"IMMEDIATE FUNCTIONAL LOADING WITH BICORTICAL SCREW SINGLE PIECE IMPLANTS IN MANDIBLE AND MAXILLA – A PROSPECTIVE CLINICAL STUDY."

By

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(BRANCH III)

Under the guidance of
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BELAGAVI, KARNATAKA

2019 – 2022

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Dr. HARSHINI AJAY PATEL

I dedicate my work to

my Family

Mr. Ajay Patel,

Mrs. Rajeshwari Patel,

Mrs. Jinal Patel

&

Mr. Achintya Patel

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LIST OF ABBREVIATIONS

Pre-op	:	Pre-operative
Post-op	:	Post-operative
Intra-op	:	Intra-operative
POD	:	Post-operative day
M	:	Male
F	:	Female
Hb	:	Hemoglobin
BT	:	Bleeding time
CT	:	Clotting time
RBS	:	Random Blood Sugar
IOPA	:	Intra-oral peri-apical radiograph
OPG	:	Orthopantomogram
VAS	:	Visual Analog Scale
BCS	:	Bicortical Screw
CBCT	:	Cone beam computed tomography
BOP	:	Bleeding on probing

ABSTRACT

Background and Objectives: The use of conventional dental implants has proven to be successful for very few techniques and if enough jaw bone is present. Also 2 stage endosseous implant surgery is time consuming procedure in which functional loading can be done minimum after 3 months of implant placement. The newer BCS implants can be inserted in patients having atrophied jaws and immediate functional loading can be done within 72 hours of the implant placement. The aim of this study was to evaluate the outcomes after placing BCS implants in terms of soft tissue changes around the implants and implant stability.

Materials and method: This study was a prospective clinical trial in which 18 implants were placed in patients who had single or multiple missing teeth and reported to Department of Oral & Maxillofacial Surgery, KLE VK Institute of Dental Sciences, K. A. H. E. R, Belagavi who met the inclusion criteria and gave consent to participate in the study. After pre-op assessment, BCS implants were inserted in these patients and they were evaluated for the outcomes such as pain, mobility, plaque index, bleeding on probing, marginal bone loss and bone density post-operatively after 4 days, 1 month and 6 months of implant placement. Radiographic evaluation was done only after 6 months of implant placement.

Results: The cumulative survival rate of these implants was found out to be 88.89%. There was no significant evidence of peri-implantitis in these implants as the design of the implant is such that it has smooth, polished surface which does not allow the growth of bacteria thus resistant to peri-implantitis. Also, in most of the cases, bone density value showed a significant rise post-operatively after 6 months which could be attributed to reactionary osteoblastic activity after implant placement.

Conclusion: Within the limits of the study, it can be concluded that BCS implants are better alternative to standard endosseous implants as they can be inserted in atrophied jaws, immediately loaded into function within 72 hours, flexible and can be bent as per the requirement and shows promising results. The survival of these implants depends upon the chosen target cortical.

Keywords: Bicortical screw implants, basal implants, single piece implants, immediate loading, functional loading.

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INTRODUCTON

In this modern world, shorter treatment period and a smaller number of follow ups are desired by the patients. Also, there is increase in esthetic demand which has resulted in implantologist to come up with immediate loading of dental implants

The conventional endosseous implant procedure is a two-stage surgery that involves a healing period free of functional load which is to be done after 6 months in case of maxilla and 3 months in case of mandible. Since this procedure is time consuming and also demands a greater number of follow ups, single stage surgery was adopted. However, single-stage surgery with immediate prosthetic loading (instant loading) has become popular due to the increased need for less invasive and shorter procedures that meet aesthetic requirements.[1]

One of the benefits of adopting one-piece implants is that space between the implant body and abutment are eliminated, and also prevents recurrent loosening of abutments.[2]

Implant fixation in the fully edentulous maxilla is sometimes limited as a result of bone resorption (atrophy), which is mostly common in the maxillary arch's distal aspect. Bone grafting is commonly used in such instances, according to traditional notions. Implant tilting has been shown to be a viable option to bone grafting in the maxilla. A more distal implant and abutment location can be achieved, by distal tilting of the posterior implants in the arch, for example, All- on- 4 concept. Simultaneously, the cortex of the sinus wall and the nasal floor can be used for enhanced implant anchorage. In the notion used, however, the abutments of the posterior implants are anchored to the pterygoid region in the jaw into mesial

direction. In the distal region of mandible, the lingual cortex of mandible were the target cortices.[4]

Tulasne was the first to report the use of pterygoid implants, and many other investigators followed suit. They are anchored in the pterygoid; however, in certain investigations, they are positioned more anteriorly, in the pterigomaxillary region and parallel to the posterior wall of the maxillary sinus. Such implants provide a number of benefits over other approaches: provides steady anchorage in the distal part of resorbed maxilla where sinus lifts or bone grafts are not required, resulting in better long-term survival rates. Furthermore, distal cantilevers can be minimized, and occlusal loading can be enhanced.[3]

Internal tension in the region of the shaft of implant are caused by tilting the necks of these implants, this procedure of tilting the stable implant imposes extensive forces on the bone. These types of flexible implants which can be bent at the neck have equal distribution of stress along the long axis of the implant as compared to symmetrically shaped implant with angulated abutments, assuming all other parameters remain constant. As a result, bendable basal implants are likely to withstand masticatory stresses superior to preangulated, machine angulated implants, and possibly even more superior to unbent implants with a narrow vertical implant area.[5]

The single piece implant is distinguished by the fact that the abutment is attached with the implant, making it a sole component. As a result, this design removes the microspace between the abutment and the implant. The insertion of single piece implant can be done without flap or with flap raised. In the flapless technique, the osteotomy is prepared directly through piercing by the soft tissue. This

approach was proposed by Gomez-Roman to avoid interproximal bone loss and probable papillae loss, whereas Campelo and Camara recommended elevating the flap when manipulating the desirable soft-tissue position. Implants can be loaded with a temporary restoration at the same visit or immediately after one-stage surgery.[6] The flapless approach is claimed to cause less crestal bone loss, which may positively affect the final aesthetic results, and the lack of suture adds advantage to this technique.[7]

The aim of this study was to evaluate and differentiate the changes in soft tissue, crestal bone levels and bone density around bicortical screw single piece implants which are inserted and immediately loaded within 72 hours of insertion.

AIMS AND OBJECTIVES

AIM OF THE STUDY

To assess the survival and success rate of immediate functional loaded Bicortical screw implants.

OBJECTIVES

- To assess the marginal bone level.
- To assess the stability of the load transmitting parts of the implants.
- To assess occurence of peri-implantitis.
- To assess the reliability of possible target cortical bone.

HYPOTHESIS

Null hypothesis: Use of Bicortical screw implants shows significant marginal bone loss, unequal load transmission in all parts of implants and unreliable stability of target cortical bone.

Research hypothesis: Use of Bicortical screw implants shows negligible marginal bone loss, equal load transmission in all parts of implants and reliable stability of target cortical bone.

REVIEW OF LITERATURE

Dobrinin Oleg et al. 2019 conducted a retrospective cohort study in 394 patients where 4570 single piece implants were placed with immediate loading and all the patients were followed up at 6, 12, 18 and 24 months after implant insertion. In his study it was found that immediate functional loaded implants for both upper and lower arches had a survival rate of 95.7%. In his study, it was also found that bending of the implant neck increased the rate of survival as compared to unbent implants i.e., 98.5% vs 94.5%. These implants showed better results in edentulous & partially edentulous maxilla and mandible and also for replacement of solitary tooth. From the results, it can also be observed that anchoring the implants to 2nd cortical bone showed better survival rates as it works on the principle of osseofixation rather than anchoring to only 1st cortical bone and underlying spongy bone which works on the principle of osseointegration[5].

Taranpreet Kaur et al. 2019 conducted a study to assess the bone level encompassing the implant in immediately loaded and conventional loaded implants using flap or flapless techniques. The study was done in 40 patients and were equally splitted into 4 groups. In group 1 - immediate loading was done by raising the flap, in group 2 – immediate loading was done without raising the flap, in group 3 – conventional loading was done by raising the flap, in group 4 – conventional loading was done by flapless technique. It was observed that immediate loading by using flapless method showed lesser amount of bone loss when compared to other techniques. Also, the postoperative pain was comparatively lesser in the flapless technique and was more compliable to the patient[7].

Eugenia Candel et al. 2012 reviewed 13 articles on pterygoid implants. In this systematic review, 1053 pterygoid implants placed in atrophic/ resorbed posterior maxilla in 676 patients were assessed. It was found that the average success rate of all the pterygoid implants placed in atrophic posterior maxilla was 90.7%. It was found that pterygoid implants were more successful, had very few complications and better patient compliance when compared to conventional implants[3].

Nancy Singla et al 2018 conducted a study where they evaluated bone loss after placement of single piece implants during their 3 months follow up period. 20 patients were a part of this study and they were equally splitted into 2 groups. In one group, placement of single piece implants was done using flapless method while in the other group implant placement was done by raising the flap. It was found that the marginal bone loss was more when implants were placed by raising the flap as compared to that without raising the flap.[6]

Fariz Salimov et al. 2013 conducted a study to evaluate bone density in cone beam computed tomography (CBCT) and correlated with implant stability parameters. It was found that the bone density value helped in predicting the initial implant stability and thus helps to predict the possibility of early loading before placing the implants.[20]

Stefan Ihde, Lukasz Palka 2018 reported a case of a 28-year-old male, this patient had H/O trauma over upper jaw in childhood which resulted in comminuted fracture of the maxilla. There was communication of maxillary sinus through tuberosity. All the teeth from 11 to 19 were extracted. Four BCS implants were placed, one engaging the nasal floor, one engaging the maxillary sinus floor and the other two engaging the pterygoids. Immediate loading was done in this patient and

was followed up for 2 years. Hence, bicortical screw implants helped in covering maxillary defect and covered the oroantral communication.[21]

Marcos Martins Curi et al in 2015 conducted a retrospective study on patients with atrophied/ resorbed posterior maxilla. In this study, pterygoid implants and nasal floor implants were inserted in these patients and were followed up for 36 months.238 implants in total were inserted, 66 in the pterygoids and 172 in nasal floor region was placed. It was found that the overall 3-year survival/ success rate was 99% for pterygoid implants and for prosthesis, it was found that the overall survival/ success rate was 97.7%. Average bone loss in pterygoid implants subsequent to 3 years of early loading was found to be 1.21 mm.[22]

Giovanni Nicoli et al in 2019 conducted a prospective study in 33 patients where 115 implants were placed. Out of 33 patients, 24 patients received immediate loading i.e., 86 implants and 9 patients received delayed loading i.e., 29 implants. Out of 115 implants, 53 implants were engaged to the nasal floor. After 6 months of follow up, it was found that nasal floor implants had 98% of survival rate. Nasal floor implants are better and safe alternatives to zygomatic implants, have less failure rates and do not have any complications associated. They can be useful in cases of atrophied maxilla.[23]

T. K Pal et al. in 2018 published a case report of a 68-year-old women with upper and lower edentulous jaws which were severely atrophied. After all the necessary investigations, they planned to place 18 BCS implants, out of which 10 in the upper arch and 8 in the lower arch. All implants were planned to be placed by 'supporting polygon' rule.[24] In this system, canine and 2nd molar position is considered to be strategic position and rest of the implants are placed according to the

geometry of the polygon i.e., in semicircular position. Immediate loading was done within 50 hours of implant placement. Follow-up was done on 7th day and every month for up to 6 months. This report explains the concept of load bearing capacity of cortical bone thus yielding in primary stability and is much higher than cancellous bone. Also, there is negligible chance of infection and bone resorption. The polished surfaces of this implant do not allow the growth of bacteria and thus minimize the chances of peri implantitis.[25]

Vivek Gaur et al. in 2018 published a case report of a 65-year-old female with edentate lower jaw. After all the necessary investigations, 8 BCS implants for the lower jaw was planned for the patient. Four implants of the size 3.6 in diameter and length 14 mm were placed in posterior mandible, 2 implants each on both the sides. Other four implants were of same diameter and 23 mm in length which were placed anteriorly in the mandible in between the foramen. Immediate loading was done within 72 hours and followed up for 6 months after the implant placement, both clinically and radiographically. In this report, it was concluded that basal implants are more stable than conventional implants in atrophic mandible and also, they are patient compliable and meets all the demands of the patient i.e., immediate loading and less no. of appointments.[16]

Mustafa Ayna et al. in 2019 conducted a study on 29 patients in which immediate loading was done. 14 patients were loaded with acrylic based material whereas 15 patients received ceramic based prosthesis. Patients were followed up for 6 years. It was observed that all implants regardless of its position showed some amount of bone loss. Thus, it is advisable to increase the biomechanical strength by increasing the anteroposterior dimension of the implant for immediate function rather

than concentrating on the implant site. The plaque index in this study showed not much of a difference during the years.[26]

Aleksandar Lazarov in 2019 conducted a prospective cohort study on 87 patients where 1169 BCS implants were inserted. The implants were loaded immediately with metal ceramic restoration within 72 hours. It was observed that these implants had high survival rate and diabetes, hypertension and smoking had no influence on the success rate of the implant. All the patients were followed up for 57 months and it was observed that these implants showed no signs of peri implantitis.[18]

A. Zembic et al. in 2011 conducted a study on 47 patients where 57 BCS implants were placed. The implants were placed in maxillary lateral incisor region or mandibular incisor region. Immediate loading was done with provisional restoration. All implants were permanently restored after 1.9 to 14.5 months. Only 44 patients in which 54 implants were placed were looked upto 1 year. The survival rate of these implants was 98%. Bone loss of more than 3mm was observed in 18% of the cases. Plaque was found in 15% of the cases. Bleeding on probing was absent in 83% of the implants. Since provisional restoration was provided initially, fracture of restoration and loss of retention were few complications encountered during the study.[19]

Aurelio Tomasi Morgano et al. in 2013 conducted a case series in which 3 methos were used for placing BCS implants which were oblique BCS implants, parasinusal BCS implants and palatine BCS implants. One of the cases was a 46-year-old man who had atrophied edentulous upper jaw and partially edentulous lower jaw in whom BCS implants were placed and patient was followed up for 8 months. This case included oblique variety of implants. Second case was that of parasinusal implants in a 65-year-old woman. In this case, implants were placed in the tuberosity

region and these implants were not bent. The third case was a 45-year-old man in whom palatine implants were placed. In this study, it was concluded that the oblique implants were more stable in balancing the compressive masticatory forces.[27]

Łukasz R. Pałka et al. in 2019 conducted a retrospective study which included 87 patients, out of which 77 patients had a past history of suffering from periodontitis. In this study, a total of 1019 polished BCS implants were placed followed by immediate loading with prosthesis. All patients were followed up for 35 months and it was observed that the survival rate at the end of 12, 24 and 35 months were 99.3%, 98.6% and 97% respectively.[28]

Mayur Khairnar et al in 2021 presented a case report of a 62-year-old female with atrophied maxilla. In this case, 3 BCS implants were placed beyond the nasal floor from 21 to 23. Indirect lift of nasal membrane was possible due to smooth polished surface of the implant at the apex. Patient was kept under observation for 1 year. After one year, CBCT was done and it was observed that there was new bone formation in the nasal floor leading to primary stability of the implant. The mechanism of action for new bone formation could be as a result of blood clot because of indirect lift of nasal membrane which may act as a scaffold for osteoblastic activity of new bone. Patient did not turn up with any symptoms of nasal dripping or infection during 1 year follow up period.[29]

Paulo Maló et al. in 2014 conducted a retrospective study on 88 patients where 124 bicortical anchorage implants were inserted in posterior maxillary region. Patients were followed up for the average range of 6 months to 13 years and were looked for ourcomes like survival rate, marginal bone loss and complications. The survival rate in this study was found to be 94.2% for implants and 100% for prosthesis. Mean

marginal bone loss was found to be 1.56 mm. Biological complications were observed in 17 patients and mechanical complications were noticed in 49 patients out of which 30 were found to be bruxers.[30]

John C. Minichetti et al. in 2018 conducted a retrospective study on 24 patients where 33 one piece tapered implants were inserted and out of occlusion provisional restoration was given immediately after the implant placement. It was found in this study that the implant survival rate was 100% after 2.6 to 10 years of follow up. Definitive restoration was provided after 3 months of provisional restoration.[31]

Juraj Strecha et al. in 2010 conducted a study where they placed 256 bicortical screw implants and 84 blade implants. In this study, they observed that only 4 bicortical screw and 1 blade implant failed. The surgical success rate was found to be 98% and prosthetic success rate was 100%. This method of implant placement was proved to be more affordable and successful option.[32]

Fathima Banu Raza et al. in 2017 conducted a study on 12 completely edentulous patients, 2 myriad snap fit implants were placed in interforaminal region of mandible. These implants were conventionally loaded after 3 months and crestal bone loss was measured after 1 year and 3 years of follow up period. The average bone loss at the end of 3 years was found to be 1.5 mm and there was no significant difference in bone loss levels between 1 and 3 years interval.[33]

MATERIALS AND METHODS

All the patients who had single or multiple missing teeth reporting to "Department of Oral and Maxillofacial Surgery, KLE VK Institute of Dental Sciences" and were willing to undergo implant placement were considered for the study.

SAMPLE SIZE:

A total of 18 bicortical screw single piece implants were inserted in the patients from November 2019 to January 2021 who fulfilled all the inclusion criteria.

CRITERIA FOR SELECTION OF PATIENTS:

INCLUSION CRITERIA:

- Patients within age group of >18 years.
- Patients with single or multiple missing teeth.
- Patients with atrophic maxilla and mandible where conventional implants are not possible.

EXCLUSION CRITERIA:

- Patients who have known history of allergy to the drugs or anaesthetics used in the surgical procedure.
- Patients who are chronic smokers.
- Patients who have missing maxillary 1^{st} molar with intact 2^{nd} and 3^{rd} molar.
- Patients who have delineated previous treatment with bisphosphonates in their past history.
- Patients who refuse to be a part of the study.

CONSENT:

After procuring ethical clearance from the ethical committee of the university (Annexure I), the procedure with its advantages, disadvantages and possible complications were explained to the patients. Written informed consent was prevailed from the patients or their close relatives. (Annexure II)

PREOPERATIVE ASSESSMENT:

RADIOGRAPHIC ASSESSMENT:

"Cone Beam Computed Tomography":

To measure the available bone height and width for implant placement and bone density around the site of implants to be placed pre-operatively.

To assess the position of the nerve pre-operatively.

HEMATOLOGICAL EVALUATION:

Hb, BT, CT, RBS

SURGICAL ARMAMENTARIUM:

- Surgical gloves
- Mouth mirror
- Dental explorer
- Tweezer
- Kidney tray
- Surgical drape
- Towel clip
- Suction tip
- Retractor
- Gauze piece
- 2 ml disposable syringe

- 20 ml disposable syringe
- BP handle, 15 no. BP blade
- Periosteal elevator
- Needle holder
- Adson’s tissue forceps
- Artery forceps
- Scissors
- Insertion tool
- Path finder
- Hex instrument
- Spiral drill
- Form drill
- Cortical drill
- Torque wrench
- Physiodispenser
- Handgrip with adaptors
- BCS implants
- Impression tray
- Impression caps
- Implant analog

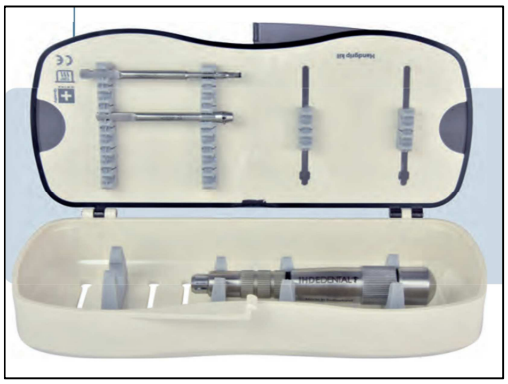


Fig. 1: Handgrip and Adaptors

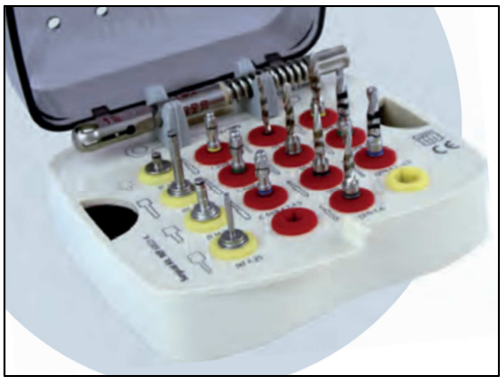


Fig. 2: Pilot drill, Spiral drill and rachet

METHODOLOGY:

Patients with single or multiple missing teeth diagnosed by established clinical and radiographic parameters and who meet the inclusion criteria will be included in the study.

Total number of implants to be placed were 15. Total no. of implants placed – 18.

Follow up:

After 4 days, 1 month and 6 months of implant placement.

After 4 days, patient will be evaluated for pain or discomfort, mobility of implant and peri-implantitis or mucositis.

After 1 month, patient will be evaluated for pain or discomfort, mobility and peri-implantitis or mucositis.

After 6 months, cone beam computed tomography evaluation will be done along with the above parameters to check for significant marginal bone loss and cortical bone stability.

SELECTION OF SUBJECTS:

Patients with single or multiple missing teeth diagnosed by established clinical and radiographic parameters and who meet the inclusion criteria will be included in the study.

SURGICAL TECHNIQUE:

After all the radiographic and hematological evaluation, patient was planned for the surgery. In radiographic evaluation the length between both the cortex i.e., from alveolar crest upto the 2nd cortex i.e., nasal, lingual or pterygoids was measured prior. Also, the width of the alveolar ridge was measured. Based on these measurements the size of the bicortical implants was decided beforehand. After deciding on the size of implants, patient was taken up for the surgery. Thorough betadine irrigation was done intraorally. 2% lignacaine with 1:80,000 was administered over the site of implant placement. Points where BCS implants were supposed to be placed were decided considering adequate distance from adjacent tooth and adjacent implants in case multiple implant placement.

The reference points were marked on the ridge where the initial pilot drill was supposed to be placed. Points are marked in mid-crestal region replacing the centre of the natural tooth to be replaced. After marking the reference points, the pilot drill was placed. Next, the 2mm drillbit was used to drill, making sure adequate length is reached upto the 2nd cortical bone. While placing the first drill, the angulation was also checked so that it properly engages the 2nd cortical plate and does not perforate it. After drilling with 2mm drillbit in adequate length and proper angulation, the next drillbit to be used was 2.5mm in same length and angulation. Subsequently, in the

same way drillbits were used till adequate width of the implant was reached. The last diameter of the drillbit used should be 1mm less than the diameter of implant to be placed. This helps in placing the implants with compression thus helping in osseointegration of the implants.

The bicortical implants were loaded on the insertion tool and placed with handgrip and adaptor in case of maxilla and with rachet in mandible. The implants were inserted till the neck of the abutment was reached. The position of the abutment was checked along the arch and the abutment was angulated with the help of handgrip such that it should lie in the arch and parallel to the natural teeth. The BCS implants are flexible and can be bent from the neck of the implant to achieve the proper position of the abutment.

After the placement of the implant, OPG was taken to assess the position of implant post-operatively. Next, impression caps were placed on the abutments and pick-up impressions were taken on the same day of the procedure. After placing the implant analog into the impression, cast was poured. Immediate loading was done within 72 hours the implant placement with acrylic crowns (temporization) for 3 to 6 months. Following which patient can go for permanent restoration with PFM or zirconia crowns.

Patient was recalled again after 1 month to check for parameters like pain, peri-implantitis or mucosities. Patient was also recalled after 6 months to check for above parameters as well as bone resorption and stability of bone by measuring bone density in the CBCT postoperatively.

CASE 1 PRE-OP

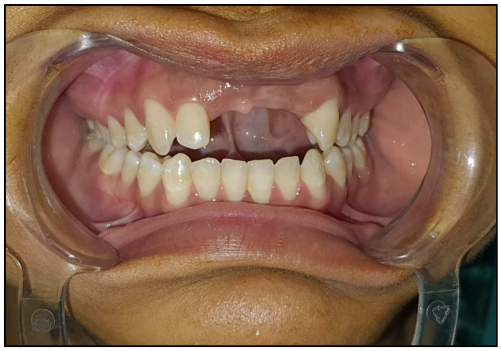


Fig. 3: Pre-op picture showing missing 11,21,22

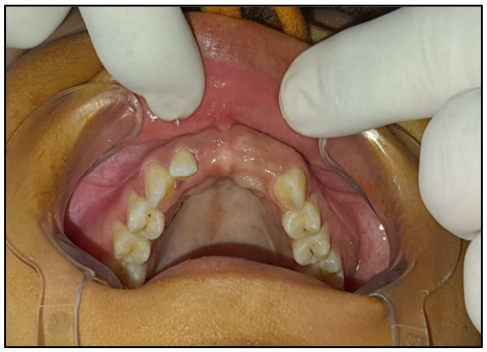


Fig. 4: Occlusal view

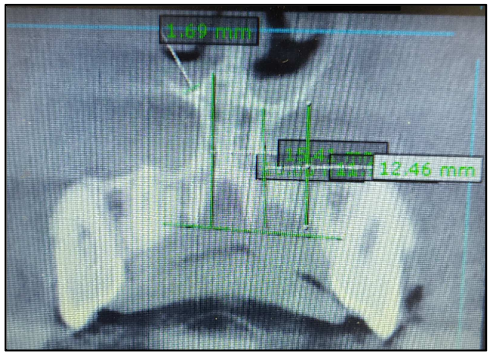


Fig. 5: Bone height & width measured on CBCT

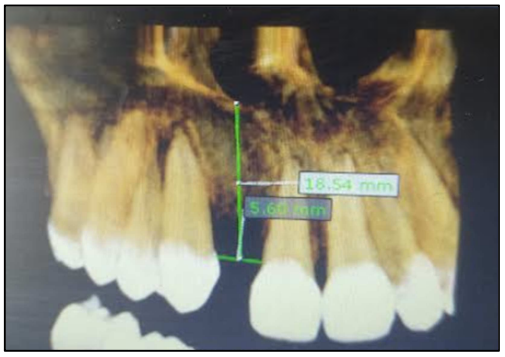


Fig. 6: Bone height measured on 3D view

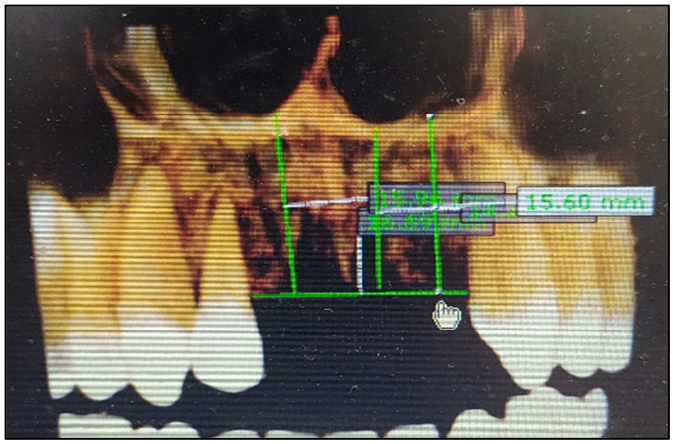


Fig. 7: Bone height & width measured on 3D view

INTRA-OP

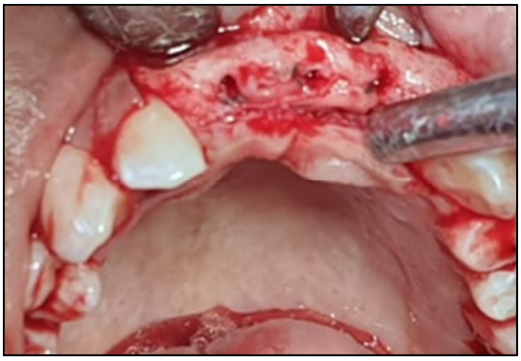


Fig. 8: Osteotomy done after raising flap

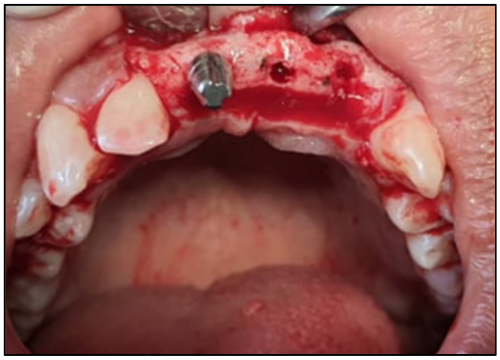


Fig. 9: Implant placed with 11

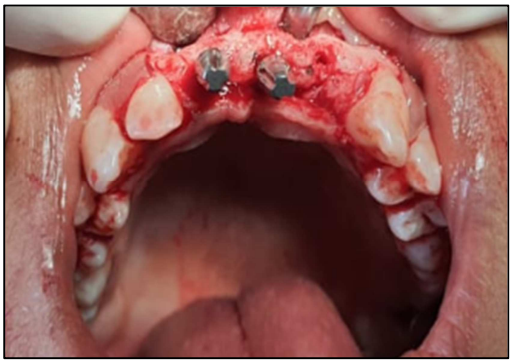


Fig. 10: Implants placed in 11, 21 region

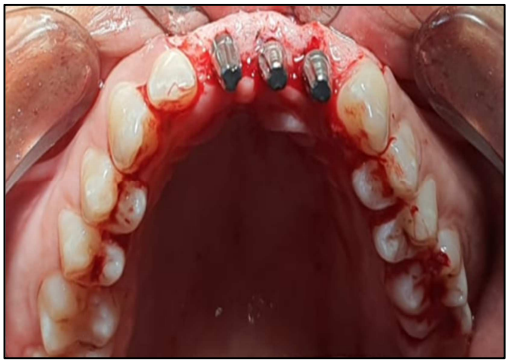


Fig. 11: Implants placed with 11, 21, 22

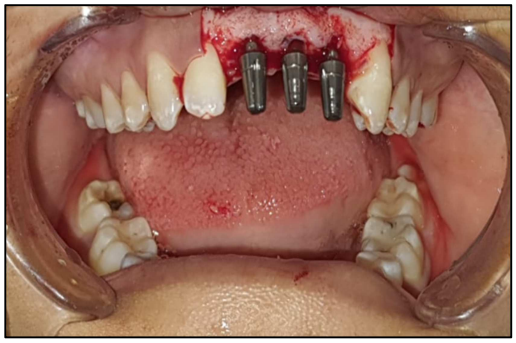


Fig. 12: Implants bent into desired position

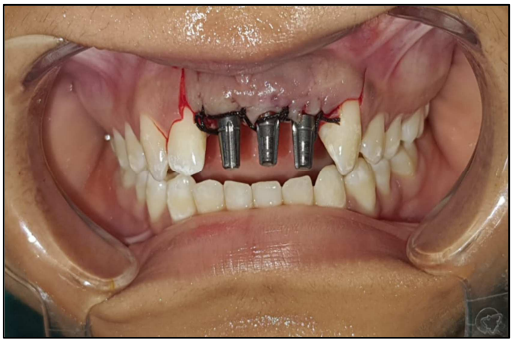


Fig. 13: Closure done and abutment height checked in occlusion.

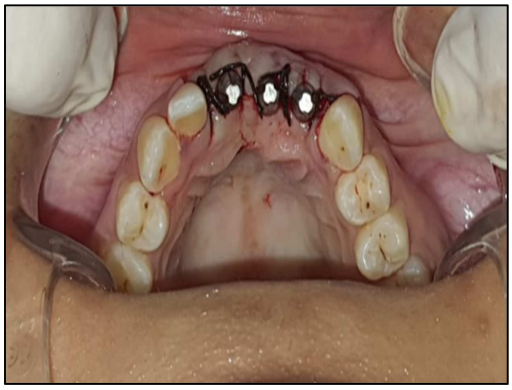


Fig. 14: Occlusal view (along the arch)

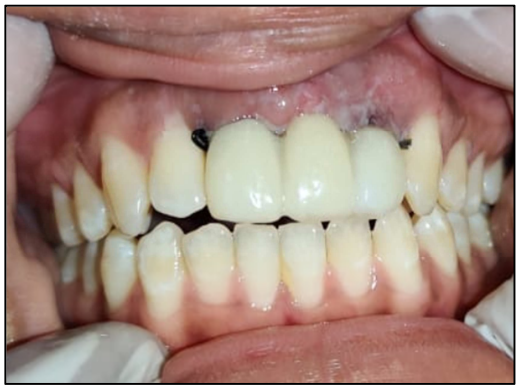


Fig. 15: Acrylic restoration within 72 hours

POST-OP

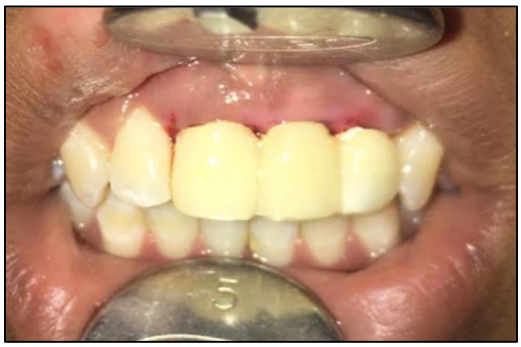


Fig. 16: POD7 – After suture removal

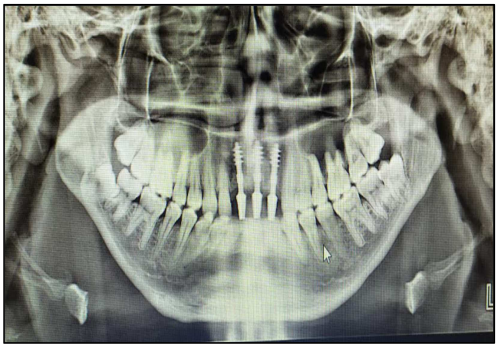


Fig. 17: Post-op OPG

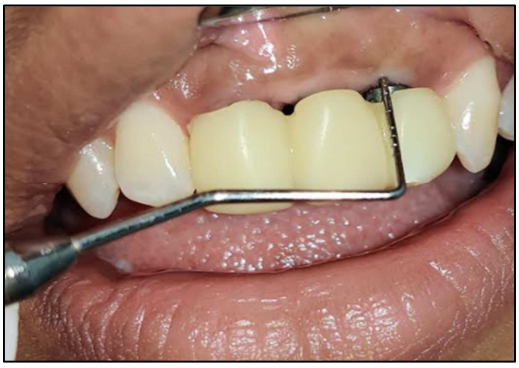


Fig. 18: Post-op 1 month

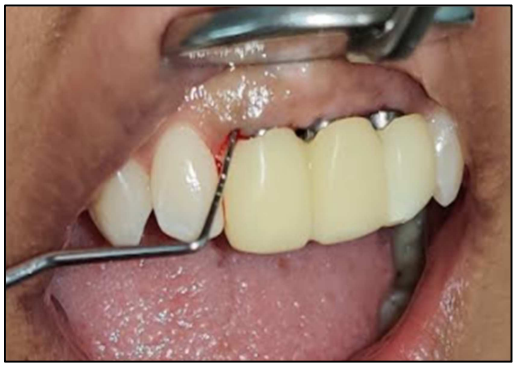


Fig. 19: Post-op 6 months

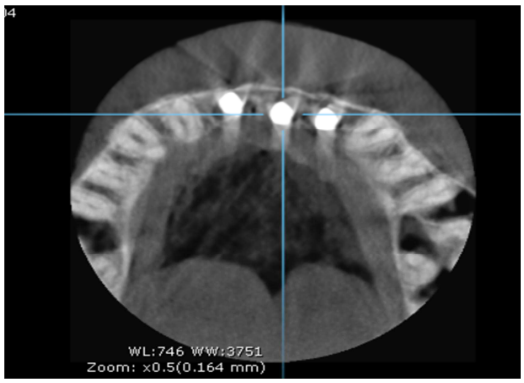


Fig. 20: Sagittal view of CBCT post-op

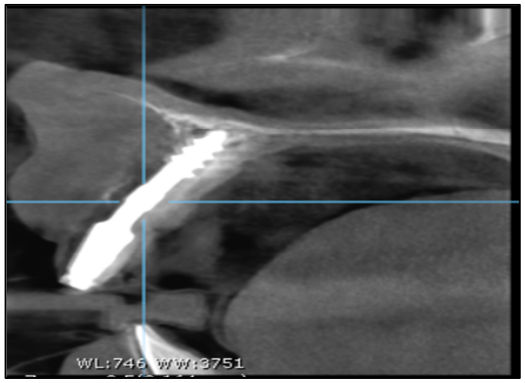


Fig. 21: Axial view

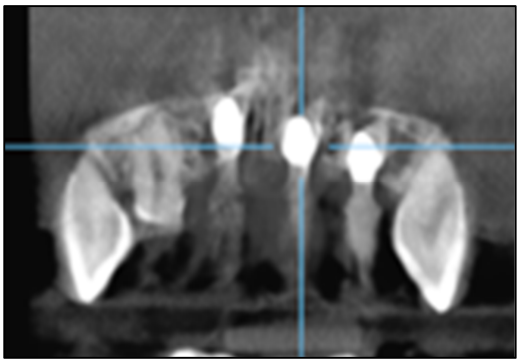


Fig. 22: Coronal view

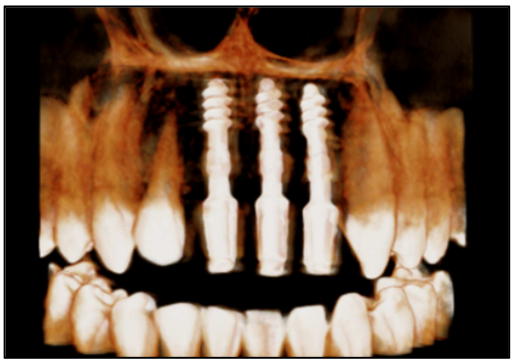


Fig. 23: 3D imaging

CASE 2 INTRA-OP

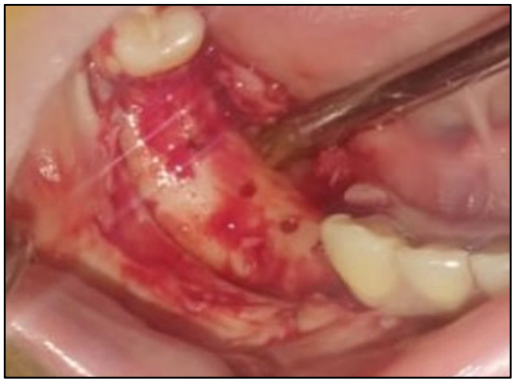


Fig. 24: Osteotomy drills placed

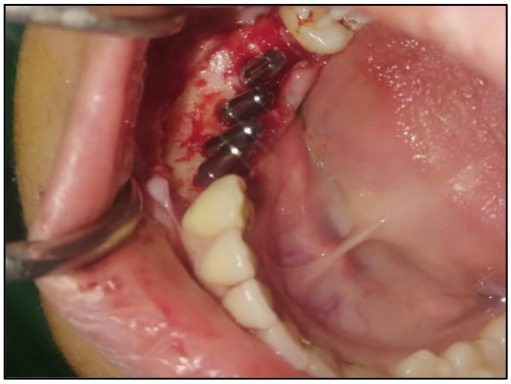


Fig. 25: Implants placed in 44, 45, 46,47

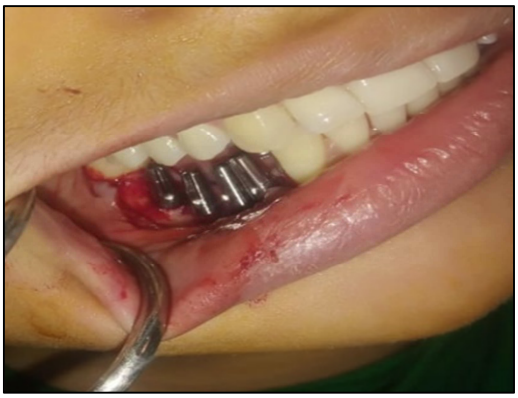


Fig. 26: Implants checked into occlusion

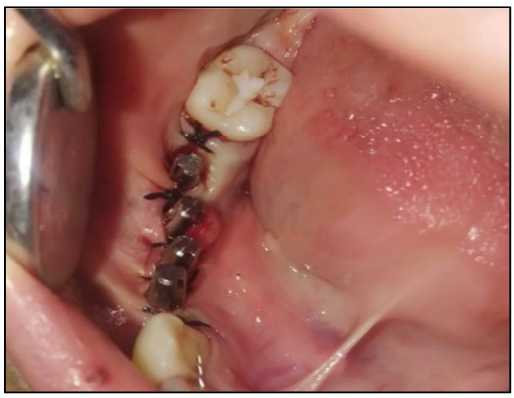


Fig. 27: Closure done

POST-OP

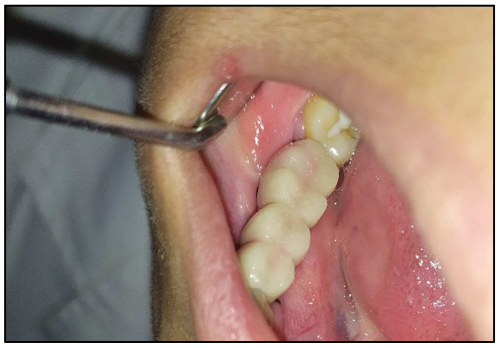


Fig. 28: Loading done within 72 hours

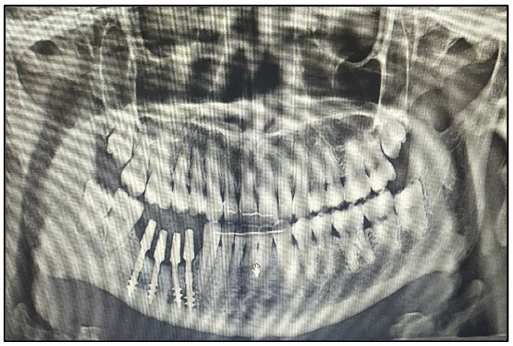


Fig. 29: Post-op OPG

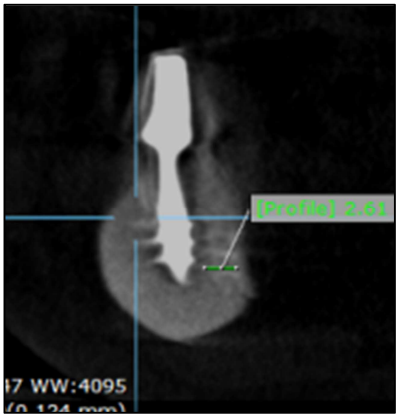


Fig. 30: Sagittal view of implant placed

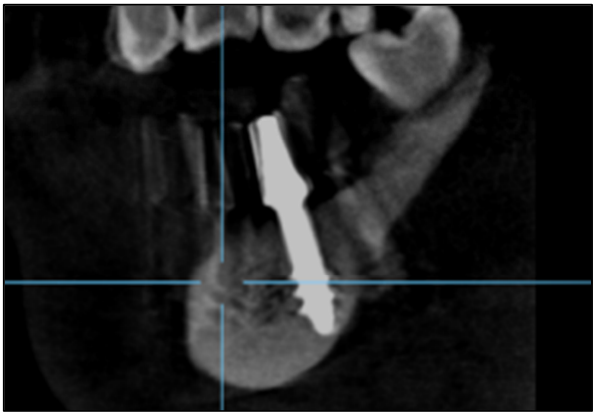


Fig. 31: Coronal view

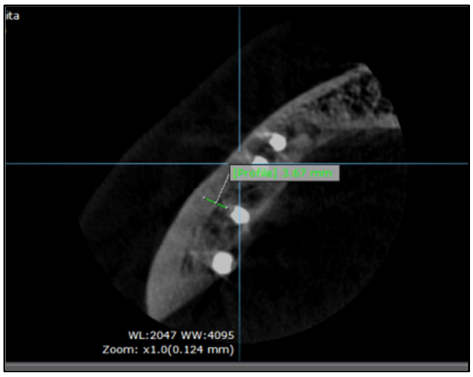


Fig. 32: Axial view

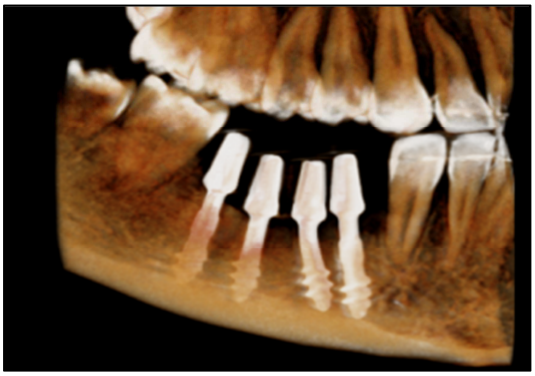


Fig. 33: 3D imaging of implants placed

CASE 3 PRE-OP

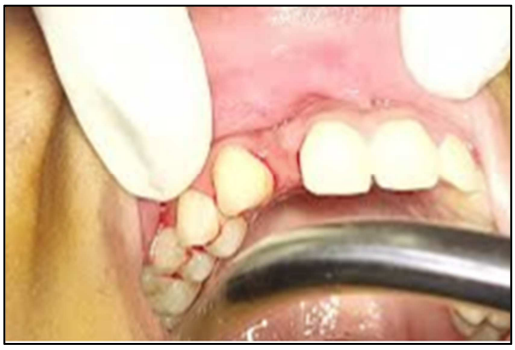


Fig. 34: Missing teeth with 12

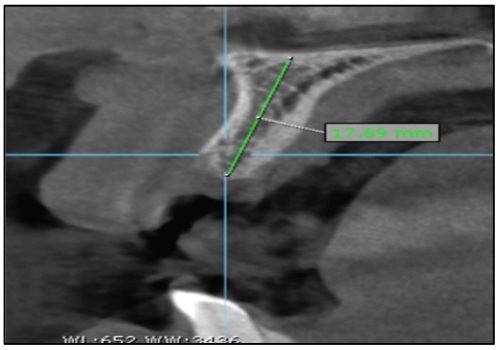


Fig. 35: Measuring bone height in sagittal view

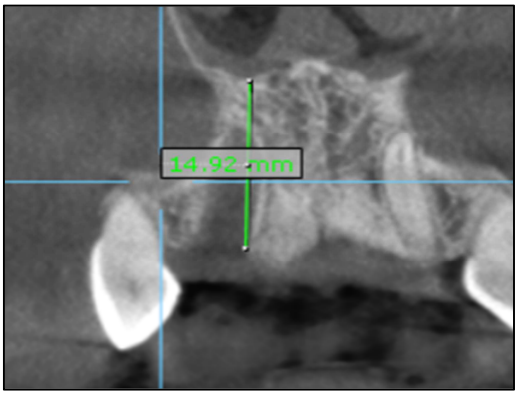


Fig. 36: Bone height in coronal view

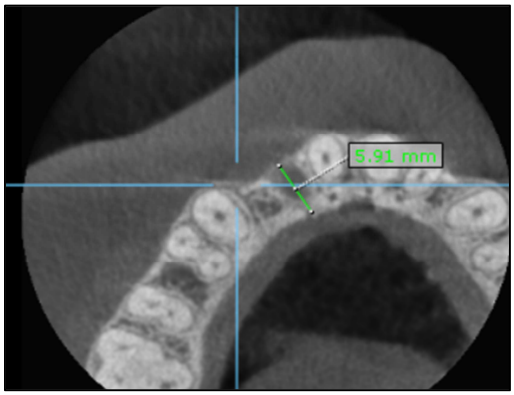


Fig. 37: Bone width (bucco-palatal) in axial view

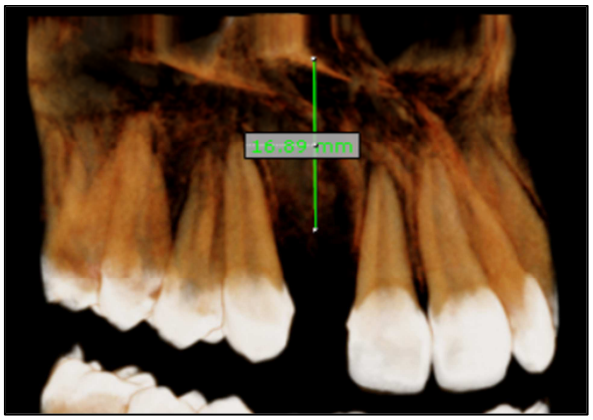


Fig. 38: 3D imaging – bone height measured

INTRA-OP

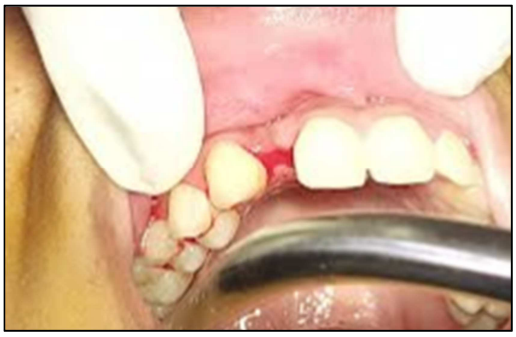


Fig. 39: Crestal incision placed

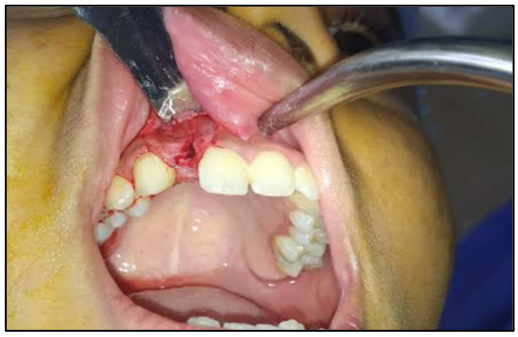


Fig. 40: Flap raised and osteotomy done

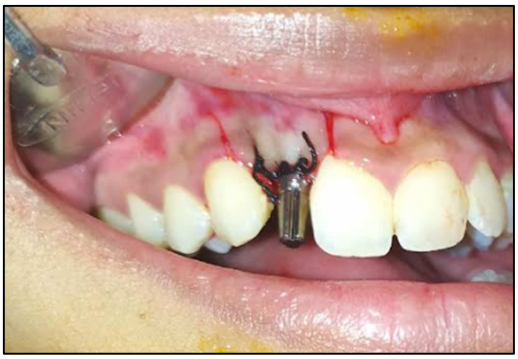


Fig. 41: Implant placed and closure done

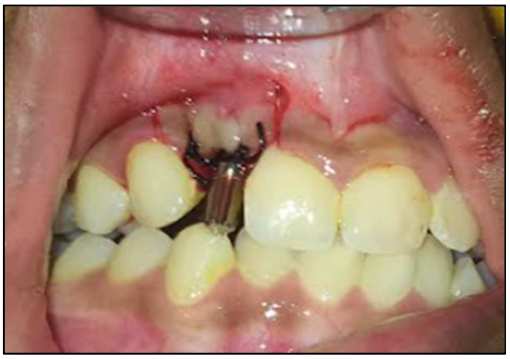


Fig. 42: Implant checked into occlusion

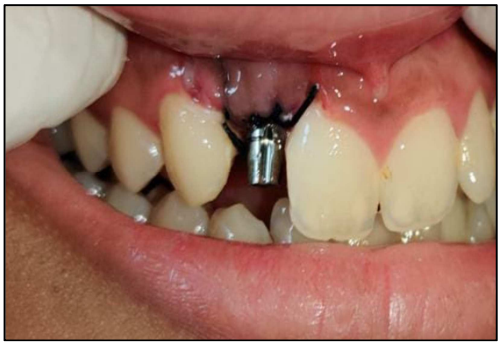


Fig. 43: Excess abutment trimmed

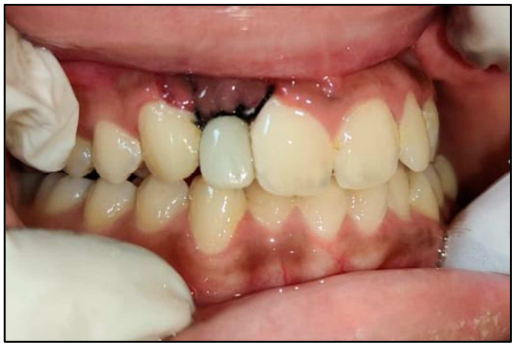


Fig. 44: Loading done within 72 hours - Acrylic

POST-OP

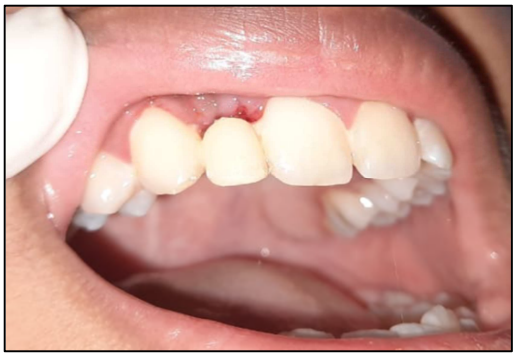


Fig. 45: Suture removal done

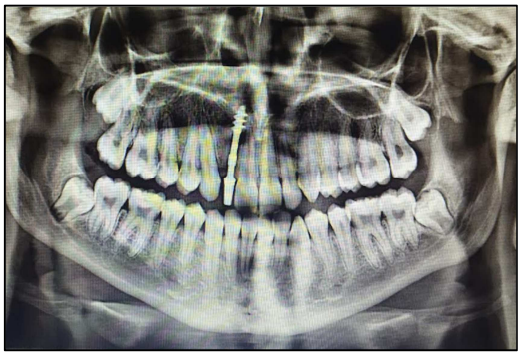


Fig. 46: Post-op OPG

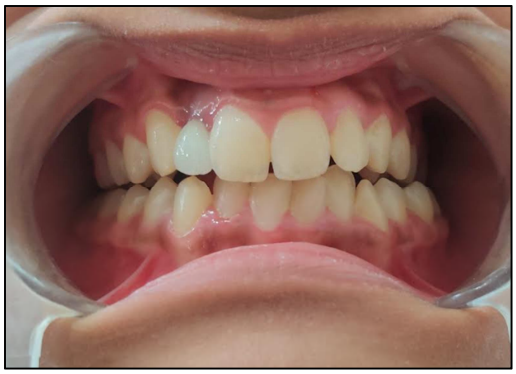


Fig. 47

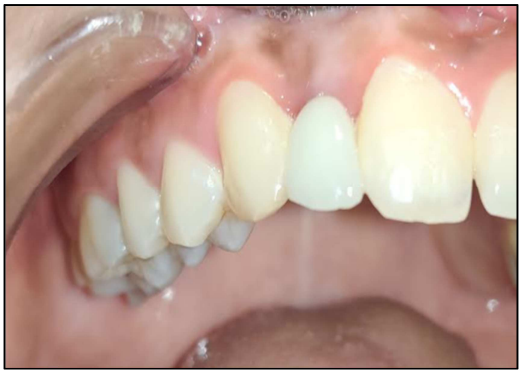


Fig. 48

Fig. 47, 48: Permanent restoration done with all ceramic material

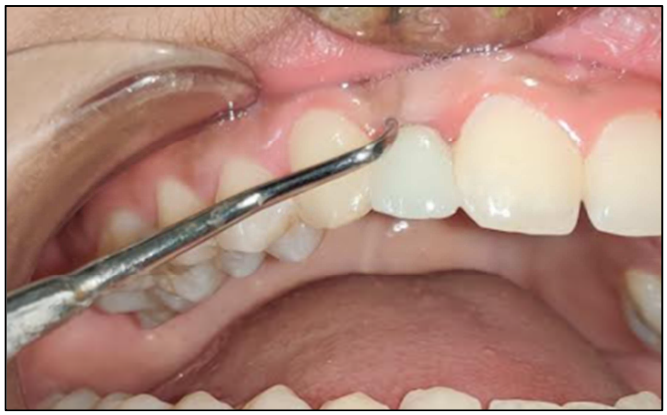


Fig. 49: BOP checked after permanent restoration

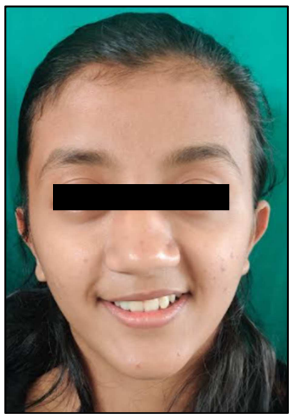


Fig. 50: Profile view

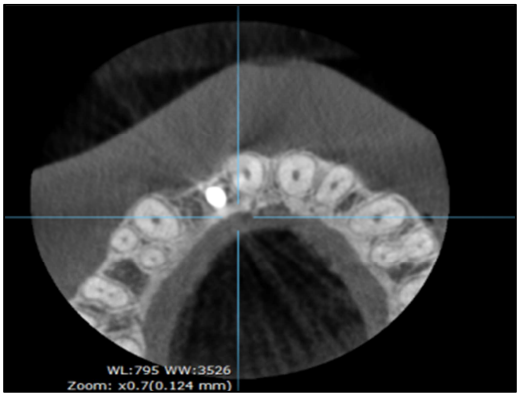


Fig. 51: Axial view on CBCT after implant placement

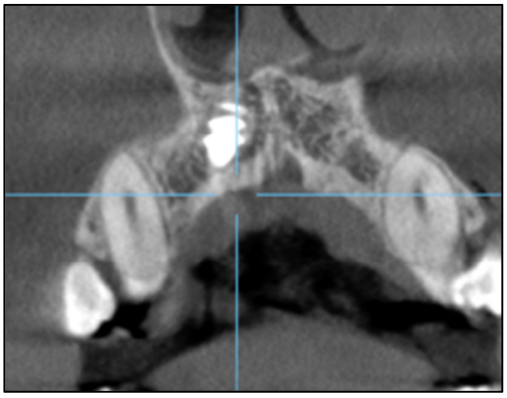


Fig. 52: Coronal view

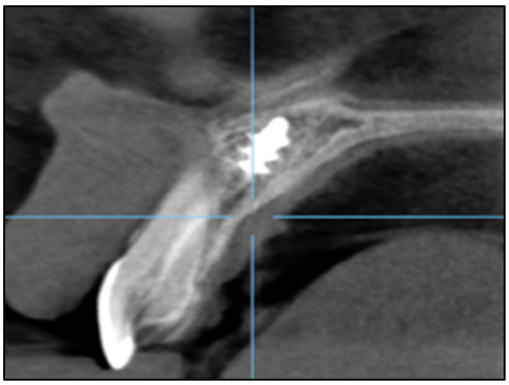


Fig. 53: Sagittal view – implant engaging nasal floor

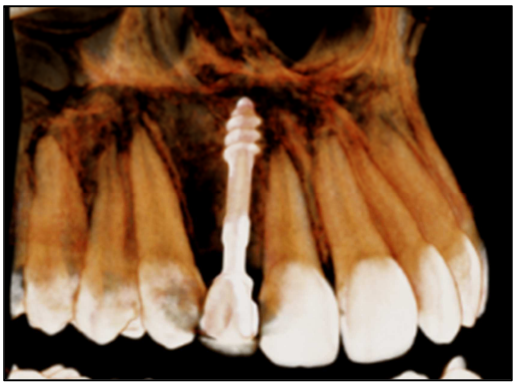


Fig. 54: 3D imaging after implant placement

RESULTS

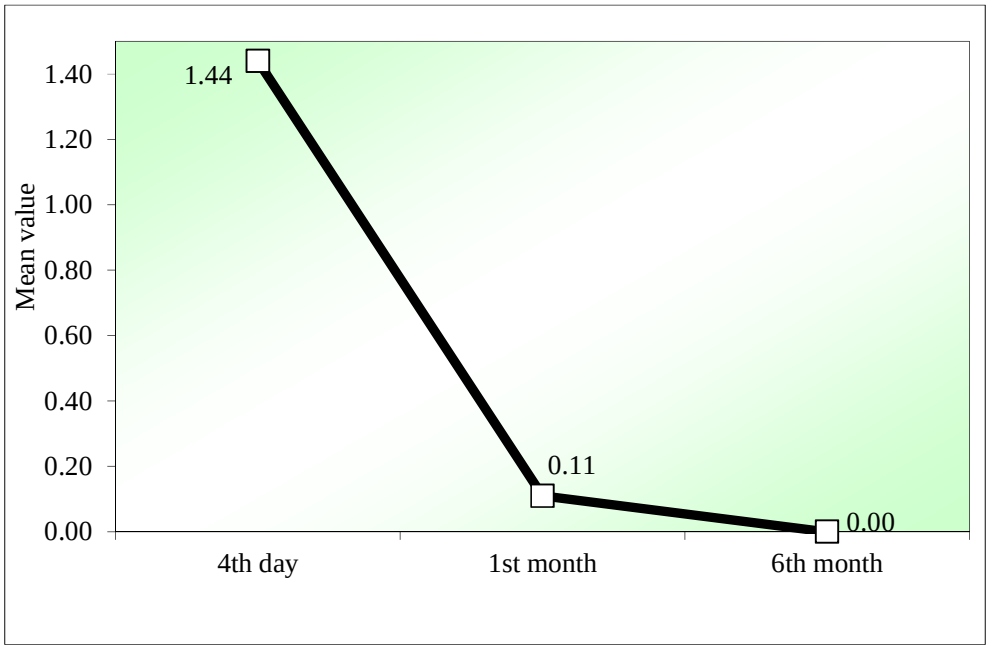
ASSESSMENT OF PAIN

Table 1: Comparison of 4th day, 1st month and 6th month treatment times with Pain (VAS) scores by Wilcoxon matched pairs test

Summary	4th day	1st month	6th month	4th day vs 1st month		4th day vs 6th month		1st month vs 6th month	
				Z-value	P-value	Z-value	P-value	Z-value	P-value
Mean	1.44	0.11	0.00	3.6214	0.0003*	3.7236	0.0002*	0.0000	1.0000
SD	0.51	0.32	0.00						
Median	1.00	0.00	0.00						
IQR	0.50	0.00	0.00						

*p<0.05

Graph 1: Comparison of 4th day, 1st month and 6th month treatment times with Pain (VAS) scores



Observations:

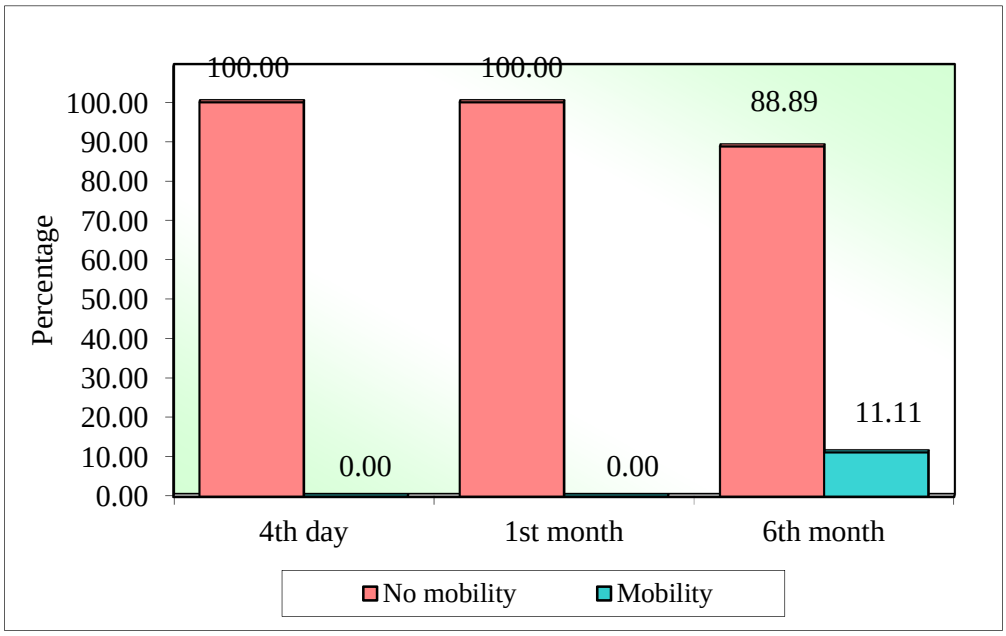
Pain using VAS was checked postoperatively at 4th day, 1st month and 6th month of implant placement. Wilcoxon matched pairs test was used for assessment of pain. Pain when compared between 4th day and 1st month, there was significant decrease in pain at the end of 1st month (P = 0.0003). When pain was compared between 4th day and 6th month, there was statistically significant difference where pain was reduced at the end of 6 months (P = 0.0002). On the other hand, when pain was compared between 1st month and 6th month, it was found that there was no statistically significant difference in the reduction of pain between 1st and 6th months postoperatively (P = 1.0000). As seen in the Fig. 1, the graph goes down as time progresses and it almost nullifies at the end of 6th month.

ASSESSMENT OF MOBILITY

Table 2: Comparison of 4th day, 1st month and 6th month treatment times with mobility scores by Mc Nemars test

Summary	4th day	1st month	6th month	4th day vs 1st month	4th day vs6th month	1st month vs 6th month
				P-value	P-value	P-value
No mobility	18	18	16	0.0000	0.0000	0.0000
%	100.00	100.00	88.89			
Mobility	0	0	2			
%	0.00	0.00	11.11			

Graph 2: Comparison of 4th day, 1st month and 6th month treatment times with mobility scores



Observations:

Mobility was checked at the end of 4^{th} day, 1^{st} month and 6^{th} month postoperatively (Table 2). It was found that there was no mobility noted on the 4^{th} day and 1^{st} month. At the end of 6^{th} month, it was observed that 88.89% implants showed no mobility whereas 11.11% showed mobility.

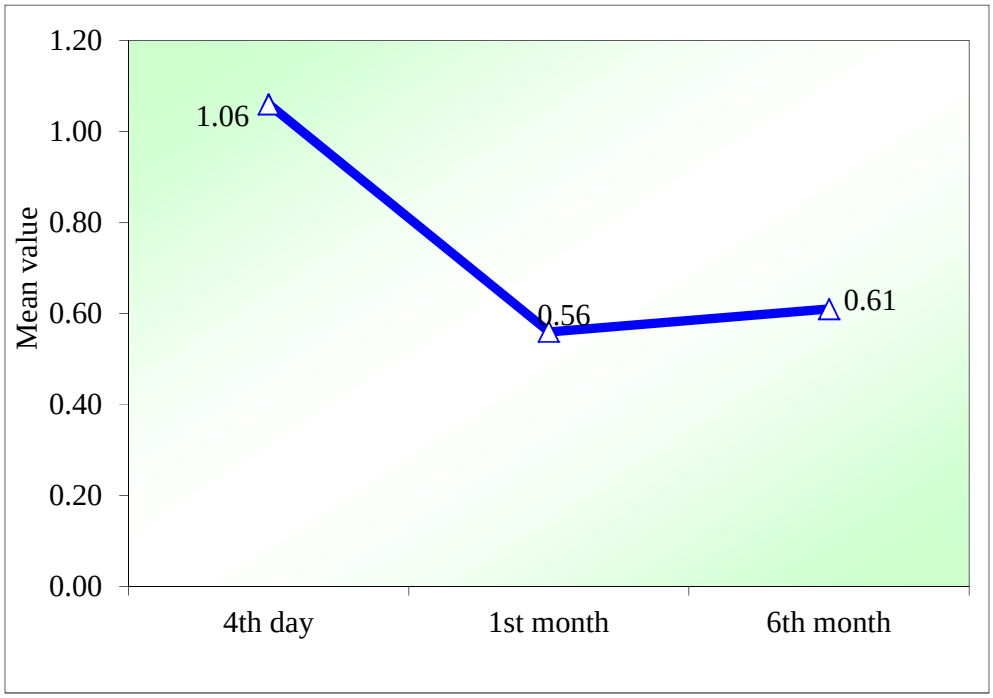
ASSESSMENT OF BLEEDING ON PROBING (PERI IMPLANTITIS)

Table 3: Comparison of 4th day, 1st month and 6th month treatment times with bleeding on probing scores by Wilcoxon matched pairs test

Summery	4th day	1st month	6th month	4th day vs 1st month		4th day vs6th month		1st month vs 6th month	
				Z-value	P-value	Z-value	P-value	Z-value	P-value
Mean	1.06	0.56	0.61	2.6656	0.0077*	2.0396	0.0414*	0.3381	0.7353
SD	0.54	0.51	0.85						
Median	1.00	1.00	0.00						
IQR	0.00	0.50	0.63						

*p<0.05

Graph 3: Comparison of 4th day, 1st month and 6th month treatment times with bleeding on probing scores



Observations:

Bleeding on probing (BOP) was checked after 4 days, 1 month and 6 months postoperatively and was compared using Wilcoxon matched pairs test. It was noted that there was significant decrease in BOP when compared between 4th day and 1st month (P = 0.0077). When BOP was compared between 4th day and 6th month, it was found that there was significant decrease in BOP at the end of 6th month (P = 0.0414). On comparison between 1st month and 6th month, there was no significant statistical difference in bleeding on probing. As seen on the graph, (Fig. 3), BOP progressively reduces with time.

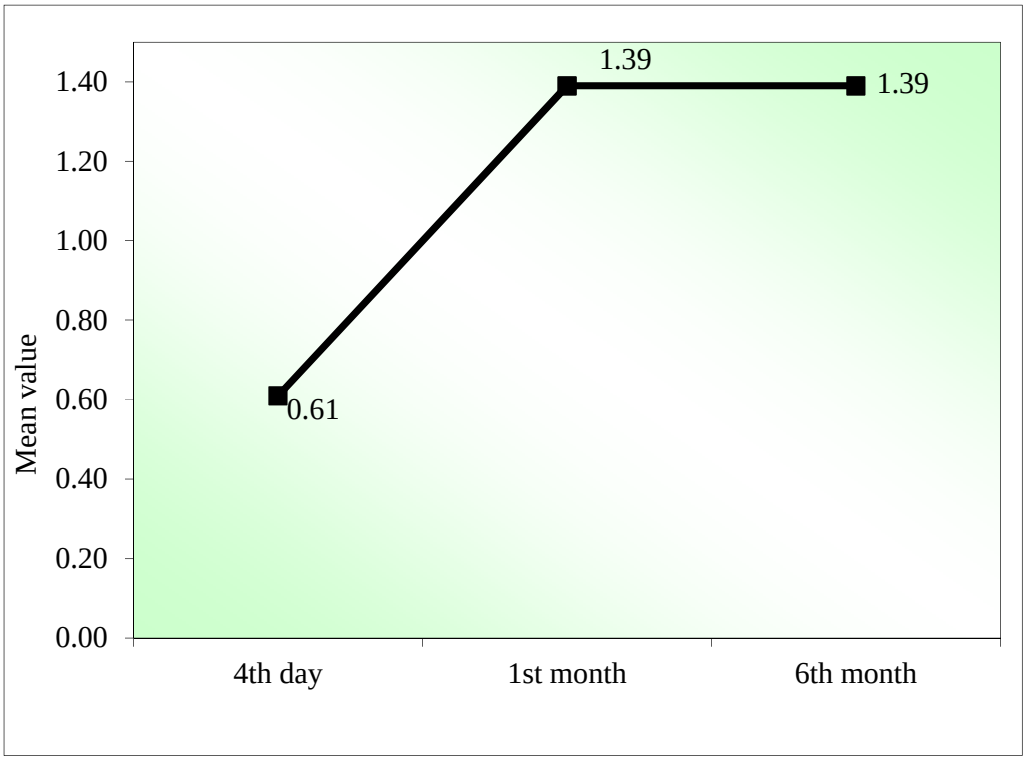
ASSESSMENT OF PLAQUE INDEX (PERI IMPLANTITIS)

Table 4: Comparison of 4th day, 1st month and 6th month treatment times with plague index scores by Wilcoxon matched pairs test

Summery	4th day	1st month	6th month	4th day vs 1st month		4th day vs 6th month		1st month vs 6th month	
				Z-value	P-value	Z-value	P-value	Z-value	P-value
Mean	0.61	1.39	1.39	2.7954	0.0052*	2.4706	0.0135*	0.0510	0.9594
SD	0.50	0.70	0.85						
Median	1.00	1.50	2.00						
IQR	0.50	0.50	0.63						

*p<0.05

Graph 4: Comparison of 4th day, 1st month and 6th month treatment times with plague index scores.



Observations:

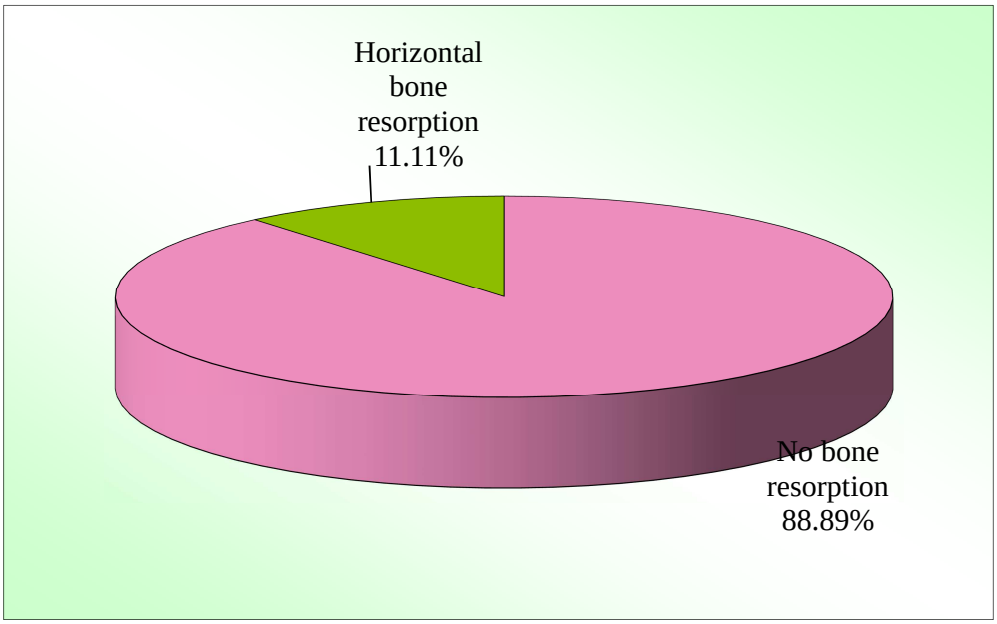
Plaque index was checked after 4th day, 1st month and 6th month of implant placement. On comparison between 4th day and 1st month, it was found that there was significant increase in plaque after 1 month (P = 0.0052). When comparison was done between 4th day and 6th month, it was found that plaque significantly increased after 6 months (P = 0.0135). But there was no significant difference in plaque index between 1 month and 6 months (P = 0.9594). As observed in the graph (Fig. 4) plaque index progressively increases with time.

ASSESSMENT OF BONE LOSS:

Table 5: Comparison of Radiographic analysis at 6th month treatment time

Summary	Number	%
No bone resorption	16	88.89
Horizontal bone resorption	2	11.11
Total	18	100.00

Graph 5: Comparison of Radiographic analysis at 6th month treatment time



Observations:

Radiographic analysis of bone loss was done after 6 months of implant placement. It was found that 11.11% of cases showed presence of bone loss while 88.89% of cases had no evidence of bone loss.

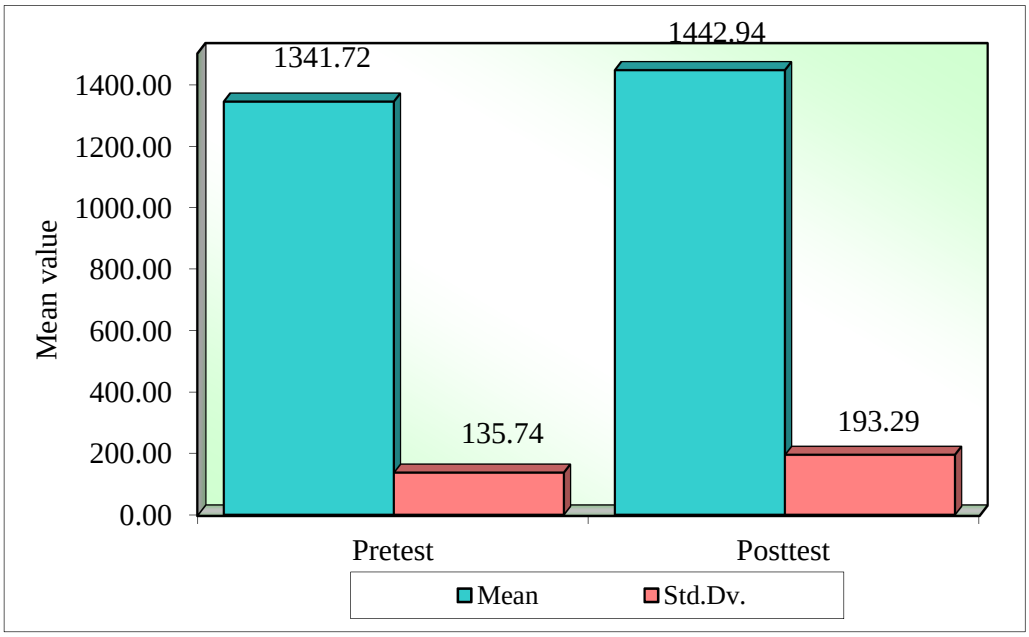
ASSESSMENT OF BONE DENSITY:

Table 6: Comparison of pretest and posttest bone density scores by dependent t test

Treatment times	Mean	Std.Dv.	Mean Diff.	SD Diff.	% of change	t-value	p-value
Pretest	1341.72	135.74					
Posttest	1442.94	193.29	-101.22	182.21	-7.54	-2.3569	0.0307*

*p<0.05

Graph 6: Comparison of pretest and posttest bone density scores



Observations:

Bone density was examined after 6 months of implant placement using cone beam computed tomography (CBCT). It was found that there was statistically significant increase in bone density of cortical bone after implant placement (P = 0.0307).

DISCUSSION

The standard endosseous implants needs 2 stage surgery, but when it comes to single-piece BCS (bicortical screw) implants, recently been produced in which second-stage surgery is not required and abutments are directly attached to implants.[6] The development and description of unique methods of implant placement, as well as the inclusion of BCS (bicortical screw) implants in immediate loading protocols (since 2005), have resulted in a distinctive, impactful, and efficient treatment concept. The notion of the "Bicortical Screw," was established into our vocation at the end of the 1980s, was not adequate in clinical reality since neither the different qq that we use today were understood and specified at the time, nor were implants of adequate length accessible to reach and attach into the nasal floor or tuberopterygoid region.[5]

The cortical bone is securely anchored by bicortical screw implants. Cortical bone has a load bearing capacity that is many times greater than cancellous bone; it is also robust, infection-free, and resistant to resorption.[11] Screwable cortical implants were created with the intention of engaging into this robust bone, despite the nature and volume of cancellous bone in the ridge.[12] These can be easily placed into cortical and basal bone, either through an extraction socket or into the heavily mineralized section of the basal bone, providing excellent primary stability. Bacteria cannot grow on the trans-mucosal polished thin shaft, hence peri-implant infections are mainly avoided.[11,12,13]

Implants are employed in the stable compact basal (2nd cortical) bone and also the buttress in this method, resulting in exceptional mechanical stability. After bone remodelling, these implants can attain biological stability / osseointegration.[16] The

BCS implant is secured to the cortical bone, and the technique of doing so is called "osseofixation."[14,15] Secondary osseointegration into cancellous bone, from which the endosseous components of implants protrude, is predicted to occur later. The macro-mechanic anchorage i.e., osseofixation in the second or third cortex, on the other hand, is critical for primary stability, i.e., therapeutic success.[16]

When examined using resonance frequency analysis, Wang et al. found that bicortical anchoring, which involves corticals of both the cervical and lateral sides, produced remarkable outcomes.[17] The treatment idea takes advantage of the cortical bone of maxillary and sphenoid bones' load-bearing capabilities. The thread of the implant can be secured in compact bone structures due to deliberate tilting especially in the lingual cortices of the posterior region of mandible, the pterygoid plate of the sphenoid bone and the nasal floor.[18] On the lingual and vestibular regions of the distal mandible, adequate 2nd cortical can be obtained. Long implants can be used to access the base of the mandible (which is a second cortical) in the inter-foraminal region. When compared to the vestibular cortex, employing the lingual 2nd cortical is easier because osteotomy can be done with a straight hand piece and implant can be inserted with a hand grip rather than ratchet. Since the bone is produced in the compressive zone and tenting effect is accomplished, lingual cortical engagement is more anticipated.[16]

Immediate loading reduces overall treatment time by providing an interim prosthesis to the patient early after implant placement. Osseointegration is a morphological term which is used to define immediate contact between implant surface and bone with absence of fibrous connective tissue between them which is required for a favourable outcome of implant therapy. Bone remodelling occurs as a

consequence of implant insertion, according to Wolffe's law.[10] Immediate loading with temporary rehabilitation was chosen for this study because it furnishes aesthetics, function, space preservation, and periodontal recovery. A fixed acrylic restoration was provided to the patient 72 hours after surgery as a temporary restoration. Acrylic has shock-absorbing property, which minimises strains on the bone and, as a result, reduces bone resorption.[6]

Bone does not repair or integrate with implant surface in 72 hours, nor does it develop mineralization in that time. Rather than waiting for "osseo-integration," bicortical screw implants are "osseo-fixated" instantly in resorption-stable, densely mineralized cortical bone, a bone with essentially no metabolism and therefore more stability and a high potential for regeneration by nature.[5] Immediate functioning of fixed lower full-arch prosthesis sustained by 3 or 4 implants, or on several BCS implants, has been reported in the literature showing high survival rates[8] however, published research on delayed loading demonstrate equal results when compared with the use of 4 or 6 maxillary implants as support for fixed complete-arch prosthesis, a larger number of implants are commonly employed when early loading is given in the upper arch.[9]

Unless the practitioner decides to provision the implant heads with angulation adapter device, the necks of single-piece implants must be bent to allow for non-parallel insertion and equipping them with fixed cemented prosthetic designs. The survival rate of tilted vs. non-tilted was 98.3 percent vs 94.2 percent in a study done by Dobrinin Oleg et al. Only those implants with extremely stable anchorage in the second cortex were thought to be bendable, and the durability was tested during the

bending process. Unbent implants, on the other hand, are not checked for stability in the second cortex, thus some of them may have failed to reach there.[5]

Aleksandar Lazarov conducted a study where he placed 1170 BCS implants with immediate loading in 87 patients. Folllow up was done for 57 months. In his study it was found that 99.7% of the patients were not subjected to pain during follow up period. Only 0.3% of them had pain.[18]

Dobrinin Oleg et al conducted a study on 394 patients where 4570 BCS implants were placed with immediate loading. In this study follow up was done for 24 months and it was found that pain was present only in 0.2% of the cases whereas it was absent in 99.8% of the cases.[5]

In our study, pain was measured with the help of "VAS (Visual Analog Scale)". Pain was inspected on the day 4, 1st month and 6th month post op. It was found that pain almost nullified to zero during 6th month. On the graph, pain kept on decreasing as the months passed. (Graph 1)

In a study conducted by Dobrinin Oleg et al on 4570 BCS implants, it was observed that only 17 out of 4570 implants showed mobility at the end of 24 months. 99.6% of the implants did not show any signs of mobility.[5]

Another study conducted by Aleksandar Lazarov on 1170 implants where follow up was done for 57 months showed the results where mobility was seen only in 3 out of 1170 patients. 99.7% of implants showed no mobility.[18]

In this study mobility was observed in 2 implants i.e., 11.11 % of cases after 6 months of implant placement. Rest 88.89% showed no mobility. It was also found that the patient who had mobility was a chronic smoker. This might be attributed that smoking increases the risk of implant failure. (Graph 2)

In a study conducted by A. Zembic et al., 57 one-piece implants were inserted in 47 patients and follow up was done for 1 year. Bleeding on probing was checked at 3 months, 6 months and 12 months interval. Results suggested that bleeding on probing decreased from 29% (3 months) to 15% (12 months) as the months passed by.[19]

Bleeding on probing in this study was checked at the 4^{th} day, 1^{st} month and 6^{th} month of implant placement. It has been observed that as months passed by, bleeding on probing showed a fall on the graph. However, there was not much of a significant change in bleeding on probing between 1 month and 6 months interval. (Graph 3)

A. Zembic et al. conducted a study on 57 one-piece implants where follow up was done for 1 year. In his study, it was found that plaque index reduced from 29% (3 months) to 15% (1 year). This implies that as the months passed by, plaque index decreased.[19]

In this study, plaque index was checked on 4^{th} day, 1^{st} month and 6^{th} month of implant placement. It was found that plaque increased gradually with time. However, there was not much of a difference in plaque levels at 1 month and 6 months interval. (Graph 4)

In a study conducted by Dobrinin Oleg et al. on 4570 BCS implants, it was found that there was bone loss in 15.7% of the cases. Vertical bone loss was found in 14.5% of the cases, crater like bone loss in 0.1% of cases and retrograde bone loss (from 2nd cortical) was found in 1.1% of the cases.[5]

In this study, bone loss was inspected after 6 months post operatively. And it was observed that there was 11.11 % of the cases showed horizontal type of bone loss. Bone loss could be due to improper loading of the prosthesis which may lead to masticatory stress around the implants. (Graph 5)

Fariz Salimov et al. conducted a study on 17 patients where 65 implants were placed with immediate loading. In his study, bone density was checked with the help of cbct and was found that there was not much of a difference in bone density values when measured pre operatively and post operatively. This implies that the implants were stable and there was significant amount of bone healing after implant placement.[20]

In this study, bone density value was inspected post operatively after 6 months of implant placement. It was found that there was significant increase in bone density value after 6 months of implant placement. This could be attributed to the physiologic bone healing of the cortical bone which leads to osteoblastic activity and deposition of dense cortical bone after implant placement. Hence, BCS implants are more stable after 6 months as there is increase in bone density value of the cortical bone. (Graph 6)

Fundamentals and merits of the BCS implants include the following[16]:

- It engages all the basal bone – "nasal floor, maxillary sinus floor, walls of sinus, septa of sinus, wall of nasal cavity, palatal bone, crest of alveolar bone, pterygoid bone, zygomatic bone."
- These implants have belligerent threads and thus achieve very high primary stability and early functional loading.
- The design of the implant is such that it has smooth, even & polished surface and one piece with little peri-mucosal perforation, which is resistant to infection.
- They should be rigidly & firmly splinted within 72 hours – "activation, resorption and formation" (A-R-F) occurs when bone remodelling starts to take place after 72 hours. A-R-F takes atleast 4-6 months to complete and hence mechanical stability is transformed into biological stability.
- By tilting the implants, increased macro retention can be achieved.

BCS implants come with certain disadvantages[6]:

- Customized abutments are not possible.
- Once the implants are placed, the abutment trimming needs to be directly completed in the mouth.
- Screw sustained prosthesis cannot be given.
- The implant mount might fracture if the osteotomy is not sufficient.
- After the placement of these implants, the abutment emerges from the mucosa which may be uncomfortable for the patient.

SUMMARY AND CONCLUSION

This prospective cohort study was done determine the efficacy of bicortical screw single piece implants with immediate loading. Postoperatively patient was followed up for inspecting pain, peri-implantitis, bone loss and bone density.

In this study, survival rate of the implants was found to be 88.89%. It was found that there was no evidence for peri-implantitis. The design of the implants is such that there is smooth, polished surface which engages the cortical and the cancellous bone, hence does not allow the bacteria to grow which in turn helps in reducing the risk of peri-implantitis. It was found in this study that the bone density significantly increases after 6 months of implant placement. This may be due to physiologic deposition of cortical bone by osteoblastic activity due to masticatory load.

This study concluded that bicortical screw implants are patient compliable as there are less number of appointments and immediate loading can be done within 72 hours of implant placement. These implants achieve better biomechanical stability by principles of osseointegration and osseofixation and it is evident that bone density significantly increases post operatively. As these implants are single piece implants, there is equal distribution of masticatory loads throughout the surface of the implants. Studies are recommended with more no. of sample size to assess the bone density after long term follow up period.

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ANNEXURE I

ETHICAL CLEARANCE

Research and Ethics Committee
KLE V K INSTITUTE OF DENTAL SCIENCES
KLE University

Accredited 'A' Grade by NAAC Placed in Category 'A' by MHRD (GoI)

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Sl. No. : 1339

CERTIFICATE

This is to Certify that the synopsis titled

IMMEDIATE FUNCTIONAL LOADING WITH BICORTICAL SCREW SINGLE PIECE IMPLANT IN THE MANDIBLE AND MAXILLA : A PROSPECTIVE CLINICAL STUDY

Submitted by

Dr. **REG.NO. – IF0219001** *P. G. Student / Staff, Guided by* _____ *from Department of* ORAL & MAXILLOFACIAL SURGERY *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

Date :

Member Secretary
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

MEMBER SECRETARY
Research & Ethical Committee
KLEVK Institute of Dental Sciences
BELAGAVI.

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee
KLE VK Institute of Dental Sciences
Belgaum

BIOSTATISTICS CLEARANCE

KLE V.K. Institute of Dental Sciences
(A Constituent unit of KLE Academy of Higher Education & Research
Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi-590 010 INDIA
Re-Accredited 'A' grade by NAAC (2nd Cycle) & Placed in Category 'A' by MHRD (GoI)
: 0831-2470362
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Biostatistics Clearance Certificate

This is to certify that the Biostatistics aspect of the Dissertation / Research work of **REG.NO. – IF0219001** , **Post Graduate Student, Department of Oral & Maxillofacial Surgery** under the guidance of , **Department of Oral & Maxillofacial Surgery**, entitled **"IMMEDIATE FUNCTIONAL LOADING WITH BICORTICAL SCREW SINGLE PIECE IMPLANTS IN MANDIBLE AND MAXILLA – A PROSPECTIVE CLINICAL STUDY"** has been done under my guidance and considered satisfactory.

Place: Belagavi
Date: 06/12/2021

Name & Signature of Biostatistician
(Dr. S. B. Javali)

PLAGIARISM CHECK REPORT

Scientific Correspondence and Review Committee

KLE VK Institute of Dental Sciences
A Constituent Unit of KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi - 590 010, Karnataka State
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Date : 21.12.2021 **Serial No. :** 073

PLAGIARISM CHECK REPORT

Name of the Applicant : **REG.NO. – IF0219001**
UG / PG / Ph.D / Staff : POSTGRADUATE
Batch & Year : 2019-22
Department : Oral and Maxillofacial Surgery

The soft copy of Research Work / Manuscript by DR. HARSHINI PATEL entitled

"IMMEDIATE LOADING WITH BICORTICAL SCREW SINGLE PIECE IMPLANTS IN MANDIBLE AND MAXILLA – A PROSPECTIVE CLINICAL STUDY"

under the guidance of .....has been submitted for Anti-Plagiarism check to the Scientific Correspondence & Review Committee of KLE VK Institute of Dental Sciences using "Turn-it-in" software.

The scan has been carried out and the scanned output reveals a Similarity Index of 9%, which is **within** / **not within** the acceptable limits of 10% as per the UGC guidelines.

Member Secretary
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER-Belagavi

Chairman
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER - Belagavi

ANNEXURE II

K.A.H.E.R's KLE VK Institute of Dental Sciences

Department of Oral and Maxillofacial Surgery, Belagavi

'IMMEDIATE FUNCTIONAL LOADING WITH BICORTICAL SCREW SINGLE PIECE IMPLANTS IN MANDIBLE AND MAXILLA – A PROSPECTIVE CLINICAL STUDY'

CONSENT FORM

I…… age … have been explained the details of the study undertaken. I am fully satisfied with the procedure and instructions given by Dr. _____ and hereby give my permission to participate in this study.

Place:

Date:

Signature of participant:

Contact no:

Address:

K.A.H.E.R's KLE VK Institute of Dental Sciences
Department of Oral and Maxillofacial Surgery, Belagavi

'IMMEDIATE FUNCTIONAL LOADING WITH BICORTICAL SCREW SINGLE PIECE IMPLANTS IN MANDIBLE AND MAXILLA – A PROSPECTIVE CLINICAL STUDY'

CONSENT TO SURGERY & ANAESTHETICS

Date: Time: a.m./p.m.

1. I, _____ aged_____ years have been informed about my involvement in the study.
2. I agree to give my personal details like Name Age, Sex, Address, Past dental and any other details required for the study to the best of my knowledge.
3. I will cooperate with the surgeon for examination and also for various investigations.
4. I permit the operator to utilize the information given by me and the results obtained from this study for presentation and publication purpose.
5. I permit the surgeon to take my photographs to utilize them for presentation and publication purpose.
6. I am participating in this study with my own wish and will and the surgeon has explained the nature and the effect of procedure including extraction of tooth followed by placement of cortical implants and temporary prosthetic rehabilitation within 3 days in my vernacular language.
7. The nature and purpose of the operation and the materials being used, possible alternative methods of treatment, the risk involved and the possibility of complications have been fully explained to me in my vernacular language. No guarantee or assurance has been given by anyone as to the results that may be obtained.
8. I have been informed about the follow up after 1 month and 6 months and I agree to visit for the same.
9. I have read and understood the above information given by surgeon about the study and willingly agree to participate in the study.

Name: Date:

Signature: Mob. No:

Name of doctor: _____

Doctor's contact: _____

Hospital contact: _____

के. एल. ई. एस. व्ही.के. दंत विज्ञान संस्था

तोंडी आणि मॅक्सिलोफेसियल शस्त्रक्रिया विभाग, बेलगावी.

'IMMEDIATE FUNCTIONAL LOADING WITH BICORTICAL SCREW SINGLE PIECE IMPLANTS IN MANDIBLE AND MAXILLA – A PROSPECTIVE CLINICAL STUDY'

शस्त्रक्रिया आणि भूल देण्यास संमती

तारीख: वेळ: सकाळी / दुपारी

1. मी, _____ वयाची _____ अभ्यासात माझ्या सहभागाबद्दल वर्षे माहिती दिली आहे
2. मी माझे वय जसे की वय, लिंग, पत्ता, भूतकाळातील दंत आणि इतर उत्तम माहितीसाठी माझ्या वैयक्तिक माहिती देण्यास सहमती देतो.
3. मी शल्यचिकित्सकांना तपासणीसाठी तसेच विविध तपासण्यांसाठी सहकार्य करीन.
4. मी ऑपरेटरला माझ्याद्वारे दिलेली माहिती आणि या अभ्यासाद्वारे प्राप्त झालेल्या परीक्षेचा सादरीकरण आणि प्रकाशनासाठी वापर करण्याची परवानगी देतो.
5. मी शल्य चिकित्सकांना माझा फोटो ग्राफ घेण्याचा अभ्यास व सादरीकरणाच्या उद्देशाने वापरण्यास परवानगी देतो.
6. मी या अभ्यासामध्ये माझ्या स्वतःच्या इच्छेनुसार आणि इच्छेने सहभाग घेत आहे आणि सर्जनने दात काढणे आणि त्यानंतर कॉर्टिकल इम्प्लांट्स ठेवणे आणि तात्पुरती कृत्रिम पुनर्वसन यासह आपल्या स्थानिक भाषेत 3 दिवसांच्या आत प्रक्रियेचा परिणाम आणि प्रक्रियेचा परिणाम याबद्दल स्पष्ट केला आहे.
7. ऑपरेशनचे स्वरूप आणि उद्देश आणि वापरल्या जाणा साहित्य सामग्री, उपचारांच्या संभाव्य पर्यायी पद्धती, त्यात जोखीम आणि गुंतागुंत होण्याची शक्यता माझ्या स्थानिक भाषेत मला पूर्णपणे स्पष्ट केली आहे. प्राप्त झालेल्या निकालांबद्दल कोणालाही कोणतीही हमी किंवा आश्वासन दिले गेले नाही.
8. मला, 1 महिन्यात आणि 6 महिन्यांनंतर पाठपुरावा याबद्दल माहिती देण्यात आली आहे आणि मी त्यास भेट देण्यास सहमती देतो.
9. मी अभ्यासाबद्दल सर्जनने दिलेली वरील माहिती वाचली व समजली आहे आणि अभ्यासात भाग घेण्यास इच्छुक आहात.

नाव: तारीख:

स्वाक्षरी: मोबाइल क्रमांक:

ಕೆ. ಎಲ್. ಇ. ಎಸ್. ವಿ.ಕೆ. ಇನ್ಸ್ಟಿಟ್ಯೂಟ್ ಆಫ್ ಡೆಂಟಲ್ ಸೈನ್ಸಸ್

ಓರಲ್ ಮತ್ತು ಮ್ಯಾಕ್ಸಿಲೊಫೇಶಿಯಲ್ ಸರ್ಜರಿ ಇಲಾಖೆ, ಬೆಳಗಾವಿ

'IMMEDIATE FUNCTIONAL LOADING WITH BICORTICAL SCREW SINGLE PIECE IMPLANTS IN MANDIBLE AND MAXILLA – A PROSPECTIVE CLINICAL STUDY'

ಶಸ್ತ್ರಚಿಕಿತ್ಸೆ ಮತ್ತು ಅರಿವಳಿಕೆಗೆ ಒಪ್ಪಿಗೆ

ದಿನಾಂಕ: ಸಮಯ: ಬೆಳಿಗ್ಗೆ / ಸಂಜೆ

1. ನಾನು, _____ ವಯಸ್ಸಿನ _____ ವರ್ಷಗಳನ್ನು ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಒಳಗೊಳ್ಳುವಿಕೆ ಬಗ್ಗೆ ತಿಳಿಸಲಾಗಿದೆ.
2. ನನ್ನ ವೈಯಕ್ತಿಕ ವಿವರಗಳಾದ ಹೆಸರು ವಯಸ್ಸು, ಲೈಂಗಿಕತೆ, ವಿಳಾಸ, ಹಿಂದಿನ ದಂತ ಮತ್ತು ಅಧ್ಯಯನಕ್ಕೆ ಬೇಕಾದ ಯಾವುದೇ ವಿವರಗಳನ್ನು ನನ್ನ ಜ್ಞಾನದ ಅತ್ಯುತ್ತಮವಾಗಿ ನೀಡಲು ನಾನು ಒಪ್ಪುತ್ತೇನೆ.
3. ನಾನು ಶಸ್ತ್ರಚಿಕಿತ್ಸಕನೊಂದಿಗೆ ಪರೀಕ್ಷೆಗೆ ಮತ್ತು ವಿವಿಧ ತನಿಖೆಗಳಿಗೆ ಸಹಕರಿಸುತ್ತೇನೆ.
4. ನಾನು ನೀಡಿದ ಮಾಹಿತಿಯನ್ನು ಮತ್ತು ಈ ಅಧ್ಯಯನದಿಂದ ಪಡೆದ ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಸ್ತುತಿ ಮತ್ತು ಪ್ರಕಟಣೆಗಾಗಿ ಬಳಸಿಕೊಳ್ಳಲು ಆಪರೇಟರ್‌ಗೆ ನಾನು ಅನುಮತಿ ನೀಡುತ್ತೇನೆ.
5. ನನ್ನ ಫೋಟೋಗ್ರಾಫ್‌ಗಳನ್ನು ಅಧ್ಯಯನ ಮತ್ತು ಪ್ರಸ್ತುತಿ ಉದ್ದೇಶಕ್ಕಾಗಿ ಬಳಸಿಕೊಳ್ಳಲು ಶಸ್ತ್ರಚಿಕಿತ್ಸಕನಿಗೆ ನಾನು ಅನುಮತಿ ನೀಡುತ್ತೇನೆ.
6. ನಾನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಸ್ವಂತ ಆಸೆ ಮತ್ತು ಶಸ್ತ್ರಚಿಕಿತ್ಸಕ ಶಕ್ತಿಯಿಂದ ಭಾಗವಹಿಸುತ್ತಿದ್ದೇನೆ ಮತ್ತು ಹಲ್ಲಿನ ಹೊರತೆಗೆಯುವಿಕೆ ಸೇರಿದಂತೆ ಕಾರ್ಟಿಕಲ್ ಇಂಪ್ಲಾಂಟ್‌ಗಳನ್ನು ಇಡುವುದು ಮತ್ತು ತಾತ್ಕಾಲಿಕ ಪ್ರಾಸ್ಥೆಟಿಕ್ ಪುನರ್ವಸತಿ ಸೇರಿದಂತೆ 3 ದಿನಗಳೊಳಗೆ ನನ್ನ ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿ ಶಸ್ತ್ರಚಿಕಿತ್ಸಕನು ಸ್ವರೂಪ ಮತ್ತು ಪರಿಣಾಮವನ್ನು ವಿವರಿಸಿದ್ದಾನೆ.
7. ಕಾರ್ಯಾಚರಣೆಯ ಸ್ವರೂಪ ಮತ್ತು ಉದ್ದೇಶ ಮತ್ತು ಬಳಸುತ್ತಿರುವ ವಸ್ತುಗಳು, ಚಿಕಿತ್ಸೆಯ ಪರ್ಯಾಯ ವಿಧಾನಗಳು, ಒಳಗೊಂಡಿರುವ ಅಪಾಯ ಮತ್ತು ತೊಡಕುಗಳ ಸಾಧ್ಯತೆಯನ್ನು ನನ್ನ ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿ ನನಗೆ ಸಂಪೂರ್ಣವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ. ಪಡೆಯಬಹುದಾದ ಫಲಿತಾಂಶಗಳಿಗೆ ಸಂಬಂಧಿಸಿದಂತೆ ಯಾರಿಂದಲೂ ಯಾವುದೇ ಭರವಸೆ ಅಥವಾ ಭರವಸೆ ನೀಡಲಾಗಿಲ್ಲ.
8. 1 ತಿಂಗಳು ಮತ್ತು 6 ತಿಂಗಳ ನಂತರ ಫಾಲೋ ಅಪ್ ಬಗ್ಗೆ ನನಗೆ ತಿಳಿಸಲಾಗಿದೆ ಮತ್ತು ಅದಕ್ಕಾಗಿ ಭೇಟಿ ನೀಡಲು ನಾನು ಒಪ್ಪುತ್ತೇನೆ.
9. ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಶಸ್ತ್ರಚಿಕಿತ್ಸಕ ನೀಡಿದ ಮೇಲಿನ ಮಾಹಿತಿಯನ್ನು ನಾನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ ಮತ್ತು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಸಿದ್ಧರಿದ್ದೇನೆ.

ಹೆಸರು: ದಿನಾಂಕ:

ಸಹಿ: ಮೊಬೈಲ್ ಸಂಖ್ಯೆ:

ANNEXURE III - PROFORMA FOR CASE HISTORY

NAME: **AGE:** **SEX:**

OCCUPATION: **O.P. NO.:**

ADDRESS: **DATE:**

CONTACT NO:

CHIEF COMPLAINT:

HISTORY OF PRESENTING ILLNESS:

PAST DENTAL HISTORY:

PAST MEDICAL HISTORY:

DRUG ALLERGY:

PERSONAL HISTORY:

Smoking/Alcohol/Tobacco chewing

GENERAL PHYSICAL EXAMINATION:

EXTRA-ORAL EXAMINATION:

Facial Symmetry:

TMJ:

Lymph Node:

Mouth Opening:

INTRA-ORAL EXAMINATION:

Missing teeth:

Crown height:

Bone width:

Bone height:

Occlusion:

PROVISIONAL DIAGNOSIS:

INVESTIGATIONS:

IOPA:
OPG:
Routine Blood Investigations**:**
CBCT:

RADIOGRAPH AND CLINICAL CORRELATION:

DIAGNOSIS:

TREATMENT PLANNING:

DETAILS OF SURGERY:

DATE:

SURGICAL PROCEDURE:

Local Anesthesia:

Incision:

Osteotomy:

Implant placement:

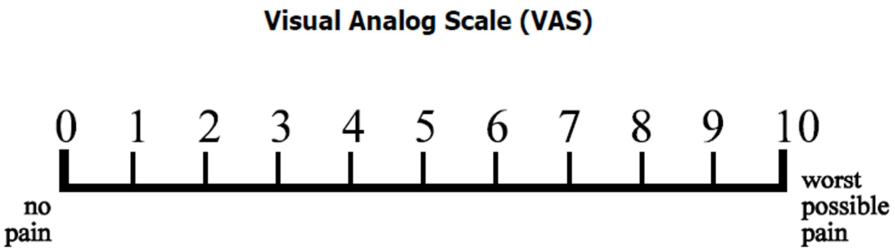
Closure:

Impression:

MEDICATION:

FOLLOW-UP:

PAIN- Visual **A**nalog **S**cale (VAS)



MOBILITY: Yes/No

BLEEDING ON PROBING:

Modified sulcular bleeding index: MOMBELLI, VAN OOSTEN, & S. CHURCH ET AL in 1987

SCORE	CRITERIA
0	No bleeding when probe is passed along the gingival margin
1	Isolated bleeding, spots visible
2	Blood forms a confluent red line on margins
3	Heavy or profuse bleeding

PLAQUE INDEX:

Modified Plaque index: TURESKY ET AL

SCORE	CRITERIA
0	No plaque
1	Separate flecks of plaque at the cervical margin of tooth
2	A thin continuous band of plaque at the cervical margin of the tooth
3	A band of plaque wider than 1 mm covering less than $1/3^{rd}$ of the crown of the tooth
4	Plaque covering atleast $1/3^{rd}$ but less than $2/3^{rd}$ of the crown of the tooth.
5	Plaque covering $2/3^{rd}$ or more of the crown of the tooth.

RADIOGRAPHIC ANALYSIS (TO CHECK CRESTAL BONE LEVEL):

Schwartz et al classified based on level of bone loss:

Class I: Intraosseous defects

Class II: Supraalveolar defects

Class I can be further divided into 5 subtypes:

Class IA: Dehiscence defect with position of implant within or beyond the envelope.

Class IB: Dehiscence defect with semicircular bone resorption to the middle of the implant body with position of implant within or beyond the envelope.

Class IC: Dehiscence defect with circular bone resorption under maintainence of the buccal compact layer, position of implant within or beyond the envelope.

Class ID: Circular bone resorption with buccal loss of compact bone layer, position of implant within or beyond the envelope.

Class IE: Circular bone loss under maintainence of buccal compact layer.

Spikermenn's radiographic classification 1995

Class I: Horizontal bone resorption

Class II: Patelliform bone resorption

Class III: Funnel form bone resorption

Class IV: Gap form bone resorption

CORTICAL BONE STABILITY:

Preoperatively and postoperatively, bone density value checked and compared on CBCT.

COMPLICATIONS:

Mobility:

Paresthesia:

Peri-implantitis:

Infection:

Any other:

ANNEXURE IV -MASTER CHART

Patient's Name	Age/ Sex	No. of implants	Follow up	Pain (VAS)	Mobility	Bleeding on probing (BOP)	Plaque index	Radiographic analysis	Bone density (HU)
Sushmita	19/F	4 implants 44,45,46,47	1 year	**4th day-** 44 - 2 45 - 1 46 - 1 47 - 1 **1 month-** 44 - 0 45 - 0 46 - 0 47 - 0 **6 months-** 44 - 0 45 - 0 46 - 0 47 - 0	**4th day-** 44 - No mobility 45 - No mobility 46 - No mobility 47 - No mobility **1 month-** 44 - No mobility 45 - No mobility 46 - No mobility 47 - No mobility **6 months-** 44 - No mobility 45 - No mobility 46 - No mobility 47 - No mobility	**4th day-** 44 - 1 45 - 0 46 - 1 47 - 1 **1 month-** 44 - 0 45 - 0 46 - 1 47 - 0 **6 months-** 44 - 0 45 - 0 46 - 0 47 - 0	**4th day-** 44 - 0 45 - 0 46 - 1 47 - 1 **1 month-** 44 - 0 45 - 1 46 - 2 47 - 2 **6 months-** 44 - 1 45 - 0 46 - 0 47 - 0	**6 months -** 44 - No bone resorption 45 - No bone resorption 46 - No bone resorption 47 - No bone resorption	**Pre-op:** 44 - 1286 45 - 1345 46 - 1277 47 -1468 **Post-op (6 months)** 44 - 1321 45 - 1378 46 - 1487 47 - 1564
Manisha	32/F	4 implants 41,43,31,33	6 months	**4th day -** 41 - 1 43 - 2 31 - 2 33 - 1 **1 month -** 41 - 0 43 - 0 31 - 0 33 - 0 **6 months -** 41 - 0 43 - 0 31 - 0 33 - 0	**4th day -** 41 - No mobility 43 - No mobility 31 - No mobility 33 - No mobility **1 month -** 41 - No mobility 43 - No mobility 31 - No mobility 33 - No mobility **6 months -** 41 - No mobility 43 - No mobility 31 - No mobility 33 - No mobility	**4th day -** 41 - 1 43 - 1 31 - 0 33 - 1 **1 month -** 41 - 0 43 - 1 31 - 0 33 - 1 **6 months -** 41 - 0 43 - 0 31 - 0 33 - 0	**4th day**- 41 - 1 43 - 0 31 - 0 33 - 1 **1 month**- 41 - 1 43 - 2 31 - 2 33 - 1 **6 months**- 41 - 1 43 - 2 31 - 2 33 - 2	**6 months -** 41 - No bone resorption 43 - No bone resorption 31 - No bone resorption 33 - No bone resorption	**Pre-op:** 41 - 1462 43 - 1371 31 - 1543 33 - 1366 **Post - op:** 41 - 1533 43 - 1584 31 - 1673 33 - 1513
Reanne D'souza	18/F	1 implant 12	9 months	**4th day -** 12 - 2 **1 month -** 12 - 0 **6 months -** 12 - 0	**4th day -** 12 - No mobility **1 month -** 12 - No mobility **6 months -** 12 - No mobility	**4th day -** 12 - 1 **1 month -** 12 - 0 **6 months** - 12 - 0	**4th day** - 12 - 0 **1 month** - 12 - 1 **6 months** - 12 - 2	**6 months** - 12 - No bone resorption	Pre op: 12 - 1178 Post op: 12 - 1267
Raashi	23/F	3 implants 11, 21, 22	9 months	**4th day -** 11 - 1 21 - 2 22 - 1 **1 month** - 11 - 0 21 - 0 22 - 0 **6 months -** 11 - 0 21 - 0 22 - 0	**4th day -** 11 - No mobility 21 - No mobility 22 - No mobility **1 month** - 11 - No mobility 21 - No mobility 22 - No mobility **6 months -** 11 - No mobility 21 - No mobility 22 - No mobility	**4th day -** 11 - 1 21 - 1 22 - 1 **1 month** - 11 - 0 21 - 1 22 - 0 **6 months -** 11 - 0 21 - 1 22 - 0	**4th day** - 11 - 1 21 - 1 22 - 1 **1 month** - 11 - 1 21 - 2 22 - 2 **6 months** - 11 - 2 21 - 1 22 - 2	**6 months -** 11 - No bone resorption 21 - No bone resorption 22 - No bone resorption	**Pre-op:** 11 - 1540 21 - 1128 22 - 1116 **Post op:** 11 - 1631 21 - 1296 22 - 1798

Shraddha	20/F	2 implants 31, 42	9 months	**4th day -** 31 - 1 42 - 2 **1 month -** 31 - 0 42 - 0 **6 months -** 31 - 0 42 - 0	**4th day -** 31 - No mobility 42 - No mobility **1 month -** 31 - No mobility 42 - No mobility **6 months -** 31 - No mobility 42 - No mobility	**4th day -** 31 - 1 42- 2 **1 month -** 31 - 1 42 - 1 **6 months -** 31 - 1 42 - 1	**4th day -** 31 - 1 42- 0 **1 month -** 31 - 2 42 - 1 **6 months -** 31 - 2 42 - 2	**6 months -** 31 - No bone resorption **4**2 - No bone resorption	**Pre op:** 31 - 1489 42 - 1368 **Post op:** 31 - 1533 42 - 1585
Karthik	28/M	4 implants 41, 43, 31,33	6 months	**4th day -** 41 - 1 43 - 2 31 - 2 33 - 1 **1 month -** 41 - 1 43 - 0 31 - 1 33 - 0 **6 months -** 41 - 0 43 - 0 31 - 0 33 - 0	**4th day -** 41 - No mobility 43 - No mobility 31 - No mobility 33 - No mobility **1 month -** 41 - No mobility 43 - No mobility 31 - No mobility 33 - No mobility **6 months -** 41 - Mobility present 43 - Mobility present 31 - No mobility 33 - No mobility	**4th day -** 41 - 2 43 - 2 31 - 1 33 - 1 **1 month -** 41 - 1 43 - 1 31 - 1 **33 -** 1 **6 months** - 41 - 2 43 - 2 31 - 2 33 - 2	**4th day** - 41 - 0 43 - 1 31 - 0 33 - 1 **1 month -** 41 - 1 43 - 2 31 - 2 33 - 1 **6 months -** 41 - 2 43 - 2 31 - 2 33 - 2	**6 months-** 41 - Horizontal bone resorption 43 - Horizontal bone resorption 31 - No bone resorption 33 - No bone resorption	**Pre op**: 41 - 1230 43 - 1176 31 - 1385 33 - 1423 **Post op**: 41 - 1129 43 - 1083 31 - 1329 33 - 1269