conducted a study in which they reported crestal bone resorption 5 years after implant loading through clinical and radiologic results with a 2-stage implant system. Clinical assessment was done through parameters which included plaque score monitoring, bleeding on probing, probing depth, type of occlusion, and prosthetic adaptation. Peri-implant bone resorption was measured through Intraoral radiographs and compared using suitable software. Survival rate of the implants was 100%. Plaque was present on 42% implants. Bleeding on probing was evident 15.5%. Probing depth was noted > 5 mm for 5 implants (4.5%). Crestal bone resorption was > 3 mm for 28.6% implants; the average observed crestal bone resorption was 2.17+/-1.6 mm.Relatively short functional period and strict and frequent clinical evaluations with oral hygiene procedures during the supportive periodontal therapyresulted in the survival rate of the implants.

Vasconcellos L G O et al (2011)[31] studied effect of axial loads on implant supported partial fixed prosthesis by means of strain gauge analysis. They stated that when an occlusal load is employed on a prostheses supported by implant, the load is transferred partially to bone, with the highest stress occurring in the neck area of implant. Therefore, greatest micro deformation occurs in cervical area of implant, and this is not dependent on the bone type, the implant design, prosthesis configuration and the type of load applied.

P Papaspyridakos et al (2012)[8]conducted a systematic review of biologic and technical complications with fixed implant rehabilitations for edentulous patients. They concluded that crestal bone loss more than 2mm was the most common

biologic complication. Screw fracture was found to be the most common technical complication

A Dannan (2012) [32] published review article titled "Crestal Bone Loss Around Dental Implants; A Short Communication." In this article he stated that non-submerged implants demonstrated early crestal bone loss. Maxilla had greater bone loss than mandible, with a range of 0.6 mm to 1.1 mm during 1st year of function. Mean crestal bone loss around these implants was 0.71 mm at the mesial and 0.60 mm at the distal side; bone losses more than 1 mm for 29.7% sides and more than 2 mm for 2.5% sides were recorded. In this study it was found that when implants are placed with their polished surface in contact to the bone a higher amount of bone loss is present.

Also, they pointed out that it is a common belief nowadays, that increased bone loss around implants which have less than 1 mm implant shoulder-to-bone crest distance (DIB) might be because of following reasons which are 1) Higher bone resorption occurs because of plaque accumulation in the subgingival microgap between the implant and the abutment 2) the polished surface is in contact or 3) the biologic width is encroached. It is established that biologic width of implants which are placed with a DIB less than 1 mm is insufficient. Thus, this results in a major increase in bone loss.

Suarez et al (2013)[33] did a systematic review comparing marginal bone level between implants that were loaded immediately, early and conventionally . The review concluded that timing of restoration has no effect on implant crestal bone level.

Nemli et al (2014)[34] conducted a clinical study to evaluate submerged and non-submerged implants for posterior tooth replacements. 20 patients were involved in this study out of which 2 dropped out, thus 18 patients (split mouth design) were studied. The results reported significantly higher marginal bone loss around submerged implants (around 0.7 mm) than around nonsubmerged implants (approximately 0.6 mm) in a period of 2 years.

Kapoor et al (2014)[35]conducted a study to evaluate the crestal bone loss around platform switched implants. Radiographic examination was conducted using a parallel cone technique for IOPA radiograph. They used a lead grid with $1mm^2$ grid

pattern which was affixed on to the film during exposure to allow for image distortion errors.

Adobe photoshop software was used to analysis the IOPAs . Bone loss was measured on a micrometer scale using the measuring tool available in the software. Points selected were as follows:

Mesial : Distance between the 1st coronal thread on the implant to the most coronal point on the mesial alveolar bone crest.

Distal: Distance between the 1st coronal thread on the implant most coronal point on the distal alveolar bone crest.

Lekholm et al (2014)[63] conducted a study in which 1591 partially edentulous patients from age 17-70 years were treated With Branemark Implant system, five years follow-up was done in this study on implant success and prosthesis stability. Periodontal parametres like plaque and gingival index and probing depth were recorded. Marginal bone was determined through intra oral radiograph. 558 implants were placed in 68 maxilla and 91 mandible in cases including Applegate Kennedy class 1, 2 and 4. Second stage surgery was done 521 out of 528 implants were restored. After follow-up it was noted that 36% Implant failed16% could not be re-examined.

On follow-up Implant success rate 92% and 94% for Maxilla and mandible respectively and Corresponding prosthesis stability was 94%. Plaque and gingivitis index showed similar pattern of good health around titanium abutments. Mean marginal bone loss in five years recorded did not exceed 1mm. Study indicated that safe and predictable treatment results were obtained for 5 years in partially edentulous jaws treated with the Brånemark implant technique.

Kim et al (2015)[36] studied factors associated with crestal bone loss following dental implant placement in a longitudinal follow-up study. In their study, changes in crestal bone height were estimated by measuring radiographs amended for magnification errors by calculating a ratio of the known implant length divided by the implant length measured radiographically. The first postoperative radiograph and

the latest follow-up radiograph were compared. Measurements of the bone levels were done at the mesial and distal sides . The lowest crestal height point was used for study.

They also stated that CBL < 1.5 mm in the first year and following annual bone loss of 0.2 mm is normally accepted as within physiologic limits. However, continued CBL may result in more mobility and consequent failure

Robert F. Heary et al (2017)[20]conducted an in vitro study to examine the modulus of elasticity of different materials used as interbody implants. Theystated in their article that Implants with greater stiffness than surrounding bone, such as metal implants, cause acceleration of the deteriorating process at the adjacent levels.

Flanagan D (2017)[37] reviewed bite force and dental implant treatment. He stated that at the time of prosthetic delivery, Keeping occlusal surface approximately 30µ short of the opposing tooth contact apparently does not reduce loading during mastication significantly. Many dentists leave a small occlusal gap to avoid occlusal contact of solely the implant crown during function as remaining natural teeth undergo functional intrusion which the implant cannot undergo because of absence of PDL. This done so that loading impact on the prosthesis during parafunctional activities may be lessened. Nevertheless, load created during mastication may not be lessened. Generally a maximum jaw force is in a span of 50 to 900N.

Kushaldeep, Tandan A, Upadhyaya V, Raghuvanshi M (2018)[38] conducted a radiographic and clinical study for comparative evaluation of the influence of immediate versus delayed loading protocols of dental implants. For analysis of crestal bone loss Intra oral peri-apical radiographs were developed for all the implant sites present in the selected patients' mouth. Imaging errors were compensated by the use of a lead mesh with a 1-mm^2 grid pattern which was placed on the sensor during exposure. Standard long cone paralleling technique with film positioning device was used. Once the first restoration on implant as placed, the follow-up was scheduled at 1, 3, and 6 months for radiographic evaluation at each time interval. The distance was measured between abutment junction to the point of 1st contact between bone and implant Measurements were done on mm scale for mesial and distal side.

Szpak P, Szymanska J (2018)[39]conducted a study to assess the impact of the specific characteristics of implant-prosthetic treatment on marginal bone loss around

implants. 28 subjects were included in this study. The marginal bone loss was assessed in these patients for upto 46 months, They reported that MBL around implants in incisors region was significantly greater viz. by 0.296 mm ($p = 0.038$), and around implants placed in canine regions – by 0.364 mm ($p = 0.023$) as compared to premolars which was used a reference category. The differences in marginal bone loss between implants placed in the molar area and premolar area was not found to be statistically significant ($p = 0.187$).

In the regression model, difference occurred in the bone loss around implants place above the compact bone level, in comparison to the implant placed below the level was not found to be significant ($p = 0.339$).

Also, there was a statistically significant correlation with time implant placement and loading and marginal bone loss.

Jafarian, Mirhashemi, Emadi (2019)[40] supported in their finite element analysis of stress distribution around a dental implant with different amounts of bone loss the findings of other research, reporting no significant difference in the level of stress at 1 mm of crestal bone resorption however, bone resorption of 2 mm or more was followed by higher levels of stress.

David French et al (2019)[41] conducted a retrospective cohort study of 4,591 dental implants: for analysis of risk indicators for bone loss and prevalence of peri-implantitis. They grouped the risk factors for marginal bone loss around implants into patient related and implant related risk factors. The following patient related risk indicators were found to be significant with regard to MBL: autoimmune disease, smoking and bisphosphonate use. As for implant factors, including location, diameter and design, all were found to be significant with regard to marginal bone loss. Interestingly, diabetes (pooled type 1 and type 2) was not found to have a significant effect on MBL. Of the surgically related risk indicators, immediate implant loading and presence of a bone defect with bone grafting were found to have an effect on MBL. Bone grafting during implant placement was also found to be a significant risk indicator for bone loss, with more MBL in grafted sites when compared with native bone.

Adrien Naveau et al (2019)[42] in their structured and detailed review article on etiology and measurement of Peri-Implant Crestal Bone Loss (CBL) have described the various techniques for measuring Crestal Bone loss around endosseous implants. They stated that standardized intraoral (or periapical) radiographs have been, and is also presenly, one of the most commonly used techniue for longitudinal assessment of peri-implant bone loss. Nonetheless, digital radiography is being increasingly used in dental practice.

The long cone paralleling technique is considered standard rather than bisecting angle technique.

When digital radiography (RVG) is used, a sliding gauge tool can be used which is available with most of RVG related software to measure the distance between selected reference-points.

Also, the digital subtraction technique can be used to directly measure bone loss by superimposing two sequential radiographic images to distinguish bone changes and quantify the difference with ease.

These days majority of studies integrate digitalization of a conventional radiograph film and using graphic softwares like adobe photoshop for measuring the radiographic parameters. They found that conventional film and digital radiography exhibit the same accuracy. Digitized conventional films may display more noise artefacts and may mislay density range but still provide comparable measurements. They described the pros and cons of IOPA for measuring crestal bone loss in this study which stated that advantages of conventional IOPA are the low exposure dose and ease of availability. Combined with its low cost, the reliability of linear distance measurements, this technique remains the gold standard for routine clinical measurements. However, only the mesial and distal CBL can be assessed with this technique. Additionally, in cases of peri-implantitis, bone levels were often shown to be more apical than measured radiographically. The oblique measurements can be influenced by geometric distortions and superimposition of anatomical structures, especially since a strict parallel projection is difficult to obtain in some clinical situations. additionally, Standard IOPA do not permit identification of the 3D morphology of a bone defect (intra-bony and supracrestal components)

Further on, they have discussed novel methods for measuring crestal bone loss like CBCT and photoacoustic ultrasound.

Rubashree et al (2021)[61] conducted a study in which the crestal bone loss in prefabricated titanium abutmemts and castable cobalt-chromium abutments were evaluated and compared. The study was conducted on five partially edentulous patients who needed fixed replacement of missing teeth. Each of the patients received Prefabricated abutments on the right side and Castable abutments on the left side.The available bone height and width and vital structures were assessed through Intraoral periapical radiograph and orthopantomogram.

Patients were reviewed after 3 months. The measurement of bone levels on the mesial and distal side of the implant was performed parallel to the long axis of the implant from point of reference to the first bone-to-implant (BIC).

It was evaluated that mean values for group 1 and group 2 shows no significant difference at the time of loading and 3 months later. When compared to group 1 the crestal bone loss for group 2 was found to be less at the time of loading and after 3 months of loading. It was concluded that there was no statistically significant difference in crestal bone loss between prefabricated and castable abutments at the time of loading while there is a significant increase in bone loss for prefabricated abutments after 3 months of loading.

BACKGROUND AND APPLICATION OF BIO-HPP

Kolbeck C, Rosentritt M (2012)[43] stated in their presentation that Bio HPP - High Performance Polymer - is a thermoplastic material, It is easy to use clinically, It is biologically inert material without any side effects.

This material has been used for more than 2 decades in human heart valve replacements, spinal interbody implants, hip joint replacements etc.

Siewert B, Parra M (2013)[44]described Polyether ether ketone (PEEK) as a thermoplastic resin used in medicine for several years. This semi-crystalline

composite offers a exclusive blend of exceptional physical properties, high thermal stability and impressive resistance to chemical damage. These are some of the reasons because of which PEEK can be used as a material for fabrication of framework for RPD, tooth-implant-supported and implant-supported bridges

The Bredent official[22] website has information on BioHPP as follows: BioHPP (High Performance Polymer) is based on polyether-ether-ketone (PEEK) polymer and was introduced as dental material for manufacturing the hybrid denture framework by the Bredent factory. The strength of PEEK is anadequate, thus it is improved by adding ceramic filler particles (with the grain size of 0.3 to 0.5 µm). The homogeneity produced because of small grain size is a significant criterion for these exceptional material properties and forms the basis for unswerving quality.

The Elatic modulus of BioHPP lies in the range of 4 GPa, which is very similar the modulus of elasticity of cancellous bone (e.g. in the mandible), so that the chewing forces receive a cushioning effect. The maximum fracture resistance, indicating the force (in Newtons) at which the sample fails, were found to be approximately 1200N , which can be considered adequate for safety margin, in comparison to maximum chewing force of 500N for a human bite. The bond strength of BioHPP framework bonded with crea.lign composite veneering system is of about 25 MPa. The surface quality of the material and its low roughness depth of 0.018 µm RA (Jena Uni) rules out gum irritation. Other characteristics of BioHPP polymeric dental material are: flexural strength is >150 MPa, , water solubility <0.3µg/mm3, M=melting range (DSC) is approx. 340°C, water absorption=6.5 µg/ mm3, thickness=1.3-1.5 cm3, hardness (HV)=110 HV 5/20, thermocycling 10,000 cycles 5°C/55°C in accordance with DIN EN ISO 10477

*** http://www.bredent.com/en/bredent/download/26737/

Vosshans et al (2013)[45] mentioned the many advantages of BioHPP as a framework material like restorations made Bio-HPP are less heavy because of low specific gravity of the material, modulus of elasticity between that of compact and cancellous bone, Occlusal load damping effect, metal-free restorations, low material fatigue, good biocompatibility, low plaque deposit, no corrosion, no viscoplastic fractures; It gratifies various requirements like osseointegration , stress-free primary

framework, convenient insertion/removal of movable prostheses for patients, good hygiene, plaque resistance, colour stability, fixedness of prostheses.

27. Rzanny A, Gobel R, Fachet M (2013)[46] reported that Breaking biopersistence of HPP is greater than twice as compared with that of Lithium Ceramics Disilicate. Contrasting to other materials generally used presently for skeleton restorations, the modulus of elasticity of Bio HPP is quite similar to that of bone. This resemblance to bone offers particular advantages, especially for large stretch frames

A summary of the Bio HPP main features can be structured as follows:

- Good alternative to metals and alloys;

- Biologically inert and stable

- The less thickness of the walls can be achieved easily;

- Easy to polish with good results;

- Not abrasive to antagonist;

- It can be used in does per gram, thus, waste of material is greatly reduced;

- it has a light processing;

- the elasticity of the material is closer to that of human bone thus kinder to bone;

- No contraction;

- specific weight is very less, less than titanium

- the cost price is low, due to reduced material wastage

Cigu et al (2015)[21] studied the behaviour of Bio-HPP material in oral cavity, in vivo. In their research, they found, for the 10 patients who used the Bio HPP system, the dentist detected a positive development of the treatment both in the oral sphere and in the other organs and systems. Therefore, a highly positive aesthetic and adaptation effect was obtained, the intervention not affecting grinding of the remaining teeth, while tooth antagonists enamel was protected and no metal galvanic cell effect occurred in the mouth, and no pigmentation. Clinical and laboratory

results and track record analysis of the clinical cases resulted in the replacement of the full dentures existing in the mouth of patients.

Edwin Sever Bechir et al (2016) [23] presented the results of their clinical trials referring the avantages of BioHPP Polymer as superstructure material in oral implantology. The results demonstrate that BioHPP polymer as superstructure on dental implants present many advantages, therefore this PEEK type of dental material represents a beneficial new acquisition for patients'oral health.

With a modulus of elasticity of around 4 GPa, BioHPP is about as elastic as bone, which helps mitigate any stress that might develop and reduces stress shielding. This also means bone-related torsion can also be balanced out t some extent, which is important with larger implant work In addition, BioHPP is also particularly suitable for patient with allergies because of its very low water solubility of 0.3 μg/mm3 and its low reactivity to other materials.

Heary RF, Parvathreddy N, Sampath S, Agarwal N (2017)[20] The aim of their study was to examine the stiffness characteristics and define the modulus of elasticity for a variety of materials commonly utilized in spinal surgery: titanium alloy, 316 L stainless steel, cobalt-chromium, PEEK, CFRP (30% carbon, 70% PEEK), cortical allograft bone, and cancellous allograft bone.

They stated that implants with stiffness much greater than that of surrounding bone, such as those made of metals, have been shown to cause acceleration of the degenerative process at the untreated adjacent levels.

Georgiev et al (2018)[24]conducted a acritical survey among 299 literature sources related to PEEKs and in particular with BioHPP. The authors states that conferring to the literature in this field the physical properties (Particularly the modulus of elasticity) of BioHPP are closer to those of the bone tissues, and this feature gives an advantage of it as compared to the alloys and ceramics. BioHPP has a wide array of applications in prosthetic dentistry. It can be used for fixed and removable restorations, frameworks, suprastructure for implants. Processing of this material is done by pressing and by CAD/CAM technology.

Jin H et al (2019)[47] did a comparative evaluation of BioHPP and titanium as a framework veneered with composite resin for implant supported fixed dental prosthesis. This study preliminarily tested the fracture resistance of veneered implant-supported FDPs. Differences were found in the compressive strength between the 2 veneered framework materials. The BioHPP frameworks fractured at a mean load of 1518 ±134 N, with lower compressive strength than that of group Ti. However, the value was still higher than the reported maximum molar masticatory force of 600 to 920 N.31,32 This suggested that veneered BioHPP FDPs exhibited acceptable resistance to fracture for posterior use.

This study found that BioHPP, as a framework material, exhibited relatively good properties, especially high shear bond strength with composite resin, suggesting that this nonmetallic framework material may serve as an alternative for implant-supported FDPs and even Complete-arch fixed implant supported prostheses.

PERI IMPLANT SOFT TISSUE HEALTH

Mombelli A,Van Oosten MAC (1987)[48]in their article: "The microbiota associated with successful or failing osseointegrated titanium implants" developed the clinical indices for assessment of soft tissue around implant by modifying the conventional indices given by Silness and Loe for natural teeth.

They mentioned that no standard indices similar to those used for the evaluation of periodontal conditions have been defined for the characterization of peri-implant tissues.

Periodontal parameters are not strictly applicable to the features of tissues encountered around implant fixtures. It seems reasonable to define parameters applicable to the periimplant area which are based on periodontal indices such as the Plaque Index , Sulcus Bleeding Index and Gingival Index. Such parameters were developed to assess plaque by the criteria of a modified Plaque Index (mPlI) The bleeding tendency of the marginal periimplant tissues was evaluated using a modified Sulcus Bleeding Index (mBI)

Buser D, Weber HP, Lang NP (1990)[49] evaluated correlations between bone levels recorded on radiographs and the extent of peri-implant probe penetration have been

observed. In screw-type implants, the tip of the apparently stoped 1.4 mm coronal to bone level. The mean discrepancy between probe penetration and the location of the bone margin in radiographs was 1.17 mm in 100 non-submerged hollow-screw and hollow- cylinder implants measured 1 year after implantation.

35. Ciancio et al (1995) [50]reported the effect of antiseptic mouth rinse on parameters important to dental implant maintenance in anRCT, At the end of 3 months, the use of antiseptic mouth rinse resulted in statistically significant reductions in plaque index, gingival index and bleeding index compared to the placebo group. However, no significant differences between groups were observed in terms of PD or CAL. Thus, twice daily use of an antiseptic mouth rinse may provide benefits in the maintenance of dental implants

Zitzmann NU, Berglundh T, Ericsson I, Lindhe J. et al (2004)[51] An experiment trial was carried in which implants were exposed to "experimental peri-implantitis" in 5 Labrador dogs to study the presence and progression of inflammatory lesions in tissues surrounding implants. The results indicated loss of one implant during "experimental peri-implantitis" period and 2 implants during 12 months after ligature removal. The radiographic examination also revealed varying amounts of additional bone loss in the majority of the implant sites also following ligature removal. It was concluded that a decrease of the damaging inflammatory lesion in the soft tissues around implant was seen in some sites after ligature was removed, but in most sites added loss of supporting bone ensued.

Giovanni E. Salvi et al (2004)[52] reviewed the literature on clinical, radiographic, and biochemical parameters used for monitoring peri-implant conditions of literature upto August, 2003.

They reported that Bleeding on probing (BOP)recorded after the insertion of a probe into the sulcus with light pressure (ie, 0.25 N) has been shown to detect the presence of an inflammatory lesion in the gingiva around teeth with a normal and a healthy but reduced periodontium. On the other hand, absence of bleeding on probing (BOP–) has been reported to represent periodontal health with a negative predictive value of 98.5%.

Also, this study showed less clinical significance of Gingival Index System (GI) to be used as a parameter based on the fact that they found only a weak correlation between GI scores and changes in the marginal bone level was stated in a longitudinal study.

Their concluded that research efforts are still in progress to find a correlation between biologic parameters to morphologic changes in peri-implant hard and soft structures. Nonetheless, consistent prognostic indicators are still scarce to assess peri-implant hard and soft tissue changes.

Rismanchian et al (2006)[65] conducted study in which they reported the Effect of Plaque on Peri Implant Soft Tissue Health for which 4 Years Follow up was done. In this study 45 patients with 211 dental implants were examined clinically for four years after prosthodontic implant treatment. Periodonat parameters including Plaque index and health indices of soft tissue including pocket depth, attachment level, bleeding index, and gingival index were measured for 4 years. The results were compared between two groups of zero and nonzero plaque. ANOVA and Friedman test were used for statistical data analysis.

The results showed that in the first group, in which the plaque index was zero, probing pocket depth, probing attachment level, bleeding index, and gingival index were lower than in the second group in 4 year time. In accordance to the results of this study, aggregation and increase of plaque around dental implants decreases the health level of soft tissue around dental implants and its continuation may cause disease in perimplant soft tissues of the implant.

Roos-Jansaker AM et al (2006)[53] conducted a follow-up study to assess factors related to peri-implant lesions. The results suggested that the presence of keratinized mucosa and plaque were associated with mucositis. Smoking was found to be associated with mucositis, bone level and peri-implantitis. History of periodontitis has been shown to have relation with peri-implantitits. Thus, authors concluded that individuals with a history of periodontitis and individuals who smoke are more likely to develop peri-implant lesions.

Monica H. Abreu et al (2007)[54]conducted a cross-sectional observational study to evaluate periodontal and peri-implant conditions in patients with implant-supported

prosthesis clinically and radiographically. 41 patients were examined in this study. Following implant-associated parameters were examined: Modified Plaque Index (mPlI), Modified Bleeding Index (mBI), probing depth (PD), clinical attachment level (CAL) and bleeding on probing of the bottom of the crevice (BOP). The remaining teeth were also examined by recording the scores of Plaque Index (PlI), Gingival Index (GI), PD, CAL and BOP. The crestal bone loss was evaluated by means of periapical radiographs. Bone loss was estimated using measurements of pre-operatory and final bone levels associated to teeth and a comparison with bone loss around implants. None of the implants failed during the course of the study. No statistically significant differences were observed between PlI (0.90±0.07) and mPlI (0.82±0.13), or between GI (0.11±0.02) and mBI (0.10±0.02). Nonetheless, implants showed higher values of PD, CAL and BOP natural teeth (Wald Test, $p<0.01$). Implants presented a mean annual bone loss during the study period of 0.77mm (SE=0.06).

Measurements were assessed at four sites (distal, buccal, mesial and lingual/palatal) of each implant and remaining teeth, rounded to the closest millimeter..

In order to test for reproducibility, double measurements were taken with a 40 minute interval in 10 patients with the same characteristics as those of the study sample Examination was performed with a North Carolina periodontal probe.

Dr Mohammed A. Alshehri (2011)[55] stated the importance of biological width around implant and deleterious action of peri-implantits on crestal bone in his review article "The maintenance of crestal bone around dental implants."

In this article, the author described biological width as one which denotes the dimensions of periodontal and peri-implant soft-tissue structures such as the gingival sulcus, the junctional epithelium, and the supra-crestal connective tissues

It is established in literature through abundant studies which have shown that crestal bone resorption does not start until the implant is uncovered.

The exposure of implant to the oral cavity perpetually leads to bacterial contamination of the microgap between the implant and the prosthesis. Bone

remodelling will continue until the biological width has been established and stabilised. This width progresses not only apically along the vertical axis but also 1 to 1.5 mm horizontally, according to studies conducted by Tarnow et al. This is the reason for maintaining a minimum distance of 3 mm between two implants and platform switching in the aesthetic reconstruction zone in order to obtain intact papillae and stable inter-implant bone.

Theofilos Koutouzis, Joseph Richardson,Tord Lundgren (2011)[56] studied Comparative Soft and Hard Tissue Responses to Titanium and Polymer Healing Abutments. This study was done to gauge soft and hard tissue responses to titanium and polymer healing abutments over a 3-month time period. Sixteen patients were included in this prospective trial. Implants were given either titanium or polymer healing abutments. Changes of crestal bone level and soft tissue dimensions were recorded at the time of implant installation and at 3 months.

They mentioned that there is inadequate evidence from human studies assessing the soft tissue interface for abutments with different material of different chemical structures such as polymers on the basis of clinical outcome measures.

In conclusion, the findings of the current clinical study utilizing implants temporally restored with PEEK or titanium healing abutments indicate that PEEK healing abutments do not render an increased risk for marginal bone loss and soft tissue recession during the initial healing period.

Jaisika Rajpal et al (2014)[57] conducted a clinico-radiographic in vivo study to assess hard and soft tissue changes around Implants. In this study, the radiographic findings were correlated with clinical parameters of mobility, probing depth, bleeding, etc.

There was an increase in plaque accumulation from baseline to 1st and 3rd month, but there was a subsequent decrease in plaque from 1st to 6th month. This can be attributed to the plaque control by the patient and the repeated reinforcements of oral hygiene measures given to the patient by the clinician. However, the reduction was not statistically significant ($P > 0.05$) that is, a change in plaque index at different periods remained statistically the same

Bleeding on probing (probing in the depth of the pocket until a, slight resistance is met) and gingival index are one of the periodontal parameters used to evaluate the presence of an inflammatory process at the base of the periodontal pocket. There was an increase in BOP and gingival index from baseline to 1st month, but there was a subsequent decrease in BOP from 1st to 6th month. This can be attributed to the fact that after loading the implant hygiene could not be well maintained in the subgingival regions, but later when the repeated reinforcements of oral hygiene measures were given to the patient the inflammation subsided and so did BOP. However, the reduction was not statistically significant ($P > 0.05$) that is, a change in bleeding and gingival index at different periods remains statistically the same.

Plaque index, BOP, gingival index decreased over the entire 6 months period and was co-related with the other clinical parameters. Probing depth around implants at mesial, buccal, distal and lingual surfaces increased from baseline to 6 months, but this increase was nonsignificant. Calculus increased significantly from baseline to 6th month. All the implants were immobile at the end of 6 months period, with Grade 0 mobility. Radiographic evaluation of intraoral periapical radiograph of the implant at mesial and distal sites revealed significant decrease in bone height indicating bone remodelling around the implant. No radiographic peri-implant radiolucency was seen around any of the implants.

Jungwon Lee et al (2015) [58]conducted a study to evaluate the effectiveness of powered toothbrushes for plaque control in patients with peri-implant mucositis, in comparison with manual toothbrushes This randomized, prospective, controlled, clinical parallel study compared the efficacy of manual and powered toothbrushes for plaque control in implant restorations. Clinical parameters, including the modified plaque index (mPI), the modified sulcus bleeding index (mSBI), and clinical photographs (buccal and lingual views) were recorded at baseline and at one-month and two-month follow-up visits.

Xiao-Xiao Zhang et al (2016)[59] evaluated the long-term predictability of early-loaded Straumann implant-supported fixed segmented bridge works in edentulous maxillae.

Ninety-one implants were placed in 12 patients with edentulous maxillae. After placement, a healing period of 6 weeks elapsed,then, the patients were recalled and the abutments were tightened and fixed full-arch prostheses were cementated. Next, the patients were followed up at 1, 3, 5, and 10 years of time intervals after loading implants for clinical parameter evaluation. Implant success was assessed based on soft tissue condition around implant, technical complications, crestal bone loss and patients' satisfaction. The following clinical variables were recorded to assess the periimplant soft tissue conditions: modified plaque index (mPLI), pocket probing depth (PPD), modified bleeding index (mBI).

These parameters were also recorded at the baseline, except for mPLI, since it was not meaningful to evaluate mPLI immediately after the prostheses were delivered.

Biological benefits of Bio-HPP as described by the Bredent company in their reports based on clinical trials are mentioned below:

- Biocompatible –It is classified under class 2a medical device and fulfils with all relevant DIN standards, not cytotoxic (DIN 10993-05,10, 11, 03, 12)
- Metal-free thus ion exchange does not take place, allergies are minimal if not completely absent, no metallic taste
- Plaque-neutral – small particle size thus better polishibilty, less water sorption
- Kind to the gingiva
- Ease of polishing and cleaning- BioHPP can also be easily cleaned by the patient using a soft toothbrush without roughening the surface. Cleaning can be conveniently done with a soft abrasive agent and following which polishing is carried out with standard tools. Surface roughness of 0.05 μm is achieved to protect against discoloration and plaque accumulation. In the direct comparison, BioHPP provides better polishing properties than successful dentures and veneering composites.

Hammerle et al (2018)[66] narrated review of etiology of hard- and soft-tissue deficiencies at dental implants. A large number of etiological factors have been identified that may lead to hard and soft-tissue deficiencies. These factors include: systemic diseases and conditions of the patients; systemic medications; processes of tissue healing; tissue turnover and tissue response to clinical interventions; trauma to orofacial structures; local diseases affecting the teeth, the periodontium, the bone and the mucosa; biomechanical factors; tissue morphology and tissue phenotype; iatrogenic factors.

In conjunction with other factors such as periodontitis, peri-implantitis, endodontic infections, growth and development , mechanical overload, thin soft tissues, lack of keratinized mucosa, malpositioning of implants, migration of teeth. Severity of the resulting condition may increase when number of factors increase together. Importance of such etiological factors and their negative effect should be counteracted for patient's well being.

The study was conducted in the Department of Prosthodontics and Crown & Bridge, at Babu Banarasi Das College of Dental Sciences, Lucknow, to evaluate radiographically the crestal bone loss and peri-implant soft tissue health and their correlation in patients treated with BioHPP abutments and Titanium abutments after obtaining clearance from the Institutional Ethical Committee.

Partially edentulous patients reporting to the Department of Prosthodontics, Babu Banarasi Das College of Dental Sciences, Lucknow, desiring replacement of missing teeth willing for implant treatment were selected for the study, after satisfying the selection criteria.

In this "In Vivo" study, a total of 30 two piece implants were placed in selected patients.

Selection criteria:

Inclusion criteria:

1. Enlightened patients conscious of oral hygiene and willing to undergo restoration with dental implant.
2. Healthy patients with no systemic disease to ensure uneventful healing and osseointegration of implants.
3. Partially edentulous patients.
4. Male and female patients aged 21 years or above.
5. Patients with completely healed alveolar sockets.
6. Patients with good periodontal health in the remaining dentition.
7. Patients with adequate amount of bone volume and bone quality for implant placement.
8. Bucco-lingual width not less than 4mm.
9. Mesio-distal width not less than 5mm.
10. Optimum blood levels of Vitamin D3

Exclusion criteria:

1. Patients unable/ unwilling to undergo a minor oral surgical procedure.
2. Patients with any known systemic diseases/ conditions and/ or medication to interfere with wound healing or minor surgical procedures.
3. Patients with allergy to any drug and/or material used in study.
4. Patients who are current smokers or consume any form of tobacco.
5. Patients with insufficient inter-arch space to accommodate the required restorative component.
6. Patients unable to maintain adequate oral hygiene.
7. Patients on bisphosphonate therapy.
8. Patients with Para-functional habits.

ARMAMENTARIUM

Materials and instruments used during the course of the study.

A. Equipments (Figures 1 to 4)

- Physiodispensor[ǂ]
- 20:1 Reduction gear handpiece
- Periapical radiographic machine[©]
- Panoramic and linear tomographic radiograph machine[∂]
- Film positioning device[Ⱥ]
- X-Ray Mesh Gauge: Dental Size[Ŧ]
- Resonance frequency analyzer[Δ]
- Porcelain adjustment and polishing kit[€]
- Composite polishing kit[ʎ]
- Micromotor straight handpiece [ʊ]
- Contra angle hand piece and connection cord[£]

B. Implant System (Figure 5 and 6)

- Implant : Touareg™-S#
- Implant kit #

The following components of the system were used in the study: (Figures 7 and 8)

- Pilot Drill 2mmD X 16mmL Int. (RS8021)
- Twist Drill 2.5mmD X16mmL Int. (RS8022)
- Twist Drill 2.8mmD X16mmL Int. (RS8023)
- Twist Drill 3.2mmD X16mmL Int. (RS8024)
- Twist Drill 3.65mmD X16mmL Int. (RS025)
- Twist Drill 4.2mmD X16mmL Int. (RS8026)
- Twist Drill 5.2mmD X16mmL Int. (RS8027)
- Torque ratchet 35 - 100 Ncm (RS6111)
- Parallel pin 10 (RS6150)
- Parallel pin 16 (RS6155)
- Hex driver 2.4mm 18mm long (torque) (RS6012)
- Hex driver 1.25mm 15mm long (torque) (RS6082)
- RS Titanium Abutment – No End Line (RS3800)
- Ti-base (RS Ti Base Non engaged/ engaged,RS1408/1404)
- RS slim closed tray transfer (RS5113)
- RS Internal Hex Implant Analog (RS5737)
- RS Healing Abutment 4.5mmD×3mm/4mm/5mm (RS-3024 to 3026)

Materials (Figures 9 to 15)

- Alginate Hydrochloride Impression Material$^{\alpha}$
- Type III Dental stone $^{\Theta}$
- Lidocaine topical aerosol ¶
- 2% Lignocaine Hydrochloride with adrenaline Bitartate (1:80,000) §
- Single use syringe (5ml/3ml) $^{\infty}$
- Povidone iodine solution (5 w/v) *
- Saline$^{\gamma}$
- Suture material (3-0 silk-non absorbable surgical suture, 16mm, 3/8 circle

cutting body needle)ϕ

- Addition silicon rubber base impression material√
- High strength Type IV die stone ≠
- Gingival mask ؟
- Articulating paper
- Type I (luting) Glass ionomer cement Ψ
- Type II (restorative) Glass ionomer cement Ψ
- Composite restorative kit ؟
- Teflon tapeϬ
- Intraoral Periapical Radiographic films (size 21X41mm)ϑ

C. Instruments (Figure 16 and 17)

- Diagnostic Instruments
- Ruler with mm scale and divider
- Curved and straight BP blade holder Number 3F
- BP blade Number 15%
- Periosteal elevator •
- Tissue holding forceps •
- Suture needle holding forceps •
- UNC periodontal probe ※

Figure 1: Physiodispensor and Handpiece (NSK)

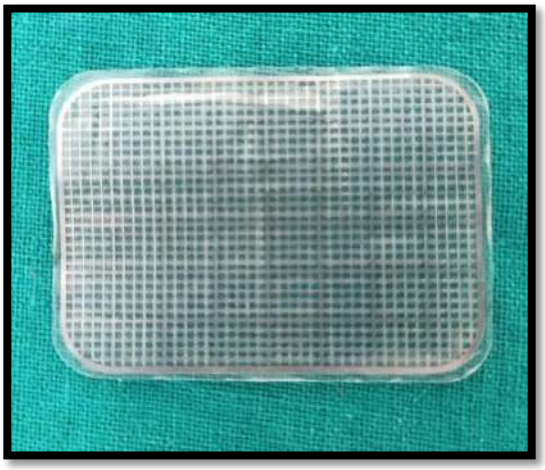


Figure 2: X ray mesh gauge (1 mm^2)

Figure 3: RFA device (OSSTELL)

Figure 4: Composite and porcelain adjustment equipments (SHOFU)

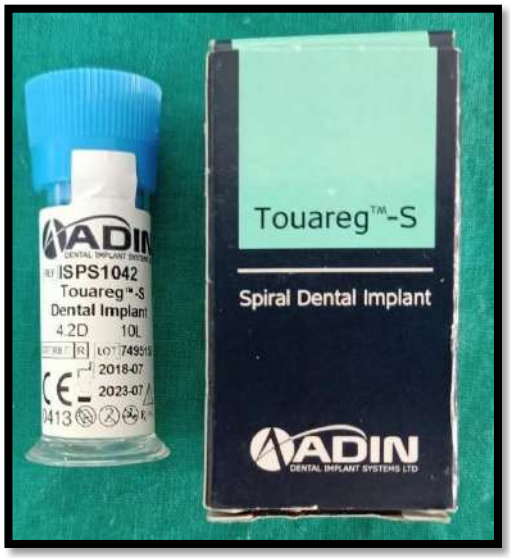


Figure 5: Threaded root form implant(ADIN)

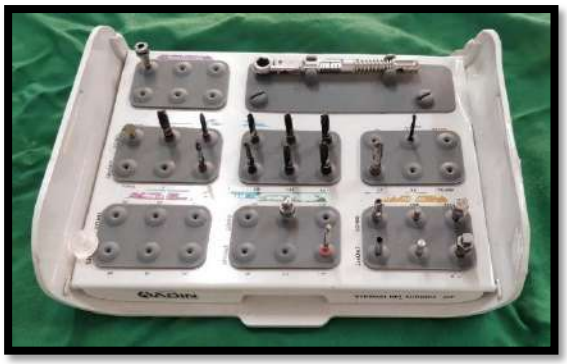


Figure 6: Implant kit (ADIN)

Figure 7 : Titanium prefabricated abutment

Figure 8 : Titanium Base (Ti-base)

Figure 9 : Teflon tape

Figure 10 : Alginate, Type IV die stone, Type III dental stone

Figure 11 : Materials used during surgery

Figure 12 : Gingival mask, Addition Silicone Impression material

Figure 13 : Light curable Composite and GIC

Figure 14 : IOPA radiographic film

Figure 15 : Articulating paper and holder

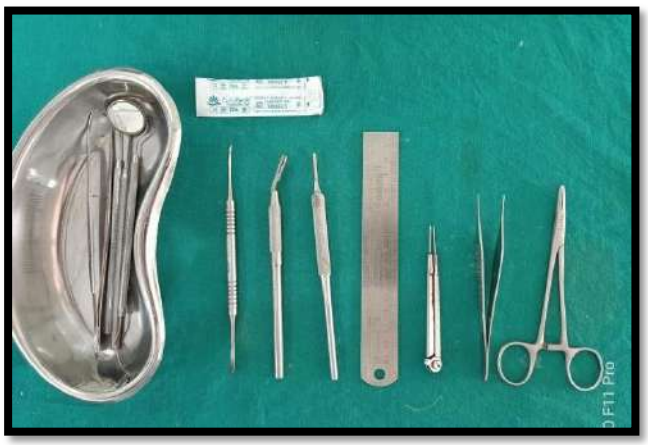


Figure 16 : Surgical Instruments

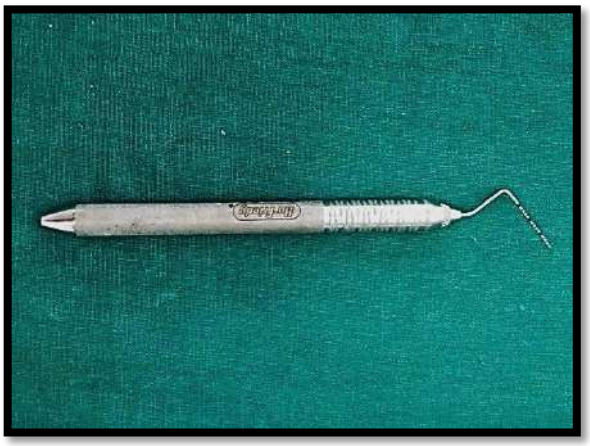


Figure 17 : UNC Probe

STUDY DESIGN (Figure 18)

- **Patient Selection:**

Thirty partially edentulous patients above 18 years of age with partially edentulous site in the mandibular posterior quadrant reporting to the Department of Prosthodontics of Babu Banarasi Das College of Dental Sciences, Lucknow, desiring replacement of missing teeth were selected for the study, after satisfying the selection criteria which included a thorough medical and dental history, current general and oral health status and routine blood levels screening. Patients were provided with a consent form and a written explanation regarding the nature of treatment, associated procedures and risks involved with the treatment.

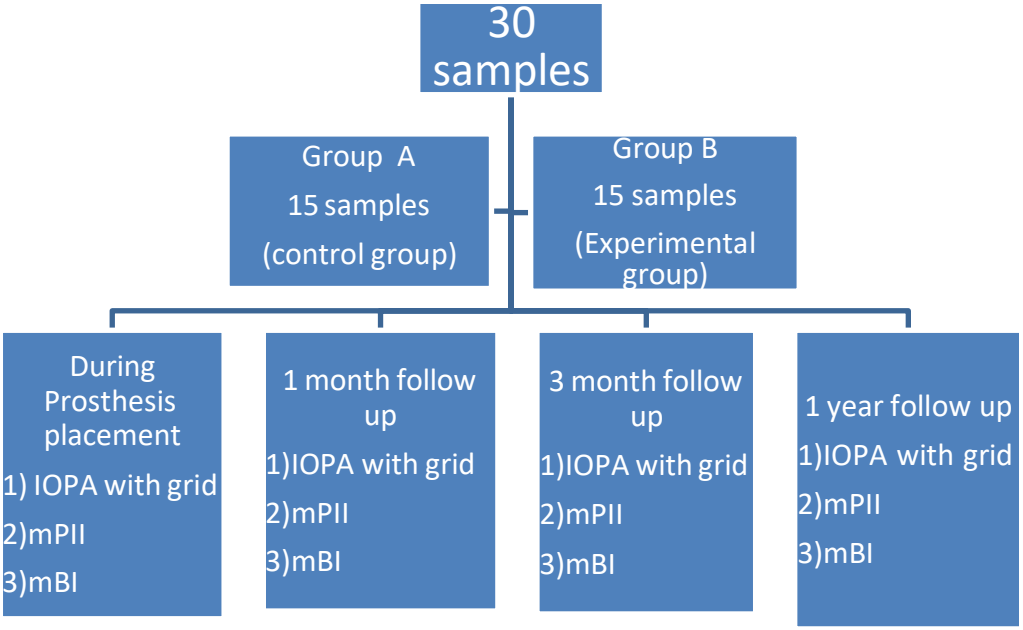


Figure 18 : Study design

Patient Preparation:

Patient preparation included patient education and motivation for optimum oral hygiene regimen. The enrolled patients were subjected to phase I periodontal therapy (Etiotropic phase). All patients who exhibited good oral hygiene with Plaque index and gingival index values of less than 20% after Phase I therapy were only considered for the study. Patients with periodontal pockets were subjected to pocket elimination or reduction surgeries. Only after a stable periodontal status was attained, patients were selected to be included in the study.

- **Initial evaluation :**

Laboratory investigation included routine blood examination along with HBsAg, HIV, HbA1c and Vit D3 levels.

Scrupulous evaluation of the implant site included study models (diagnostic and working casts) Standard Periapical radiographs, CBCT reports, Orthopantomograms, clinical evaluation and photographs. Implant size for each edentulous site was selected based on the above mentioned evaluation techniques.

- **Surgical Procedures:**

Two stage surgical approach:

I. **PHASE I Surgery :**

Flap Design **:** After achieving adequate local anesthesia, crestal incisions were placed on the edentulous site with no. 15 blade. The crestal incisions was extended to the mid-buccal and mid-lingual crevices of adjacent tooth. Full thickness mucoperiosteal flap was elevated using periosteal elevator. (Figure 19)

Osteotomy Preparation: Implant osteotomy site was prepared by using a series of drills precisely and incrementally and as per the manufacturer's instructions and site requirement along with profuse irrigation. Bone drilling was performed at revolutionary per minute recommended by Branemark i.e. 1000-1500 rpm. The depth and angulation was checked continuously with the help of depth gauge, paralleling pins and by intra-operative radiographs. After the angulation and depth of osteotomy was established, use of following drills for final osteotomy preparation capable of accepting the implant dimension was accomplished. The implant site was liberally irrigated with sterile saline to ensure no debris or bone debri left at the base or affixed to the vertical walls of the osteotomy site following preparation.

Implant Placement **:** Implant (ADIN Dental Implant Systems LTD: Touareg^{TM}-S) was inserted using torque controlled wrench, insertion torque should be >30 Ncm and <45 Ncm followed by placement of cover screw. (Figure 20)

II. PHASE II Surgery:

After 3 months of implant placement, a circular incision was placed to expose the implant. After removal of cover screw, RFA Measurements were obtained then a healing abutment or gingival former (ADIN Dental Implant Systems LTD: RS Healing Abutment) was placed on the implant for 2 weeks.

- **Impression:**

Once the physiologic contour of soft tissue was achieved (Approximately 2 weeks). The impression coping (ADIN Dental Implant Systems LTD: RS slim closed tray transfer) was placed over the implant. Single step impression was made for the fabrication of implant specific definitive restoration for all patients with addition silicone impression material with a closed tray technique.

Test Groups:

The thirty implant sites were divided randomly into 2 test groups comprising of 15 implant sites each in following manner.

Test Group I (Control group) : Conventional prefabricated titanium straight abutment (ADIN Dental Implant Systems LTD: RS Titanium Abutment – No End Line, RS3800) compatible with the implant was used over which porcelain fused with metal crowns was placed. (Figure 21)

Test Group II (Experimental group): Ti-base (ADIN Dental Implant Systems LTD: RS Ti Base Non engaged/ engaged,RS1408/1404) compatible with implant was used over which Bio-HPP (Bredent GmbH & Co.KG: REF-540F2PB3) was pressed and veneered with veneering composite (Bredent Crea.lign Veneering System). (Figure 22)

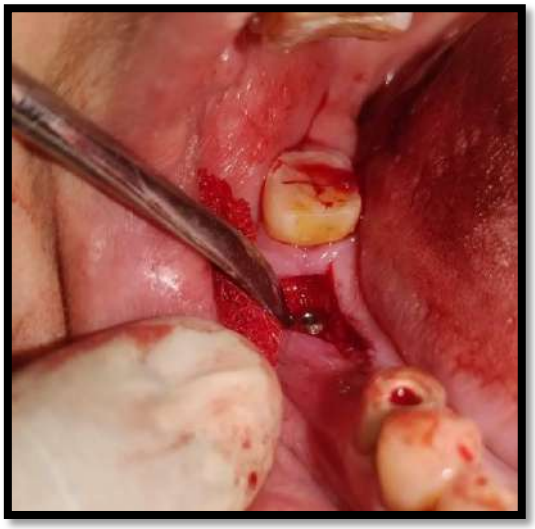


Figure 19: Flap Design

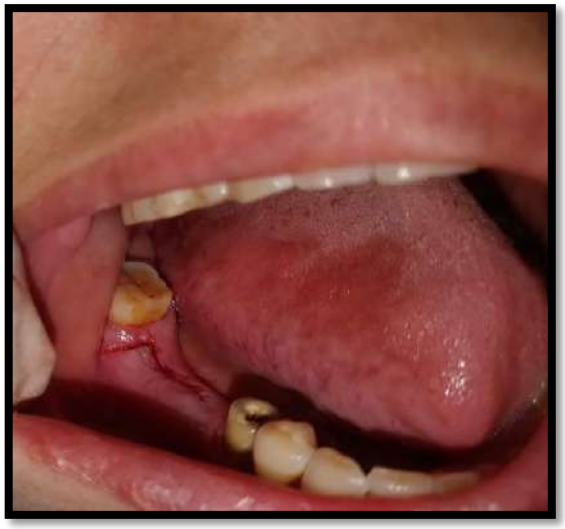


Figure 20: Implant Placed

Figure 21 : Prosthesis (Group I)

Figure 22 : Prosthesis (Group II)

- **Prosthesis fabrication and placement:**

The Implant level impressions were sent to laboratory where the prosthesis for Group I and Group II were fabricated. One or two clinical appointments were required for adjustments to obtain the final results as per requirement of the particular case.

Occlusal adjustments were done in the same fashion for both the groups in the following method: (Figure 23)

- Occlusal table was kept 20 to 30% narrower than the remaining natural teeth
- The primary occlusal contact was made to reside within the diameter of the implant body within the central fossa
- The secondary occlusal contacts were kept within 1mm of the periphery of the implant to reduce offset load
- Marginal ridge if in contact were kept as secondary occlusal contact points if it were to lie between two adjacent implants which were splinted.
- While initial occlusal adjustment, thin articulating paper (40 μm) is used in centric position under light tapping force. At this stage, the implant prosthesis should barely make contact and the surrounding teeth in the arch should exhibit greater contact.
- Once equilibration under light occlusal force is completed, the occlusion is refined under heavy occlusal contact.
- The occlusal contact should remain axial over the implant body and may be of similar intensity on the implant crown and adjacent teeth when under greater bite force.

Finishing and polishing of the prosthesis after occlusal adjustments was done using the suitable polishing material for the respective group of the prosthesis

Group I: Finishing and polishing of the modified occlusal surface of the PFM crowns was done using porcelain adjustment kit and finishing kit

Group II: Finishing and polishing of the modified occlusal surface of the Composite veneered Bio-HPP prosthesis was done using composite finishing kit (figure 24)

Figure 23 : Clinical adjustments

Figure 24: Polishing of Group II prosthesis

Figure 25 : Prosthesis tightened using torque ratchet

The prosthesis for both groups were tightened to 15N-cm torque (figure 25). The access holes were plugged with rolled Teflon tape piece and sealed with GIC or composite.

- **Collection of data:**

The following steps were performed at the time of prosthesis placement and at the 1 month, 3rd month and after 1 year follow up appointment in order to collect readings (data) for the study.

Radiographic readings: (Evaluation of crestal bone loss)

Intra oral periapical radiographs (IOPA) were taken for all the implant sites. At the time of exposing the IOPA radiographic film, a lead X—ray mesh gauge with 1 mm^2 grid was placed on the IOPA film on the side facing towards the X-ray head. The grid compensated for magnification and image distortion errors. The radiographs were standardized using the standard long cone paralleling technique with film positioning device. (figure 26 and 27)

The distance from the margins of the implant abutment junction to the first point of bone to implant contact was measured on mm scale on the mesial and distal side and the readings were documented.

Clinical readings: (Evaluation of soft tissue health)

After the removal of the suprastructure, mPlI (table 1) was assessed first followed by mBI (table 2). Score readings were documented for each side of each implant site (i.e. mesial, buccal, distal and lingual)

Periodontal probe (UNC) was used for assessment of soft tissue parameters. (figure 28)

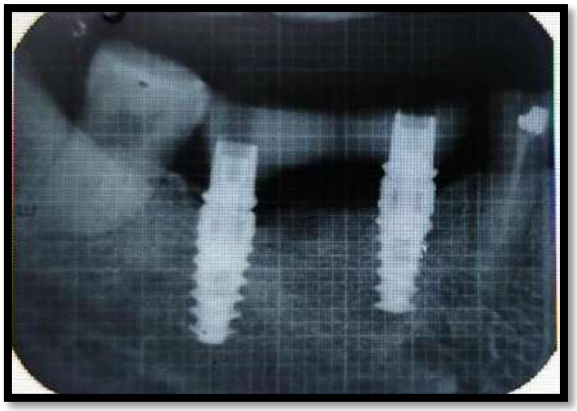


Figure 26: IOPA radiograph with grid at the time of prosthesis placement

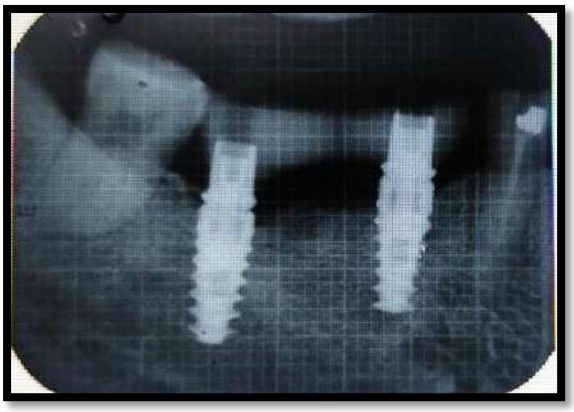


Figure 27: IOPA radiograph with grid at 1 month follow-up

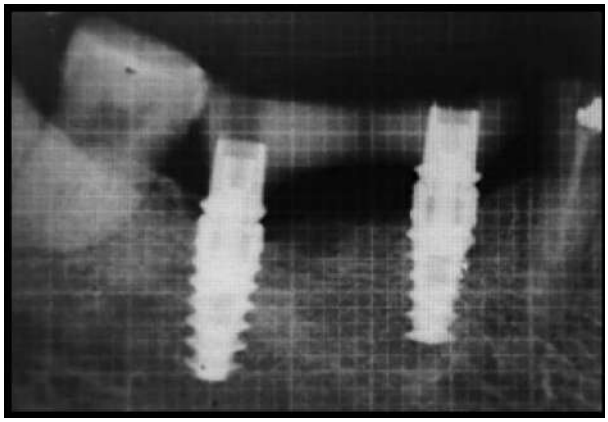


Figure 28: IOPA radiograph with grid after3 months

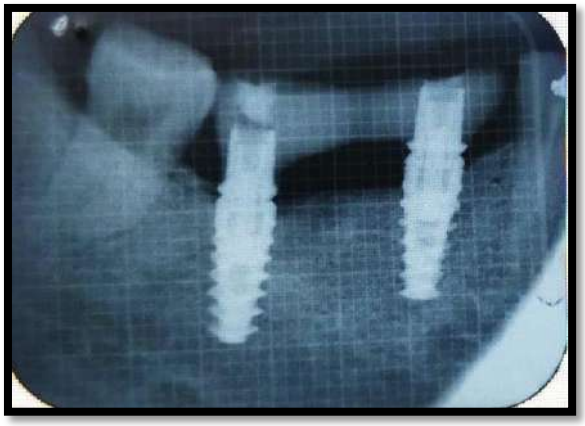


Figure 29: IOPA radiograph with grid after 1year

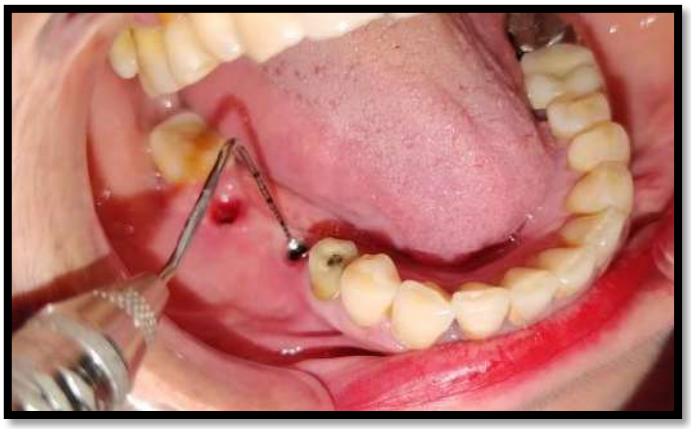


Figure 30: Clinical readings (mPlI, MbI) being recorded with UNC probe

Table 1: Modified Plaque Index (mPlI)

Score	Description
0	No detection of plaque
1	Plaque only recognized by running a probe across the smooth marginal surface of the implant. Implants covered by titanium spray in this area always score 1
2	Plaque can be seen by the naked eye
3	Abundance of soft matter

Table 2: Modified Sulcus Bleeding Index (mBI)

Score	Description
0	No bleeding when periodontal probe is passed along the gingival margin adjacent to the implant
1	Isolated bleeding spots available
2	Blood forms a confluent red line on margin
3	Heavy or profuse bleeding

Statistical analysis

Data were summarised as Mean ± SD (standard deviation). Groups were compared by two factor (groups and periods) repeated measure (RM) analysis of variance (ANOVA) and the significance of mean difference within (intra) and between (inter) the groups was done by Tukey's HSD (honestly significant difference) post hoc test after ascertaining normality by Shapiro-Wilk's test and homogeneity of variance between groups by Levene's test. A two-tailed (α=2) $P < 0.05$ was considered statistically significant. Analysis was performed on SPSS software (Windows version 22.0).

Sampling Dynamics

The 30 implant sites chosen for this study overlapped between patients. i.e. more than 1 implant site was allotted to an individual patient for sampling.

Refer table 3 to apprehend the dynamics of the patient related factors involved in the study.

Table 3 : Sampling dynamics

	Mean age	**Male (%)**	**Female (%)**	**Out of**
Group A	45.6 yrs	40	60	15
Group B	47.2 yrs	13.3	86.6	15
Total	46.4 yrs	26.7	73.3	30

Results and Observations

The present 1 year prospective clinico-radiographs follow up study evaluates soft and hard tissue responses to two different types of abutments. Total 30 partially edentulous patients, 18 years of age or older, requiring replacement of missing teeth with dental implant restorations were recruited and randomised equally into two groups and treated either with Titanium abutments with PFM crowns (*Control group or Group I, n=15*) or Bio-HPP abutments with composite veneering (*Experimental group or Group II, n=15*).

The outcome measures of the study were hard tissue (crestal bone level at mesial and distal sides) and soft tissue (modified plaque index and modified sulcus bleeding index). The outcome measures were assessed at the time of prosthesis placement, 1 month later, 3 months later and 1 year later. Crestal bone level was measured in millimetre (mm).

The objective of the study was to compare the efficacy of two treatments (Group I and Group II) on soft and hard tissue responses (measurements).

Outcome measure

A. Hard tissue measurements

(I). Crestal bone level- Mesial

The mesial crestal bone level of two groups (Group I and Group II) over the periods (at the time of prosthesis placement, 1 month later, 3 months later and 1 year later) is summarised in Table 1 and also depicted in Fig. 1. The mean mesial crestal bone level in both groups decrease gradually with time and the decrease was evident higher (i.e. loss) in Group I as compared to Group II.

For each group, comparing the difference in mean mesial crestal bone level between the periods (i.e. intra group), Tukey test showed significant ($P < 0.05$ or $P < 0.001$) decrease in crestal bone level in both groups at 1 month later, 3 months later and 1 year later as compared to at the time of prosthesis placement (Table 2 and Fig. 2). Further, in both groups, it also decreased significantly ($P < 0.01$ or $P < 0.001$) at 1 year later as compared to both at 1 and 3 months later. However, in both groups, it did not differ ($P > 0.05$) at 1 month later and at 3 months later i.e. found to be statistically the same.

Similarly, for each period, comparing the difference in mean mesial crestal bone level between the groups (i.e. inter group), Tukey test showed similar ($P > 0.05$) crestal bone level between the groups at all periods i.e. did not differ significantly (Table 3 and Fig. 3).

At final evaluation, the net mean decrease or bone loss in mesial crestal bone level (i.e. mean decrease in creastal bone level from at the time of prosthesis placement to 1 year later) of Group II (55.14%) was found to be 24.49% less as compared to Group I (79.63%).

Table 1: Mesial crestal bone level (mm) of two groups over the periods

Time period	**Group I (n=15)mm**	**Group II (n=15)mm**
At the time of prosthesis placement	1.80 ± 0.73	1.78 ± 0.43
1 month later	1.17 ± 0.62	1.42 ± 0.42
3 months later	0.88 ± 0.52	1.22 ± 0.34
1 year later	0.37 ± 0.13	0.80 ± 0.47

The mesial crestal bone level of two groups over the periods were summarised in Mean ± SD.

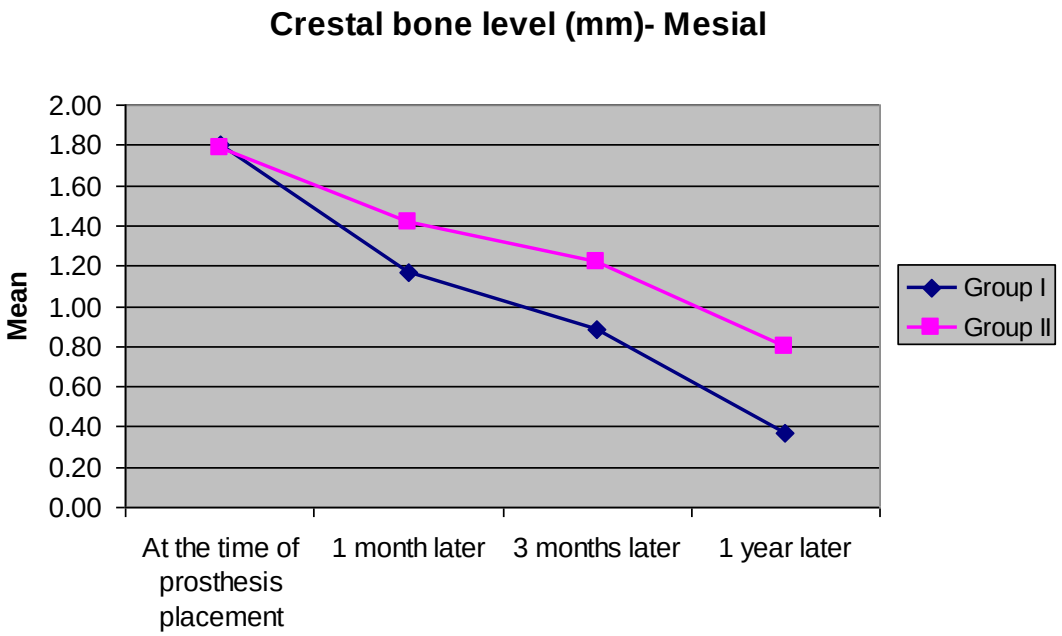


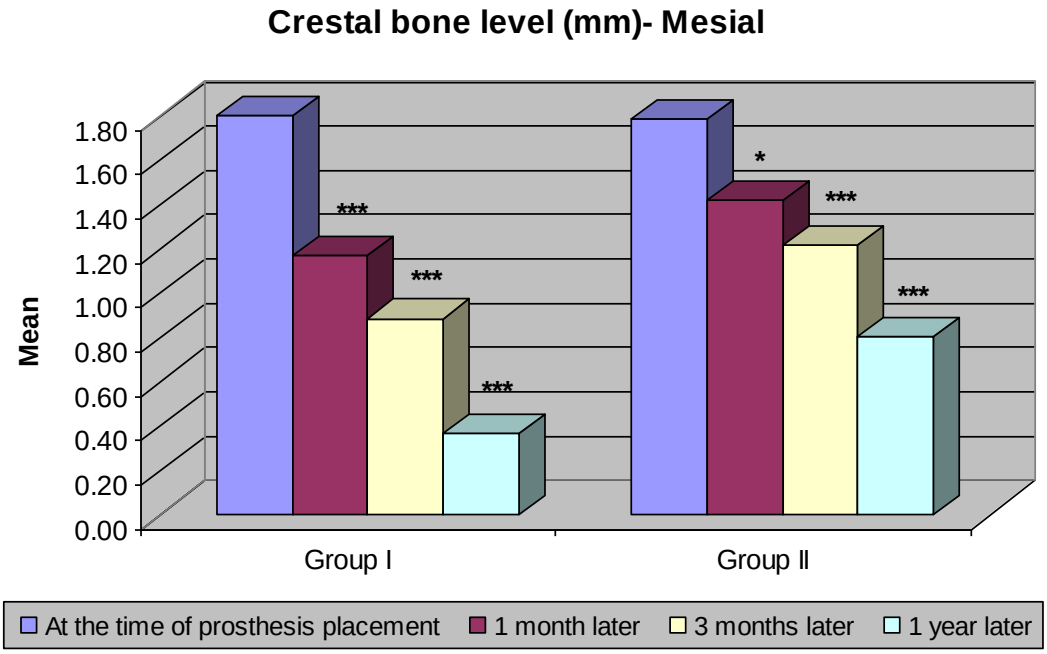
Fig. 1. Line graphs showing mean mesial crestal bone level of two groups over the periods.

Table 2: For each group, comparison (*P* value) of difference in mean mesial crestal bone level (mm) between the periods by Tukey test

Comparison	**Group I**		**Group II**	
	Mean diff.(mm)	***P* value**	**Mean diff.(mm)**	***P* value**
At the time of prosthesis placement vs. 1 month later	0.63	<0.001	0.37	0.019
At the time of prosthesis placement vs. 3 months later	0.92	<0.001	0.57	<0.001
At the time of prosthesis placement vs. 1 year later	1.43	<0.001	0.98	<0.001

1 month later vs. 3 months later	0.28	0.147	0.20	0.565
1 month later vs. 1 year later	0.80	<0.001	0.62	<0.001
3 months later vs. 1 year later	0.52	<0.001	0.42	0.004

diff: difference



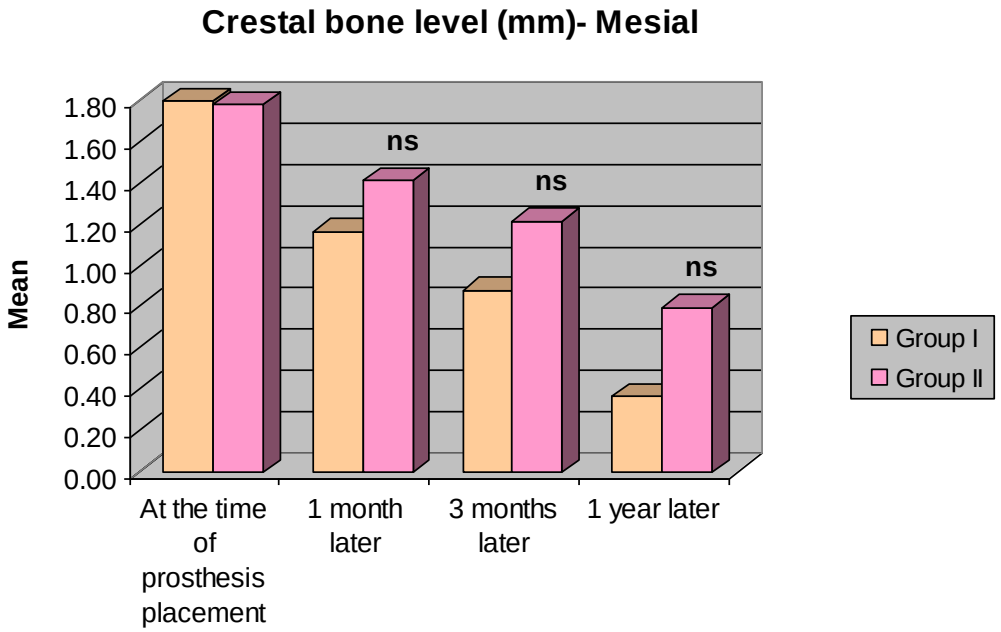
*P < 0.05 or ***P < 0.001- as compared to at the time of prosthesis placement

Fig. 2. For each group, bar graphs showing comparison of difference in mean mesial crestal bone level between the periods.

Table 3: For each period, comparison (*P* value) of difference in mean mesial crestal bone level (mm) between the groups by Tukey test

Time period	**Comparison: Group I vs. Group II**	
	Mean difference(mm)	***P* value**
At the time of prosthesis placement	0.02	1.000
1 month later	0.25	0.851

3 months later	0.33	0.576
1 year later	0.43	0.249



[ns]$P > 0.05$- as compared to Group I

Fig. 3. For each period, bar graphs showing comparison of difference in mean mesial crestal bone level (mm) between the groups.

(II). Crestal bone level- Distal

The distal crestal bone level of two groups (Group I and Group II) over the periods (at the time of prosthesis placement, 1 month later, 3 months later and 1 year later) is summarised in Table 4 and also shown in Fig. 4. The mean distal crestal bone level in both groups show similar trend as of mesial crestal bone level. The mean distal crestal bone level in both groups decrease linearly with time and the decrease was evident higher (i.e. loss) in Group I as compared to Group II.

For each group, comparing the difference in mean distal crestal bone level between the periods (i.e. intra group), Tukey test showed significant ($P < 0.05$ or $P < 0.001$) decrease in crestal bone level in both groups at 1 month later, 3 months later and 1 year later as compared to at the time of prosthesis placement (Table 5 and Fig. 5).

Further, in both groups, it also decreased significantly ($P < 0.01$ or $P < 0.001$) at 1 year later as compared to both at 1 and 3 months later. However, in both groups, it did not differ ($P > 0.05$) at 1 month later and at 3 months later i.e. found to be statistically the same.

Similarly, for each period, comparing the difference in mean distal crestal bone level between the groups (i.e. inter group), Tukey test showed similar ($P > 0.05$) crestal bone level between the groups at all periods i.e. did not differ significantly (Table 6 and Fig. 6).

At final evaluation, the net mean decrease or bone loss in distal crestal bone level (i.e. mean decrease in crestal bone level from at the time of prosthesis placement to 1 year later) of Group II (56.56%) was found to be 25.58% less as compared to Group I (82.14%).

Table 4: Distal crestal bone level (mm) of two groups over the periods

Time period	**Group I (n=15)mm**	**Group II (n=15)mm**
At the time of prosthesis placement	1.87 ± 0.69	1.88 ± 0.42
1 month later	1.12 ± 0.58	1.50 ± 0.53
3 months later	0.80 ± 0.52	1.22 ± 0.41
1 year later	0.33 ± 0.12	0.82 ± 0.36

The distal crestal bone level of two groups over the periods were summarised in Mean ± SD.

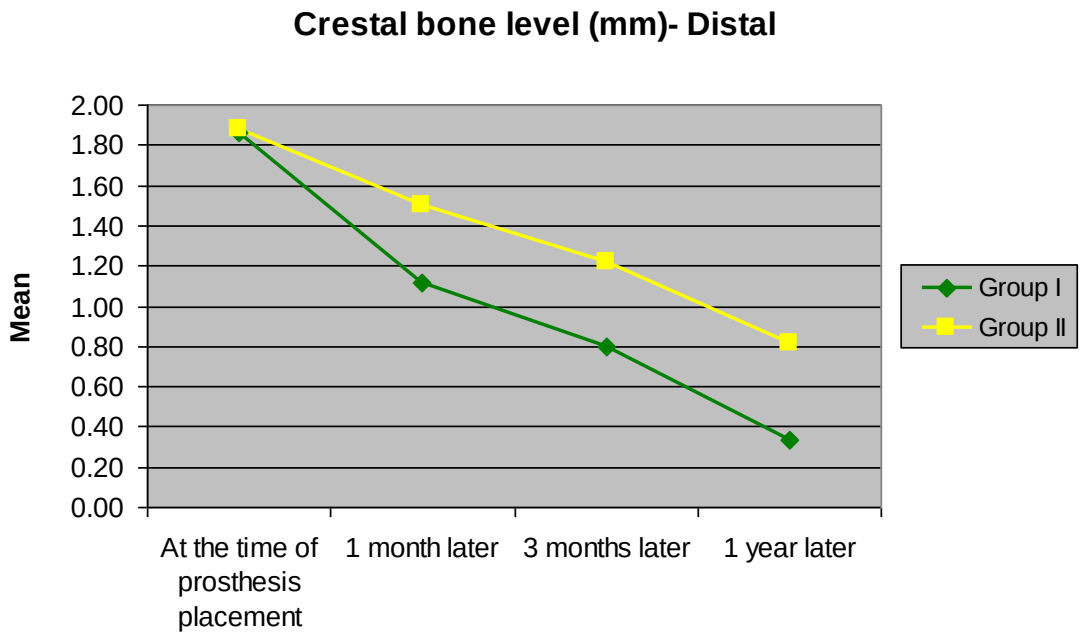


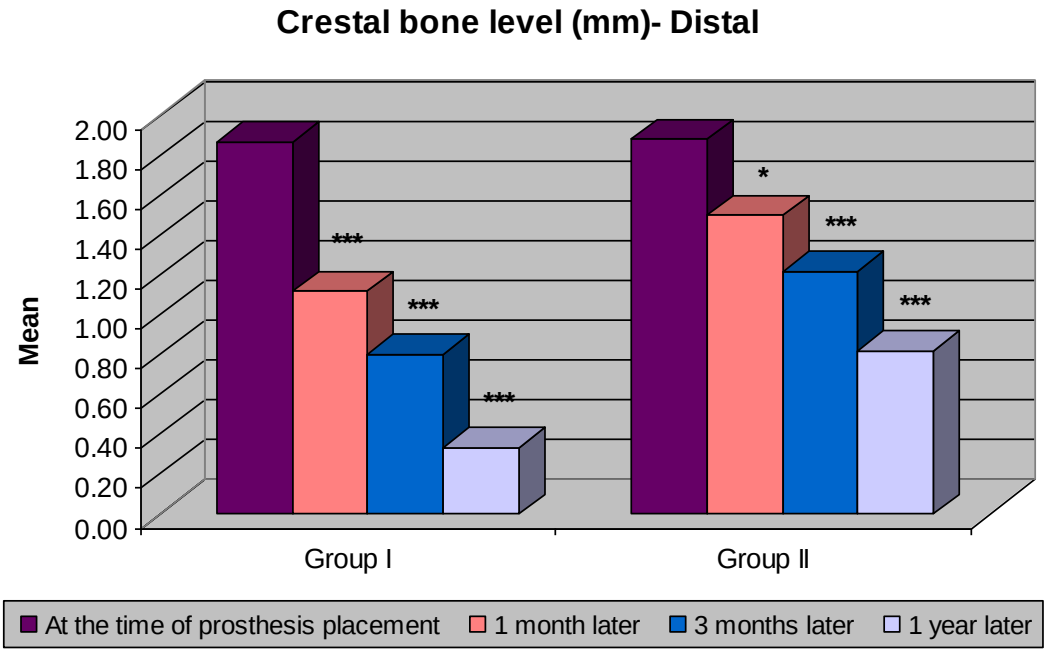
Fig. 4. Line graphs showing mean distal crestal bone level of two groups over the periods.

Table 5: For each group, comparison (*P* value) of difference in mean distal crestal bone level (mm) between the periods by Tukey test

Comparison	**Group I**		**Group II**	
	Mean diff.(mm)	***P* value**	**Mean diff.(mm)**	***P* value**
At the time of prosthesis placement vs. 1 month later	0.75	<0.001	0.38	0.014
At the time of prosthesis placement vs. 3 months later	1.07	<0.001	0.66	<0.001
At the time of prosthesis placement vs. 1 year later	1.53	<0.001	1.06	<0.001
1 month later vs. 3 months later	0.32	0.075	0.28	0.155

1 month later vs. 1 year later	0.78	<0.001	0.68	<0.001
3 months later vs. 1 year later	0.47	0.001	0.40	0.008

diff: difference

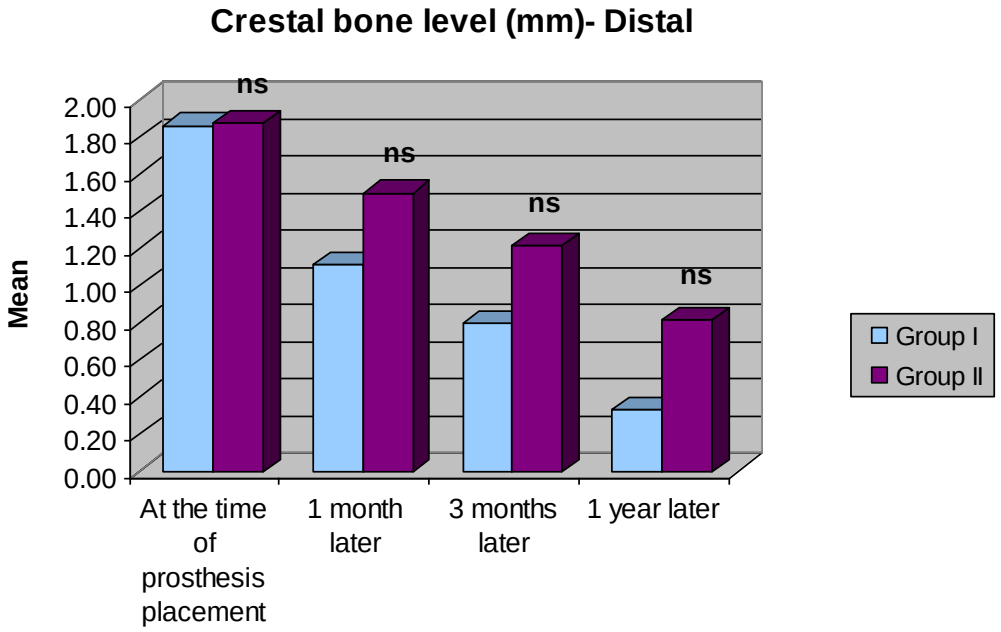


*$P < 0.05$ or ***$P < 0.001$- as compared to at the time of prosthesis placement

Fig. 5. For each group, bar graphs showing comparison of difference in mean distal crestal bone level between the periods.

Table 6: For each period, comparison (*P* value) of difference in mean distal crestal bone level (mm) between the groups by Tukey test

Time period	**Comparison: Group I vs. Group II**	
	Mean difference(mm)	***P* value**
At the time of prosthesis placement	0.01	1.000
1 month later	0.38	0.382
3 months later	0.42	0.280
1 year later	0.48	0.133



[ns]$P > 0.05$- as compared to Group I

Fig. 6. For each period, bar graphs showing comparison of difference in mean distal crestal bone level (mm) between the groups.

B. Soft tissue measurements

(I). Modified plaque index (mPII)

The modified plaque index (mPII) of two groups (Group I and Group II) over the periods (at the time of prosthesis placement, 1 month later, 3 months later and 1 year later) is summarised in Table 7 and also shown in Fig. 7. In contrast of both mesial and distal crestal bone level, the mean modified plaque index in both groups increase linearly with time and the increase was evident slightly higher (i.e. gain) in Group II as compared to Group I.

For each group, comparing the difference in mean modified plaque index between the periods (i.e. intra group), Tukey test showed significant ($P < 0.01$) increase in modified plaque index in both groups at 1 year later as compared to at the time of prosthesis placement (Table 8 and Fig. 8). Further, in Group II, it was also found significantly ($P < 0.01$) different and higher at 1 year later as compared to at 1 month

later. However, in both groups, it did not differ ($P > 0.05$) between other periods i.e. found to be statistically the same.

Similarly, for each period, comparing the difference in mean modified plaque index between the groups (i.e. inter group), Tukey test showed similar ($P > 0.05$) modified plaque index between the groups at all periods i.e. did not differ significantly (Table 9 and Fig. 9).

At final evaluation, the net mean increase or gain in modified plaque index (i.e. mean increase in modified plaque index from at the time of prosthesis placement to 1 year later) of Group II (61.11%) was found to be 7.89% higher as compared to Group I (53.23%).

Table 7: Modified plaque index (mPII) of two groups over the periods

Time period	**Group I (n=15)**	**Group II (n=15)**
At the time of prosthesis placement	1.03 ± 0.35	0.90 ± 0.23
1 month later	1.28 ± 0.23	0.95 ± 0.70
3 months later	1.35 ± 0.23	1.23 ± 0.33
1 year later	1.58 ± 0.32	1.45 ± 0.53

The modified plaque index of two groups over the periods were summarised in Mean ± SD.

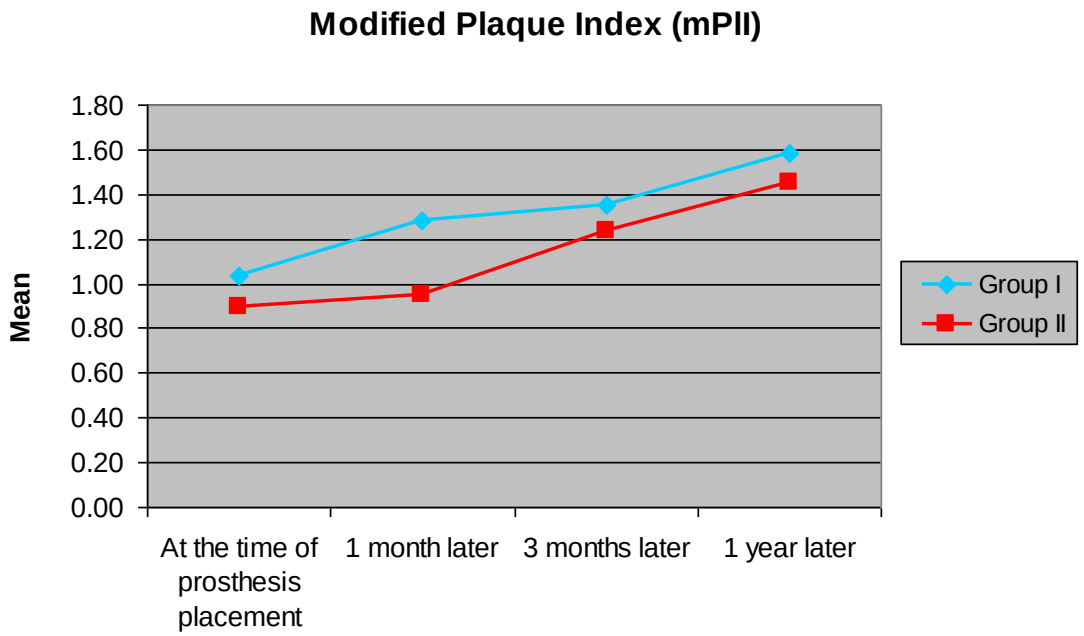
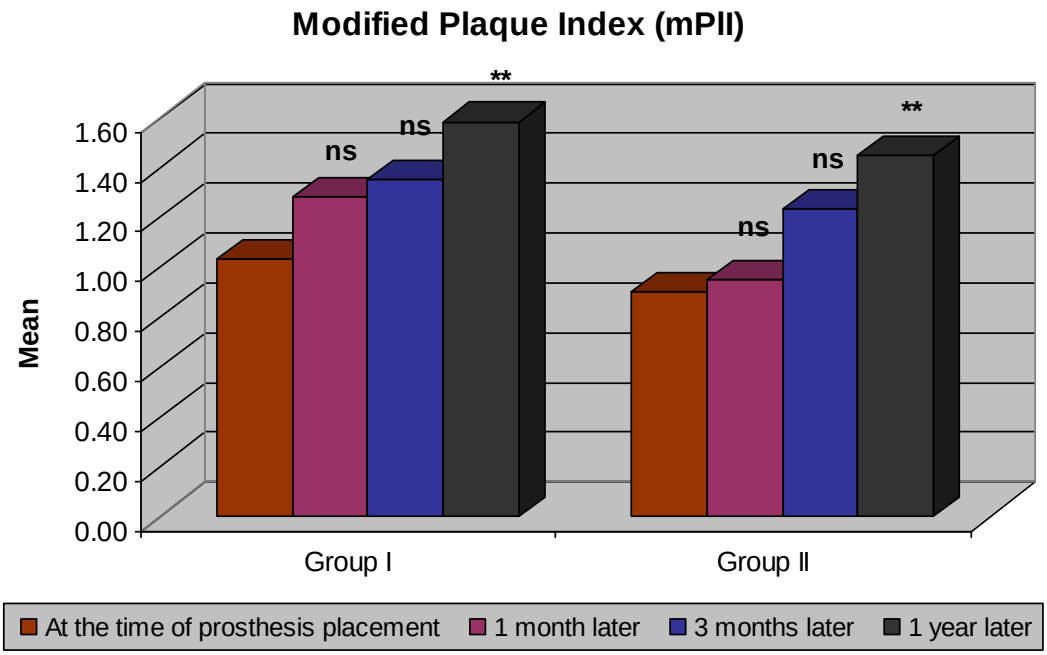


Fig. 7. Line graphs showing mean modified plaque index of two groups over the periods.

Table 8: For each group, comparison (*P* value) of difference in mean modified plaque index (mPII) between the periods by Tukey test

Comparison	**Group I**		**Group II**	
	Mean diff.	***P* value**	**Mean diff.**	***P* value**
At the time of prosthesis placement vs. 1 month later	0.25	0.479	0.05	1.000
At the time of prosthesis placement vs. 3 months later	0.32	0.189	0.33	0.142
At the time of prosthesis placement vs. 1 year later	0.55	0.001	0.55	0.001
1 month later vs. 3 months later	0.07	0.999	0.28	0.315
1 month later vs. 1 year later	0.30	0.247	0.50	0.003
3 months later vs. 1 year later	0.23	0.568	0.22	0.658

diff: difference

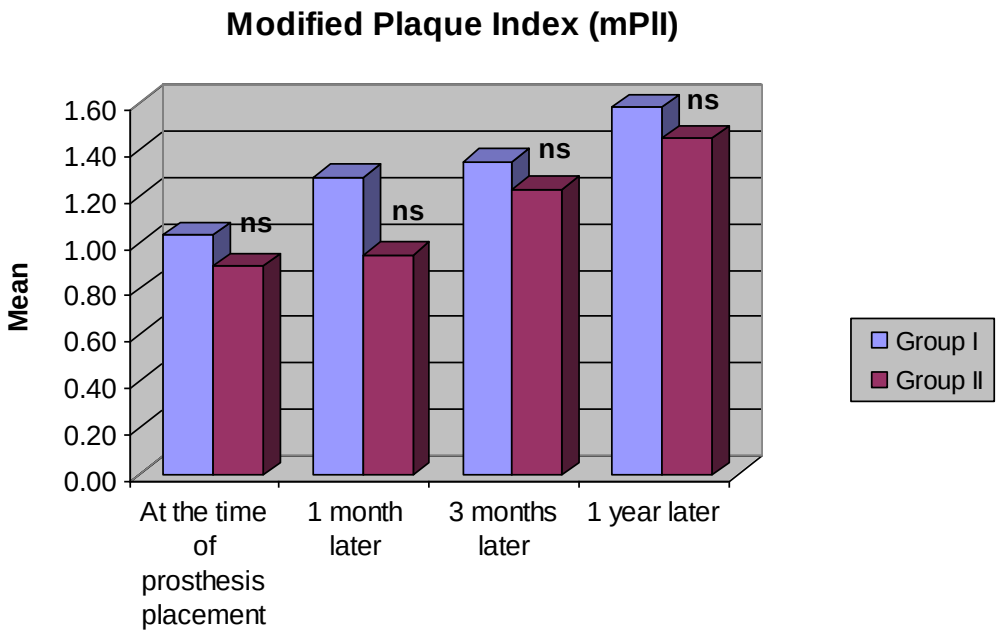


$^{ns}P > 0.05$ or $^{**}P < 0.01$- as compared to at the time of prosthesis placement

Fig. 8. For each group, bar graphs showing comparison of difference in mean modified plaque index between the periods.

Table 9: For each period, comparison (*P* value) of difference in mean modified plaque index (mPII) between the groups by Tukey test

Time period	**Comparison: Group I vs. Group II**	
	Mean difference	***P* value**
At the time of prosthesis placement	0.13	0.983
1 month later	0.33	0.304
3 months later	0.12	0.992
1 year later	0.13	0.983



[ns]$P > 0.05$- as compared to Group I

Fig. 9. For each period, bar graphs showing comparison of difference in mean modified plaque index between the groups.

(II). Modified sulcus bleeding index (mBI)

The modified sulcus bleeding index (mBI) of two groups (Group I and Group II) over the periods (at the time of prosthesis placement, 1 month later, 3 months later and 1 year later) is summarised in Table 10 and also depicted in Fig. 10. The mean modified sulcus bleeding index in both groups show similar trend as of modified plaque index. The mean modified sulcus bleeding index in both groups increase gradually with time and the increase was evident slightly higher (i.e. gain) in Group I as compared to Group II.

For each group, comparing the difference in mean modified sulcus bleeding index between the periods (i.e. intra group), Tukey test showed significant ($P < 0.01$ or $P < 0.001$) increase in modified sulcus bleeding index in both groups at 1 year later as compared to at the time of prosthesis placement (Table 11 and Fig. 11). Further, in Group I, it also showed significant ($P < 0.05$) increase at 3 months later as compared to at the time of prosthesis placement. Furthermore, in Group I, it also showed significant ($P < 0.01$) increase at 1 year later as compared to at 1 month later.

However, in both groups, it did not differ ($P > 0.05$) between other periods i.e. found to be statistically the same.

Similarly, for each period, comparing the difference in mean modified sulcus bleeding index between the groups (i.e. inter group), Tukey test showed similar ($P > 0.05$) modified sulcus bleeding index between the groups at all periods i.e. did not differ significantly (Table 12 and Fig. 12).

At final evaluation, the net mean increase or gain in modified sulcus bleeding index (i.e. mean increase in modified sulcus bleeding index from at the time of prosthesis placement to 1 year later) of Group II (52.27%) was found to be 12.17% less as compared to Group I (64.44%).

Table 10: Modified sulcus bleeding index (mBI) of two groups over the periods

Time period	**Group I (n=15)**	**Group II (n=15)**
At the time of prosthesis placement	0.75 ± 0.31	0.73 ± 0.22
1 month later	0.82 ± 0.26	0.93 ± 0.26
3 months later	1.07 ± 0.29	1.02 ± 0.35
1 year later	1.23 ± 0.22	1.12 ± 0.27

The modified sulcus bleeding index of two groups over the periods were summarised in Mean ± SD.

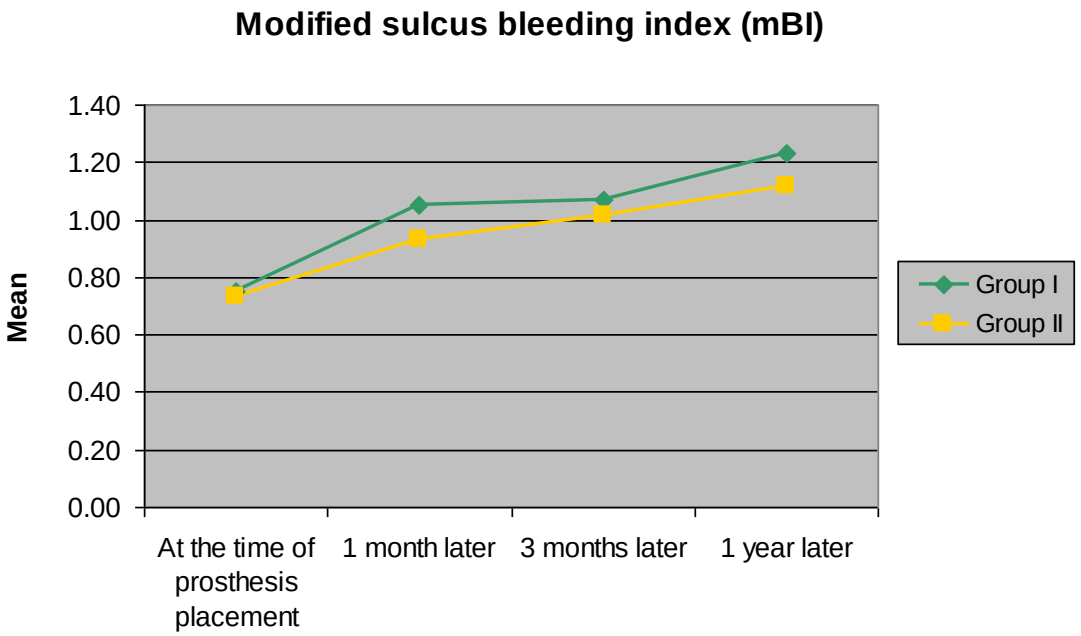
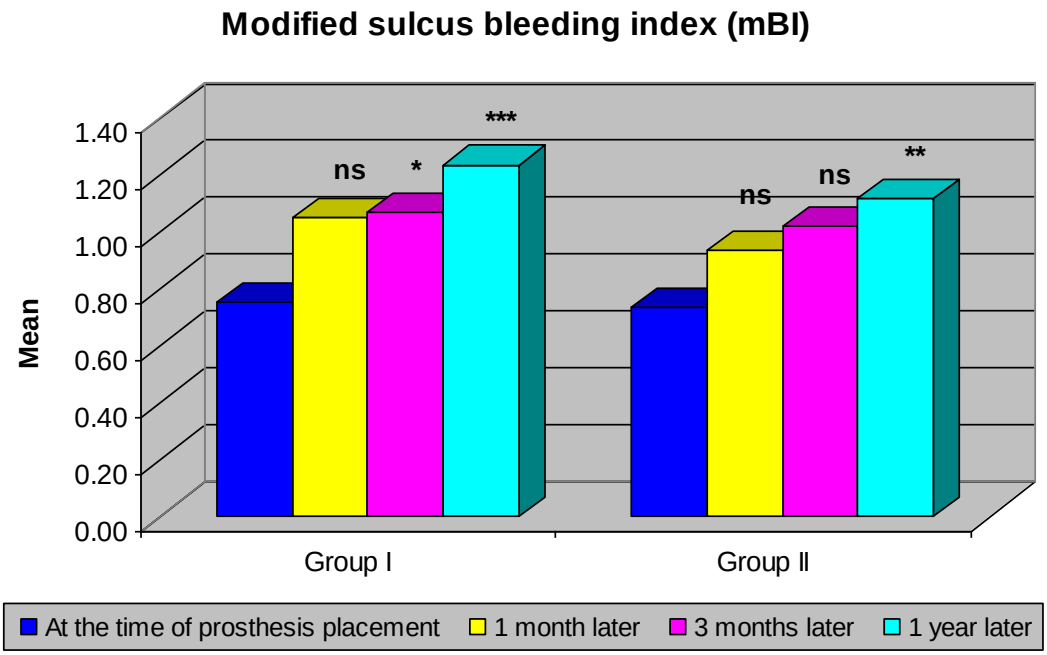


Fig. 10. Line graphs showing mean modified sulcus bleeding index of two groups over the periods.

Table 11: For each group, comparison (*P* value) of difference in mean modified sulcus bleeding index (mBI) between the periods by Tukey test

Comparison	**Group I**		**Group II**	
	Mean diff.	***P* value**	**Mean diff.**	***P* value**
At the time of prosthesis placement vs. 1 month later	0.30	0.997	0.20	0.433
At the time of prosthesis placement vs. 3 months later	0.32	0.029	0.28	0.075
At the time of prosthesis placement vs. 1 year later	0.48	<0.001	0.38	0.003
1 month later vs. 3 months later	0.02	0.169	0.08	0.988
1 month later vs. 1 year later	0.18	0.001	0.18	0.548
3 months later vs. 1 year later	0.17	0.663	0.10	0.966

diff: difference

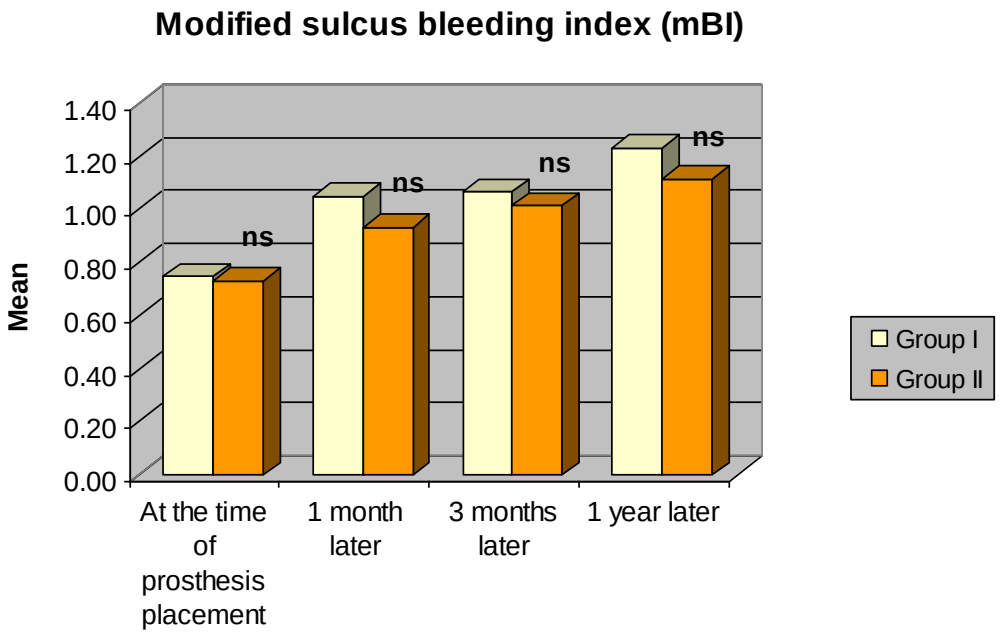


$^{ns}P > 0.05$ or $^{*}P < 0.05$ or $^{**}P < 0.01$ or $^{***}P < 0.001$- as compared to at the time of prosthesis placement

Fig. 11. For each group, bar graphs showing comparison of difference in mean modified sulcus bleeding index between the periods.

Table 12: For each period, comparison (*P* value) of difference in mean modified sulcus bleeding index (mBI) between the groups by Tukey test

Time period	**Comparison: Group I vs. Group II**	
	Mean difference	***P* value**
At the time of prosthesis placement	0.02	1.000
1 month later	0.12	0.941
3 months later	0.05	1.000
1 year later	0.12	0.941



[ns]*P* > 0.05- as compared to Group I

Fig. 12. For each period, bar graphs showing comparison of difference in mean modified sulcus bleeding index between the groups.

In this study, the relationship between crestal bone loss, modified plaque index (mPlI), and modified sulcus bleeding index (mBI) in two types of implant-supported fixed prostheses is investigated.For this study, a total of 30 samples were enrolled and evaluated.These 30 implant sites were divided into two groups, each with 15 implant sites: control and experimental. Implants in the control group received titanium preformed abutments and PFM crowns, A bio-HPP abutment layered with veneering composite was given to the experimental group.

At the time of prosthesis insertion, the crestal bone level was measured and at 1 month, 3 month and after 1 year. and was taken with a 1 mm^2 grid on the IOPAs and measured in millimetres (mm). At the time of prosthesis insertion, one month, three months, and one year later, the mPlI and mBI scores for the mesial, buccal, distal, and lingual sides were assessed to evaluate.

The study's goal was to compare the two groups' outcome measures over time.The two-stage implant system is a popular procedure with a success rate of around 99.1% in the mandible and 84.9 percent in the maxilla.[1] The success criteria for implants have been clearly described in the literature by Dr.Albrektsson et al[26],Schintman and Shulman et al.[60] and Smith and Zarb later modified it. [30]

Mean Vertical bone loss on an average in the area surrounding the implant is an important criterion for determining whether the implant will succeed or fail. Vertical bone loss of less than 0.2 mm per year after the first year of implant placement is considered acceptable by Albrektsson[26] and Smith &Zarb[30].And according to Shulman[60] bone loss of less than or equal to a third of the implant's vertical height is acceptable. However, none of these articles mentioned the acceptable levels of mean vertical bone loss around the implant within the first month or even the first year.

The maximum stresses among the load transferred to the bone through the implant, according to Dr.Vasconcellos[31]occur in the implant's most cervical region which is why crestal bone level is an important consideration. This concept is described by one of engineering's fundamental principles, which states that when two materials collide and one of them is loaded, the stresses at the initial point of contact will be higher.

Furthermore, according to the literature, the most common biological complication with fixed implant rehabilitation is peri-implant bone loss when greater than 2mm, which occurs in about 4% of cases per year. [31]

Thus, reducedcrestal bone loss around implants is a ctritical factor, for which the minimum amount of stress should be transferred to the bone through the implant, whereas other factors such as masticatory efficiency, aesthetics, etc should also be assessed.

Shock-absorbing properties of PDL compresses about 25 percent under occlusal load, due to which the stresses transferred to bone through a natural tooth are significantly reduced. The traditional implant, on the other hand, All titanium implants and prostheses are rigidly connected to one another and to the bone, on the other hand, has no such shock-absorbing properties. Furthermore,sharp stresses are being transferred to the bone through the implant due to the difference in the modulus of elasticity of titanium (115000 MPa) when compared to cancellous bone (2000 MPa) and compact bone (12000 MPa).

It seems logical to use a material that is similar to periodontium, which dampens occlusal forces within the implant prosthesis complex. Dr.VanRossen discovered through finite element analysis observed that when a stress absorbing element with a low elastic modulus is used, it serves as an cushioning element between implant and its prosthesis.[27]

The low modulus of elasticity materials possessesshock-absorbing properties that have been used in implants when they are connected to natural teeth, but the evident is sparse in case of lone standing implants. One example of such material is Bio-HPP because of its modulus of elasticity is similar to that cortical bone's and properties that are biocompatible holds a lot of potential in this context.

Bredent, a German company, was the first to market PEEK as a substructure material in the dental industry in 2004 and bio-HPP in 2011.

Bio-HPP can be used to fabricate implant abutments, FPD substructures, hybrid denture frameworks, overdentures, and cast partial dentures. Its low specific gravity (1.4 g/cm3), which is even lower than that of titanium (4.5 g/cm3), makes it ideal

forlong span or bulky frameworks. Despite the fact that evidence of simulation and testing of such long-term restorative care is sparse.

It's true that the company offers a variety of products (pressable granules, pellets, millable blocks discs, and prefabricated abutments). Bio-HPP elegance hybrid or prefabricated abutments (bio-HPP abutments with titanium core and screw channel) were not used for this study because they are only compatible with the Bredent implant system, whereas the ADIN implant system was used for the this one.

To fabricate the bio-HPP abutments, an ADIN Titanium base (Ti-base) was used, over which bio-HPP granules (Bredent) were pressed using a lost wax technique. The Visiolign composite system (Bredent) was used to veneer this abutment because its bond strength with bio-HPP was proven to be favourable.. [22,47]

As bioHPP and the veneering material is primarily composite, surface adjustments and polishing were done with a composite adjustment and polishing kit. Because the surface hardness of bioHPP is much higher than that of regular composites, the process took a long time. The adjustment kit is sold by Bredentcompany specifically for bioHPP, which may be more efficient but availability is difficult. When it came to surface smoothness and shine, a standard composite finishing kit delivered satisfactory results.

Material	BioHPP	Nature (Reference)	Pure PEEK	PMMA	PM alloy	Titanium	Zirconium
Specific weight	1.4 g/cm³		1.3 g/cm³	1.18 g/cm³	19.3 g/cm³	4.5 g/cm³	6.5 g/cm³
Hardness	30 HV = 294 N/mm²		20 HV	18 HV	190 – 240 HV	300 – 400 HV	1.200 HV
Modulus of elasticity	4.200 – 4.800 MPa*	Jaw bone 2.000 – 12.000 MPa	3,600 MPa	3,600 MPa	60,000 – 130,000 MPa too hard	115,000 MPa too hard	205,000 MPa too hard
Water absorption of composites	6.5 µg/mm³		5 µg/mm³	19 µg/mm³			
Water solubility	< 0.03 µg/mm³		0.05 mg/mm³	1-1.4 mg/mm³	insoluble	insoluble	insoluble
Flexural strength	180 - 185 MPa		165 – 170 MPa	95 – 105 MPa			100 – 180 MPa
Bond strength (with veneering material)	> 38,8 MPa [1]		20 MPa (composite)		20 – 30 MPa (with ceramic)	> 25 MPa	> 25 MPa
Thermal conductivity	low	low	low	low	high	high	low
Surface polishing characteristics	< 0,02 µm very good		poor	< 0.05 µm good	good	poor	good

* Depending on the type of processing, pressing / milling
[1] When using visio.lign and combo.lign opaquer

Table No. 7: Physical properties of Bio-HPP compared with other frequently used materials

Apart from Bredent, there have been a very few independent studies on bio-HPP as an implant suprastucture. Despite the fact that several studies have compared crestal bone loss around implants with conventional titanium abutments (prefabricated, CAD CAM milled), there is no evidence in the literature to compare the crestal bone loss around implants that have given Bio-HPP abutments.

There are limited clinical studies which were conducted to evaluate crestal bone loss using various types of abutments. In the present study the results suggested that in group I (titanium abutments with PFM crowns) Group II (Bio HPP abutments with composite veenering), on intra group comparison, the difference in the mean crestal bone level between periods on both mesial and distal side is significant ($P< 0.05$ or $P< 0.001$) from the time of prosthesis placement, at 1 month, 3 month and 1 year later suggestive of progressive bone loss around Implant. However, there is no significant change in mean crestal bone loss from the time of prosthesis placement and 1 month and 3 months later and it found to be statistically same but increased significantly after 1 year in both the groups.

While on Intergroup comparison, it was found that there was no significant difference ($P> 0.05$) in mean crestal bone loss between both the groups.

But at final evaluation, net mean decrease or crestal bone loss from the time of prosthesis placement to 1 year on mesial side of the group II (55.14%) was found to be 24.49% less as compare to group I (79.63%)

And on distal side group II (56.56%) was found to be 25.58% less as compared to group I (82.14%) suggests the use of Bio HPP improves the bone health around implants when compared to conventional abutments.

The findings can be compared to those of Kushaldeep et al. compared crestal bone loss in immediate versus delayed loading at one, three, and six months time interval and found change in radiographic bone loss in both the groups which when comparing baseline to 1, 3, and 6 months, It was discovered that the difference in bone loss between groups 1 and 2 was statistically significant, but the difference in bone loss between groups 1 and 2 was not.[38]

Rubashree et al. conducted a study. They compared crestal bone loss in prefabricated and castable abutments at the time of implant placement, at the time of loading and three months after loading. There was no significant difference in crestal bone loss between prefabricated and castable abutments after three months of loading, but there was a significant increase in bone loss for prefabricated abutments.[61]

Early crestal bone loss in cases of non-submerged implants was found to be greater in the maxilla than in the mandible, ranging from 0.6 mm to 1.1 mm in the first year of function, according to Papaspyridakos[8]. In addition, they discovered that when implants are placed with their polished surfaces, there is a greater amount of bone loss.

And since submerged implants have been used in in this study, the findings are relevant in this context, according to Nemli et al[34], who compared the mean crestal bone loss around submerged and non-submerged implants and stated that they were comparable.

In a study by Szpak and Szymanskait,[39] was discovered that crestal bone loss was greater by 0.296 mm ($p = 0.038$) around implants placed in the region of incisors, and by 0.364 mm ($p = 0.023$) around implants placed in the region of canines.

The present study could have been conducted in the mandibular premolar region without affecting the results because the difference in crestal bone loss between implants placed in the molars and premolars regions is statistically insignificant ($p = 0.187$)).[39]

The study's inclusion and exclusion criteria were based on known risk factors for crestal bone loss, as described in a retrospective cohort study by David French et al (2019)[41], who identified the various risk factors for crestal bone loss and divided them into risk factors that are related to the patient and risk factors that are related to the implant.. In terms of crestal bone loss, the following patient-related risk indicators were significantly associated: autoimmune disease, smoking, and bisphosphonate use. Implant factors such as location, diameter, and design were all found to have a significant impact on crestal bone loss. Diabetes (both type 1 and type 2) did not have a significant effect, which was surprising.Immediate implant loading and the presence of a bone defect with bone grafting were found to have an

effect on crestal bone loss among the surgically related risk indicators. Osseous defect Bone grafting at the time of implant placement was also discovered to be a significant risk factor, with grafted sites having more crestal bone loss than native bone.

The current study used standard intraoral periapical radiographs with a mesh gauge of 1 mm2 to compensate for magnification error in measuring crestal bone loss. This method has been used in a number of studies[35,38]. The ratio of actual implant length to radiographic implant length was used to compensate for magnification error in a study by Kim et al.[36]

Measurement of crestal bone loss have also been done digitally which was not which was not done in the current study because both methods were found to have the same accuracy in a systematic review by Adrien Naveau et al[42]

By superimposing two serial radiographic images before subtracting them to quantify bone changes using specially-designed software, the digital subtraction technique can be used to directly measure bone loss.

One disadvantage of using standard IOPAs to measure crestal bone loss is that only the mesial and distal crestal bone loss can be measured. Novel techniques such as CBCT and photo-acoustic ultrasound can be used to overcome these drawbacks.[42]

Other than crestal bone loss, the modified plaque index (mPlI) and modified sulcus bleeding index were used in this study (mBI). These indices are based on Sillnes and Loe's Plaque Index and Sulcus Bleeding Index, which were modified for peri-implant soft tissue evaluation by Mombelli et al in 1987.[48]

The inclusion of these soft tissue parameters in the study was motivated by the fact that the company marketing the product asserts that bio-HPP prosthesis improve gingival health around implants due to its high polishability (0.018 mRA, JenaUni) or 0.05, inertness, and low water absorption.

TheofilosKoutouzis (2011))[56] compared PEEK and titanium healing abutments in terms of peri-implant bone level and soft tissue health. In their research, they discovered a statistically significant difference between PEEK and titanium abutments in terms of plaque accumulation (20.5 percent vs 40.9 percent). During the

3-month healing period, both groups' implants showed minimal and similar crestal bone loss (20.02 mm test group vs 20.25 mm control group)

Soft tissue health around implants, as well as resistance to plaque accumulation by the prosthetic material, are critical, as these are linked to peri-implant mucositis and, in turn, vertical bone loss around the implant.

Modified plaque index, modified sulcus bleeding index, and probing depth are soft tissue parameters that are routinely used for clinical evaluation of peri-implant soft tissue health. According to a study by JaisikaRajpal et al.[57],probing depth was found to be non-significant and thus was not included in the study.

Each implant site's scores were recorded on the mesial, buccal, lingual, and distal sides, with a second reading taken after 40 hours to reduce the chance of error. For each tooth, a mean score was calculated.

The North Carolina periodontal probe have been used for soft tissue examination because it has been widely used in studies to assess these parameters.

Mean modified plaque index in both group I and II increase linearly with time. On intragroup Comparison, difference in mean modified plaque index between both groups at different time intervals showed significant ($P< 0.01$) increase from the time of prosthesis placement up to 1 year later. While in group 2 it was significantly ($P< 0.01$) different and slightly higher at 1 year later as compared to 1 month. However in both the groups it did not differ between other periods and found to be statistically same. ($P> 0.05$)

On intergroup comparison, there is no statistically significant difference in the mean modified plaque index at all periods.

Final evaluation revealed net mean increase in modified plaque index from the time of process is placement to 1year in group II (61.11%) was found to be 7.89% higher as compared to group 1 (53.23%). but was considered statistically insignificant.

The mean modified sulcus bleeding index in both groups show similar trend as of modified plaque index. The mean modified sulcus bleeding index in both groups

increase gradually with time and the increase was evident slightly higher in Group I as compared to Group II.

In intragroup comparison, the mbI increased significantly for both the groups ($P< 0.01$ or $P< 0.001$) at 1 year later as compared to at the time of prosthesis placement. Group I, it also showed significant ($P< 0.05$) increase at 3 months later as compared to at the time of prosthesis placement. Furthermore, in Group I, it also showed significant ($P< 0.01$) increase at 1 year later as compared to at 1 month later. However, in both groups, it did not differ ($P> 0.05$) between other periods i.e. found to be statistically the same.

On intergroup comparison, there is no statistically significant ($P> 0.05$) difference in the mean modified bleeding index at all periods.

At final evaluation, the net mean increase in modified sulcus bleeding index of Group II (52.27%) was found to be 12.17% less as compared to Group I (64.44%).

Modified plaque index and bleeding index are important factors to determine soft tissue health at around implant and also these parameters determine inflammation processin the periodontal pocket.

As Modified plaque index and bleeding index has not been recorded in bio HPP abutments in any of the studies done before. As there were some scores which was increasing and were statistically significant in both the parameters must be attributed to the fact that Implant hygiene is compromised after loading in sub-gingival regions.

However, this increase was not statistically significant at the end of one year i.e Plaque and bleeding Index at different time interval remain statistically same in both the groups. Asafter the initial phase some counselling and oral hygiene instructions were given to the patients so inflammation subsided. Also patient was adviced for routine check up and long term maintainence should be followed.

Findings can be compared with the study conducted by Behneke et al[62], in which hard and soft tissue reactions around implant was studied for three years in which radiologic and clinical parameters were analysed, periodontal parameter suggested statistical correlation analysis indicated healthy soft tissue around implant.

In another study, by LeKholm and Van Steenberg et al[63] where they rehabilitated partially Edentulous jaws with osseointegrated implants and conducted 5 year multicentre study they determine marginal bone level at Implant through and graphs and plaque and gingival index showed a similar pattern and good health around titanium abutments and natural teeth.

Another study conducted by Giano Ricci et al[64], they reported crestal bone resorption 5 years after loading through radiographic and clinical evaluation which also includes plaque score monitoring, bleeding on probing, probing depth. They observed plaque on 42% Implant and bleeding on probing in 15.5% implants and suggested frequent and strict clinical evaluation associated with oral hygiene procedures during supportive therapy could maintain soft and hard tissue help around Implant.

Also present study findings are in accordance with Rismanchianet al[65]. in which they evaluated effect of plaque on periimplant soft tissue health in which they found initial increase in plaque and bleeding Index suggestive of hygiene level of patients is low and reinforcement of oral hygiene education should be done otherwise it would threaten Soft tissue around Implant and may cause disease.

As there is no statistical improvement in mean score of mplI and mBI this can be attributed to number of factors such as mechanical overloading, thin soft tissue, lack of keratinised mucosa, systematic disease, medications, migration of teeth, periodontitis, peri- implantitis, endodontic infections, oral hygiene, etc. as stated by Hammerle et al[66], in review of etiological factors of hard and soft tissue deficiencies at dental implant.

Another factor being as stated in study design including the use of sonic powered toothbrush byJungwon Lee et al[58] whereas in the current study, no such method was used and most importantly, follow-up after third month was done directly after one year due to the covid pandemic so the patient counselling and periodontal supportive therapies could not be given routinely to the patient which could have better effect on soft tissue health around implant.

Conclusion

The impact of loading implants with titanium abutments with PFM crowns and Bio HPP abutments with composite veneered crowns on crestal bone level, modified plaque, and sulcus bleeding index was investigated in this study.Within the limitations of the study, following conclusions can be drawn:

1.When comparing baseline to 1 year, the change in mean crestal bone loss in both groups is statistically significant but on comparison between group I and group II the difference in meancrestal bone loss at both mesial and distal sidedid not differ significantly.

.However, net mean crestal bone loss percentage calculated between both the groups out of which group II shows 25% less bone loss as compared to group I.

So, As an abutment for fixed implant supported prostheses, bio HPP, which has a low modulus of elasticity close to that of bone, showed less crestal bone loss when compared to conventional prostheses made of titanium Abutment over which PFM was used.

2. Soft tissue parameters including modified plaque index and modified sulcus bleeding index increase significantly over one year in both the groups individually but on comparing both the groups, this increase is non-significant.

As a result, there is no statistically significant difference in Periimplant soft tissue response when Bio HPP veenered with composite is used as Abutment compared to traditional prosthesis where the Periimplant soft tissue is primarily in contact with porcelain

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Babu Banarasi Das University
Babu Banarasi Das College of Dental Sciences,
BBD City, Faizabad Road, Lucknow – 226028 (INDIA)

Dr. Lakshmi Bala
Professor and Head Biochemistry and
Member-Secretary, Institutional Ethics Committee

Communication of the Decision of the VII[th] Institutional Ethics Sub-Committee

IEC Code: 38 (Revised) **BBDCODS/01/2021**

Title of the Project: Evaluation of Soft and Hard Tissue Responses to Two Different Types of Abutments: A 1-Year Prospective Clinico-Radiographic Follows Up Study.

Principal Investigator: Dr. Taruna Choudhary **Department:** Prosthodontics and Crown & Bridge

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: Revised, MDS Project Protocol

Dear Dr. Taruna Choudhary,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 07[th] January 2021.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3.	Dr. Sumalatha M.N. Member	Reader, Department of Oral Medicine & Radiology, BBDCODS, Lucknow
4.	Dr. Akanksha Bhatt Member	Reader, Department of Conservative Dentistry & Endodontics, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The comments were communicated to PI thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Lakshmi Bala 07/01/21

(Dr. Lakshmi Bala)
Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

(Dr. B. Rajkumar)
Principal
BBDCODS
PRINCIPAL
Babu Banarasi Das College of Dental Science
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES (FACULTY OF BBD UNIVERSITY), LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Evaluation of Soft and Hard Tissue Responses to Two Different Types of Abutments: A 1-Year Prospective Clinico-Radiographic Follow Up Study."** submitted by **Dr Taruna Choudhary** Post graduate student from the **Department of Prosthodontics and Crown & Bridge** as part of MDS Curriculum for the academic year 2018-2021 with the accompanying proforma was reviewed by the Institutional Research Committee present on **04th January, 2021** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Prof. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

Participant Information Document (PID)

1. **Study title**

EVALUATION OF SOFT AND HARD TISSUE RESPONSES TO TWO DIFFERENT TYPES OF ABUTMENTS: A 1- YEAR PROSPECTIVE CLINICO-RADIOGRAPHIC FOLLOW UP STUDY.

2. Invitation paragraph

You are being invited to take part in a research study, it is therefore important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully. Ask us for any clarifications or further information. Whether or not you wish to take part is your decision.

3. What is the purpose of the study?

Purpose of this study is to evaluate effect of Bio-HPP, PEEK and Titanium abutments on bone crestal level and peri-implant soft tissue health**.**

4. Why have I been chosen?

You have been chosen for this study as you are fulfilling the required criteria for this study. The study sample includes a sufficient number of patients.

5. Do I have to take part?

Your participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you still are free to withdraw at any time and without giving a reason.

6. What will happen to me if I take part?

You will be involved in the research for one day. Research will be conducted on the day of implant surgery for four hours. And research method will be briefly explained to the patient.

7. What do I have to do?

You do not have to change your regular lifestyles for the investigation of the study. Dietary restrictions include limiting chewing to the only softest foods for few weeks.

8. What is the procedure that is being tested?

The procedure will involve is to evaluate effect of Bio-HPP, PEEK and Titanium abutments on bone crestal level and peri-implant soft tissue health**.**

You will be given description of the drugs used and a card with details of the study which you are supposed bring when you visit second time.

9. What are the interventions for the study?

There are no interventions in the study.

10. What are the side effects of taking part?

There are no side effects on patients of this study.

11. What are the possible disadvantages and risks of taking part?

There are no risk or disadvantages of taking part in this study.

12. What are the possible benefits of taking part?

This study have certain possible benefits as:

Implants restored with Bio-HPP abutments as compared to conventional prefabricated titanium abutments provides with better soft tissue health and less crestal bone loss as compared to titanium abutments.

13. What if new information becomes available?

If additional information becomes available during the course of the research you will be told about these and you are free to discuss it with your researcher, your researcher will tell you whether you want to continue in the study. If you decide to withdraw, your researcher will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

If the study stops/finishes before the stipulated time, this will be explained to the patient/volunteer.

15. What if something goes wrong?

If any severe adverse event occurs, or something goes wrong during the study, the complaints will be handled by reporting to the institution (s), and Institutional ethical community.

16. Will my taking part in this study be kept confidential?

Yes it will be kept confidential.

17. What will happen to the results of the research study?

You will not be identified in any research or publications.

18. Who is organizing the research?

This research study is organized by the academic institution (BBDCODS).

19. Will the results of the study be made available after study is over?

Yes.

20. Who has reviewed the study?

The study has been reviewed and approved by the Head of the Dept, and the IEC/IRC of the institution.

21. Contact for further information

Dr. Taruna Choudhary

Department of Prosthodontics and Crown and Bridge

Babu Banarasi Das College of Dental Sciences.

Lucknow-227105

Mob-8954001561

Dr. Amrit Tandon (HOD)

Department Prosthodontics and Crown and bridge

Babu Banarasi Das College of Dental Sciences.

Lucknow-227105

Mob-9792888809

Dr. LaxmiBala,

Member Secretary,

Babu Banarasi Das College of Dental Sciences.

Lucknow

bbdcods.iec@gmail.com

Remember to thank your patient for taking part in the study!

The patient information sheet should be dated

The Participant Information document should state that the participant will be given a copy of the information sheet and the signed consent form.

Signature of PI…….

Name……

Date …….

BabuBanarasi Das College of Dental Sciences

(A constituent institution of BabuBanarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Participant Information Document (PID)

1. अध्ययन शीर्षक
अभ्यर्थियों के दो अलग-अलग प्रकारों के लिए सॉफ्ट और हार्ड टिश्यू रिजल्ट का मूल्यांकन: 1- 1 वर्ष का प्रोस्पेक्टिव क्लिनिको-रेडियोलॉजिकल फॉलिकल स्टडी।

2. निमंत्रण पैराग्राफ
आपको एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है, इसलिए आपके लिए यह समझना महत्वपूर्ण है कि अध्ययन क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय निकालें। हमसे कोई स्पष्टीकरण या अधिक जानकारी के लिए पूछें। आप हिस्सा लेना चाहते हैं या नहीं यह आपका निर्णय है।

3. अध्ययन का उद्देश्य क्या है?
इस अध्ययन का उद्देश्य अस्थि क्रेस्टल स्तर और पेरी-इम्प्लांट सॉफ्ट टिशू हेल्थ पर बायो-एचपीपी, पीईईके और टाइटेनियम एब्यूमेंट्स के प्रभाव का मूल्यांकन करना है।

4. मुझे क्यों चुना गया है?
आपको इस अध्ययन के लिए चुना गया है क्योंकि आप इस अध्ययन के लिए आवश्यक मानदंडों को पूरा कर रहे हैं। अध्ययन के नमूने में पर्याप्त संख्या में रोगी शामिल हैं।

5. क्या मुझे भाग लेना है?
अनुसंधान में आपकी भागीदारी पूरी तरह से स्वैच्छिक है। यदि आप करते हैं, तो आपको रखने के लिए यह सूचना पत्र दिया जाएगा और सहमति पत्र पर हस्ताक्षर करने के लिए कहा जाएगा। अध्ययन के दौरान आप बिना किसी कारण के किसी भी समय वापस लेने के लिए स्वतंत्र हैं।

6. अगर मैं भाग लूंगा तो मेरा क्या होगा?

आप एक दिन के लिए अनुसंधान में शामिल होंगे। इम्प्लांट सर्जरी के दिन चार घंटे तक शोध किया जाएगा। और अनुसंधान पद्धति को रोगी को संक्षेप में समझाया जाएगा।

7. मुझे क्या करना है?
अध्ययन की जांच के लिए आपको अपनी नियमित जीवन शैली को बदलने की आवश्यकता नहीं है। आहार प्रतिबंधों में कुछ हफ्तों के लिए एकमात्र नरम खाद्य पदार्थों को चबाने को सीमित करना शामिल है।

8. वह प्रक्रिया क्या है जिसका परीक्षण किया जा रहा है?
इस प्रक्रिया में बायो-एचपीपी, पीईईके और टाइटेनियम एबटमेंट्स का अस्थि क्रेस्टल स्तर और पेरी-इम्प्लांट सॉफ्ट टिशू हेल्थ के प्रभाव का मूल्यांकन किया जाएगा।
आपको उपयोग की गई दवाओं का विवरण और एक कार्ड अध्ययन के विवरण के साथ दिया जाएगा जिसे आप दूसरी बार आने पर लाने वाले हैं।

9. अध्ययन के लिए हस्तक्षेप क्या हैं?
अध्ययन में कोई हस्तक्षेप नहीं किया गया है।

10. भाग लेने के दुष्प्रभाव क्या हैं?
इस अध्ययन के रोगियों पर कोई दुष्प्रभाव नहीं हैं।

11. भाग लेने के संभावित नुकसान और जोखिम क्या हैं?
इस अध्ययन में भाग लेने का कोई जोखिम या नुकसान नहीं हैं।

12. भाग लेने के संभावित लाभ क्या हैं?
इस अध्ययन के कुछ संभावित लाभ हैं:
पारंपरिक पूर्वनिर्मित टाइटेनियम एबूटमेंट की तुलना में बायो-एचपीपी एब्यूटमेंट के साथ बहाल किए गए प्रत्यारोपण, टाइटेनियम एब्यूमेंट की तुलना में बेहतर नरम ऊतक स्वास्थ्य और कम क्रस्टल हड्डी हानि प्रदान करते हैं।

13. यदि नई जानकारी उपलब्ध हो जाए तो क्या होगा?
यदि अनुसंधान के दौरान अतिरिक्त जानकारी उपलब्ध हो जाती है, तो आपको इनके बारे में बताया जाएगा और आप अपने शोधकर्ता के साथ इस पर चर्चा करने के लिए स्वतंत्र हैं, आपका शोधकर्ता आपको बताएगा कि क्या आप अध्ययन जारी रखना चाहते हैं। यदि आप वापस लेने का निर्णय लेते हैं, तो आपका शोधकर्ता आपकी वापसी की व्यवस्था करेगा। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपको एक अद्यतन सहमति पत्र पर हस्ताक्षर करने के लिए कहा जा सकता है।

14. जब शोध अध्ययन रुक जाता है तो क्या होता है?
यदि अध्ययन निर्धारित समय से पहले बंद / खत्म हो जाता है, तो यह रोगी / स्वयंसेवक को समझाया जाएगा।

15. अगर कुछ गलत हो जाए तो क्या होगा?
यदि कोई गंभीर प्रतिकूल घटना होती है, या अध्ययन के दौरान कुछ गलत होता है, तो संस्थान (एस), और संस्थागत नैतिक समुदाय को रिपोर्ट करके शिकायतों को नियंत्रित किया जाएगा।

16. क्या इस अध्ययन में भाग लेने को गोपनीय रखा जाएगा?
हां इसे गोपनीय रखा जाएगा।

17. शोध अध्ययन के परिणामों का क्या होगा?
आपको किसी भी शोध या प्रकाशन में पहचाना नहीं जाएगा।

18. शोध का आयोजन कौन कर रहा है?
यह शोध अध्ययन शैक्षणिक संस्थान (BBDCODS) द्वारा आयोजित किया जाता है।

19. क्या अध्ययन के परिणाम अध्ययन के बाद उपलब्ध कराए जाएंगे?
हाँ।

0. अध्ययन की समीक्षा किसने की?

अध्ययन की समीक्षा की गई है और विभाग के प्रमुख, और आईईसी / आईआरसी द्वारा अनुमोदित किया गया है।

21. अधिक जानकारी के लिए संपर्क करें

डॉ। तरूणा चौधरी
प्रोस्थोडॉन्टिक्स और क्राउन और ब्रिज विभाग
बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज।
लखनऊ -227105
मोब -8954001561

डॉ। अमृत टंडन (HOD)
विभाग प्रोस्थोडॉन्टिक्स और क्राउन और पुल
बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज।
लखनऊ -227105
मोब -9792888809

डॉ। लक्ष्मीबाला,
सदस्य सचिव,
बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज।
लखनऊ
bbdcods.iec@gmail.com

अध्ययन में भाग लेने के लिए अपने मरीज को धन्यवाद देना याद रखें!

रोगी सूचना पत्र दिनांकित होना चाहिए

प्रतिभागी सूचना दस्तावेज में कहा जाना चाहिए कि प्रतिभागी को सूचना पत्र और हस्ताक्षरित सहमति पत्र की एक प्रति दी जाएगी।

पीआई का हस्ताक्षर .....।

नाम .....

तारीख .....।

Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

Title of the Study ……..

Study Number……..
Subject's Full Name…….
Date of Birth/Age ……
Address of the Subject…….
Phone no. and e-mail address……
Qualification ……
Occupation: Student / Self Employed / Service / Housewife/
Other (Please tick as appropriate)
Annual income of the Subject……
Name and of the nominees(s) and his relation to the subject.....(For the purpose of compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated ……..for the above study and have had the opportunity to ask questions. **OR** I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I permit the use of stored sample (tooth/tissue/blood) for future research. **Yes [ ] No [ ] Not Applicable [ ]**
6. I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me.

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:……..
Signatory's Name……. Date …….
Signature of the Investigator…… Date……..
Study Investigator's Name..... Date……..
Signature of the witness…… Date……..
Name of the witness……
Received a signed copy of the PID and duly filled consent form
Signature/thumb impression of the subject or legally Date……..

Acceptable representative

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

सहमति पत्र

अध्ययन शीर्षक.....
अध्ययन संख्या.....
प्रतिभागी के पूर्ण नाम.....
जन्म तिथि / आयु.....
प्रतिभागी का पता .....
फोन नं. और ई-मेल पता .....
योग्यता .....
व्यवसाय: छात्र / स्व कार्यरत / सेवा / ग्रहिणी .....
अन्य (उचित रुप मे टिक करें) .....
प्रतिभागी की वार्षिक आय .....
प्रत्याशीयो के नाम और प्रतिभागी से संबंध...(परीक्षण से संबंधित मौत के मामले मे मुआवजे के प्रयोजन के लिए)

1. मेरी पुष्टि है कि मैने अध्ययन हेतु सुचना पत्र दिनांक ..... को पढ व समझ लिया तथा मुझे प्रश्न पुछने या मुझे अध्ययन अन्वेषक ने सभी तथ्यों को समझा दिया है तथा मुझे प्रश्न पुछने के समान अवसर प्रदान किए गये।

2. मैंने यहॉ समझ लिया कि अध्ययन में मेरी भागीदारी पूर्णतः स्वैच्छिक है और किसी भी दबाव के बिना स्वतंत्र इच्छा के साथ दिया है किसी भी समय किसी भी कारण के बिना , मेरे इलाज या कानूनी अधिकारो को प्रभावित किए बिना , अध्ययन में भाग न लेने के लिए स्वतंत्र हुँ ।

3. मैंने यह समझ लिया है कि अध्ययन के प्रायोजक , प्रायोजक की तरफ से काम करने वाले लोग, आचार समिति और नियामक अधिकारियों को मेरे स्वास्थ्य रिकार्ड को वर्तमान अध्ययन या आगे के अध्ययन के सन्दर्भ देखने के लिए मेरी अनुमति की जरूरत नही है, चाहे मैने इस अध्ययन से नाम वापस ले लिया है। हॉलाकि मै यह समझता हुँ कि मेरी पहचान को किसी भी तीसरे पक्ष या प्रकाशित माध्यम में नही दी जायेगी।

4. मै इससे सहमत हूँ कि कोई भी डेटा या परिणाम जो इस अध्ययन से प्राप्त होता है उसका वैज्ञानिक उद्देश्य (ओं) के उपयोग के लिए मेरी तरफ से कोई प्रतिबंध नही है।
5. भविष्य के अनुसंधान के लिए भंडारित नमूना (ऊतक/रक्त) पर अध्ययन के लिए अपनी सहमति देता हुँ।

हॉ [ ] नही [ ] अनउपयुक्त [ ]

6. मै परीक्षण की अनुमति देता हुँ। मुझे इसके द्वारा यदि कोई परेशानी होती है, इसके बारे में जानकारी दे दी गई है। मैने रोगी जानकारी सूचना पत्र को पढ तथा समझ लिया है।

प्रतिभागी / कानूनी तौर पर स्वीकार्य प्रतिनिधि का हस्ताक्षर (या अंगूठे का निशान.....

हस्ताक्षरकर्ता का नाम..... दिनांक .....अन्वेषक के हस्ताक्षर ..... दिनांक .....

अध्ययन अन्वेषक का नाम .....

गवाह के हस्ताक्षर ..... दिनांक .....गवाह के नाम .....

मैनें पीआईडी और विधिवत भरे सहमति फार्म का एक हस्ताक्षर की नकल प्राप्त की.

प्रतिभागी कानूनी तौर पर प्रतिनिधि का हस्ताक्षर/ अंगूठे का निशान ..... दिनांक.....

Observation

Group I: Titanium abutments with PFM crowns

Sample No	I. Crestal bone level (mm)								II. Modified Plaque Index (mPlI)				II. Modified sulcus bleeding index (mBI)			
	Mesial				Distal											
	At the time of prosthesis placement	1 month later	3 months later	1 year later	At the time of prosthesis placement	1 month later	3 months later	1 year later	At the time of prosthesis placement	1 month later	3 months later	1 year later	At the time of prosthesis placement	1 month later	3 months later	1 year later
1	1	0.5	0.5	0.25	1	0.5	0.5	0.25	1.25	1.50	1.25	1.00	1.00	1.00	1.50	1.25
2	1.5	1	1	0.5	2	0.5	0.5	0.25	0.75	1.25	1.50	1.75	0.50	0.75	0.75	1.00
3	3	1.5	1	0.25	3	2.25	2	0.5	1.25	1.25	1.50	1.25	1.00	1.00	1.50	1.00
4	2.5	1.5	1.5	0.5	2	1	0.5	0.25	0.25	1.00	1.50	1.50	0.50	0.75	1.25	1.50
5	1	0.5	0.5	0.25	1	0.5	0.5	0.25	1.00	1.25	1.50	1.75	0.50	0.75	1.00	1.25
6	2	1.5	0.5	0.25	2	1	0.5	0.25	1.50	1.25	1.25	1.75	0.75	0.75	0.75	1.50
7	1	0.5	0.5	0.25	1.5	1.25	1	0.5	1.25	1.50	1.50	2.00	0.50	0.25	1.25	1.00
8	2.5	2	1.5	0.5	2.5	1.5	1.5	0.5	1.50	1.75	1.25	1.50	0.75	1.00	0.75	1.25
9	1	0.5	0.25	0.25	2.5	2	1	0.5	0.75	1.00	1.75	1.75	0.50	0.50	0.75	1.25
10	2	1	0.5	0.5	2	0.5	0.25	0.25	1.25	1.25	1.00	1.25	0.50	0.50	1.25	1.75
11	3	2.5	2	0.5	3	2	1.5	0.5	1.00	1.50	1.50	2.00	0.75	1.25	0.75	1.00
12	1	0.5	0.5	0.25	1.5	1	1	0.25	1.00	1.00	1.25	1.25	0.50	0.75	1.00	1.25
13	2	1.5	1	0.5	2	1	0.5	0.25	1.00	1.25	1.00	2.00	1.25	1.00	1.50	1.25
14	1.5	1	0.5	0.25	1	1	0.25	0.25	1.25	1.50	1.50	1.25	0.75	1.00	1.00	1.25
15	2	1.5	1.5	0.5	1	0.75	0.5	0.25	0.50	1.00	1.00	1.75	1.50	1.00	1.00	1.00

Group II: Bio-HPP abutments with composite veneering

Sample No	I. Crestal bone level (mm)								II. Modified Plaque Index (mPlI)				III. Modified sulcus bleeding index (mBI)			
	Mesial				Distal											
	At the time of prosthesis placement	1 month later	3 months later	1 year later	At the time of prosthesis placement	1 month later	3 months later	1 year later	At the time of prosthesis placement	1 month later	3 months later	1 year later	At the time of prosthesis placement	1 month later	3 months later	1 year later
1	1.5	1	1	0.25	2	1.75	1.5	1	1.00	0.25	0.75	0.25	0.75	0.75	1.25	1.00
2	2	1	1	0.5	2	1.5	1.5	1	1.00	0.25	1.25	1.50	0.50	1.00	1.25	1.00
3	2.5	2.5	2	1.5	2.5	2.25	1	0.5	1.25	1.50	1.25	1.25	0.50	1.25	1.25	1.25
4	2	1.5	1.5	1.25	2	1.75	1.5	1	1.00	1.75	1.50	2.00	1.00	0.75	1.00	1.25
5	2.5	2	1.5	1.5	1.5	1.5	1.5	1.25	1.00	1.75	1.50	1.75	0.75	1.00	0.75	1.25
6	1	1.5	1	1	1.5	0.5	0.25	0.25	0.75	0.00	0.50	1.00	0.75	1.25	0.25	0.75
7	2	1.5	1.25	1	2.5	2	1.5	1	0.75	0.00	1.25	0.50	0.50	0.75	1.00	1.50
8	1.5	1	0.75	0.5	2	2	1.5	1	1.00	1.50	1.25	1.75	0.75	0.50	1.00	1.25
9	1.5	1.5	1	0.25	2	1.5	1.5	1.25	1.25	1.00	1.75	1.50	0.75	1.00	1.00	0.75
10	2	1.5	1.5	0.5	2	1.75	1.5	1	0.75	0.00	0.75	1.75	1.25	0.75	1.00	1.00
11	1.25	1.25	1.25	0.25	1.2	1	1	0.5	1.00	1.50	1.25	1.50	0.50	1.00	1.25	1.00
12	1.5	1	0.75	0.5	2	1.5	1	0.5	0.50	1.50	1.50	2.25	0.50	0.75	0.50	0.75
13	2	1.5	1.5	1.5	2	1	1	0.5	1.00	1.25	1.25	1.50	0.75	1.00	0.75	1.50
14	1.5	1.5	1.25	1	1	0.5	0.5	0.25	0.50	1.50	1.25	1.50	1.00	0.75	1.50	1.00
15	2	1	1	0.5	2	2	1.5	1.25	0.75	0.50	1.50	1.75	0.75	1.50	1.50	1.50

Formula used for the analysis

Arithmetic Mean

The most widely used measure of central tendency is arithmetic mean, usually referred to simply as the mean, calculated as

$$\bar{X} = \frac{\sum_{i=1}^{n} X_i}{n}$$

Standard deviation and standard error

The standard deviation (SD) is the positive square root of the variance, and calculated as

$$SD = \sqrt{\frac{\sum X_i^2 - \frac{(\sum X_i)^2}{n}}{n-1}}$$

and SE (standard error of the mean) is calculated as

$$SE = \frac{SD}{\sqrt{n}}$$

where, n= no. of observations

Minimum and Maximum

Minimum and maximum are the minimum and maximum values respectively in the measure data and range may be dented as below

Range = Min to Max

and also evaluated by subtracting minimum value from maximum value as below

Range = Maximum value-Minimum value

Median

The median is generally defined as the middle measurement in an ordered set of data. That is, there are just as many observations larger than the median as there are smaller. The median (M) of a sample of data may be found by first arranging the measurements in order of magnitude (preferably ascending). For even and odd number of measurements, the median is evaluated as

$$M = [(n+1)/2]\text{th observation- odd number}$$

$$M = [n(n+1)/2]\text{th observation – even number}$$

Analysis of Variance

Analysis of variance (ANOVA) is used when we compare more than two groups simultaneously. The purpose of one-way ANOVA is to find out whether data from several groups have a common mean. That is, to determine whether the groups are actually different in the measured characteristic. One way ANOVA is a simple special case of the linear model. For more than two independent groups, simple parametric ANOVA is used when variables under consideration follows Continuous exercise group distribution and groups variances are homogeneous otherwise non parametric alternative Kruskal-Wallis (H) ANOVA by ranks is used. The one way ANOVA form of the model is

$$Y_{ij} = \alpha_{.j} + \varepsilon_{ij}$$

where;

- Y_{ij} is a matrix of observations in which each column represents a different group.
- $\alpha_{.j}$ is a matrix whose columns are the group means (the "dot j" notation means that α applies to all rows of the j^{th} column i.e. the value α_{ij} is the same for all i).
- ε_{ij} is a matrix of random disturbances.

The model posits that the columns of Y are a constant plus a random disturbance. We want to know if the constants are all the same.

Tukey multiple comparison Test

After performing ANOVA, Tukey HSD (honestly significant difference) post hoc test is generally used to calculate differences between group means as

$$q = \frac{\bar{X}_1 - \bar{X}_2}{SE}$$

where,

$$SE = \sqrt{\frac{S^2}{2}\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}$$

S^2 is the error mean square from the analysis of variance and n_1 and n_2 are number of data in group 1 and 2 respectively.

Level of significance "*P*" is the probability signifies level of significance. The mentioned *P* in the text indicates the following:

P > 0.05- Not significant (ns)

P < 0.05- Just significant (*)

P < 0.01- Moderate significant (**)

P < 0.001- Highly significant (***)

Turiginal

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Sources included in the report

Virag Srivastava

Tarun Chowdhary