

**EVALUATION OF SURVIVAL RATE OF ZYGOMATIC IMPLANTS PLACED
USING IMMEDIATE LOADING PROTOCOL IN ATROPHIC MAXILLA-
A CLINICAL STUDY**

*A Dissertation submitted in
Partial fulfillment of the requirements
For the degree of*

MASTER OF DENTAL SURGERY

**BRANCH – III
ORAL AND MAXILLOFACIAL SURGERY**



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

2017 - 2020

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**ENDORSEMENT BY HEAD OF THE DEPARTMENT/
HEAD OF THE INSTITUTION**

This is to certify that **DR.S.JAYANANDHINI** Post Graduate student (2017-2020) in the Department of Oral and maxillofacial surgery, Tamil Nadu Government Dental College and Hospital, Chennai-600003, has done dissertation titled **EVALUATION OF SURVIVAL RATE OF ZYGOMATIC IMPLANT PLACED USING IMMEDIATE LOADING PROTOCOL IN ATROPHIC MAXILLA- A CLINICAL STUDY** our direct guidance and supervision in partial fulfillment of the regulation laid down by **The Tamilnadu Dr.M.G.R. Medical University, Guindy, Chennai-32** for **Master of Dental Surgery, Oral and Maxillofacial Surgery (Branch III) Degree Examination.**

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**PROF. DR. C.PRASAD, MDS,
GUIDE & HEAD OF THE DEPARTMENT
DEPT. OF ORAL AND MAXILLOFACIAL SURGERY,**



**Tamilnadu Government Dental College & Hospital,
Chennai - 600 003**

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DECLARATION

I, hereby declare that this dissertation “**EVALUATION OF SURVIVAL RATE OF ZYGOMATIC IMPLANT PLACED USING IMMEDIATE LOADING PROTOCOL IN ATROPHIC MAXILLA-A CLINICAL STUDY**” is a bonafide and genuine research work carried out by me under the guidance of **Prof. Dr. C.PRASAD, MDS., Professor and HOD,** Department of Oral and Maxillofacial Surgery, Tamilnadu Government Dental College and Hospital, Chennai -600003.

Signature of the candidate

DR.S.JAYANANDHINI



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ACKNOWLEDGEMENT

*I am extremely grateful to my esteemed guide **Prof. Dr.C.PRASAD, M.D.S.**, Professor and Head of the Department, Department of Oral and Maxillofacial Surgery, Tamilnadu Govt. Dental College and Hospital, for his filial attitude, valuable guidance, encouragement, lending me his precious time and never ending patience without which this study would not have been possible and also for constant inspiration throughout my post-graduation period.*

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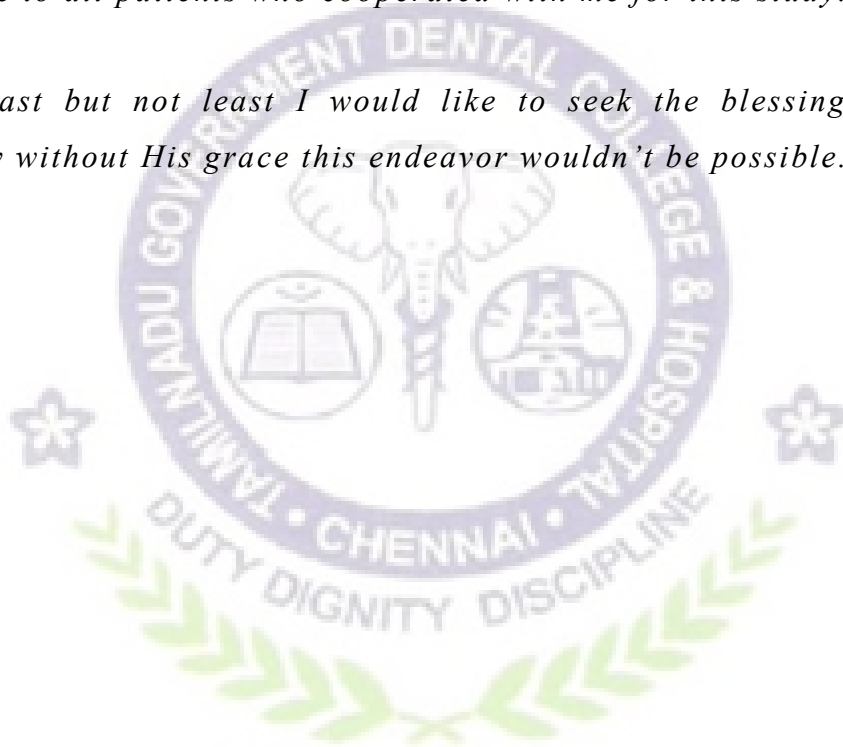
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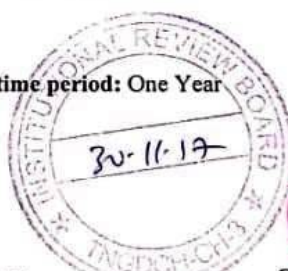
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ABSTRACT

BACKGROUND:

Zygoma implants are evidence –based surgical and prosthetic solution for rehabilitation of atrophic posterior maxilla with both classical two stage and immediate loading protocols.

Zygoma implants avoid grafting and sinus lift procedures and therefore contribute to a shorter and more comfortable treatment.

Zygoma bone is superior to that of the posterior maxilla in providing anchorage and success of zygomatic implant is due to Quad cortical stabilization, that the implant body engages four cortical bones

1. Maxillary Lingual Plate
2. Maxillary sinus floor
3. Maxillary sinus roof
4. Lateral cortex of the body of zygomatic bone

Immediate loading decreases the time of treatment and increases the acceptance of the treatment by the patient.

AIMS AND OBJECTIVES

To evaluate the survival rate of immediately loaded zygomatic implant based on clinical criteria.

MATERIALS AND METHODS

5 patients with completely edentulous atrophic posterior maxilla fulfilling the criteria were selected. Nobel Biocare zygomatic implants were

placed in the posterior region of completely edentulous maxilla and anterior conventional implants in selected subjects. The patients were assessed pre operatively and post operatively 1 week, 3 months 6, 9 and 12 months to assess clinical parameters like pain, infection, implant stability quotient, Lund – Mackay rhinosinusitis analysis, Ainamo and Bay gingival bleeding index and evaluation of position of apical third of zygomatic implant . The data collected was analyzed statistically.

RESULTS

The zygomatic implants and the anterior conventional implants were immediately loaded and a survival rate of 100% was obtained in both zygoma and conventional implants in the current study. The mean ISQ achieved on the right side was 68.80 ± 4.14 and on the left side 65.6 intra operatively which was suggestive of good primary stability. Post operatively after a period of one year follow up the mean ISQ o the right and left side was 71 which indicate secondary stability

CONCLUSION

Completely edentulous atrophic maxilla rehabilitated with immediate loaded zygomatic implants in combination with anterior conventional implants revealed a survival rate of 100% in one year follow up in current study. There were no potential complications encountered during the follow up period.

KEY WORDS

Zygoma bone, zygomatic implant, CT scan

LIST OF ABBREVIATION

| | |
|-------|--|
| ANOVA | Analysis of Variance |
| ZAGA | Zygoma Anatomy Guided Approach |
| DICOM | Digital Imaging and Communication in medicine |
| ISQ | Implant Stability Quotient |
| RFA | Resonance Frequency Analysis |
| CT | Computed Tomography |
| OPG | Orthopantamogram |
| STL | Standard Triangulated Language |
| SA | Sinus Augmentation |
| CAD | Computer Aided Design |
| VAS | Visual analog scale |
| PFAST | Pterygoid Full Arch Stabilization Technique |
| CBCT | Cone beam computed tomography |

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INTRODUCTION

Dream of every edentulous patient is to have functionally stable denture, it all the more so in a resorbed atrophic maxilla, since the atrophic edentulous maxilla is unique in its anatomical considerations, owing to the presence of the maxillary sinus. Since this limits the volume of the bone available for implant placement¹.

Severely atrophied maxilla presents major challenge in the rehabilitation, due to complexity in terms of lack of height and width of the alveolar ridge, secondary to extractions, trauma, infection or maxillary sinus pneumatization².

A classification of edentulous jaw by J.I.Cawood and R.A.Howell in 1988³.

Class I- dentate

Class II- immediately post extraction

Class III- well rounded ridge form, adequate in height and width

Class V- flat ridge form, inadequate in height and width

Class VI- depressed ridge

The placement of implant-supported prosthesis in cases with atrophic posterior maxilla with sufficient bone height is always a challenging task to the surgeons

Hence a multitude of surgical procedures were advocated to increase the bone height, these include augmentation procedures such as crestal on-lay, inlay grafting to maxillary antrum and nasal floor⁴. Lefort I osteotomy with interpositional grafting and sinus lift technique are also valuable considerations.

However the above mentioned techniques have their own drawbacks such as donor site morbidity, invasive treatment and prolonged duration⁴.

Dr. Per Ingvar Branemark in 1988² introduced zygomatic implants as a “rescue implant concept”¹, these are graft less solutions, which was a major breakthrough in the field of implantology. He was widely acknowledged as “Father of dental implantology”.

“Zygomatic fixture” are different from the commercial dental implants that they anchor into the zygomatic bone, rather than osseointegration as of in conventional implants. It is used when maxillary bone quality and quantity inadequate for the placement of conventional implants.

Zygomatic implants were originally designed to treat the victims of trauma, tumor resection and congenital defects². Later the technique has been refined, for its application in severely resorbed ridges, restoring proper function and esthetics².

Branemark studies have proved that quality of zygomatic bone is similar to that of the anterior mandible, which is widely known to have a high success rate in terms of survival rate.

NKenke et al in their studies on regional anatomy reported that the zygomatic bone is superior to that of the posterior maxilla in providing anchorage. The success of the zygomatic implant is attributed to “Quad-cortical” stabilization, that the implant body engages four cortical bones the maxillary lingual plate, maxillary sinus floor, maxillary sinus roof, lateral cortex of the body of the zygomatic bone.

Bedrossian et al, recommended various treatment option based on the presence of bone in the different zones of maxilla zone I-premaxilla, zone II- premolar area, zone II – molar area⁵.

Based on the concerned zones, the surgical options varies, cone beam computed tomography is used to determine the availability of bone in all the three zones.

Presence of bone in zone I, II, III the treatment option would be traditional and axial implants. In case of bone present in zone I and II four tilted implants can be used. If bone presents only in zone I, zygomatic implants with two or four traditional implants can be used.

Insufficient bone in all the zones, then treatment option would be four zygomatic implants⁵.

There are various surgical techniques available for fixation of the zygomatic implants; the conventional Branemark technique makes use of Lefort I incision and creation of sinus window to guide the perforations, the implants placed in intra sinus position without elevation of the sinus membrane⁶.

The path that extends from premolar region extending through the maxillary sinus entering into the mid portion of the zygomatic body is the “proper axis” of the zygomatic bone⁷.

If the entry point is anterior to the path, potential for penetration onto the orbit exists. If the axis is posterior to the path, risk of entering into the infra-temporal fossa exists. In conventional Branemark technique the emergence of the implant is located palatal to alveolar crest.

As a simplification of conventional Branemark technique, Stella and Warner proposed sinus slot technique, which makes use of “orientation grooves” on the zygomatic buttress region⁶.

This sinus slot technique eliminates the need to create sinus window, advantage with this technique is implant emerging on alveolar crest level, of the first molar in a more vertical angulation, this favours the interface with the prosthesis and hence the implant placement is simplified⁶.

Dr.Aparicio et al in 2006 reported “Extra-sinus or extra-maxillary” technique. This is mainly advised in patients with pronounced buccal concavities. The merit of extra maxillary technique is that it avoids sinusitis, which is more common in other techniques.

Moreover buccal cantilevers are improved and implant placement guided by the anatomy of zygomatic bone, ‘ZAGA’ – zygomatic anatomy guided approach classification⁸.

Zygomatic implants are an evidence-based surgical and prosthetic solution for rehabilitation of atrophic posterior maxilla using both two stage and immediate loading protocol⁹.

Immediate loading protocol substantially decreases the treatment time and increases the treatment acceptance by the patient⁹.

The purpose of the study was to clinically and radio graphically assess the quality of bone and formulate an ideal protocol taking into various parameters in placing immediate loading zygomatic implants, in atrophic posterior maxilla.

AIMS AND OBJECTIVES

Aim:

To evaluate the survival rate of immediately loaded zygomatic implant based on clinical criteria.

Objectives:

To evaluate the following parameters in immediately loaded zygomatic implants in posterior atrophic maxilla.

Pre operative evaluation criteria:

- Presence of bone in the zones of edentulous maxilla based on 'Bedrossian concept' using orthopantomograph
- Zygomatic bone quantification(height and width) using cone beam computed tomography

Post operative evaluation criteria:

- Evaluation of position of apical third of zygomatic implant using paranasal sinus view radiograph
- Lund-Mackay scoring- radiological staging of chronic rhino sinusitis using computed tomogram of paranasal sinuses and ostiomeatal complex
- Implant stability quotient (ISO) - level of stability and osseointegration using resonance frequency analysis intra operatively and 12 months follow up.
- Bleeding on probing based on Ainamo and Bay "Gingival bleeding index"

- Bone loss around the zygomatic implants using orthopantomograph
- Peri implant soft tissue condition
- Visual analogue scale

REVIEW OF LITERATURE

EDENTULOUS ATROPHIC POSTERIOR MAXILLA

J.I.Cawood and R.A.Howell in 1988³ reported a classification of edentulous jaws based on their study on 300 dried skulls; they established a “predictable resorption pattern” of the alveolar ridges and proposed a simplified classification of residual ridges that aids in the selection of appropriate surgical and prosthodontic technique.

Ernesto Barquero Cordero² in 2011 provided a new perspective for patients with atrophic maxilla. He describes major challenge in the rehabilitation of severely atrophied maxilla, due to its complexity in terms of height and width of the alveolar ridge and gives various surgical technique for increasing bone volume like iliac crest grafting, Lefort I osteotomy with interpositional graft, guided bone regeneration, sinus lifting and combination of these techniques.

REHABILITATION OPTIONS FOR SEVERELY ATROPHIC EDENTULOUS MAXILLA

SINUS AUGMENTATION

Tarun Kumar A.B. in 2016¹⁰ enumerated all the techniques used for sinus augmentation; for placement of endosseous implants in the atrophic posterior maxilla. He concludes that grafting of the maxillary sinus creates ideal bone quality and long term success of rehabilitation.

Misch 1987 proposed a classification of posterior maxilla based on amount of ridge width and available bone below the antrum. The categories range from SA₁ to SA₄ based on bone height and width.

SA₁- it has an adequate vertical bone for implant that is 12mm, no manipulation of sinus needed.

SA₂- it has 0-2mm less than ideal height of the bone and requires surgical correction.

SA₃-it has just 5-10mm below the sinus.

SA₄-it has less than 5mm of the bone below the sinus.

Sinus floor elevation is employed when the residual bone height is equal to or greater than 6mm.

GUIDED BONE REGENERATION

Maryam Farzad in 2012¹¹ enumerated guided bone regeneration, reconstructive procedure of alveolar ridge using membranes. Guided bone regeneration was based on the principles that specific cells contribute to the specific tissues. The principles were cell exclusion, tenting, scaffolding and stabilization.

Carlos Polis-Yanes in 2019¹² presented a clinical case of severe atrophy of the maxilla managed with various biomaterials like heterologous cortical lamina, xenograft and autologous bone and inclusions. He concluded heterologous cortical lamina used as barrier membranes for medium and large bone defects as “plausible” biomaterial.

FREE ILIAC CREST GRAFTING

Orhan Gurren in 2007¹³ in his report of two cases enumerates rehabilitation of severely atrophied mandible using free iliac bone grafting. It is viable alternative for rehabilitation and

gold standard for maxilla-mandibular reconstruction due to its osteoconductive and osteoinductive properties.

Mats Sjostrom in 2007¹⁴ reported a longitudinal follow up study of implant stability in 29 patients with atrophic edentulous maxilla reconstructed with free iliac crest graft using onlay / inlay or interpositional grafting techniques. A total of 192 implants were placed and with a survival rate of 90% at the 3 year follow up. The changes in the marginal bone level were 0.3 ± 0.3 mm between baseline and the 3 year follow up. Twenty patients remained for follow up and were provided with fixed implant bridges. The clinical follow up was done using radiological examinations and RFA measurements indicated a predictable and stable long term results for the patients with atrophic edentulous maxillae reconstructed with autogenous bone and delayed placement of endosteal implants.

LEFORT I OSTEOTOMY

E.Nystrom H.Nilson in 2008¹⁵ reported a prospective study of 26 patients with extreme atrophic maxillae reconstructed with Lefort I osteotomy and interpositional bone graft in combination with implants. 167 implants were placed and 24 failed. The estimated implant survival rate was 85% at the end of the follow up for 13 years. Marginal bone loss was 2.5, 2.9, 3.0 and 3.1 mm from the implant abutment junction, after 1, 2, 5 and 10 years respectively, with stabilization of bone level after 2 years.

TILTED IMPLANTS

David Penarrocha-oltra in 2013¹⁶ made a study from 1999 to 2010 on patients with atrophic maxilla rehabilitated with tilted implants. Clinical series with 10 patients rehabilitated

with tilted implants followed for 12 months after prosthetic load. Thirteen studies were included reported a total of 782 tilted implants and 666 axial implants in 319 patients. Success rate was 91.3 to 100% for axial implants and from 92.1 to 100 % for tilted implants. Radiographic marginal bone loss went from 0.4 mm to 0.92 mm in tilted implants and from 0.35 mm to 1.21 mm in axial implants.

The literature on tilted implants shows that implant placed alone or in combination with axially placed implants and rehabilitated with different prosthetic options have high success rates, minimal complications and high patient satisfaction.

S.Wentaschek in 2017¹⁷ reported a retrospective study and evaluated the outcome of six implant supported immediate fixed rehabilitation of atrophic edentulous maxillae with tilted implants. About sixty implants were placed in 10 patients, out of which twenty one implants were inserted in the fresh extraction sockets. Results reported that analyzed implants were in function in mean 64 ± 13 months. One axial and two tilted implants failed in three patients. ISQ values increased significantly after first 3 months at the osseointegrated tilted and axial implants. The failure rate of tilted implants in atrophic upper jaw was quite high.

MINI IMPLANTS

David Nisand in 2014¹⁸ reported a retrospective study 85 patients rehabilitated with mini implants in the atrophic posterior maxilla followed up for 2 years. About 96 short implants of length 6-8.5 mm were placed a cumulative survival rate of 94.6% was obtained.

Francesco Pieri reported in 2016¹⁹ a retrospective cohort study, comparing short implants of 6 to 8 mm length to standard length implants (≥ 11 mm) in combination with lateral sinus elevation procedure to rehabilitate atrophic posterior maxilla.

About 118 patients were treated with 'fluoride-modified implants' between January 2009 and December 2011. Two to four implants were placed in each patient and were loaded after 5 to 6 months. Failures of about 2 implants in 2 patients were reported. Mean marginal bone loss was 0.48 ± 0.5 mm. the results showed reduction in surgical complications and less morbidity compared with standard length implants for 3 year follow up.

Lorenz et al in 2019²⁰ presented a retrospective study of short implants in patients with advanced atrophy in posterior maxilla. Fourteen patients were included in the study, received a total of 30 implants of 7 mm length in the posterior maxilla, with a mean loading period of 5 years. Clinical and radiological follow up were done. None of the implants were lost and no technical failures occurred. A mean marginal bone loss of 0.5mm indicates healthy peri implant hard and soft tissue conditions without signs of peri-implantitis.

PTERYGOID IMPLANTS

Eugenia Candel in 2012²¹ reviewed the literature based on 13 articles, reporting a total of 1053 pterygoid implants in 676 patients. The clinical series of 5 patients with class IV and V of Cawood and Howell rehabilitated with pterygoid implants and fixed prosthesis were followed up for a period of 12 months. The average success of pterygoid implants was 90.7% and radiographic evaluation of bone loss ranged between 0 and 4.5 mm.

Pterygoid implants had high success rates, similar bone loss to those of conventional implants, minimal complication and good acceptance by the patients. Two anatomical locations in which implants were placed, reported as pterygoid process and pterygomaxillary region, implant length and angulations vary between these two techniques.

Dan Holtzelaw in 2018²² reported a retrospective study of 16 patients treated with “pterygoid full arch stabilization technique (PFAST)” protocol. A total of 13 females and 3 males were treated with 25 implants and followed up for 6 to 40 months.

The results reported an average insertion as 44.52 ± 11.89 Ncm. Average mesiodistal insertion was $70.8 \pm 7.41^\circ$. The implant length used was 11.5 mm and 13 mm and diameter were 3.5 mm and 4.5 mm. a cumulative survival rate of 93.75% was reported.

ALL ON FOUR CONCEPT

Dr.Malo in 2003²³ made a retrospective clinical study, which assessed the “immediate loading” protocol with ‘all on four’. The study concluded high survival rate after 1 year in maxilla rehabilitated with tilting of posterior implant and fixed prosthesis.

Callandriello R et al in 2005²⁴ published a prospective study where they assessed rehabilitations in atrophic maxilla with use of tilted implants and early immediate load. A survival rate of 96.7% was reported.

Ivan Contreras Molina in 2014²⁵ elaborated a retrospective study of 156 patients rehabilitated with prosthesis placed on four and six implants, followed up for 10 years. Results revealed that after 10 years survival index of the prosthesis and implants was same for both groups.

David Soto – Penaloza in 2017²⁶ made a system of systemic review of “all on four” treatment concept based on 728 articles; obtained from initial screening process. Systemic review conducted based on guidelines of transparent reporting of systematic reviews and Meta-analyses- PRISMA statement.

The results reported that all on four concept offers a predictable way to treat the atrophic jaw in patients that do not prefer regenerative procedures. Survival rate of 99.8% was reported for a follow up period of 24 months.

ALVEOLAR DISTRACTION OSTEOGENESIS

Takahiro Kanno in 2012²⁷ reported a retrospective study of 17 patients where new pre implantation regenerative augmentation technique for severely atrophic posterior maxilla was executed using sinus lifting with simultaneous alveolar distraction. After sufficient sinus lifting a track type vertical alveolar distracter was placed.

Results reported implant survival rate of 96.3% after post loading follow up of 47.5 months. A sufficient alveolus was regenerated and all patients achieved stable oral rehabilitation. The average alveolar bone height augmented for implant placement was 13.7 mm for bilateral cases and 12.9 mm for unilateral cases.

EVOLUTION OF ZYGOMA IMPLANTS

Zygoma implants were first introduced in 1988² by Dr.Per Ingvar Branemark widely acknowledged as the “father of dental implantology”. Zygoma implants used in situations in which adequate anterior maxillary bone is available for supporting conventional implants, but minimal posterior maxillary bone.

Branemark and colleagues did a prospective study of 62 patients with follow up of 1 to 10 years designed a 'new implant' with length ranging from 30 mm to 50 mm.

Aparicio and associates in 1993 mentioned zygomatic bone as a location for the definitive anchoring of dental implants. They published their work with transzygomatic implants in 29 patients.

In 2000 Stella and Warner²⁸ presented zygomatic implant based on sinus-slot technique, which improved the original technique in terms of implant orientation, elimination of sinus window and reduction of post operative symptoms.

Uchida and colleagues in 2001²⁹ carried out morphometric measurements in corpses and described the implant lengths and angulations required to avoid perforations of maxillary sinus and temporal fossa.

Boyes-Varky and associates in 2003³⁰ described surgical modifications to Branemark zygomatic protocol.

They placed 77 implants with a modified head angulation of 55 degrees in 45 patients as close to the crest of the edentulous ridge as possible, thereby improving access and ideal position of restoration ensured.

Bedrossian and Stumpel in 2006³¹ developed a technique to simplify clinical procedure and shorten the duration of treatment.

Aparicio et al in 2008³² proposed 'extra sinus technique' for patients with pronounced buccal concavities on lateral aspect of maxillary sinus, to avoid excessive palatal emergence of

implant head. He reported cohort study of 80 consecutive patients treated with zygomatic implant based on 'zygomatic anatomy guided approach' (ZAGA 0 to ZAGA 4).

Schramm et al in 2016³³ reported "computer –guided approach" for zygomatic implants as a recent concept, where CT or CBCT scan were used to determine the location of "zygomatic implant receptor sites" using 3D planning software's.

Chrcanovic and Abreu³⁴ proposed five different surgical approaches, (1) the classic approach, (2) the sinus slot technique, (3) the exteriorized approach, (4) the minimally invasive approach by use of custom-made drill guides, (5) the computer-aided surgical navigation system.

STUDIES ON ZYGOMA IMPLANTS

Yuki Uchida in 2001²⁹ made studies in 12 cadavers, elaborated information for installing zygomatic implants based on maxillary and zygomatic measurements.

Angular and linear distance between the maxilla and zygoma were measured, classified into short and tall groups by height 140 to 159 cm and 160 to 180 cm, respectively.

Based on mean and standard deviation values, the installation angle of zygomatic implants was between 43.8° and 50.6°.

The distance between the crest of maxillary alveolus near palate and jugale (JU point) was between 44.3 and 54.3mm.

The study concluded that the minimum anteroposterior length of the zygomatic body was 5.68 mm on the shorter group. Therefore the apex of the implant should be 3.75mm diameter and

thickness of zygoma must be 5.75mm or more. The threads of the implants must not be exposed from the zygoma in patients with shorter zygomatic bone.

Miguel Penarrocha in 2005³⁵ made retrospective study of 5 patients with extreme maxillary atrophy. A total of 16 conventional implants were placed, together with 2 pterygoid implants and 10 zygomatic fixations. The zygomatic fixations were based on sinus slot technique. The patients were followed up of 12 to 18 months, during which the implants remained stable and in function

Ruben Davo in 2006⁹ made a retrospective preliminary study to evaluate the survival rate of 36 immediately loaded zygomatic implants placed in 18 atrophied maxillae. Patients with average age of 58 years were followed up for 29 months.

The parameters evaluated were implant stability, using resonance frequency analysis (RFA) and evaluation of swelling, pain or discomfort. Results revealed no zygomatic implants were lost over the observation period. They were fixed with prosthesis screwed with implant within 48 hours. The survival rate was 95.6%. no relevant complications were noted.

Davo R reported a retrospective study in 2008³⁶ where the clinical outcome of 42 patients treated with 81 immediately loaded zygomatic implants were evaluated. Out of 42 patients 19 men and 23 were women in the mean age from 34 to 74 years were followed up for atleast one year.

Results revealed a success rate of 97%. All the prosthesis was stable. Oroantral fistula and sinusitis were reported in one patient. Soft tissue swelling and pain at zygomatic area found in another patient after 10 days of surgery.

M.Stievenart in 2010³⁷ reported a consecutive cohort study of 20 patients, with extremely resorbed maxilla, provided with four zygomatic implants.

The first 10 patients had a 'two staged procedure' and next 10 patients had 'one staged surgical procedure' and one of them had 'flapless guided surgery' with Nobel guide. Except one patient who lost 3 implants and all the patients received a fixed 'Procera' implant bridge and another patient received an over denture retained by a screwed bar fixed on four zygomatic implants. The cumulative survival rate after 40 months was 96%.

Reginadlo Mario in 2012³⁸ made a prospective cohort study to evaluate immediate occlusal loading of extra sinus zygomatic implants. 40 extra sinus zygomatic implants and 74 anterior standard implants were evaluated.

After 8 years of follow up the success rates of extra sinus zygomatic implants, standard implants and definitive prosthesis were 97.5%, 95.9% and 95.2% respectively. The results concluded immediate occlusal loading of extra sinus zygomatic implants presents a predictable treatment options for the atrophic maxilla.

Jamie G Rodriguez –Chessa 2014³⁹ reported retrospective study in 29 consecutive patients rehabilitated with 67 zygomatic implants and 84 conventional implants. The implant success rate was 79.1 % and the immediate and delayed load was associated to statistical difference ($p=0.104$). The main complication was the loss of osseointegration and mucositis.

Humberto Fernandez⁴⁰ reported in 2014. A retrospective analysis of severely atrophied maxilla managed with zygomatic implants. The sample consisted of 80 patients in whom 244 implants were inserted. 111 zygomatic implants were placed in women and 133 in men. Overall

complication rate of 9.9% was observed with sinusitis having the most frequent complication (7.5%), parasthesia (0.4%) and oro-antral fistula (0.4%). The follow up period was 6 to 48 months.

Gunaseelan Rajan ⁴¹ in 2014 reported a clinical study of rehabilitation of patients with ‘generalized aggressive periodontitis’ with zygomatic implants and followed up for 2 years. The patients were evaluated with modified bleeding index, clinical mobility, suppuration and mucosal seal efficiency. The study showed that there was no statistically significant differences in both short term and long term implant survival between the patient with the history of chronic periodontitis and periodontically healthy individuals.

Araujo in 2016 ⁶ reported retrospective cohort study in 28 patients who received a combination of conventional and zygomatic implants and 14 patients rehabilitated only with conventional implants.

The follow up period ranged from minimum of 15 months to maximum of 53 months. The results showed that Stella and Warner’s technique minimized the length of the implant into maxillary sinus, improving the emergence of the implant. No pathological changes were found on peri implant tissues. Radiographs showed satisfactory bone levels in conventional implants and good positioning of apex of zygomatic implants.

High survival rate of 100% was evident. No case had obstruction of maxillary sinus ostium.

Giorgo Lombardo in 2016⁴² proposed a retrospective study based on clinical, microbiologic and radiological assessment of soft and hard tissue surrounding zygomatic

implants. A total of 65 zygomatic implants placed in 20 patients were assessed. As one zygomatic implant was lost. The cumulative survival rate is 98.5%. All the prosthesis was successful. Peri implant soft tissue was generally in a healthy condition. The implant recipients had low levels of crest and zygomatic bone loss and high VAS scores including their general satisfaction.

Paulo H.T Almeida in 2017⁴³ reported a prospective cohort study to evaluate the satisfaction of individuals with atrophic maxilla rehabilitated with fixed dental prosthesis, anchored on zygomatic implant with variables leaving the anesthetic procedure, general anesthesia or local with sedation.

30 patients were included in the study, 15 individuals underwent surgery under general anesthesia and other 15 were treated under local anaesthesia and sedated. The results concluded no difference between the groups as regards the anaesthetic procedure.

Rowland Agbara in 2017⁴⁴ reported a retrospective study of 28 patients with posterior maxillary defect. 22 females and 6 males were treated. In the prosthetic rehabilitation of the patients, 2 had epithetic prosthesis and 2 had obturators while 18 patients had conventional removable dental prosthesis.

Results showed four patients (14.3%) had peri implantitis. A cumulative success rate of 88.1% reported.

Frank J.Tuminelli in 2017⁴⁵ made a systematic review of implant survival, prosthesis survival and potential complications. Research was performed to identify case report, prospective and retrospective studies of immediately loaded zygomatic implants with a mean

follow up of 12 months. Full text analysis was performed on 67 articles, resulting in the inclusion of 38 articles for this systemic review. The results revealed a success of implant and prosthesis ranged from 96% to 100%.

Kai Zhao in 2018⁴⁶ reported a retrospective radiographic analysis using CBCT (Cone beam computed tomography) evaluating long term schneiderian membrane thickness changes following zygomatic implant placement. In total 84 zygomatic implants and 30 regular implants were placed in patients. The schneiderian membrane thickness increases from 1.03 mm to 1.33 mm after a median follow up time of 23 months. The percentage of sinuses observed with ostium potency also increased from 2.0 % to 12.2%. The study concluded chronic schneiderian membrane thickening could result from zygomatic implant insertion.

Chris Butterworth in 2019⁴⁷ reported a 10 year prospective study to evaluate the survival of zygomatic implants used in management of patients with maxillary and mid face malignant disease. 53 patients received 140 zygomatic implants as part of their rehabilitative treatment. Study population consisted of 49 patients with 131 zygomatic implants. All surviving implants were utilized and overall prosthetic follow up of cohort was 24 ± 20 months with the longest follow up being 70 months. Results concluded that the use of zygomatic implants in the management of oro-facial malignancy is a predictable prosthetic treatment modality. The installation of implants at the time of primary tumor resection is advantageous and can result in high implant survival and useability.

STUDY ON SURVIVAL RATE OF ZYGOMA IMPLANTS

Takamaru et al⁴⁸ suggest that the thickness at the 90° angle point is less than 2.8 mm which is the diameter of the apex of the zygoma implant. This will result in the apex of the

zygoma implant to be exposed on the inner side or both (inner and outer) sides of the temporal process of zygomatic bone, even if the twist drill orientation was perfect.

Frodel et al⁴⁹ reported that the bone surrounding an osseointegrated implant should had atleast 1mm thicker; hence the thickness of the zygomatic bone should be more than 6.3 mm. Aiming of the twist drill at 90° angle point from the alveolar process is difficult as the surgical field is narrow. Therefore they suggested an insertion method where the twist drill is directed infero-anterior to 90° angle point.

Weishar et al⁵⁰ reported the use of zygoma as a support structure in the rehabilitation of patients who have undergo maxillectomies.

Nkenke et al⁵¹ in the study used CT and histomorphometry to examine 30 human zygoma. The study revealed that the zygomatic bone consists of trabecular bone, which is unfavorable parameter for implant placement. The success of implant placed in the zygomatic bone was achieved quad cortical stabilization.

Edward B. Sevetz⁵² suggested the drilling orientation, if it was too far anterior, not much of the zygomatic bone will be available for osseointegration, if it was too posterior, infratemporal fossa containing important anatomic structures such as temporalis muscle, maxillary artery and its branches and the pterygoid plexus may be encountered leading to complications. It is necessary to pierce the fronto zygomatic notch or slightly anterior to it.

Extra sinus technique was advocated by Aparicio et al overcomes the disadvantages of the palatal emergence of the implant head where the implant head emerges at or near the top of the residual alveolar crest, usually in the second premolar or first molar region⁵³.

Bedrossian reported that the 45° angulation⁵⁴ of the zygomatic implant allows for the platform of the zygomatic implant to be on the same plane as vertically placed implant in the premaxilla.

Aparicio et al⁵⁵ in their study using intra sinus technique reported sinusitis in 9.09% patients and 45.45% presented signs of sinus opacification. He advocated ZAGA method which aims to maximize the peri implant mucosal seal and to preserve the schneiderian membrane, is associated with a lower incidence of post operative rhino sinusitis complications.

Bothur et al⁵⁶ in their study using intra sinus approach reported a sign of otitis in all but one patient, primary ostium was obstructed in 9 maxillary sinuses and 2 patients complained about rhinosinusitis symptoms. They concluded that the incidence and severity of rhinosinusitis alterations in their patients were similar to those in patients who underwent Caldwell –Luc maxillary sinus procedure. Most patients were asymptomatic although they did present some sub clinical disturbances indicative of the need for further endoscopic surgery.

Antonio D Agostino et al⁵⁷ reported that 52 maxillary sinuses had an LMS score of 0, 23 had an LMS score of 1 and 7 had an LMS score of 2, a statistically significant greater incidence of rhino sinusitis alterations in patients who underwent intra sinus procedures compared to extra sinus technique.

RFA⁵⁸ has gained popularity as it is a non invasive diagnostic method that measures implant stability. ISQ is a measurement unit in place of hertz. A high ISQ suggests greater stability whereas a low value implies instability. The manufacture guidelines suggest that a successful implant typically has an ISQ greater than 65. An ISQ <50 indicates potential failure or increased risk of failure.

Bedrossian et al⁵⁹ also reported a survival rate of 100% where there was no loss in 28 zygomatic and 65 regular implants in 14 patients a one year follow up period.

Penarrocha et al⁶⁰ reported a success rate of 100% I 21 patients where 40 zygoma implants were placed after a follow up period of 29 months. Davo et al lost none of 36 zygomatic implants but there of 68 conventional implants after a follow up from 6 to 29 months.

On the contrary, Pi Urgell⁶¹ showed a survival rate of 96.04% where 4 implant failed (two before and two after prosthetic loading). Similarly Balshi⁶² et al reported a survival rate of 96% after follow up period of 9 months to 5 years.

Miglioranca et al⁶³ after a follow up rate of 12 months and Davo et al after a follow up period of 5 years reported a survival rate of 98%.

Ostman et al⁶⁴ reported the loss of one implant of 123 implants in 20 patients after 1 year of loading.

Davo et al⁶⁵ reported a survival rate of 98.5% for the immediately loaded zygomatic and anterior implants which was higher than other published results for this combination of implants in atrophied maxilla using a 2-stage protocol.

SURGICAL ANATOMY

ANATOMY OF ZYGOMATIC BONE:

The zygomatic bone is quadrangular⁶⁶, occupying upper and lateral part of the face, forming the cheek prominences; it is a part of lateral wall and floor of the orbit and part of temporal bone and infratemporal fossa.

Zygomatic bone is compared to a pyramid offering solid anatomic structure for the implant anchorage. It comprises of dense cortical and trabecular bone.

Histological analysis reveals presence of regular and dense bone with very high osseous density upto 98%. When occlusal forces are applied to implant fixture, load is transferred to cortical bone⁶⁷ and trabecular bone.

According to anatomic study the mean length of bone available in this region is 14mm.

SURFACES:

The 'malar surface' is convex, perforated near its centre by zygomaticofacial foramen, for passage of zygomaticofacial nerves and vessels, below this foramen is a slight elevation that gives origin to the zygomaticus muscle.

The 'temporal surface' is directed backwards and medial. It is concave, presenting medially a rough triangular area for articulation with the maxilla, and laterally a smooth concave surface, the upper part of which forms the anterior boundary of the temporal fossa; the lower part forms the anterior boundary of infratemporal fossa. Near the centre of this surface is the zygomaticotemporal foramen for the transmission of zygomaticotemporal nerve.

ANATOMIC LANDMARKS OF THE ZYGOMATIC BONE:

The “antero- superior” or “orbital border” is smooth, concave and forms the considerable part of the circumference of the orbit.

The “antero-inferior” or “maxillary border” is rough and beveled at the expense of its inner table to articulate with maxilla; near the orbital margin it gives origin to “quadrates labii superioris” muscle.

The “postero-superior” or “temporal border” is curved like an italic letter ‘f’ and is continuous above with commencement of temporal line and below with upper border of zygomatic arch. The temporal fascia is attached to it.

The “postero-inferior” or “zygomatic border” affords attachment by its rough edge to the masseter muscle.

ARTICULATIONS:

The zygomatic bone articulates with four bones, the frontal, sphenoidal, temporal and maxilla.

COURSES OF BLOOD SUPPLY AND NERVE SUPPLY:

Blood supply for the facial bones is mainly by maxillary artery, which is a terminal branch of external carotid artery. The facial artery plays a co dominant role in the blood supply of facial bones, as it forms anastomoses with the maxillary artery and vascularizes the body, maxillary, frontal and temporal processes of the zygomatic bone.

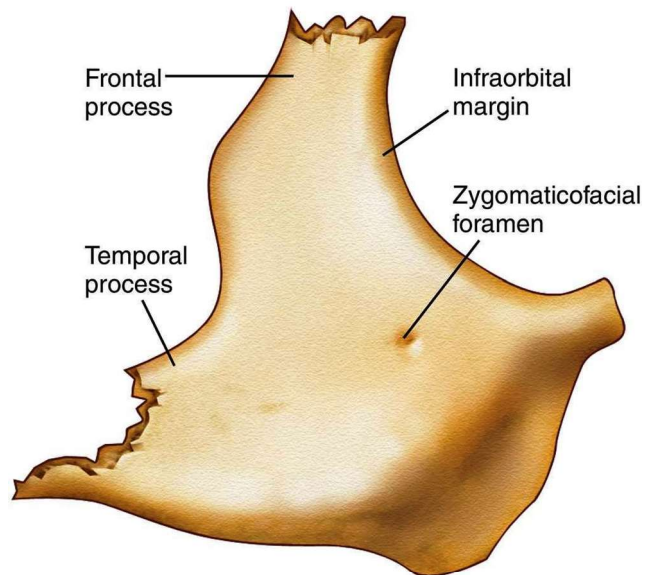
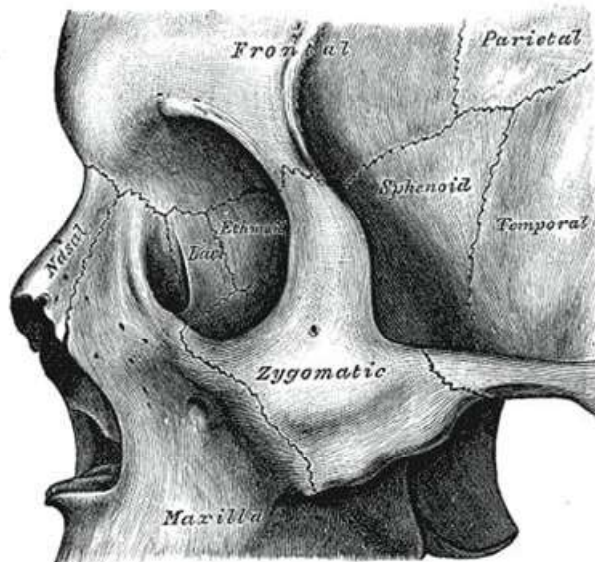
Zygomatic nerve, branch of maxillary division of trigeminal nerve, divides off after emerging from foramen rotundum to enter pterygopalatine fossa. It receives some parasympathetic fibers from the pterygopalatine ganglion. Coursing superiorly it enters the orbit laterally through inferior orbital fissure.

It runs anteriorly in the inferolateral aspect of the extra coronal space before branching into two sensory branches, each exists through similarly named foramina of the zygomatic bone

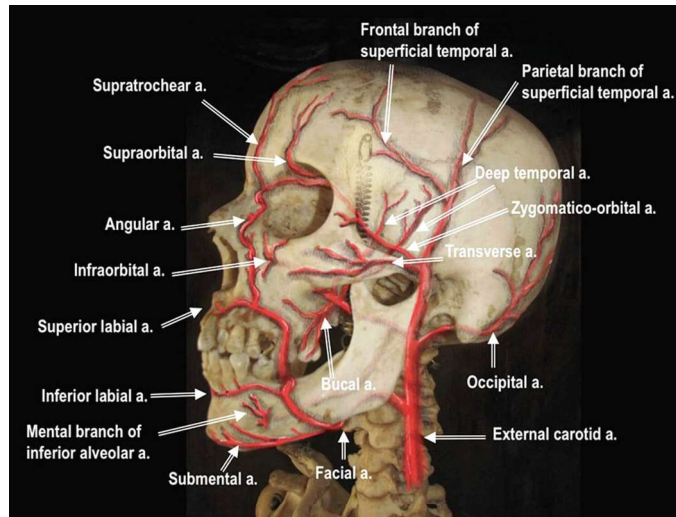
- Zygomaticotemporal nerve
- Zygomaticofacial nerve

In lateral orbit it contributes secretomotor parasympathetic fibers to the ‘lacrimal nerve’, which in turn supplies the lacrimal gland.

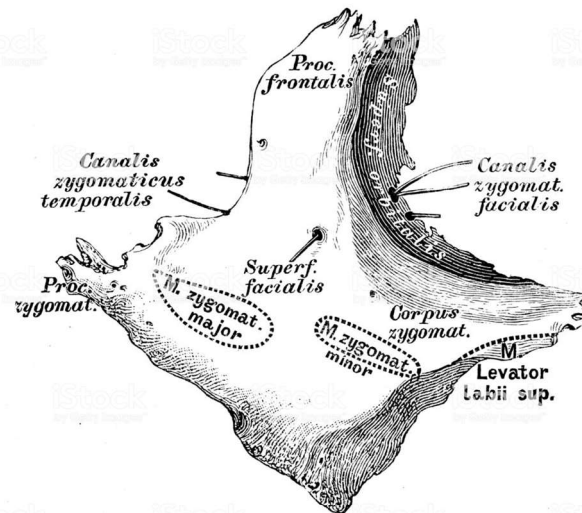
ZYGOMATIC BONE ANATOMY



VASCULAR ANATOMY OF ZYGOMATIC BONE



MUSCLE ATTACHMENT IN RELATION TO THE ZYGOMATIC BONE



MATERIALS AND METHODS

The study population were selected from the outpatient section of the department of Prosthodontics and referred to the department of oral and maxillofacial surgery, Tamilnadu Government dental college and hospital, Chennai. Patient had chief complaint of edentulous maxilla.

SAMPLE SIZE:

The proposed sample size was 5 patients. Nobel Biocare zygomatic implantsTM were placed in the posterior region of completely edentulous maxilla in selected subjects.

STUDY METHOD:

Prospective non-randomized interventional study with mean follow up period between 2018-2019.

INCLUSION CRITERIA:

Patients with presence of bone only in zone I according to Bedrossian classification¹, within the age group of 40-60 years were included in the study. Patients with posterior atrophic maxilla that could not be surgically managed with techniques like sinus lifting, bone grafting and wide implants were included in the study.

EXCLUSION CRITERIA:

Patients with acute sinusitis, heavy smokers, patients with systemic diseases⁹, radiation therapy for head and neck region 12 months prior to proposed therapy were excluded for the study.

PROSTHETIC REHABILITATIVE STEPS:

- Surgical implant placement and interim prosthesis
- Healing Abutment
- Open tray impression
- Jig trial
- Bite registration
- Wax try in
- Frame work trial
- Final prosthesis

ARMAMENTARIUM

Basic principles of zygomatic implants
Instruments for Brånemark System® Zygoma implants

The Brånemark System Zygoma Surgical Kit includes:

- A. Depth indicator angled
- B. Depth indicator straight
- C. Drill guard short
- D. Drill guard
- E. Handle



SURGICAL PROCEDURE

The patients were treated under general anesthesia. Pre operative investigations including routine blood investigations, chest x-ray, ECG, ENT evaluation, physician fitness and anesthetist opinion were obtained.

Nasoendotracheal intubation was performed. Sterile draping and patient painting were done according to standard protocol. Local anesthesia containing 1:100000 adrenaline injected into the maxillary buccal and palatal region.

A midcrestal incision was done from tuberosity to tuberosity and vertical incision placed posteriorly along the maxillary buttress, bilaterally. A full thickness mucoperiosteal flap was elevated to expose the entire maxillary alveolar process and hard palate. Sub periosteal dissection was carried out to further expose the lateral maxilla, maxillary antral wall, lateral surface of the zygomatic bone. Infra orbital nerve was identified and preserved on both sides.

Retractors were placed for complete exposure and visualization of the infra zygomatic crest, base of the zygomatic body and osteotomy sites were planned.

A 20:1 implant hand piece with preset torque of 35NCM was used for osteotomy. Sterolithographically planned surgical template was secured to the right maxillary alveolar process. Sequential osteotomy drilling was initiated with 2.9 mm twist drill and subsequently followed by 3.5 mm pilot drill and 3.5 mm twist drill.

The final twist drill could penetrate both cortices of the zygomatic bone till its desired length. The osteotomy depth was measured using depth gauge, to determine the appropriate length of the implant to be chosen. Zero degree angulated implant with length of 45 mm was

inserted through the osteotomy site using implant carrier and final tightening was done with hand wrench. The implant engages the lateral wall of the maxillary sinus, entering the base of the zygomatic body and emerges in the mid portion of the zygomatic body. About 1mm apical emergence of implant at the mid portion of the body of zygoma ensures the stability. A screw driver was used to check the orientation of the occlusal head of the zygomatic implant.

A 17° angulated multiunit abutment was screwed to the implant.

The same sequential osteotomy procedure was performed on the other side using drills 2.9 mm twist drill, 3.5 mm pilot and 3.5 mm twist drill. Implant length of 40 mm was placed after the measurement with depth gauge.

Conventional implants were placed in 12 and 22 regions after sequential osteotomy with 2.4 mm, 3.1 mm and 3.65 mm sequential drills. Implant of dimension 3.5 X 16 mm was placed in 12 region and 4.2 X 13 mm placed in 22 region. Bone grafts were placed in 12 region and buccal aspect of 15 regions.

Cover screw were placed for the conventional implants and healing caps were screwed to the zygoma implants. After copious betadine and saline irrigation closure was done with 3-0 vicryl.

The patient was followed up for one month post operatively, 6 weeks, 3 months and 6 months thereafter.

PROSTHETIC PROCEDURE

Prosthetic procedure follows screw retained implant supported prosthesis

After the surgical placement of zygomatic implants and conventional implants an interim prosthesis was given. Later healing abutments were placed for conventional implants which helped the gingival tissue to heal around the implant site. An open tray impression was made and jig trial was done. The purpose of an implant verification jig is to mimic the fit of the final frame. This was followed by bite registration and wax try in, preliminary viewing of denture was made to evaluate the desired appearance of the final prosthesis. Frame work trial was then checked to ensure fit, passive seating, optimal cross arch stabilization during functional and parafunctional loading. Finally metal bar- reinforced implant supported prosthesis was given.

CASE REPORT

Patient name: Mr. Anandhan

Age/Sex: 60/male

CHIEF COMPLAINTS: C/O completely edentulous upper and partially edentulous lower arch

HISTORY: patient had ill fitting denture

GENERAL EXAMINATION: Patient conscious, alert, oriented. Moderately built and nourished.

No signs of pallor, icterus, cyanosis, clubbing, pedal edema and regional lymphadenopathy.

CLINICAL EXAMINATION

- Mouth opening adequate
- Inter arch distance: Adequate
- Maxilla: Atrophic posterior maxilla

INVESTIGATIONS:

OPG: Atrophic edentulous posterior maxilla

DIAGNOSIS:

Completely edentulous atrophic posterior maxilla and partially edentulous mandible

TREATMENT PLAN:

Rehabilitation with zygomatic implants and conventional implants in maxilla.

PHOTOGRAPHS

CASE 1



FRONTAL VIEW



PROFILE VIEW

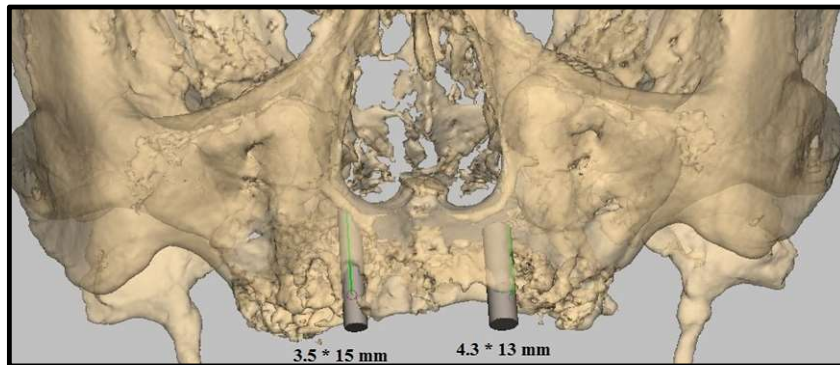


OCCLUSAL VIEW

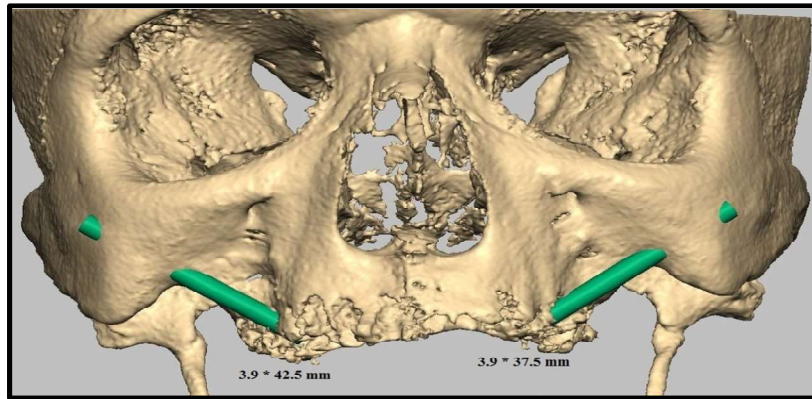


PRE OPERATIVE OPG

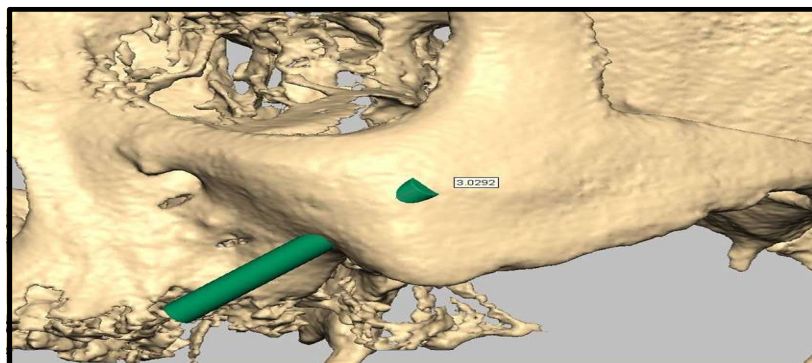
DICOM TREATMENT PLANNING



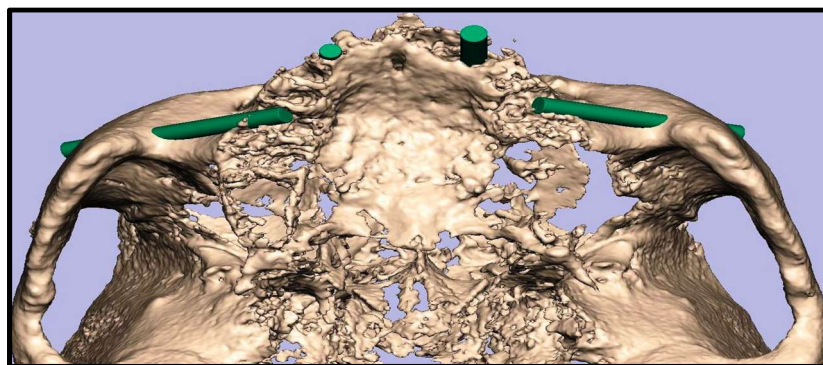
CONVENTIONAL IMPLANTS



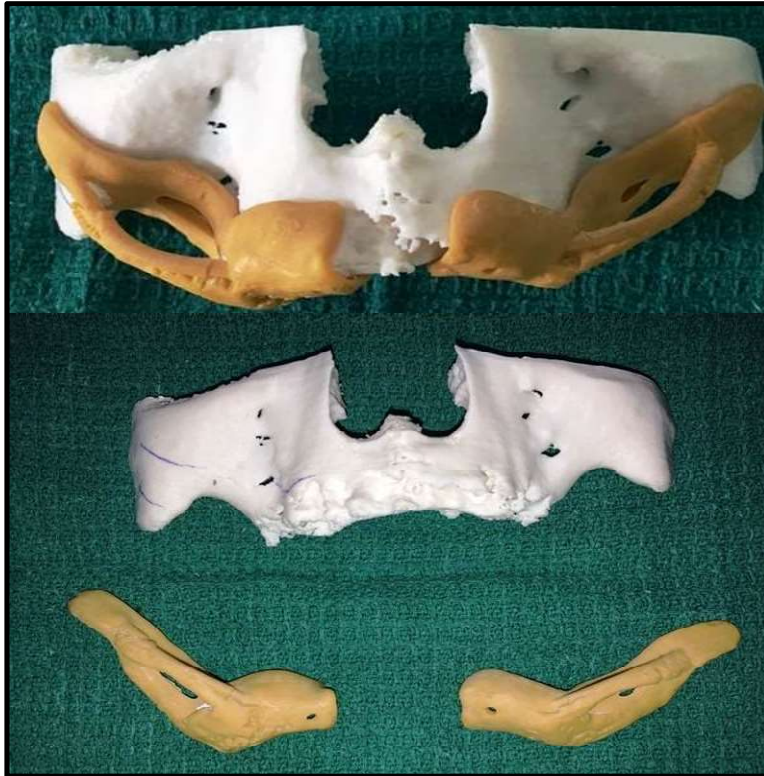
ZYGOMATIC IMPLANTS



APICAL EMERGENCE



STEREOLITHOGRAPHIC MODEL AND SURGICAL STENT

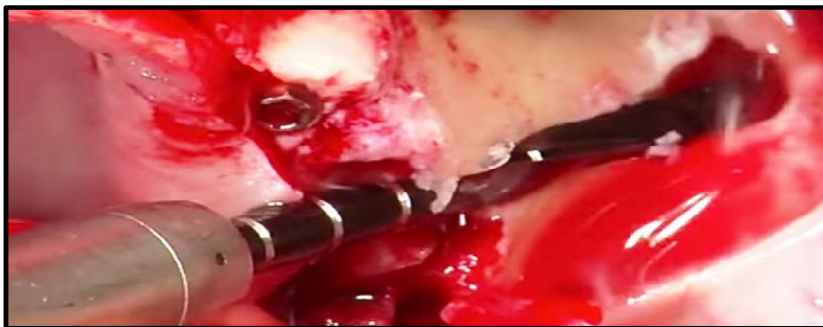


SURGICAL PRECEDURE





SURGICAL STENT IN POSITION

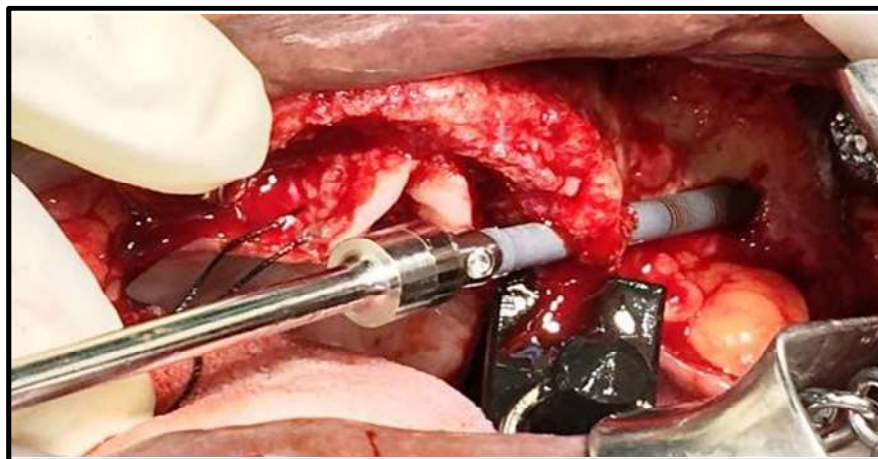
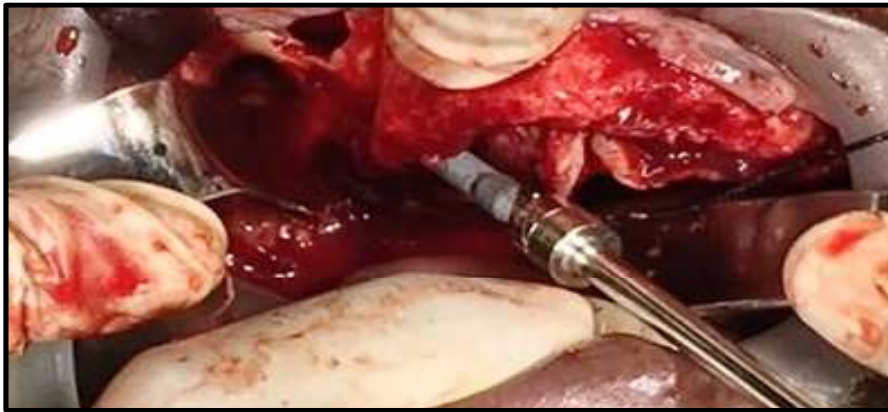


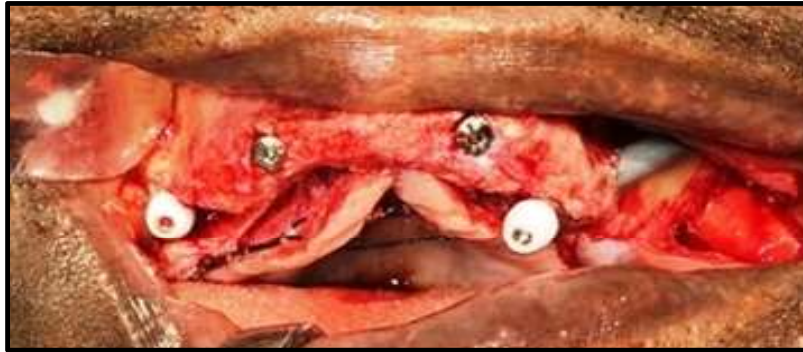
SEQUENTIAL DRILLS



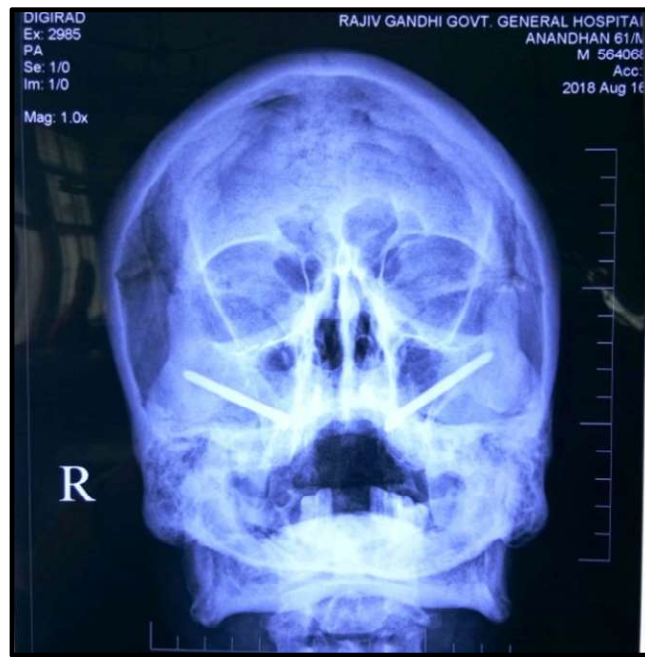
DEPTH GAUGE

ZYGOMA IMPLANTS PLACED ON RIGHT AND LEFT SIDE



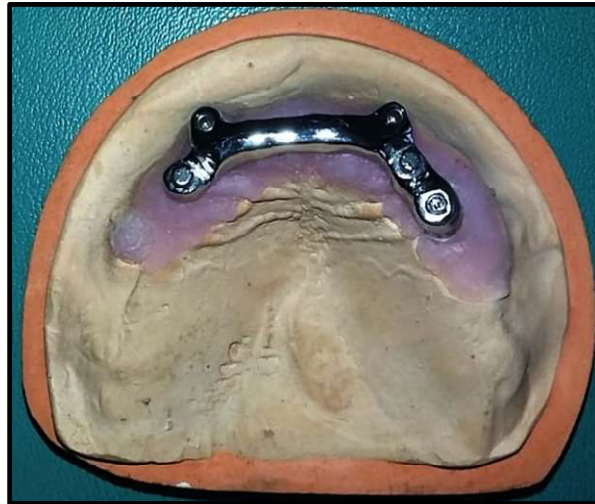


MULTI UNIT HEALING ABUDMENT



POST OPERATIVE PNS VIEW

PROSTHETIC PROCEDURE



BAR CONNECTOR

POST PROSTHETIC VIEW



CASE 2



FRONTAL VIEW



PROFILE VIEW

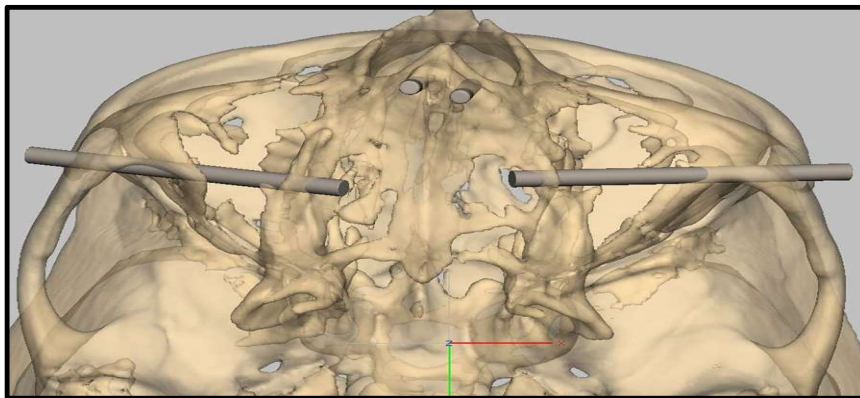


OCCLUSAL VIEW

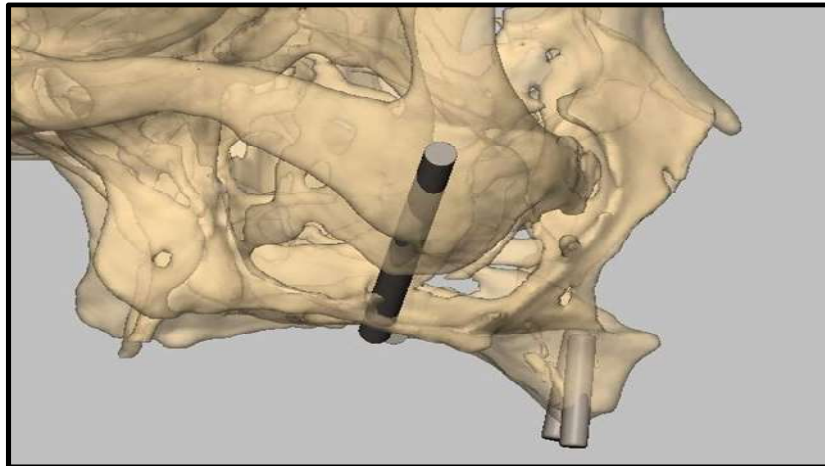


PRE OPERATIVE OPG

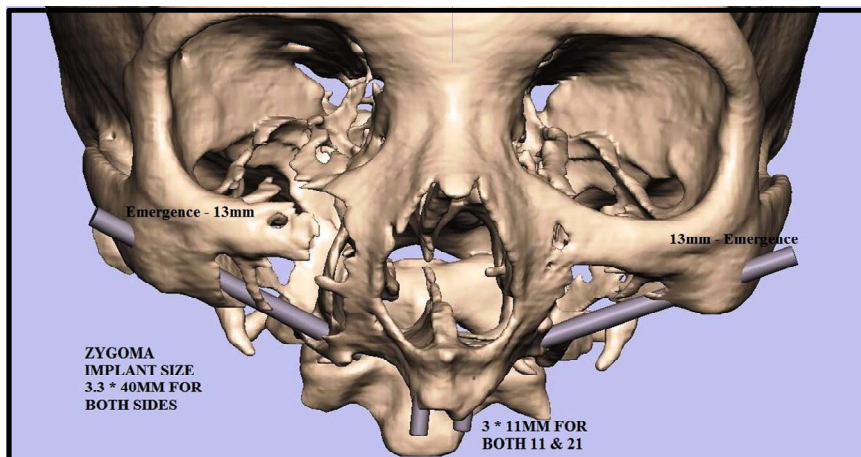
DICOM TREATMENT PLANNING



OCCLUSAL VIEW

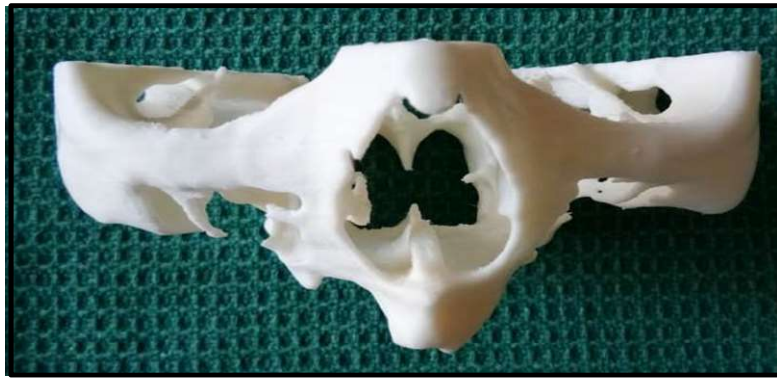


APICAL EMERGENCE



CONVENTIONAL AND ZYGOMA IMPLANTS

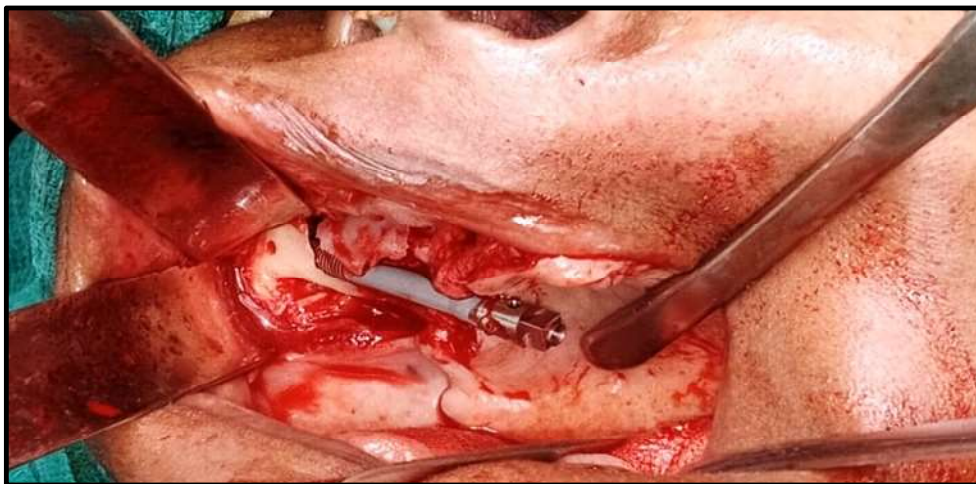
STEREOLITHOGRAPHIC MODEL



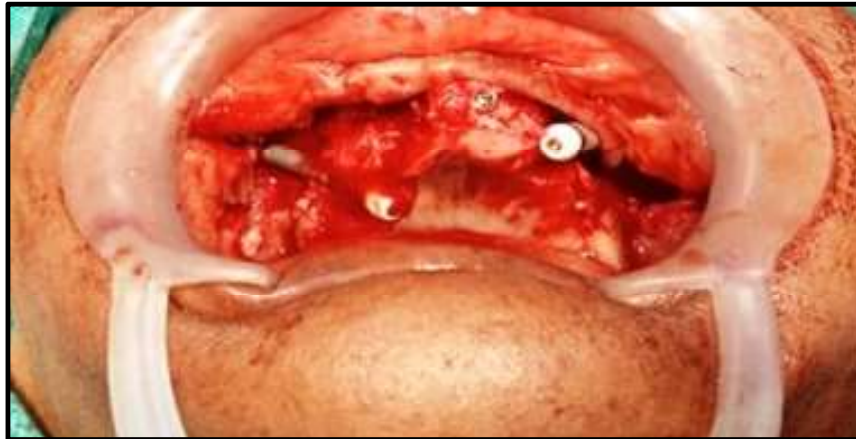
SURGICAL PRECEDURE



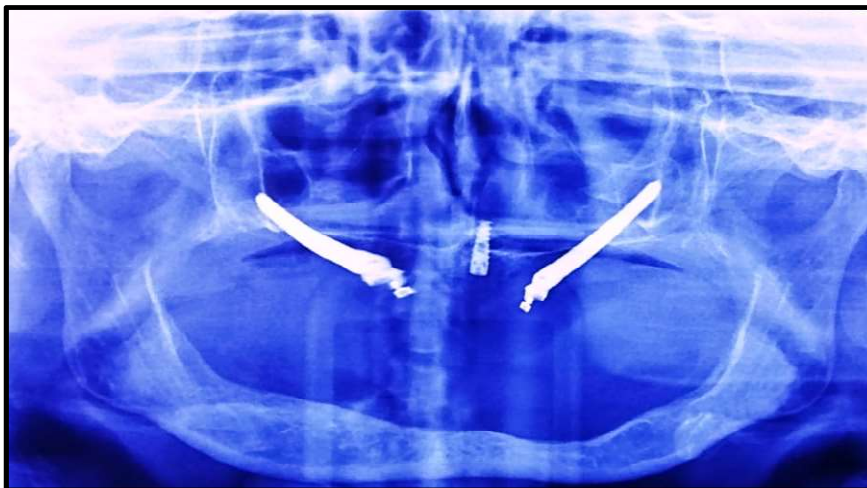
FLAP ELEVATION



ZYGOMA IMPLANT –RIGHT SIDE



MULTI UNIT HEALING ABUDMENT



POST OPERATIVE OPG

OBSERVATIONS AND RESULTS

Five patients with the chief complaints of completely edentulous atrophic maxilla referred to the department of Oral and Maxillofacial Surgery were included in the study. The study was done after approval from the Institutional ethical committee.

Informed consent was obtained from the patient in Tamil. The statistics were analyzed in the SPSS software version 20.0.

DEMOGRAPHIC DATA:

Out of five cases 4 patients were male, 1 patient was female with a Mean age of 55.8 ± 2.8 years.

Four patients had completely edentulous maxilla and mandible and one patient had completely edentulous maxilla and partially edentulous mandible (Table I). The mean follow up period was 1 year.

Table: I – DEMOGRAPHIC DATA

| CA SE NO | AGE /SEX | CLINICAL FEATURES | Radiographic evaluation- macroscopic | | | TREATMENT PLAN | | | |
|----------------|-------------|--|--------------------------------------|---------------------|----------------------|--------------------------|------|---|------------|
| | | | bone quality | | | Zygomatic implant length | | Conventional implant | |
| | | | zygomatic bone quality | Anterior Maxilla | Posterior maxilla | in mm | | measurement in mm (diameter X length) | |
| | | | | | | Right | Left | 12 region | 22 region |
| 1 | 60/M | Completely edentulous atrophic maxilla & partially edentulous mandible | D1 | D2 | D3 | 45 | 40 | 3.5 X 16 | 4.2 X 13 |
| 2 | 55/F | Completely edentulous atrophic maxilla & mandible | D1 | D3 | D4 | 37.5 | 40 | - | 3.5 X 10 |
| 3 | 58/M | Completely edentulous atrophic maxilla & mandible | D1 | D3 | D4 | 46 | 45 | 3.5 X 14 | 4.2 X 10 |
| 4 | 54/M | Completely edentulous atrophic maxilla & mandible | D1 | D2 | D3 | 38 | 42 | 3.8 X 16 | 3.5 X 13 |
| 5 | 52/M | Completely edentulous atrophic maxilla & mandible | D1 | D3 | D4 | 44 | 46 | 4.2 X 14 | 3.8 X 11.5 |

PARAMETER ASSESSMENT

Criteria A:

Evaluated the presence of bone in the zones of maxilla zone I, zone II and zone III. The statistical results were analyzed with SPSS software 20.0. The qualitative one-way ANOVA test was performed.

Table-II

PRESENCE OF BONE IN ZONES OF EDENTULOUS MAXILLA

| CASES | ZONE-I PRE MAXILLARY | | ZONE – II PREMOLAR | | ZONE-III MOLAR | |
|----------|-------------------------|---------------|--------------------|---------------|-------------------|---------------|
| | Height (mm) | Width (mm) | Height (mm) | Width (mm) | Height (mm) | Width (mm) |
| CASE-I | 17.5 | 5.4 | 8 | 4.4 | 3.8 | 2.6 |
| CASE-II | 13 | 4.2 | 6.2 | 3.8 | 2.7 | 2.1 |
| CASE-III | 18.2 | 6.2 | 6.5 | 4.8 | 3.5 | 2.7 |
| CASE-IV | 16.4 | 5.9 | 5.4 | 4.2 | 2.6 | 2.7 |
| CASE-V | 16.8 | 5.4 | 6.7 | 3.9 | 2.8 | 2.9 |

Table: III

Descriptive Statistics for Presence of Bone in Zones of Edentulous Maxilla

| Variable | Zones | Mean | SD | Std. Error | 95% CI for Mean | | P value |
|----------|--------|-------|-------|------------|-----------------|-------|---------|
| | | | | | Lower | Upper | |
| Height | Zone 1 | 16.38 | 2.010 | .899 | 13.88 | 18.87 | <0.001 |
| | Zone 2 | 6.56 | .9449 | .422 | 5.386 | 7.733 | |
| | Zone 3 | 3.08 | .5357 | .239 | 2.414 | 3.745 | |
| Width | Zone 1 | 5.42 | .7628 | .341 | 4.472 | 6.367 | <0.001 |
| | Zone 2 | 4.22 | .4024 | .180 | 3.720 | 4.719 | |
| | Zone 3 | 2.60 | .3000 | .134 | 2.227 | 2.972 | |

Test:One-way ANOVA

Inference: The test shows that the height and width of bone is different for each Zone from each other (Height and Width varies significantly between Pre-maxilla, premolar and molar region)

The mean height of bone observed in zone I was 16.3 ± 2.0 mm and in zone II 6.56 ± 0.94 mm and zone III 3.08 ± 0.5 mm.

The mean width of bone observed in zone I was 5.42 ± 0.8 mm and in zone II 4.22 ± 0.4 mm and zone III 2.60 ± 0.3 mm.

Chart-I

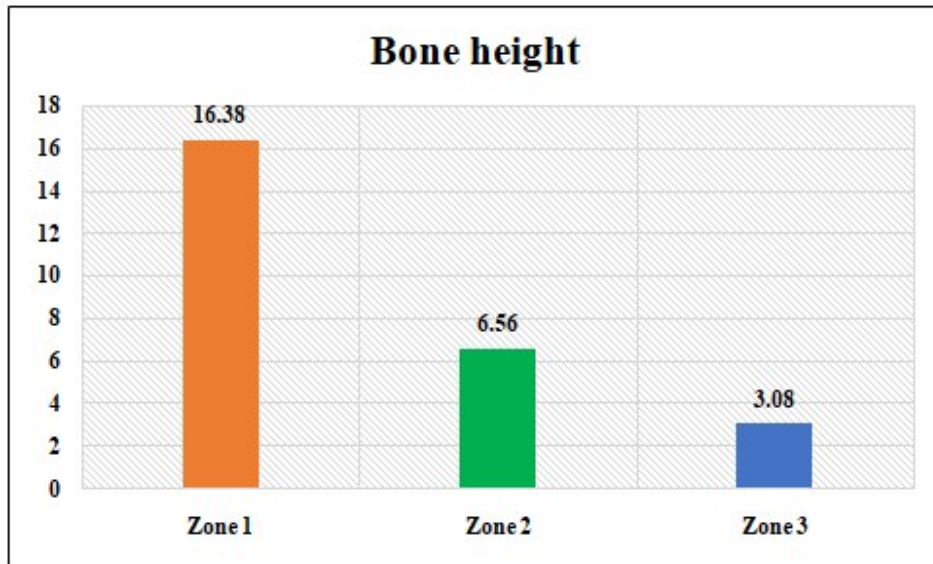
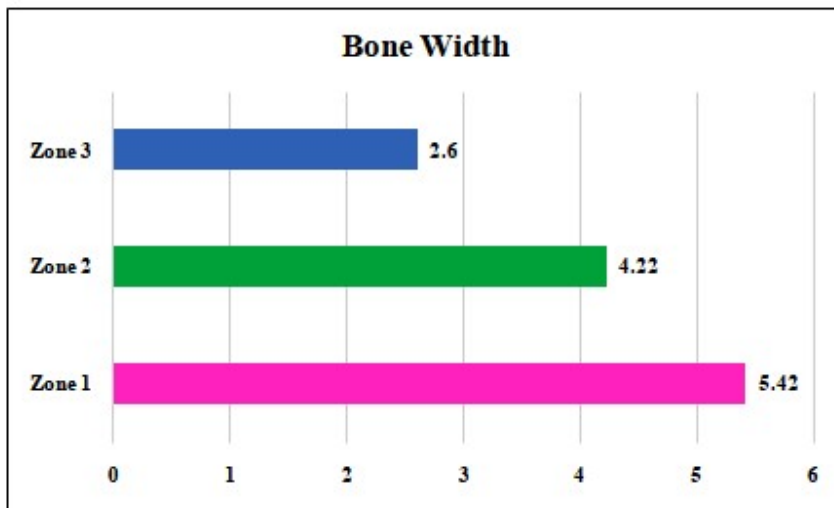


Chart-II



Criteria B:

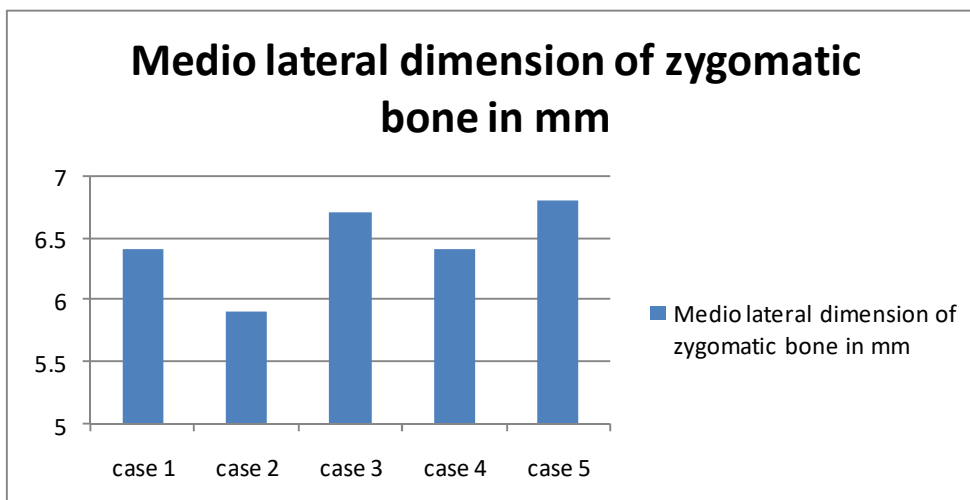
The zygomatic bone measurements were done with DICOM planning.

Table-IV

| Zygomatic bone measurement based on DICOM planning | |
|---|--|
| Case no | Medio-lateral dimension (distance between medial & lateral cortex tangent to cortical layer of maxillary sinus) |
| 1 | 6.4mm |
| 2 | 5.9mm |
| 3 | 6.7mm |
| 4 | 6.4mm |
| 5 | 6.8mm |

The mean Medio-lateral dimension of the zygomatic bone noticed was 6.44 ± 0.31 mm

Chart-III



Criteria C:

The position of apical third of the zygomatic implants was evaluated.

Table-V

EVALUATING THE POSITION OF APICAL THIRD OF ZYGOMATIC IMPLANT

| CASES | POSITION OF APICAL THIRD OF IMPLANT (INTERIOR TO EXTERIOR) | |
|----------|---|--------------|
| | RIGHT IMPLANT | LEFT IMPLANT |
| CASE-I | INTERIOR | EXTERIOR |
| CASE-II | EXTERIOR | EXTERIOR |
| CASE-III | EXTERIOR | EXTERIOR |
| CASE-IV | EXTERIOR | INTERIOR |
| CASE-V | EXTERIOR | EXTERIOR |

Table-VI

POSITION OF APICAL THIRD OF ZYGOMATIC IMPLANT

| | Right Implant | Left Implant |
|-----------------|----------------------|---------------------|
| Exterior | 80% | 80% |
| Interior | 20% | 20% |

About 80% of apical third of right and left sided implants were exterior in position in relation to the zygomatic bone, implying increased anchorage and stability of the zygomatic implants on both right and left sides.

Criteria: D

Bleeding on probing based on Ainamo and Bay index (1975) was used to evaluate six surfaces around the zygomatic implants. The surfaces evaluated were mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual and distolingual and compared at 6 months and 12 months post operatively.

Table-VII

BLEEDING ON PROBING-AINAMO AND BAY 1975

| Cases | Surface Examined (Presence or Absence of Bleeding on Probing) | | | | | | | | | | | |
|----------|---|-----------|------------|-----------|--------------|-----------|---------------|-----------|-------------|-----------|---------------|-----------|
| | Mesio Buccal | | Mid Buccal | | Disto Buccal | | Mesio Lingual | | Mid Lingual | | Disto Lingual | |
| | 6 months | 12 months | 6 months | 12 months | 6 months | 12 months | 6 months | 12 months | 6 months | 12 months | 6 months | 12 months |
| Case-I | - | - | - | - | - | - | - | - | - | - | - | - |
| Case-II | - | - | - | - | + | - | - | - | - | - | - | - |
| Case-III | - | - | - | + | - | - | - | - | - | - | - | - |
| Case-IV | + | - | - | - | - | - | + | - | - | - | - | + |
| Case-V | - | - | - | - | - | - | - | - | - | - | - | - |

Table-VIII

BLEEDING ON PROBING-AINAMO AND BAY 1975

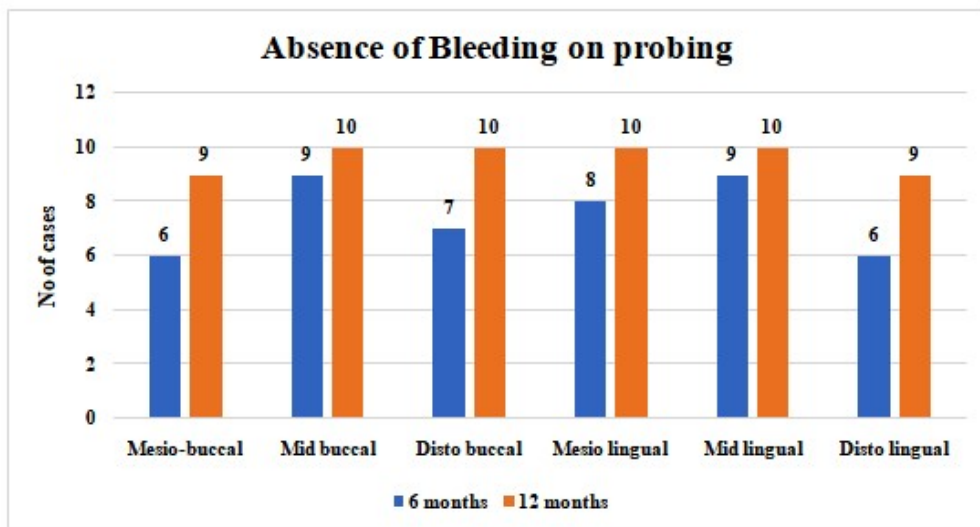
| Absence of Bleeding on probing | Surface examined | | | | | |
|--------------------------------|------------------|------------|--------------|---------------|-------------|---------------|
| | Mesio Buccal | Mid Buccal | Disto Buccal | Mesio Lingual | Mid Lingual | Disto Lingual |
| 6 months | 6 | 9 | 7 | 8 | 9 | 6 |
| 12 months | 9 | 10 | 10 | 10 | 10 | 9 |
| Chi-square P value | 0.04 | | | | | |

Test: Chi-square test

Inference: There is a significant reduction in presence of bleeding on probing in the surfaces examined

The statistical analysis based on chi-square test revealed (p value-0.04). The study was noticed to have a significant reduction of bleeding on probing after 12 months post operatively

Chart-IV



Criteria E: Visual Analogue Scale

There was no evidence of pain in 40 % of the patient during 1st post operative week, and about 20% of the patients had slight pain and 40% of the patients had moderate pain.

Table-IX

| CASES | POST OP PAIN |
|---|---------------------|
| CASE-I | 1 |
| CASE-II | 2 |
| CASE-III | 2 |
| CASE-IV | 0 |
| CASE-V | 0 |
| 0- NONE 1-SLIGHT 2- MODERATE 3- SEVERE | |

VISUAL ANALOUGE SCALE

Table-X

| 1st post operative week | Post Op Pain |
|---|---------------------|
| None | 40% |
| Slight | 20% |
| Moderate | 40% |
| Severe | |

Criteria F:

Nasal bleeding, nasal obstruction, periorbital edema and post operative edema were evaluated.

Table-XI

| CASES | POST OP EDEMA | NASAL OBSTRUCTION | PERI ORBITAL EDEMA | NASAL BLEEDING |
|--|----------------------|--------------------------|---------------------------|-----------------------|
| CASE-I | 1 | 0 | 0 | 0 |
| CASE-II | 2 | 1 | 0 | 0 |
| CASE-III | 1 | 0 | 0 | 0 |
| CASE-IV | 1 | 0 | 0 | 0 |
| CASE-V | 2 | 0 | 0 | 0 |
| 0- NONE 1-SLIGHT 2-MODERATE 3-SEVERE | | | | |

Table-XII

| | Post Op Edema | Nasal Obstruction | Peri Orbital Edema | Nasal Bleeding |
|-----------------|----------------------|--------------------------|---------------------------|-----------------------|
| None | | 80% | 100% | 100% |
| Slight | 60% | 20% | | |
| Moderate | 40% | | | |
| Severe | | | | |

The study revealed about 80% of the patients had no nasal obstruction. There was no evidence of nasal bleeding and peri orbital edema in any of the patients. About 60% of the patients had slight post operative edema.

Criteria G:

Lund Mackay scoring for maxillary sinusitis was performed based on computed tomogram.

Table-XIII

LUND-MACKAY SCORING OF CT-SCAN FOR MAXILLARY SINUSITIS

| CASES | SCORE |
|--|--------------|
| CASE-I | 0 |
| CASE-II | 0 |
| CASE-III | 1 |
| CASE-IV | 0 |
| CASE-V | 0 |
| 0- NO ABNORMALITY 1- PARTIAL OPACIFICATION 2-COMPLETE OPACIFICATIO | |

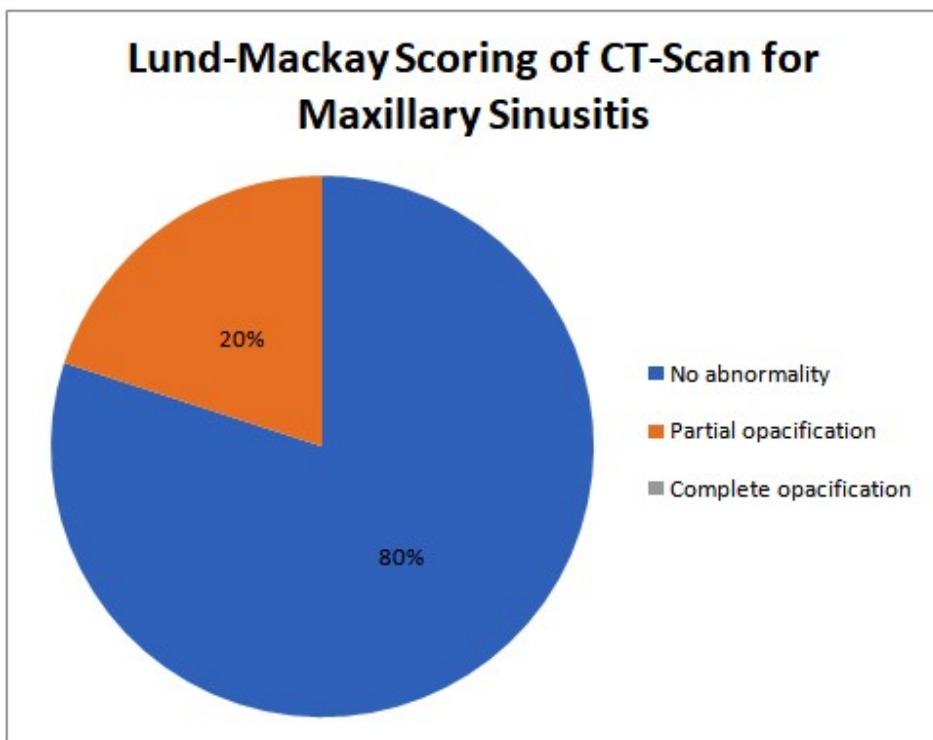
Table-XIV

Lund-Mackay Scoring of CT-Scan for Maxillary Sinusitis

| CASES | SCORE |
|-------------------------------|--------------|
| No abnormality | 80% |
| Partial opacification | 20% |
| Complete opacification | 0 |

The study revealed about 80% of the patients had no abnormality and about 20% of the patients had partial opacification

Chart-V



Criteria H:

Evaluation of presence of pus after 3 months was performed.

Table-XV

| CASES | PRESENCE OF PUS |
|--------------------------------|------------------------|
| CASE-I | - |
| CASE-II | - |
| CASE-III | - |
| CASE-IV | - |
| CASE-V | - |
| - NONE + PRESENT | |

Table-XVI

| Presence of Pus | Percentage |
|------------------------|-------------------|
| None | 100% |
| Present | 0 |

The study revealed there was no evidence of infection post operatively in any of the patients.

Criteria I:

Comparison of the implant stability ISQ based on resonant frequency analysis was done intra operatively and post operatively after 12 months.

Table-XVII

IMPLANT STABILITY QUOTIENT ISQ – RESONANT FREQUENCY ANALYSIS

| CASES | IMPLANT STABILITY QUOTIENT (HERTZ) | | | |
|----------|------------------------------------|------|---|------|
| | INTRA OPERATIVE | | POST OPERATIVE (12 MONTHS FOLLOW UP) | |
| | RIGHT | LEFT | RIGHT | LEFT |
| CASE-I | 67 | 60 | 69 | 70 |
| CASE-II | 69 | 64 | 68 | 67 |
| CASE-III | 63 | 67 | 70 | 72 |
| CASE-IV | 74 | 68 | 77 | 69 |
| CASE-V | 71 | 74 | 73 | 77 |

Table-XVIII

IMPLANT STABILITY QUOTIENT ISQ – RESONANT FREQUENCY ANALYSIS

| Side | Timeline | Mean | SD | SEM | P value |
|-------|----------------|-------|---------|---------|---------|
| RIGHT | Intraoperative | 68.80 | 4.14729 | 1.85472 | 0.114 |
| | Post-operative | 71.40 | 3.64692 | 1.63095 | |
| Left | Intraoperative | 66.60 | 5.17687 | 2.31517 | 0.046 |
| | Post-operative | 71.00 | 3.80789 | 1.70294 | |

Paired t test was done

Inference: On the left side, there is a significant difference between intra-operative and post-operative ISQ

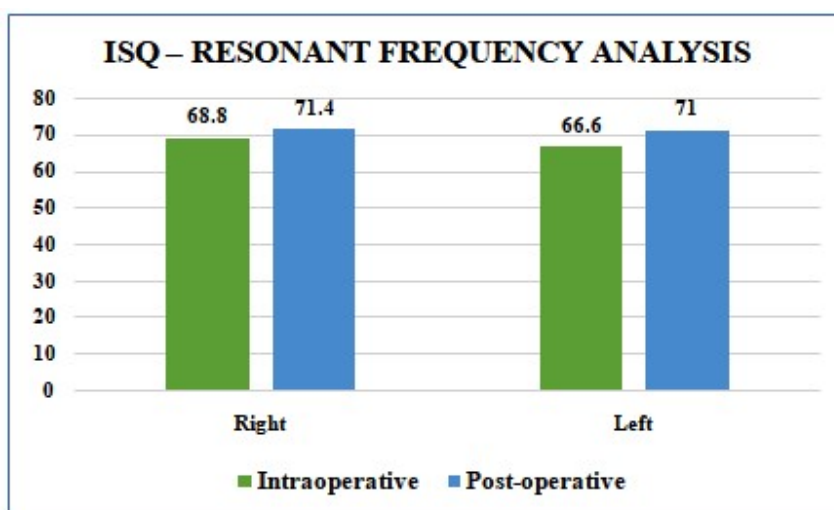
The results were obtained perceived a mean intra operative stability of the right side zygomatic implant was 68 ± 4.14 HZ and that for the left side zygomatic implant was 66.6 ± 5.17 HZ.

After a follow up period of 12 months, the mean zygomatic implant stability of the right side was 71.4 ± 3.6 HZ and that of left side zygomatic implant was 71.0 ± 3.8 HZ.

Statistical analysis based on paired t-test showed there was significant difference in the zygomatic implant stability on the right side, since p value was ≤ 0.05 ($p=0.114$)

On the contrary there was no significant difference in the implant stability on the left side based on intra operative and post operative resonant frequency analysis values ($p=0.046$)

Chart-VI



DISCUSSION

Rehabilitation of the edentulous atrophic maxilla has evolved over years. The edentulous maxilla presents with unique anatomic considerations, as the presence of the maxillary sinus limits the volume of the available bone for placements of implants⁶⁸.

This has consequently resulted in implant placement only in the premaxilla if bone grafting is not performed resulting in a “tissue borne over denture”⁶⁹ appliance.

Bone grafting procedures for implant placement works on the concept of biomechanical stimulation of entire maxilla via antero - posterior distribution of implants. The unpredictability of the graft uptake, delay in loading and donor site morbidity⁷⁰ are the disadvantages with grafting procedure.

Tilted implants⁷¹ as viable option for rehabilitation of the atrophic maxilla has advantages of biochemically reducing the moment of force and improves load distribution, by placement of longer implants and anchorage into dense bone.

The potential drawback with tilted implants is prosthetic rehabilitation particularly with posterior implants due to “bending moments” and unfavorable lateral movements⁷².

Wider implants⁷³ with diameter of 5-6mm can be considered in the posterior maxilla when the available bone height is 6 mm.

The concept of pterygoid implants was advocated by “Tulasne”⁷⁴. Advantages with these implants were elimination of posterior cantilever and improvement in axial loading⁷⁵.

But the disadvantages are the proximity to internal maxillary artery⁷⁶, venous bleeding encountered during drilling few millimeters into the retro-pterygoid area⁷⁷.

The history of zygomatic implants dates back to 1998, Per Ingvar Branemark introduced zygomatic implants for the rehabilitation of the atrophic maxilla. He was considered as “Father of modern dental implantology”⁷⁸.

The concept of zygomatic fixture according to Branemark were “Quad-cortical stabilization”, implant piercing four cortical bones namely maxillary alveolar process, maxillary sinus floor, maxillary sinus roof and zygomatic bone⁷⁹.

In our study five patients with completely edentulous atrophic maxilla were rehabilitated with zygomatic implants in combination with anterior conventional implants.

A Complete systemic pre-operative evaluation was done for all the patients in our study. Pre-operative orthopantomograph were taken to evaluate the available bone in zone I, zone II and zone III based on “Bedrossian concept”.

Cases were selected based on the criteria of the availability of bone in zone I and lacking bone in zone II and zone III.

After a preliminary selection of the case, computed tomogram of 0.5 slice thickness was taken for each patient. Digital imaging and communication in medicine (DICOM) data extracted from the CT scan were imported into the simulation software, implants dimensions for both zygomatic and anterior conventional implants were determined.

Software segmentations were used and exact replica of the entire maxilla and zygomatic bone exported into STL⁸⁰ (Standard Triangulation Language) format and skeletal model was fabricated via 3D printing in actual scale model size.

A “bone supported surgical template” with lateral opening at the buccal side was designed and printed via stereo lithographic 3D printing; using computer-aided design.

Virtual planning for ‘angulation’ of implants, its ‘apical exit’ in the zygomatic bone, its ‘palatal emergence’ were precisely also done.

Apical, coronal, angular deviations were determined for each implant. The precise planning of the location of the each implant helped us to eliminate potential damage to the vital structures.

The surgical template provided visual control of the drilling protocol, being placed close proximity to the entry point of the zygomatic body aided control of the drills up to the vicinity of the exit point, significantly limiting the problems.

A mock surgical procedure was performed for each patients on the 3D-printing stereo lithographic model, based on pre determined drill lengths and drill angulations by virtual planning.

There are different techniques for fixation of zygomatic implants the original Branemark technique uses Lefort I incision, to facilitate exposure of the zygomatic bone and creating window in the maxillary sinus to aid in the sequential drilling and subsequent implant placement.

The “sinus slot technique” by Stella and Warner has advantages of maintaining the integrity of the sinus membrane, as no window is created in the maxillary sinus. The technique makes use of the implant is guided into the sinus.

The sinus slot technique provided large implant bone interface with vertical orientation and better emergence of the implant closest to the crest of the maxillary alveolar bone.

The third technique, “extra sinus technique” by Aparicio, had no window opening or a channel in the wall of the maxillary sinus. The principle behind the technique was ‘externalization’ of the zygomatic implant in relation to the maxillary sinus.

The implant body in the extra sinus technique preferably engages the lateral bone wall of the maxillary sinus while penetrating the zygomatic bone. This technique has advantage of eliminating bulky dental prosthesis at the palatal aspect due to palatal emergence of the implant head, encountered in other techniques. In extra sinus technique the ‘implant head’ emergence is at or near the top of the residual alveolar crest, usually in the second premolar or first molar region. This technique is of particular importance in patient with ‘pronounced buccal concavities’ where implant head emergence often creates prosthetic complications.

A proposed classification of system was given by Dr. Aparicio comprising of five basic skeletal forms of “zygomatic buttress – alveolar crest complex” and implant pathways, grouped from ZAGA 0 to ZAGA 4 (zygoma – anatomy guided approach). This classification helps the clinician to refine the original technique by understanding the possibility of finding out inter – individual and intra – individual anatomy differences.

Establishment of intra oral coronal entrance point at the maxillary alveolar process is the key factor for a successful outcome of ZAGA procedure.

Four patients in our study underwent extra sinus approach and we performed intra sinus approach in one patient. We used crestal incision and posterior releasing incision bilaterally posterior to maxillary tuberosity. The dissection proceeded with identification of the zygomatic buttress, zygomatic bone and infra orbital foramen superiorly. The identification of ‘fronto – zygomatic’ notch or ‘Incisura’ point was the key factor in the procedure.

Noble Biocare drill kit comprising of short and long drills with 2.9 mm twist drill, 3.5 mm pilot drill and 3.5 mm twist drill, in a motor – driven hand piece at 200 RPM were used in our study for sequential osteotomy

We followed a drilling orientation dictated by “proper path – of axis”, which was discussed by various authors like Edward B Sevetz the proper path of axis is the one that extends from first premolar region through the maxillary sinus to the midpoint of zygomatic buttress as described by Bedrossian et al.

The drill orientation to the proper – axis would lead to penetration into the infra temporal fossa, and orientation posterior to the proper – axis would result in potential penetration into the orbit. The bone – supported surgical template established a proper axis and eliminate the possibility of these potential complications in our study.

The apical exit of the zygomatic implant in our work was either anterior to the fronto – zygomatic notch or penetrating the fronto – zygomatic notch. We planned apical emergence of implant ≤ 1 mm in 4 of our cases and implant were left submerged in one patient.

Nobel Biocare zygomatic implants were available in two comfortable angulations 45° and zero degrees. Ti-unite Nobel Biocare implants are of superior biocompatibility with both threaded and smooth surfaces. We used 45° angulated implants for all the patients with either zero degrees or 17 degree angulated multi unit – abutment based on the planned emergence of the implant head.

Immediately after the implant placement in each patient, the primary implant stability was evaluated using ‘Resonance frequency analyzer’, ‘OSTELL’. The values of both right and left sided implants were recorded.

The mean intra – operative primary stability in our study was 68.8 ± 4.14 and 66.6 ± 5.17 for right and left sided implants which significantly indicated a good primary stability.

Immediate loading protocol involves placement of restoration within 48 hours of implant placement, can be applied only if sufficient primary stability is achieved.

We followed ‘immediate – loading protocol’ for each patient, straight and angulated multi unit abutments attached to the implants during surgery. ‘Interim prosthesis’ were loaded intra – operatively and later provisional prosthesis was replaced by a definite metal bar – reinforced prosthesis after 6 months.

Immediate – loading protocol has advantage of decreasing the treatment time and beneficial to the patients, eliminating ‘psychological trauma’ of edentulism, restoring an instant esthetic appearance and immediate function were possible.

Post – operatively orthopantomogram and paranasal sinus view were taken for each patients evaluating the zygomatic implant position and apical exit at fronto – zygomatic notch and position of conventional implant. Implant positions were satisfactory in all cases.

Patients were followed for a minimum of 12 months and were evaluated for the ‘survival rate’ for its supportive function and stable when tested individually.

We followed ‘Misch Protocol’ to evaluate the survival criteria, which are as follows
a)absence of pain, b) lack of excessive bone resorption, c)absence of excessive bleeding and
d)radiographic success.

As a highlight of our study we determined the ‘secondary stability’ at 12 months, it was recorded and compared with the primary stability.

The mean secondary stability was 71.4 ± 3.6 Hz and 71.0 ± 3.80 Hz for right and left zygomatic implant respectively, which indicated significant raise in the zygomatic implant stability establishing good osseointegration.

We evaluated maxillary sinus health at 12 months using computed tomogram – paranasal sinus view. Based o Lund – Mackay scoring, rhinosinusitis alteration were evaluated. There were no abnormalities in any of the patients, substantiating the benefit of ‘extra sinus’ approach but in one patient underwent intra sinus technique there was partial opacification in the CT paranasal view and nasal obstruction clinically but subsequently resolved within two weeks.

Through out our follow – up period of 12 months, there were no anticipated complications. Minor complication like bleeding on probing at 3 month post – operatively in 2

patients were corrected by 'biofilm control measures' like using high pressure water spray devices twice a day.

Nasal obstruction encountered in one patient, was resolved within two weeks.

In our follow – up appointments assessment of oral hygiene, soft tissue health (peri – implantitis), radiographic assessment of bone – implant interface, implant and prosthetic stability, screw loosening were considered.

The study on five patients with completely atrophic edentulous maxilla rehabilitated with Nobel Biocare Ti-unite zygomatic implants I combination with conventional implant sin anterior region, with immediately loading protocol and 12 months follow – up established a survival rate of 100%, with excellent secondary stability, at the end of one year. Extra sinus technique we used enhanced the prosthetic rehabilitation creating 'ideal emergence of implant head' on the alveolar crest, eliminating the bulky prosthesis, improving the patient comfort and subsequent maintenance of oral health.

The maxillary sinus health was excellent in all the patients with extra sinus technique. In intra sinus technique the initial complication resolved around two weeks.

Virtual planning of the surgical procedure and determination of implant dimension and angulations, use of 3D printing STL skeleton model of the individual patient enhanced the precise surgical outcome being more accurate, less time consuming, lower in surgical morbidity and high success rate.

SUMMARY AND CONCLUSION

The zygomatic implants have revolutionized the rehabilitation of completely edentulous atrophic posterior maxilla.

Zygomatic implants are 'graft less' solutions eliminating the need for bone grafting techniques and its associated donor site morbidity.

Success of zygomatic implants is due to the primary stability achieved from the compact zygoma. Recent advances with computer aided design and surgical planning helps for precise placement using zygoma implants.

Immediate loading protocol vastly improved oral health quality of life index (OHQOL), by eliminating the 'psychological trauma period' of edentulism as well as decreasing the treatment period,

Completely edentulous atrophic maxilla rehabilitated with immediate loaded zygomatic implants in combination with anterior conventional implants showed a survival rate of 100% in one year follow up in our current study. There were no major complications encountered during the follow up period.

To conclude our study, barring the cost of zygoma implants and prosthesis, zygomatic implants are viable rehabilitative option for edentulous atrophic maxilla. However since the sample size was small and follow up period was short, large randomized clinical trials and good Prosthodontic backup are needed to assess the long term clinical success of the zygomatic implants.

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ANNEXURE

PARTICIPANT INFORMATION SHEET

Title of the study: “EVALUATION OF SURVIVAL RATE OF ZYGOMATIC IMPLANT PLACED USING IMMEDIATE LOADING PROTOCOL IN ATROPHIC MAXILLA-A CLINICAL STUDY”

Investigator: Dr.S.JAYANANDHINI Guide: Prof. Dr. C. PRASAD, M.D.S.,

Name of the research institution: TAMILNADU GOVERNMENT DENTAL COLLEGE & HOSPITAL, CHENNAI-600003

Purpose of the study: To evaluate the survival rate of immediately loaded zygomatic implant based on the clinical criteria.

Procedures of the study that involves your participation is as follows:

- Intra oral /extra oral examination will be done. About one teaspoon of blood will be withdrawn for Blood investigations.ECG, Chest X-ray, pre operative CBCT, Axial CT, OPG will be taken
- Anesthetic assessment will be obtained
- Photographs with face recognizable will be taken along with intra oral views.
- Local anaesthesia, 0.5 ml of 2% Lignocaine hydrochloride will be injected in the arm as a test dose before the procedure.
- The entire procedure will be carried out under general anesthesia

- Stereo lithographic surgical template is secured to the edentulous maxilla with anchor pins. Crestal and apical osteotomy completed with 3.5 mm and (2.9 mm & 3.5mm) twist drills respectively with their corresponding drill guides and with chosen drill length(implant length) for the patient. Implant mount zygoma procedure used to guide the implant placement. Implant insertion torque of 35 to 45 NCm is confirmed. The surgical site will be sutured. Implants are loaded with fixed screw- retained acrylic resin implant denture within 48 hours.
- The I.V Antibiotics & Analgesics given in the post operative period are Cefataxime 1gm, Dexamethasone 8mg, Raniditine 50 mg, Metronidazole 500 mg, Diclofenac 75 mg given twice daily for 5 days. Dexamethasone dosage will be gradually tapered.
- You will be advised to take liquid /semisolid diet for 2 week and to take rest for 1week
- You will be advised to visit for check up on the 1 post operative day, 1st week, 1st month, 3rd, 6th and 12th month.
- Again one radiograph (OPG) will be taken post operatively to assess the Osseo-integration

Risk of participation:

- If you are allergic to local anesthesia then you will be treated with using adequate medical emergency procedures.
- You may be expected to have pain and swelling for a maximum of 4 days in the post operative period.
- There is a possibility of minimal Scar.
- If the surgical wound gets infected it will be managed by giving antibiotics and analgesics or if necessary the implants will be removed after 3 months.

Benefits:

You will be treated for your edentulous jaws and esthetics and functional efficiency will be restored.

1. Confidentiality:

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

2. Voluntary participation:

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

3. Compensation: NIL

INFORMED CONSENT FORM
“EVALUATION OF SURVIVAL RATE OF ZYGOMATIC IMPLANT PLACED USING IMMEDIATE LOADING PROTOCOL IN ATROPHIC MAXILLA-A CLINICAL STUDY”

Participant ID No:

“I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care.”

 Date

 Name of the participant Signature/thumb impression of
 the participant

[The literate witness selected by the participant must sign the informed consent form. The witness should not have any relationship with the research team; If the participant doesn't want to disclose his / her participation details to others, in view of respecting the wishes of the participant, he / she can be allowed to waive from the witness procedure (This is applicable to literate participant ONLY). This should be documented by the study staff by getting signature from the prospective participant]

“I have witnessed the accurate reading of the consent form to the potential participant and the individual has had opportunity to ask questions. I confirm that the individual has given consent freely”

 Date

 Name of the witness

 Signature of the witness

 Date

 Name of the
 interviewer

 Signature of the interviewer

PROFORMA FOR TREATMENT GROUP

Date : OP No.: S.No:
Name : Age : Sex:
Occupation : Income:
Address : Phone Number:

CHIEF COMPLAINTS AND DURATION:

HISTORY OF PRESENT ILLNESS:

PAST MEDICAL HISTORY:

PAST DENTAL HISTORY:

FAMILY HISTORY:

PERSONAL HISTORY:

- a) Oral Hygiene Practices :
- b) Habits :

GENERAL EXAMINATION

- a) Extra-Oral Examination

b) Examination of Lymph nodes

INTRA-ORAL EXAMINATION WITH CLINICAL FINDINGS:

Investigations:

1. Hematological Investigation :

2. Others :

Blood Pressure:

Pulse:

Respiratory Rate:

RADIOGRAPHIC EVALUATION:

Orthopantomogram (OPG)

Computed Tomography (CT)

PROVISIONAL DIAGNOSIS

PROGNOSIS

TREATMENT PLAN

FITNESS FOR TREATMENT

TREATMENT DONE

DATE:

PROCEDURE:

SIGNATURE:

SIGNATURE OF THE PROFESSOR

ஆராய்ச்சி பற்றிய தகவல் படிவம்

ஆராய்ச்சி மேற்கொள்பவர்
மரு.ச.ஜெயநந்தினி

வழிநடத்துபவர்
பேரா.மரு.சி.பிரசாத், எம்.டி.எஸ்

ஆராய்ச்சி நிறுவனத்தின் பெயர்:

தமிழ்நாடு அரசு பல் மருத்துவக் கல்லூரி மற்றும்
மருத்துவமனை, சென்னை.

ஆராய்ச்சியின் தலைப்பு

செயல்நிலை அடைந்த முற்றிலும் பல் உதிர்த் மேல்தாடையில் உடனடியாக ஏற்றப்படும் ஐகோமா இம்பிளான்ட்ஸ் உட்பொருத்திகளின் பிழைப்பு விகிதம் கண்டறியும் ஓர் ஆராய்ச்சி.

செய்முறை

கீழ்க்கண்ட ஆய்வுகள்/பரிசோதனைகள் உங்களுக்கு செய்யப்படும்.

- வாய் பரிசோதனை
 - உட்புறம்
 - வெளிப்புறம்
- வழக்கமான இரத்தப் பரிசோதனைக்கு இரண்டு தேக்கரண்டி அளவு இரத்தம் உங்கள் கையிலிருந்து எடுக்கப்படும்.
- அறுவை சிகிச்சைக்கு முன் ஒன்று மற்றும் அறுவை சிகிச்சைக்குப் பின் ஒன்று கதிர் படம் மற்றும் ஸ்கேன் எடுக்கப்படும். கதிர்படம் மற்றும் ஸ்கேன் எடுக்கும்போது பாதுகாப்பு முறைகள் பயன்படுத்தப்படும்.
- மயக்க மருந்து நிபுணரிடம் ஒப்புதல் பெறப்படும்
- புகைப்படம்: அறுவை சிகிச்சைக்கு முன்னர், அறுவை சிகிச்சையின் போது, அறுவை சிகிச்சைக்குப் பின்னர் எடுக்கப்படும்.
- ஒவ்வாமைகளை அடையாளம் கண்டறிய சோதனை மறப்பு ஊசி 0.2மி.லி. செலுத்தப்படும்.

ஆய்வு சிகிச்சை முறை

- ❖ மயக்க மருந்து செலுத்திய பின் அறுவை சிகிச்சை டெம்பிளேட் மேல் தாடையில் பொறுத்தப்படும். பின்பு துளைக்கும் கருவி உதவியுடன் ஐகோமா இம்பிளான்ட் உட்பொருத்திகள் மேல்தாடையில் பொருத்தப்பட்டு தையல் போடப்படும். பின்பு நிலையான திருகு கொண்டு பொறுத்தப்படும். அக்ரிலிக் பல் செட் உடனடியாக இம்பிளான்ட்ஸ் உட்பொருத்திகளில் ஏற்றப்படும்.
- ❖ கீழ் தாடையிலும் இம்பிளான்ட் கொண்டு பல் செட் பொருத்தப்படும்.
- ❖ அறுவை சிகிச்சைக்கு 2 முதல் 3 மணி நேரம் ஆகும்.

அறுவை சிகிச்சைக்குப் பின்னர்

அறுவை சிகிச்சை செய்த இடம் ஆறுவதற்கும் வலி குறைவதற்கும் மாத்திரைகள் கொடுக்கப்படும்.

அறுவை சிகிச்சை செய்த மறுநாள் மற்றும் 1, 3, 6, 12 மாதங்களுக்கு பிறகு மறு பரிசோதனை செய்யப்படும்.

பங்கேற்புதீனால் வரக்கூடிய பக்கவிளைவுகள்

- மறப்பு ஊசிக்கு ஒவ்வாமை ஏற்படலாம்.
- இந்த ஆய்வின்போது வலி, வீக்கம் மற்றும் நோய்தொற்று ஏற்பட வாய்ப்புகள் உள்ளது. மருந்து மருந்துகள் மூலம் சரிசெய்துகொள்ளலாம்.
- மேலும் 4 வாரங்களுக்கு மிருதுவான உணவு அருந்த வேண்டும் மற்றும் ஒரு வாரத்திற்கு முழு ஓய்வு எடுக்க வேண்டும்.
- நோயாளியின் இயல்பான வாழ்க்கை தற்காலிகமாக பாதிக்கப்படலாம்.
- நோயாளிகள் எடையை இழக்க நேரிடலாம்.

பங்கேற்புதீனால் விளையும் நன்மைகள்

மேல் மற்றும் கீழ் தாடையில் இம்பிளான்ட்ஸ் கொண்டு பல்செட்டுகள் பொறுத்தப்பட்டு அதன் செயல்திறன் மீட்டெடுக்கப்படும்.

இரகசிய காப்பு

உங்களைப் பற்றிய குறிப்புகள் பிறர் அறியா வண்ணம் ஆராய்ச்சி முடியும் வரை இரகசியமாக பாதுகாக்கப்படும். அதை வெளிப்படுத்தும் நேரங்களில் எந்த தனி அடையாளங்களும் வெளிப்பட வாய்ப்பு கிடையாது.

தன்னார்வ பங்கேற்பு

இந்த ஆராய்ச்சியில் பங்குபெறுவது தங்களின் தனிப்பட்ட முடிவு மற்றும் இந்த ஆராய்ச்சியில் இருந்து நீங்கள் எப்போது வேண்டுமானாலும் விலகிக்கொள்ளலாம். தங்களின் இந்த தீர் முடிவு உங்களுக்கோ அல்லது ஆராய்ச்சியாளருக்கோ எந்தவித பாதிப்பும் ஏற்படுத்தாது என்பதை தெரியப்படுத்துகிறோம்.

நோயாளியின் பெயர்

கையொப்பம்/ கைரேகை

ஆராய்ச்சி தொடர்புடைய தகவல்களுக்கு
மரு.சு.ஜெயநந்தினி
முதலாமாண்டு முதுநிலை மாணவர்,
வாய்முக அறுவை சிகிச்சைத் துறை,
தமிழ்நாடு அரசு பல் மருத்துவக் கல்லூரி
மருத்துவமனை, சென்னை-3.
செல்: 9489542620

பங்கேற்பாளரின் உரிமை தொடர்புடைய
தகவல்களுக்கு: மரு.பி.சரவணன்
தலைவர், நிறுவன நெறிமுறைகள் குழு,
தமிழ்நாடு அரசு பல் மருத்துவக் கல்லூரி
மற்றும் மருத்துவமனை, சென்னை-3.

ஆராய்ச்சி ஒப்புதல் படிவம்**ஆராய்ச்சியின் தலைப்பு**

செயல்நலிவு அடைந்த முற்றிலும் பல் உதீர்ந்த மேல்தாடையில் உடனடியாக ஏற்றப்படும் கைகோமா இம்பிளான்ட்ஸ் உட்பொருத்திகளின் பிழைப்பு விகிதம் கண்டறியும் ஓர் ஆராய்ச்சி.

பெயர் புறநோயாளி எண்
வயது/ பால் ஆராய்ச்சி சேர்க்கை எண்
முகவரி

தொலைபேசி

நான் வயது என்னுடைய சுய நினைவுடனும் மற்றும் முழு சுதந்திரத்துடனும் இந்த மருத்துவ ஆராய்ச்சியில் என்னை சேர்த்துக்கொள்ள ஒப்புதல் அளிக்கிறேன்.

கீழ்க்காணப்படும் நிபந்தனைகளுக்கு நான் சம்மதிக்கிறேன்.

நான் இந்த ஆராய்ச்சியின் நோக்கம் மற்றும் செயல்முறைகள் பற்றி முழுமையாக தெரிவிக்கப்பட்டுள்ளேன்.

என்னுடைய மேல் மற்றும் கீழ் தாடையில் அறுவை சிகிச்சை மூலம் இம்பிளான்ட்ஸ் பொறுத்தப்பட்டு பல் செட்டுகள் பொறுத்தப்படும் என்பது எனக்கு தெரிவிக்கப்பட்டது.

என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறான நோய்குறிகள் தென்பட்டாலோ அதற்கு சிகிச்சை பெற்றுக்கொள்வதற்கும் முழு உரிமை உள்ளதாக அறிகிறேன்.

நான் ஏற்கனவே உட்கொண்ட மற்றும் உட்கொள்கின்ற மருந்துகளின் விபரங்களை ஆராய்ச்சியாளரிடம் தெரிவித்துள்ளேன்.

என் மருத்துவ குறிப்பேடுகளை இந்த ஆராய்ச்சியில் பயன்படுத்திக்கொள்ள சம்மதிக்கிறேன். இந்த ஆராய்ச்சி மையமும் ஆராய்ச்சியாளரும் என்னுடைய விபரங்கள் அனைத்தையும் இரகசியமாக வைப்பதாக அறிகிறேன்.

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| நோயாளியின் பெயர் | கையொப்பம் | தேதி |
| ஆராய்ச்சியாளர் பெயர் | கையொப்பம் | தேதி |