

**AUGMENTATION OF ALVEOLAR BONE HEIGHT IN
PARTIALLY & COMPLETELY EDENTULOUS JAW
WITH DISTRACTION OSTEOGENESIS**

*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.**

2012 – 2015

CERTIFICATE

This is to certify that **Dr.K.MOHAMED FAROOK**, Post Graduate student (2012–2015) in the Department of Oral and maxillofacial Surgery, Tamil Nadu Government Dental College and Hospital, Chennai – 600 003 has done this dissertation titled **“AUGMENTATION OF ALVEOLAR BONE HEIGHT IN PARTIALLY & COMPLETELY EDENTULOUS JAW WITH DISTRACTION OSTEOGENESIS”** under my direct guidance and supervision in partial fulfillment of the regulations laid down by **The Tamil Nadu Dr. M.G.R. Medical University**, Chennai – 600 032 for **M.D.S., (Branch – III) Oral and Maxillofacial Surgery** degree examination.

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TITLE OF DISSERTATION	“Augmentation of alveolar bone height in partially & completely edentulous jaw with distraction osteogenesis”
PLACE OF STUDY	Tamil Nadu Government Dental College & Hospital, Chennai-600003.
DURATION OF THE COURSE	3 Years.
NAME OF THE GUIDE	Prof. Dr. B. Saravanan,MDS,Ph.D.,
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And

Dr.K.Mohamed Farook, aged 37 years currently studying as final year **Post Graduate student** in the Department of Oral and Maxillofacial surgery, Tamil Nadu Government Dental College and Hospital, Chennai -600 003 residing at Karaikudi, Sivagangai District. (here after referred to as the ‘PG student and co- investigator’)

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Date: 21.02.2014

Title of the work: "Augmentation of alveolar bone height in partially & completely edentulous jaw with distraction osteogenesis"

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The request for an approval from the Institutional Ethical Committee (IEC) considered on the IEC meeting held on **29.01.2014** at the Principal's Chambers Tamil Nadu Government Dental College and Hospital, Chennai – 3

"Advised to proceed with the study"

The Members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above , submitted by the principal investigator.

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ACKNOWLEDGEMENT

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ABSTRACT

INTRODUCTION AND AIM :

Alveolar distraction is a relatively novel procedure which utilizes the body's own growth mechanisms by which both the alveolar bone and underlying mucosa are regenerated simultaneously. The aim of this study is to evaluate the efficiency of the Distraction Osteogenesis in the vertical augmentation of the resorbed alveolar ridges in the anterior mandibular region of the partially and completely edentulous patients and to measure the formed bone regenerate in increasing the vertical alveolar bone height, obtained through the Alveolar Distraction Osteogenesis.

MATERIAL AND METHODS:

Five patients (3 men and 2 women) between 30 and 50 of age (mean 40 years) four completely edentulous and one partially edentulous presented with vertical alveolar ridge deficiency due to atrophy (n=4) and sequelae of oncological surgery (n=1) with atrophied partial / completely edentulous alveolar ridges referred to the Department of Oral & Maxillofacial surgery, Tamilnadu Government Dental College & Hospital, Chennai, were included in this prospective study.

DISTRACTION DEVICE (TRACK):

The vertical distraction was performed using Intra oral extra osseous distraction device. This device provides distraction length of 0.5 mm per 360⁰ revolution (pitch 0.5 mm). The distractors were made up of stainless steel, with a distracting capacity of 10 mm. Two miniplates with six holes (three on either side) of 1.5mm diameter were welded on to the sliding mechanism of distraction device. Alveolar Distraction Device consisted of 4 components namely ,threaded rod,transport plate,base plate and guide rod.

Fully informed consent was obtained from all patients prior to surgical treatment. Under local anesthesia a horizontal vestibular incision / crestal incision were used to expose the bone at the level of the planned horizontal osteotomy. Mucoperiosteal flap was elevated exposing the lateral cortex, preserving the lingual periosteum intact. Devices were fixed by drilling the bone using 701 fissure bur and 1.5 mm x 12 mm screws along the extreme ends of the plates for stabilising the device. Horizontal osteotomy was completed with 6 mm width osteotome and great efforts were taken to preserve the lingual mucoperiosteum.

Vertical osteotomy cut was completed in a slightly diverged fashion towards the alveolar crest and in converging direction buccolingually to avoid lingual tilting of the transport segment. Distraction devices were inserted and fixed with 1.5mm x 12 mm screws (12). Button hole was made exactly on the mucoperiosteum of the crestal attached gingival for the central rod of the activation arm to exit.

RESULTS

Distraction protocol was followed . The device was removed and the bone gain was compared and measured with OPG and CBCT. The mean bone height gain was 8.8 mm.

CONCLUSION

In conclusion, Distraction Osteogenesis is a versatile, valuable and safe method for the vertical augmentation of the alveolar ridges in the anterior mandibular region. However to ascertain and consolidate the efficacy of the surgical procedure a larger sample with a long term follow up is essential.

ABBREVIATION

DO	- Distraction Osteogenesis.
ARA	- Alveolar Ridge Augmentation.
LEAD	- Leibinger Endosseous Alveolar Distraction System. Stryker-Leibinger, Freiburg, Germany.
TRACK	- Tissue Regeneration Alveolar Callus distraction Ko'ln, Martin, Tuttlingen, Germany.
DISSIS	- Distraction Implant System; SIS, Klagenfurt, Austria.
3D	- Three Dimensional.
CBCT	- Cone Beam Computed Tomogram.
FEA	- Finite Element Analysis.
IAN	- Inferior Alveolar Nerve.
OPG	- Ortho Pantomogram.
ECG	- Electrocardiogram.
LFT	- Liver function test.
RFT	- Renal function test.
ICTC	- Integrated counseling and testing centre.
β-TCP	- β-tricalcium phosphate granules.
CPC	- Calcium phosphate cement powder.
TW	- Web form of titanium fibers.
VDO	- Vertical distraction osteogenesis.
ADO	- Alveolar distraction osteogenesis.
ABG	- Autogenous onlay bone grafting.
PRP	- Platelet rich plasma.

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Alveolar ridges are the columns of bone that surround and anchor the teeth and run the entire length, mesiodistally, of both the maxillary and mandibular dental arches. The alveolar bone is unique in that it exists for the sake of teeth it retains, when the teeth are absent, the bone slowly resorbs.

The vertical height of the alveolar ridge plays a pivotal role in maintaining the vertical dimension of the face which in turn maintains the facial aesthetics and masticatory efficiency. Reduced vertical height can be the result of congenital mal development, traumatic injury, surgical ablation, or generalised atrophy accompanying tooth loss or old age.

Augmentation of the vertical height benefits in providing sufficient retention to the prosthesis, stability in function and excellent esthetics. This may result in increased masticatory efficiency, prevents collapsing of the lower third of face, improves the quality of life with social security. The success of prosthodontic rehabilitation should be measured by the satisfactory restoration of function and esthetics. Atrophic mandibular alveolar ridge generally complicates prosthodontic restoration especially full denture.

Numerous techniques^{1-4,9,13-15} and methods has been developed to reconstruct the alveolar ridge defects and deformities. These includes autogenous bone grafts¹, implantation of alloplastic materials², guided bone regeneration.

Onlay bone grafting¹ can improve the height and width of the alveolar bone and can be used for both anterior and posterior defects. Autogenous and allogeneous bone grafts can be used for alveolar ridge augmentation. Autogenous bone grafting^{1,3,14} in any reconstructive procedure is considered the primary choice because of high success rates. However, harvesting of the graft requires a second surgical site, which could increase the level of post operative discomfort.

Allografts can be alternative to autogenous grafts. The advantages of allografts include ready availability, elimination of donor site morbidity, decreased anesthesia and surgical time, and decreased blood loss⁸. A potential disadvantage of the allografts is their quality, and the osseointegration of the graft material varies accordingly.

Guided bone regeneration involves the use of membrane to separate tissues during healing, retard apical migration of epithelium to the site, maintain the necessary space for bone growth (tenting) and protect the graft material in the defect. Each of these modalities has its own advantages and disadvantages.

Ilizarov⁶ demonstrated that “gradual traction on bone after corticotomy creates stress that can stimulate bone generation” termed Distraction Osteogenesis. Subsequently, the same principle of distraction osteogenesis has been applied to the cranio maxillo facial skeleton. The results of the distraction

osteogenesis observed implies that the distraction osteogenesis may be a viable alternative method to augment the vertical height of the atrophied alveolar ridges.

Alveolar distraction was first evaluated in an animal model^{6,40} and later the technique was expanded to increase the vertical height of the alveolar bone in human being. This technique when applied to alveolar ridge augmentation, provides the advantages of formation of required amount of bone volume, with simultaneous lengthening of the surrounding soft tissues and without any donor site morbidity.

The aim of this study is to vertically augment the atrophied completely and partially edentulous mandibular alveolar ridges in five patients reporting to the Department of Oral & Maxillofacial surgery, Tamilnadu Government Dental College & Hospital, Chennai, using the unique biological process named Distraction osteogenesis and to measure the quantum of the bone regenerate.

AIM

Alveolar distraction is a relatively novel procedure which utilizes the body's own growth mechanisms by which both the alveolar bone and underlying mucosa are regenerated simultaneously. The low predictability of other vertical or horizontal bone regeneration methods has increased interest in this promising technique.

The aim of this study is to evaluate the Distraction Osteogenesis procedure and its unique biological process in the reconstruction of the vertically deficient alveolar ridges in the anterior mandibular region of the partially and completely edentulous patients.

OBJECTIVES

1. To evaluate the efficiency of the Distraction Osteogenesis in the vertical augmentation of the resorbed alveolar ridges in the anterior mandibular region of the partially and completely edentulous patients.
2. To measure the formed bone regenerate in increasing the vertical alveolar bone height, obtained through the Alveolar Distraction Osteogenesis.
3. To estimate the advantages and disadvantages of Distraction Osteogenesis over the other conventional alveolar bone height regeneration techniques.

VARIOUS METHODS OF AUGMENTATION

Michael A. Pikos¹, (2005) reviewed the indications, limitations, presurgical evaluation, surgical protocol, and complications associated with mandibular block autografts harvested from the symphysis and ramus buccal shelf for alveolar ridge augmentation from 14 years of experience with more than 500 mandibular block autografts. He concluded that the overall morbidity of mandibular block autografts for alveolar ridge augmentation was minimal. He summarised that most of the complications were preventable, and those that occur can be handled predictably with minimal adverse effects to patients.

Hiroshi Masago² et al (2007) performed Alveolar Ridge Augmentation Using Various Bone Substitutes namely β -tricalcium phosphate (β -TCP) granules, calcium phosphate cement (CPC) powder and web form of titanium fibers (TW) by implanting them into an artificial hole of the rabbit maxilla with PRP, and assessed the histologic findings by light microscopy. They concluded that titanium fibers found to promote the rapid bone development within a period of less than 5 months, because TW had an appropriate gap between the titanium fibers for new bone progression.

Stoelinga PJ³ et al (1983) performed A reappraisal of the interposed bone graft augmentation of the atrophic mandible in which they followed 148 patients who had undergone an interposed bonegraft augmentation of the atrophic mandible. They discussed post-operative bone resorption. The high incidence of nerve disturbances as found in their study was regarded as unacceptable. The dissection of the mandibular nerve out of its canal (decompression) in order to avoid nerve

damage during the operation was not found to be of any advantage. They concluded that modified technique was recommended to circumvent this problem.

Cordaro et al⁴ (2002) studied the Clinical results of alveolar ridge augmentation with mandibular block bone grafts in partially edentulous patients prior to implant placement They concluded that from a clinical point of view their procedure was simple, safe and effective for treating localised alveolar ridge defects in partially edentulous patients.

Evolution of distraction osteogenesis

Codivilla A.⁵ (1905) advocated moderate traction applied through a pin in the calcaneus and using ferrule attached to a plaster to incrementally apply traction after an interval of a few days either without or with narcotics as appropriate. He noted the desired lengthening could be obtained in an average of 20 days. He concluded that the means of limb lengthening provided the very best results, correcting the deformity, and diminishing, or completely removing the shortness of the limb.

Ilizarov⁶ (1989) conducted a study to assess the influence of both the rate and the frequency of distraction on osteogenesis during limb elongation, a canine tibia was used with various combinations of distraction rates (0.5 mm, 1.0 mm, or 2.0 mm per day) and distraction frequencies (one step per day, four steps per day, 60 steps per day). He found that distraction at a rate of 0.5 mm per day often led to premature consolidation of the lengthening bone, while a distraction rate of 2.0

mm per day often resulted in undesirable changes within elongating tissues. A distraction rate of 1.0 mm per day led to the best results.

Snyder C et al (1973) gave the first report of experimental distraction of the craniofacial skeleton. They created a cross bite by removing 1.5 cm segment of canine mandible. They distracted the mandible back to its original length by using modified external fixator device.

Mc carthy, et al³⁹ (1992) They performed first human clinical trial for distraction osteogenesis to correct mandibular hypoplasia secondary to hemifacial microsomia and TMJ ankylosis with succceccful and predicted results.

Meyer V et al⁴⁰ (1994) erformed a study on 36 rabbits to evaluate the effect of magnitude and frequency of interfragmentary strain on the tissue response to DO. They concluded that the magnitude and not the frequency of the mechanical loading control the differentiation of the bone cells and subsequent formation of bone tissues.

Fisher E et al⁴¹ (1997) studied the effect of distraction on the associated muscles of mastication. Biopsy of muscle showed that the muscle affected by distraction in the same plane and vector adapts with compensatory regeneration and hypertrophy, while those in a different plane showed the evidence of atrophy with decreased protein synthesis.

TREATMENT MODALITIES:

Ole T.Jensen et al³⁴ (2008) studied alveolar modification by distraction osteogenesis to establish diagnostic and treatment planning criteria including presentation of a site classification to help establish treatment. They concluded that practitioners should treat to the conceptual ideal of orthoalveolar form and classify osseous defects in a team approach according to a surgical / prosthetic treatment planning protocol.

Chin M, Toth et al¹⁷ (1996) reviewed five cases of Distraction osteogenesis in maxillofacial surgery and reported the feasibility and potential advantages of using internal devices for distraction osteogenesis in the management of maxillofacial skeletal deficiencies. They concluded that the internal distraction devices have potential benefits of elimination of skin scarring caused by translation of transcutaneous fixation pins, improved patient compliance during the fixation or consolidation phase because there is no external component, and improved stability of the attachment of the device to the bone.

Matteo Chiapasco et al¹⁰ (2004) conducted a prospective multicenter study in thirty seven patients with the intra oral alveolar distractor to evaluate the use of vertical distraction osteogenesis in the correction of vertically deficient alveolar ridges and to evaluate the quality of the regenerated bone . They concluded that distaction osteogenesis is a reliable technique for the correction of the vertically deficient edentulous ridges and the ability of the regenerated bone to withstand the functional load appeared optimal.

Rachmiel A, et al⁸(2001) performed vertical alveolar distraction osteogenesis in Fourteen patients . An alveolar segmental osteotomy was carried out and the vertical distraction device was mounted. The distraction was started on the fourth postoperative day at a rate of 0.8 mm/day for 10–16 days, followed by a consolidation period of 60 days. Vertical distraction osteogenesis (VDO) was completed successfully in all patients with segment lengths in the range of 8 to 13 mm and with an average of 10.3 mm. Subsequently, the devices were removed and 23 threaded titanium dental implants were placed for osteointegration. Earlier mineralization in the vertically distracted area was seen. They concluded that the main advantages of VDO were augmentation of alveolar bone height with new bone formation and simultaneous expansion of the soft tissues, no need for bone harvesting ,the lower morbidity rate compared with conventional techniques and the feasibility of insertion of longer dental implants.

Garcia-García A, et al. (2003)¹¹ investigated the efficacy of alveolar distraction for reducing crown height:implant length ratio in the posterior mandible. they performed ten alveolar distractions in seven patients and they concluded that Alveolar distraction was effective for increasing the height of the alveolar ridge in the posterior mandibular region, and should be considered when the height of the predicted crown that is required was greater than or equal to the maximum height of bone available for implantation.

R. González-García, et al¹² (2011) investigated a modified technique to perform Alveolar split osteotomy for the treatment of the severe narrow ridge maxillary atrophy in the horizontal dimension. They evaluated thirty-three

dental implants in eight consecutive patients retrospectively and concluded that it provides an acceptable inter-cortical gap with decrease risk of necrosis of the outer cortex, and provides a firm-wall box for the placement of particulate bone grafting.

Nina Beatrice Lehrhaupt⁹ (2001) presented a case report describing the alveolar distraction osteogenesis and concluded that it is a relatively simple procedure with minimal risk and complications.

Katsuyuki Funaki et al¹³ (2009) Compared the horizontal alveolar ridge augmentation using distraction osteogenesis with the conventional bone-splitting method in a dog model. They observed sufficient bone augmentation and significant increase in the keratinised soft tissues compared with the conventional BS method. They concluded that the horizontal DO appears to be a useful augmentation technique for implant placement in a narrow alveolar ridge, because it increases both hard and soft tissues.

Ibrahim E. Zakhary, et al¹⁶(2012) . performed a status review to illustrate and compare different alveolar ridge augmentation procedures before dental implant placement. They concluded that although the ridge splitting and distraction osteogenesis techniques have advantages like no donor site morbidity, circumvention of the use of grafting materials, and reduced operation time, some disadvantages and limitations should be considered.

VECTOR CONTROL

Pushkar Mehra et al³⁷ (2008) presented their experience with some simple techniques that successfully provided proper vector control during internal ADO. They modified the vertical osteotomy cut converging towards lingually to avoid the lingual tilting. They used bone plate device, modified orthodontic mechanics and modified prosthetics in their study and concluded with the proper vector control mechanically.

Abel Garcia-Garcia et al²⁵ (2008) reported a simple modification of the LEAD System distractor to prevent tilting of the distractor rod during alveolar distraction in the mandibular symphyseal region. They modified by removing the thread in the terminal part of the distracting rod to allow it to sink into the drilled hole in the basal bone to prevent the lingual tilting. They concluded that this modification cannot be used in the more posterior regions due to the risk of damage to the inferior alveolar nerve

Hee-Kyun Oh et al³⁸ (2009) in their study discussed the measures to control and correct the vector of the malpositioned distracted segments in the immediate post distraction phase. They treated by removing the screw from the base plate and attaching a wire splint on the adjacent teeth during osseous consolidation as an anchorage to fix the malpositioned segment toward the desired direction. They observed a normal arch shape at the end of the traction application. They concluded that the described treatment strategy appeared to have good potential for providing an ideal final position of the lingually or palatally inclined bone segment.

D. Aizenbud. et al ²² (2011) proposed a combined surgical orthodontic protocol which included presurgical orthodontic preparation and a preimplantation surgical augmentation stage for insertion of a vertical distractor. During the active vertical alveolar distraction process TADs were inserted. Intraoral orthodontic elastics were attached to the main orthodontic archwire exerting multidirectional forces to control the vertical distraction vector. After 3 months of vector controlling and active bone moulding, they removed the TADs. Anterior alveolar ridge augmentation using distraction osteogenesis was achieved. They concluded that a combined surgical orthodontic management protocol involving vertical alveolar distraction osteogenesis for augmentation purposes was an efficient treatment method to improve alveolar ridge volume for the preimplantation.

RECENT CONCEPTS

Shakaki M . et al ³⁶ (2010) assessed compared the effect of a modified protocol of ADO namely compression stimulation or callus massage on the formation of bone with that of the conventional DO protocol. They concluded that the new protocol provided more stable callus, with dense new bone and decreased consolidation time needed.

Kye-Joon Yi . et al ¹⁸ (2009) conducted study to examine the effect of using a titanium nitride (TiN)-coated vertical distractor on osseointegration after implantation in four adult mongrel dogs. The lower premolars were extracted, and vertical distraction was performed after 10 weeks using 8 distraction devices .A 7-day latency period was allowed before distraction began. The distraction device

was activated at a rate of 0.5 mm twice a day for 5 days. After completing distraction, the device was removed after a consolidation period of 6 weeks and 24 implants were installed. They found the implant success rate was 100% in all of the study groups. They concluded that the nitrified distraction device does not negatively affect osseointegration in the vertical distraction osteogenesis; therefore, it has the advantageous potential to substitute for the conventional distractor.

T. Kanno, et al²¹(2007) Conducted study in thirty five patients to investigate the decrease in bone height after vertical alveolar DO and determine the need for overcorrection with implant placement. Alveolar ridge height was evaluated using digital orthopantomographic radiographs taken shortly after the end of distraction, at consolidation and before implant placement. The mean distraction was 9.7 mm. They concluded that any alveolar DO protocol should include a waiting period after the surgical intervention, as well as consider an overcorrection of more than 25% within the limits of the applied surgical protocol.

Seiji lida et al²⁰(2006) presented a procedure involving 2-stage alveolar distraction osteogenesis using eccentric distraction devices for the augmentation of the resorbed transplanted iliac bone following mandibular tumour resection. They followed consolidation period of 6 months between the two distractions and placed endosseous implants 4 months after the second distraction. Bone from both the distractions showed enough maturity for implantation. They concluded that 2-stage alveolar distraction osteogenesis can

be a useful and safe procedure for excessive alveolar lengthening if a sufficiently long consolidation period is allowed.

Sina Uckan et al³⁵ (2007) compared and evaluated intraosseous and extraosseous ADO in 21 patients with alveolar ridge deficiencies. They observed no statistically significant complication rates and implant success rates between the two methods. They concluded that the device should be selected according to the defect size, shape, patient tolerance, and distance to the opposing arch.

M.Chin, et al¹⁷ (2006) reviewed fifty patients who underwent vertical transport distraction osteogenesis with a modified protocol. The lateral osteotomy cuts were diverged apically and converged lingually to prevent the lingual tilting of the transport segment. They revised the position of the distraction segments before consolidation and treated the regeneration chamber with morphogenic protein (rhBMP-2). They concluded that application of the modified protocols resulted in the improved quality of distracted bone.

Jorge Cano, Julia'n Campo et al, (2006) pioneered the concept of Osteogenic alveolar distraction with the review of the literature to summarize the results of clinical and experimental studies on alveolar distraction and on distraction at other anatomical sites that contribute important findings on tissue biology, molecular mechanisms, and other factors that influence and participate in the alveolar distraction procedure. They concluded that alveolar distraction are hampered by the lack of clinical

and experimental studies to date. Greater knowledge of the factors that influence the distraction process may lead to a more predictable and efficacious distraction technique and a better distractor design.

PARAMETERS FOR ASSESSMENTS

C. U. Joss, et al ²⁴ Performed investigation to assess the neurosensory status and craniomandibular function of 19 patients treated by combined surgical orthodontic treatment with distraction osteogenesis of the mandibular anterior alveolar process was compared with that in 41 orthodontically treated patient. Neurosensory status was determined by two-point discrimination . There was no significant difference in craniomandibular function and neurosensory status between the group. They found that Gender, age, the amount of advancement, and relapse showed no correlation with craniomandibular function and neurosensory impairment and concluded that DO of the mandibular anterior alveolar process is a valuable and safe method with minor side effects regarding neurosensory impairment .

COMPLICATIONS

Garcia-Garcia A et al (2002). They monitored complications that arose during alveolar distraction osteogenesis in 5 patients who underwent a total of 7 distractions, in all cases using an intraosseous distractor .They observed complications, although many were minor and readily avoided by the use of appropriate techniques . The complications were, first, intraoperative complications, namely fracture of the transport segment, difficulties in finishing the osteotomy on the lingual side, and excessive length of the threaded rod.

Second, complications arose during distraction, namely incorrect direction of distraction, perforation of the mucosa by the transport segment, and suture dehiscence. Third, there were postdistraction complications, namely bone formation defects. They concluded that numerous complications may arise during alveolar distraction osteogenesis and most of these complications can be considered minor which were readily avoided or resolved by the use of appropriate procedures.

Sina Uckan, et al¹⁴. (2008) Conducted study to define the techniques and compare the complications and implant survival rates in localized alveolar deficiencies reconstructed by alveolar distraction osteogenesis (ADO) or autogenous onlay bone grafting (ABG). Thirty-six patients were treated with ADO or ABG harvested from the mandibular ramus. Twenty-four distractions in 22 patients (ADO group) and 18 ramus grafts in 14 patients (ABG group) were performed. Complications and implant survival rates were evaluated. They concluded that the complication rate was higher in the ADO group, but the complications were mainly minor, and management was easier in this group than in the ABG group.

Eppo B. Wolvius, et al²⁶ (2007) evaluated the Complications and relapse in alveolar distraction osteogenesis in twenty partially edentulous patients who underwent distraction osteogenesis by means of extraosseous distractor. The intraoperative and postoperative problems encountered by them were fracture and lingual and palatal displacement of the transport segment. The authors concluded that the DO seems to be a suitable treatment for vertically

deficient alveolar bone, but a relatively high although manageable complication rate must be confronted, including considerable relapse.

Saulacic N. Martin et al.²⁷ (2007) Carried out an investigation to evaluate the Complications in vertical alveolar distraction osteogenesis and to observe the effect of these complications on the final outcome in 23 patients who underwent a total of 29 distraction procedure .They used intraosseous and juxtaosseous distractors following the same distraction protocol. They reported complications during intraoperative phase, postoperative phase and , during distraction and consolidation phases. They observed that the frequency of complications were high but with less severity. Authors concluded that Distraction osteogenesis is a viable option for treating vertical alveolar bone defects.

R. Mazzonetto, et al ²⁸(2009) conducted retrospective study to analyze the potential complications during alveolar distraction osteogenesis in 55 patients. The existing bone deficiencies were secondary to atrophy after periodontal disease or tooth extraction. The overall success rate of this technique was 89.1%. On the basis of the obtained results,they concluded that alveolar distraction osteogenesis is an effective technique to treat vertical alveolar ridge deficiencies.

Faysal Ugurlu et al ²⁹ (2013) performed a retrospective study in 40 patients to analyse the outcome and to investigate the complications, precautions, and treatment associated with alveolar distraction osteogenesis. Complications associated with the intraoperative, postoperative, distraction, and consolidation

periods were recorded and evaluated. They recorded most of the complications in the anterior mandibular anterior region management of related complications crucial for increasing the success rate of ADO procedures.

Gaggl et al⁴² (1999) conducted a study in the alveolar ridge augmentation by distraction implants. They concluded that alveolar distraction with distraction implants is an adequate method of alveolar ridge augmentation resulting in an improved implant site and better gingival conditions and requiring only a single, small operative procedure.

George Enslidis et al³⁰, (2005) analysed the complications following alveolar distraction osteogenesis and implant placement in the partially edentulous mandible and they concluded that DO is not an un complicated procedure.

Nikola saulacic et al³¹ (2007) conducted this study to evaluate distraction osteogenesis for reconstruction of vertically deficient alveolar ridges and to investigate the occurrence of complications during treatment and the effect of these complications on the final outcome. They observed high frequency of complications but with less severity. Most of the complications had simple solutions, not jeopardizing the final outcome. They concluded that Distraction osteogenesis is a viable option for treating vertical alveolar bone defects.

Abel Garcia et al²⁵ (2002), evaluated the complications that arise during the mandibular ADO and suggested treatments. They concluded the study that

most of the encountered complications were minor that can be readily avoided or resolved by the use of appropriate procedures.

Tay fun Gunbay et al³² (2008) retrospectively analysed the outcome and complications of ADO for the correction of vertically deficient ridges by using intra and extra osseous distractors. They concluded that ADO is an effective means of restoring the vertical alveolar ridge deficiencies and the complications can be solved with simple treatments.

Manuel Somoza Martin et al³³ (2005) studied the necessity of over correction regarding the occurrence of bone height relapse at the end of consolidation period in the distracted bone. They concluded that the overcorrection should be included when performing alveolar distraction osteogenesis.

Ole T.Jensen et al³⁴ (2008) studied alveolar modification by DO to establish diagnostic and treatment planning criteria including presentation of a site classification to help establish treatment. He concluded that practitioners should treat to the conceptual ideal of orthoalveolar form and classify osseous defects in a team approach according to a surgical / prosthetic treatment planning protocol.

Tomoo Oda, et al¹⁹ (1999) ,Carried out an experimental study to augment Alveolar ridge by distraction osteogenesis using titanium implants. They concluded that simultaneous implant insertion and augmentation of bone is possible.

AGE CHANGES IN MANDIBLE

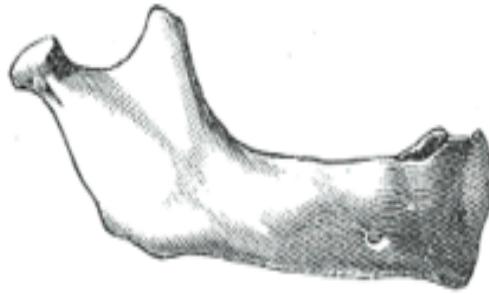


Fig. 1

At birth [Fig. 1] the body of the bone is a mere shell, containing the sockets of the two incisors, the canine, and the two deciduous molar teeth, imperfectly partitioned off from one another. The mandibular canal is of large size, and runs near the lower border of the bone; the mental foramen opens beneath the socket of the first deciduous molar tooth. The angle of the mandible is obtuse (175°), and the condyloid portion is nearly in line with the body. The coronoid process is of comparatively large size, and projects above the level of the condyle.

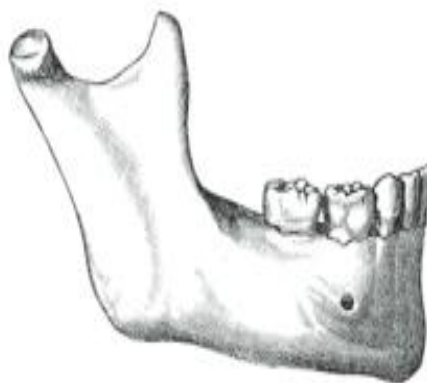


Fig. 2

After birth [Fig. 2] the two segments of the bone become joined at the symphysis, from below upward, in the first year but a trace of separation may be

visible in the beginning of the second year, near the alveolar margin. The body becomes elongated in its whole length, but more especially behind the mental foramen, to provide space for the three additional teeth developed in this part. The depth of the body increases owing to increased growth of the alveolar part, to afford room for the roots of the teeth, and by thickening of the sub dental portion which enables the jaw to withstand the powerful action of the masticatory muscles; but the alveolar portion is the deeper of the two, and, consequently, the chief part of the body lies above the oblique line. The mandibular canal, after the second dentition, is situated just above the level of the mylohyoid line; and the mental foramen occupies the position usual to it in the adult. The angle of the mandible becomes less obtuse, owing to the separation of the jaws by the teeth; about the fourth year it is 140° .

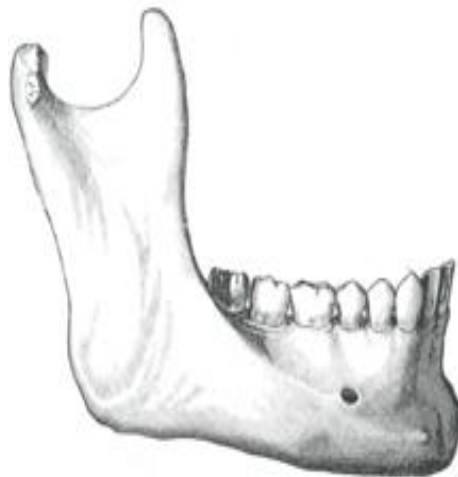


Fig. 3

In the adult [Fig. 3] the alveolar and sub dental portions of the body are usually of equal depth. The mental foramen opens midway between the upper and lower borders of the bone, and the mandibular canal runs nearly parallel with the

mylohyoid line. The ramus is almost vertical in direction, the angle measuring from 110° to 120° , also the adult condyle is higher than the coronoid process and the sigmoid notch becomes deeper.



Fig. 4

In old age [Fig. 4] the bone becomes greatly reduced in volume due to the loss of teeth and consequent resorption of the alveolar processes and interalveolar septa. Consequently, the chief part of the bone is below the oblique line. The mandibular canal, with the mental foramen opening from it, is closer to the alveolar border. The ramus is oblique in direction, the angle measures about 140° , and the neck of the condyle is more or less bent backward⁷.

RESIDUAL RIDGE FORM HAS BEEN DESCRIBED AND CLASSIFIED

BY CAWOOD AND HOWELL

- Class I—dentate
- Class II—post extraction
- Class III—convex ridge form, with adequate height and width of alveolar process
- Class IV—knife-edge form with adequate height but inadequate width of alveolar process.
- Class V—flat-ridge form with loss of alveolar process
- Class VI—loss of basal bone that may be extensive but follows no predictable pattern.

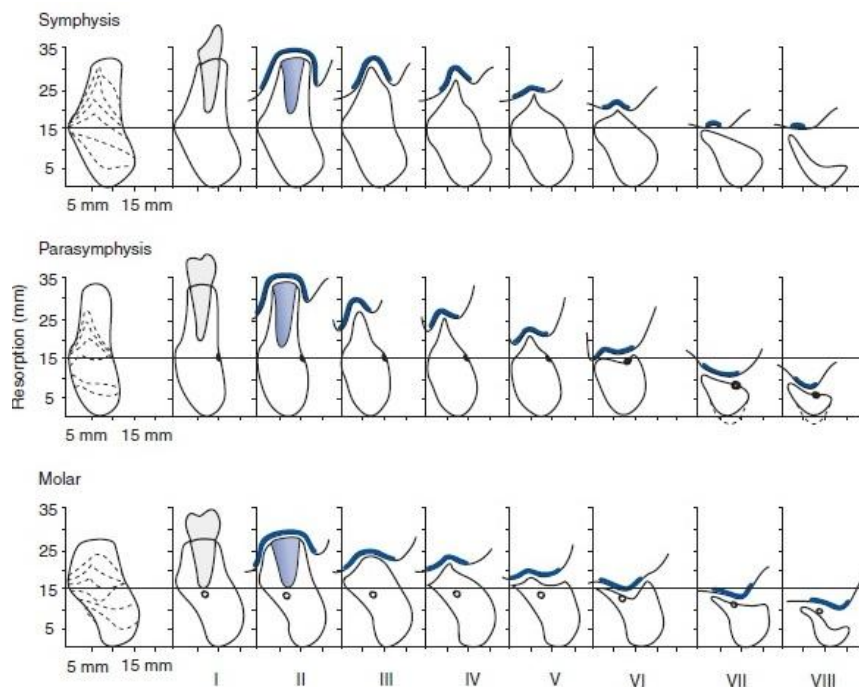


Fig. 5

Five patients with atrophied partial / completely edentulous alveolar ridges referred from the Department of prosthodontics for increasing the height of the alveolar ridges and subsequently for construction of dentures, reported to the Department of Oral & Maxillofacial surgery, Tamilnadu Government Dental College & Hospital, Chennai, were included in this prospective study.

Inclusion Criteria

1. Patients willing to give informed consent.
2. Patients of both sexes between 30 – 50 years of age.
3. Acquired alveolar defect.
4. Patients able to maintain meticulous oral hygiene.
5. Patient able to report daily during the distraction phase of this study.
6. Patients willing for follow-up of 6 months.

Exclusion Criteria

1. Edentulous ridge defects associated with a severely knife edged ridge.
2. Inadequate basal bone of less than 5mm.
3. Medically compromised conditions like severe renal and liver diseases.
4. Tobacco and Panchewers.
5. Uncontrolled diabetes.
6. Local factors like active periodontal disease affecting the residual teeth.
7. Poor oral hygiene.
8. History of radiotherapy and / or chemotherapy for malignant tumours in the head and neck region.
9. Non compliance of the patient.

Study Design

Five apparently health individuals (3 men and 2 women) between 30 and 50 of age (mean 40 years) four completely edentulous and one partially edentulous presented with vertical alveolar ridge deficiency due to atropy (n=4) and sequelae of oncological surgery (n=1) were selected for vertical augmentation of alveolar ridge deficiency by using unique process of Alveolar Distraction Osteogenesis.

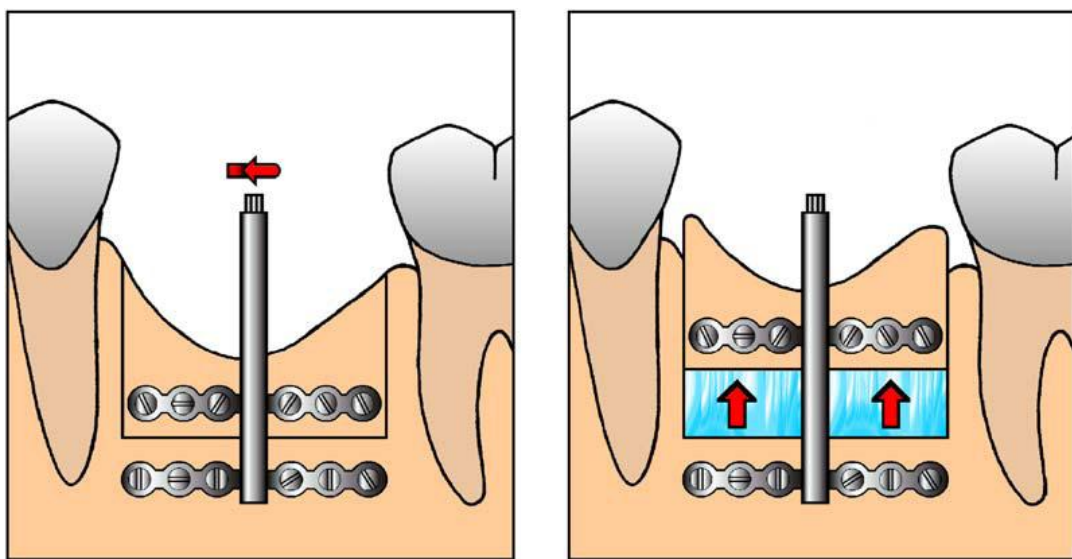


Fig. 6 - TRACK 1.0 DISTRACTOR²³

Table 1

Patient No.	Age	Diagnosis	Location	Vertical distraction performed	Follow-up	Complications
1.	34/M	Alveolar defect due to marginal mandibulectomy done for ameloblastoma.	41-35 region in partially edentulous mouth	10 mm	9 months	Device breakage on the 9 th day of active distraction period.
2.	39/F	Resorbed alveolar ridge due to atrophy.	Anterior mandibular defect –complete edentulous.	9.5 mm	7 months	No complications observed.
3.	45/M	Resorbed alveolar ridge due to atrophy.	Anterior mandibular defect –complete edentulous.	7.8 mm	7 months	Dehiscence and exposure of the device.
4.	46/F	Resorbed alveolar ridge due to atrophy.	Anterior mandibular defect –complete edentulous.	9 mm	6 months	No complications observed.
5.	43/M	Resorbed alveolar ridge due to atrophy.	Anterior mandibular defect –complete edentulous.	8 mm	4 months	No complications observed.

The surgery for augmentation (Distraction osteogenesis) of the alveolar bone height by using the “Intra Oral Distractor” was performed in the anterior mandibular edentulous regions for the selected five patients under local anesthesia in an aseptic atmosphere with meticulous care and concern during intra operative, post operative phases.

Distraction device

The vertical distraction was performed using Intra oral extra osseous distraction device. This device provides distraction length of 0.5 mm per 360⁰ revolution (pitch 0.5 mm). The distractors were made up of stainless steel, with a distracting capacity of 10 mm. Two miniplates with six holes (three on either side) of 1.5mm diameter were welded on to the sliding mechanism of distraction device.

Alveolar Distraction Device²³ consisted of 4 components namely

- a) Threaded rod
- b) Transport plate
- c) Base plate
- d) Guide rod

All the five patients who underwent distraction osteogenesis for vertically increasing the atrophied alveolar bone height were evaluated clinically and radiologically. Detailed medical and dental history, including the intra oral and extra oral clinical examination were carried out.

Clinical examination included.

1. Checking the mucosa for signs and inflammations, flabby tissue etc
2. Mandibular tori
3. Sharp bony edges
4. Evaluation of the adjacent teeth

Pre operative photograph and Study models were taken.

Radiological investigation included OPG and CBCT to evaluate.

- 1) The presence of remaining roots or any pathological lesions.
- 2) The height of the residual alveolar segment to the augmented.

Radiographic documentation was carried out immediately after the application of the device, during the activation phase, at the end of the activation, at the end of the consolidation phase and after removal of device.

Surgical procedure

Fully informed consent was obtained from all patients prior to surgical treatment. All the patients were subjected for oral prophylaxis before the surgical procedure.

Under local anesthesia a horizontal vestibular incision / crestal incision were used to expose the bone at the level of the planned horizontal osteotomy. Mucoperiosteal flap was elevated exposing the lateral cortex, preserving the lingual periosteum intact, thereby preserving the blood supply via periosteum. Mental nerves were identified and preserved with great care. The anatomic plane

joining the soft tissue was kept intact to the maximum to get optimal response by allowing efficient transfer of energy from the device to the transport segment.

Distraction devices were contoured and placed over the bone in the pre determined distraction vector using bending pliers. Vector was chosen based on the desired direction of distraction, final bone segment position and avoidance of occlusal interference. Devices were fixed by drilling the bone using 701 fissure bur and 1.5 mm screws along the extreme ends of the plates for stabilising the device.

Horizontal osteotomy sites were marked in between two plates using 701 bur so that the transport segment is ≥ 7 mm from the crestal region. Vertical cuts were marked 5mm mesial to the mental foraminae¹⁷ and the devices were removed. Horizontal osteotomy was completed with 6 mm width osteotome and great efforts were taken to preserve the lingual mucoperiosteum.

Vertical osteotomy cut was completed in a slightly diverged fashion towards the alveolar crest and in converging direction buccolingually to avoid lingual tilting of the transport segment³⁷. Distraction devices were inserted and fixed with 1.5mm screws(12). Button hole was made exactly on the mucoperiosteum of the crestal attached gingival for the central rod of the activation arm to exit.

The device was activated to check the free movement of the transport segment in the desired direction. The device was then deactivated to its initial

position. The surgical wound was copiously irrigated and closed primary by suturing with 000 vicryl in layers carefully to maintain the distraction space needed for bone generation.

At the completion of the operative procedure, the distractor protrudes through the oral mucosa into the mouth only a few millimeters, thereby minimizing discomfort to the patient. Radiographic studies were performed immediately after device placement and after completion of distraction. During the early postoperative period, Short-term antibiotics (broad-spectrum amoxicillin) and analgesics were administered for 2 to 4 days. Post operative instructions were focused on soft diet and oral hygiene.

FOLLOWUP AND OBSERVATION

Distraction protocol ^{6,10}

All the patients were evaluated one day prior to the surgery and followed up at first post operative day, 1 week, continuously during the second week for activation, at one month for device removal, three months and six months intervals for evaluation of the bone regenerate.

After a waiting period (**latency phase**) of 5 days of closure of the surgical wound, the sutures were removed and the distraction device were activated using special driver. A distraction of 1 mm per day was performed until the desired amount of distraction (7-9 mm) were obtained (**distraction phase**). The performance of the distraction was recorded in a tabular column for further evaluation. The distraction process was almost painless, requiring no analgesics.

On completion of distraction procedure, the distractor was then maintained in position for two months, (**consolidation phase**) during which the bone regenerate formed between the basal bone and distracted segment mature. After consolidation period the distraction device was removed under local anaesthesia.

EVALUATION

Vertical bone gain (augmentation) by distraction osteogenesis was evaluated clinically by summing the number of rotations performed with the activating device (every complete rotation was equal to 0.5mm). Clinically the distance in millimeter between the upper and lower mini plates of the distractor was measured (at the time of removal) before removing the distractor. Radiologically the distance (vertical augmentation) was measured with a transparent ruler on panoramic radiographs taken at the end of the distraction procedure ³⁶. Measurements were made at the beginning and at the end of the distraction. The possibility of surgical sequelae were evaluated during the distraction period.



Fig. 7 - TRACK DISTRACTOR KIT



Fig. 8 - ARMAMENTARIUM

CASE SHEET NO 1

AUGMENTATION OF ALVEOLAR RIDGES OF THE
PARTIALLY/COMPLETELY EDENTULOUS ANTERIOR MANDIBULAR
REGION BY DISTRACTION OSTEOGENESIS

PATIENT'S NAME : Mr. Vedhagiri_____

AGE/ SEX : 39/M_____

PATIENT'S

IDENTIFICATION NO : _____31324_____

CONTACT ADDRESS : _____

CONTACT No : _____

INSTITUTION : TN Govt. Dental College & Hospital,
Chennai - 600 003.

CENTRE : Dept. of Oral & Maxillofacial Surgery,
TN. Govt. Dental College and Hospital,
Chennai - 600 003

CHIEF COMPLAINT:

Partially edentulous jaw, reported to the Department of prosthodontics for complete denture, referred from the Department of prosthodontics for increasing the vertical height of the alveolar bone in the lower jaw.

HISTORY OF THE PRESENTING ILLNESS: Nil

CLINICAL FINDINGS:

Extra Oral :

Condylar movements - palpable

Mouth opening - normal

Intra oral :

Mucosa - normal texture & colour

Any other abnormality - Nil

Partially edentulous - Missing 31,32,33,34

INVESTIGATION Routine blood investigation,ICTC,ChestX ray,
ECG, RFT, LFT, Blood group, Digital OPG ,CBCT.

DIAGNOSIS Deficient alveolar bone height in the lower jaw 31-34region

.

TREATMENT Alveolar ridge augmentation.

Procedure followed : Alveolar Distraction Osteogenesis

FOLLOW UP

1. Distraction Protocol
2. 6 Months Follow up

NAME OF THE INVESTIGATOR :

SIGNATURE OF INVESTIGATOR :

CASE SHEET 2

**AUGMENTATION OF ALVEOLAR RIDGES OF THE
PARTIALLY/COMPLETELY EDENTULOUS ANTERIOR
MANDIBULAR REGION BY DISTRACTION OSTEOGENESIS**

PATIENT'S NAME : Mrs.Anandammal_____

AGE/ SEX : 39/F_____

PATIENT'S

IDENTIFICATION NO : 3212_____

CONTACT ADDRESS : _____

CONTACT No : _____

INSTITUTION : TN Govt. Dental College & Hospital,
Chennai - 600 003.

CENTRE : Dept. of Oral & Maxillofacial Surgery,
TN. Govt. Dental College and Hospital,
Chennai - 600 003.

CHIEF COMPLAINT: edentulous jaw, reported to the Department of prosthodontics for complete denture, referred from the Department of prosthodontics for increasing the vertical height of the alveolar bone in the lower jaw.

HISTORY OF THE PRESENTING ILLNESS: Nil

CLINICAL FINDINGS: **Extra Oral :**

Condylar movements - palpable

Mouth opening - normal

Intra oral :

Mucosa - normal texture & colour

Any other abnormality - Nil

Completely edentulous

INVESTIGATIONS: Routine blood investigation, ICTC, Chest X ray, ECG,
RFT, LFT, Blood group, Digital OPG ,CBCT .

DIAGNOSIS ; Deficient alveolar ridge completely edentulous mandible

TREATMENT : Alveolar ridge augmentation.

Procedure followed : Alveolar Distraction Osteogenesis.

FOLLOW UP

1. Distraction Protocol
2. 6 Months Follow up

NAME OF THE INVESTIGATOR :

SIGNATURE OF INVESTIGATOR :

CASE SHEET 3

**AUGMENTATION OF ALVEOLAR RIDGES OF THE
PARTIALLY/COMPLETELY EDENTULOUS ANTERIOR
MANDIBULAR REGION BY DISTRACTION OSTEOGENESIS**

PATIENT'S NAME : Mr.Selvam V _____
AGE/ SEX : 45/M _____
PATIENT'S
IDENTIFICATION NO : 32567 _____
CONTACT ADDRESS : _____

CONTACT No : _____
INSTITUTION : TN Govt. Dental College & Hospital,
Chennai - 600 003.

CENTRE : .Dept. of Oral & Maxillofacial Surgery,
TN. Govt. Dental College and Hospital,
Chennai - 600 003

CHIEF COMPLAINT:

Edentulous jaw, reported to the Department of prosthodontics for complete denture, referred from the Department of prosthodontics for increasing the vertical height of the alveolar bone in the lower jaw.

HISTORY OF THE PRESENTING ILLNESS: NIL

CLINICAL FINDINGS:

Extra Oral :

Condylar movements - palpable
Mouth opening - normal

Intra oral :

Mucosa - normal texture & colour
Any other abnormality - nil
Completely edentulous

INVESTIGATIONS: Routine blood investigation, ICTC, Chest X ray, ECG,
RFT, LFT, Blood group, Digital OPG ,CBCT.

DIAGNOSIS : Deficient alveolar ridge completely edentulous
mandible.

TREATMENT : Alveolar ridge augmentation.

Procedure followed : Alveolar Distraction Osteogenesis.

FOLLOW UP

1. Distraction Protocol
2. 6 Months Follow up

NAME OF THE INVESTIGATOR :

SIGNATURE OF INVESTIGATOR :

CASE SHEET 4

**AUGMENTATION OF ALVEOLAR RIDGES OF THE
PARTIALLY/COMPLETELY EDENTULOUS ANTERIOR
MANDIBULAR REGION BY DISTRACTION OSTEOGENESIS**

PATIENT'S NAME : Mrs.Balkis _____
AGE/ SEX : 46/f _____
PATIENT'S
IDENTIFICATION NO : 33674 _____
CONTACT ADDRESS : _____

CONTACT No : _____
INSTITUTION : TN Govt. Dental College & Hospital,
Chennai - 600 003.
CENTRE : .Dept. of Oral & Maxillofacial Surgery,
TN. Govt. Dental College and Hospital,
Chennai - 600 003

CHIEF COMPLAINT

Edentulous jaw, reported to the Department of prosthodontics for complete denture, referred from the Department of prosthodontics for increasing the vertical height of the alveolar bone in the lower jaw.

HISTORY OF THE PRESENTING ILLNESS: nil

CLINICAL FINDINGS:

Extra Oral :

Condylar movements - palpable
Mouth opening - normal

Intra oral :

Mucosa - normal texture & colour
Any other abnormality - nil
Completely edentulous

INVESTIGATIONS: Routine blood investigation, ICTC, Chest X ray, ECG,
RFT, LFT, Blood group, Digital OPG ,CBCT.

DIAGNOSIS : Deficient alveolar ridge completely edentulous mandible

TREATMENT Alveolar ridge augmentation:
Procedure followed : Alveolar Distraction Osteogenesis

FOLLOW UP

1. Distraction Protocol
2. 6 Months Follow up

NAME OF THE INVESTIGATOR :

SIGNATURE OF INVESTIGATOR :

CASE SHEET 5

**AUGMENTATION OF ALVEOLAR RIDGES OF THE
PARTIALLY/COMPLETELY EDENTULOUS ANTERIOR
MANDIBULAR REGION BY DISTRACTION OSTEOGENESIS**

PATIENT'S NAME : Mr.selvam G_____

AGE/ SEX : 43/M_____

PATIENT'S

IDENTIFICATION NO : 34216_____

CONTACT ADDRESS : _____

CONTACT No : _____

INSTITUTION : TN Govt. Dental College & Hospital,
Chennai - 600 003.

CENTRE : Dept. of Oral & Maxillofacial Surgery,
TN. Govt. Dental College and Hospital,
Chennai - 600 003

CHIEF COMPLAINT:

Edentulous jaw, reported to the Department of prosthodontics for complete denture, referred from the Department of prosthodontics for increasing the vertical height of the alveolar bone in the lower jaw.

HISTORY OF THE PRESENTING ILLNESS: NIL

CLINICAL FINDINGS:

Extra Oral :

Condylar movements - palpable

Mouth opening - normal

Intra oral :

Mucosa - normal texture & colour

Any other abnormality - nil

Completely edentulous

INVESTIGATIONS: Routine blood investigation, ICTC, Chest X ray, ECG,
RFT, LFT, Blood group, Digital OPG ,CBCT.

DIAGNOSIS : Deficient alveolar ridge completely edentulous mandible.

TREATMENT : Alveolar ridge augmentation.

Procedure followed : Alveolar Distraction Osteogenesis.

FOLLOW UP

1. Distraction Protocol
2. 6 Months Follow up

NAME OF THE INVESTIGATOR :

SIGNATURE OF INVESTIGATOR :

Case - 1

Pre Op Photo

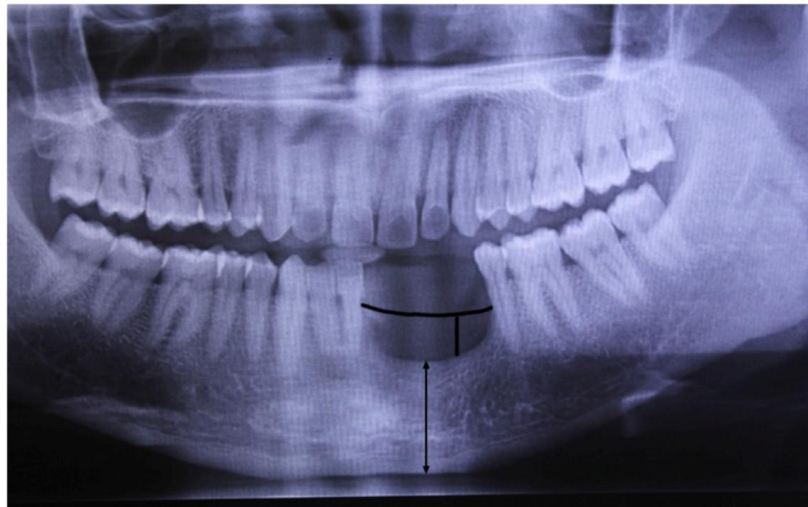
Frontal View



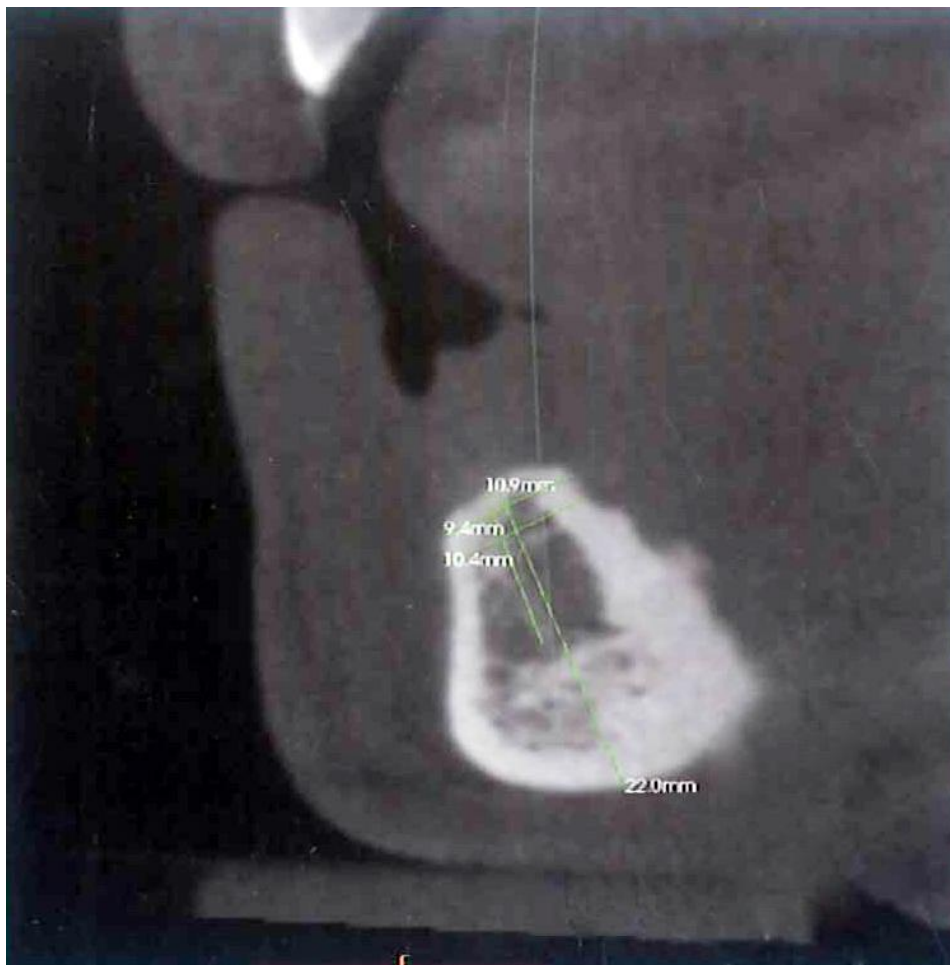
Intra Oral View



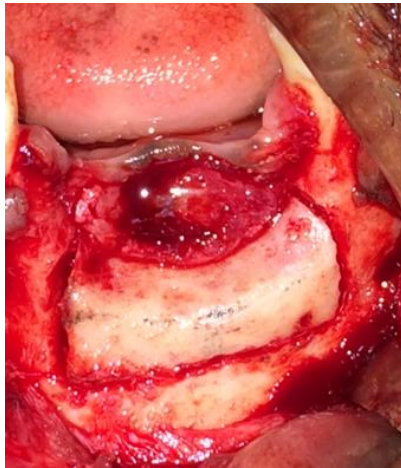
Pre- Op OPG



Pre op CBCT



Osteotomy cut



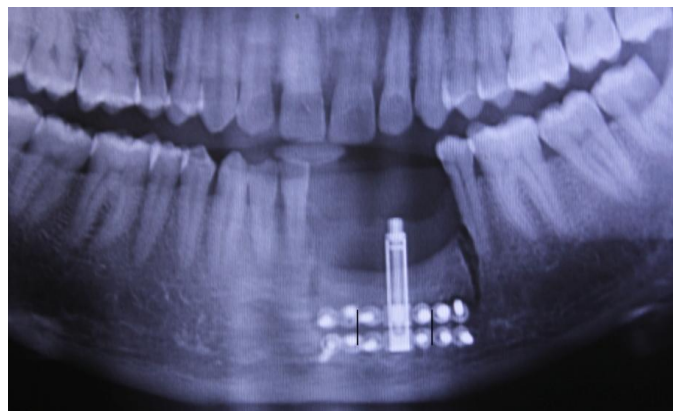
Device fixed



At the latency Intra Oral view



OPG



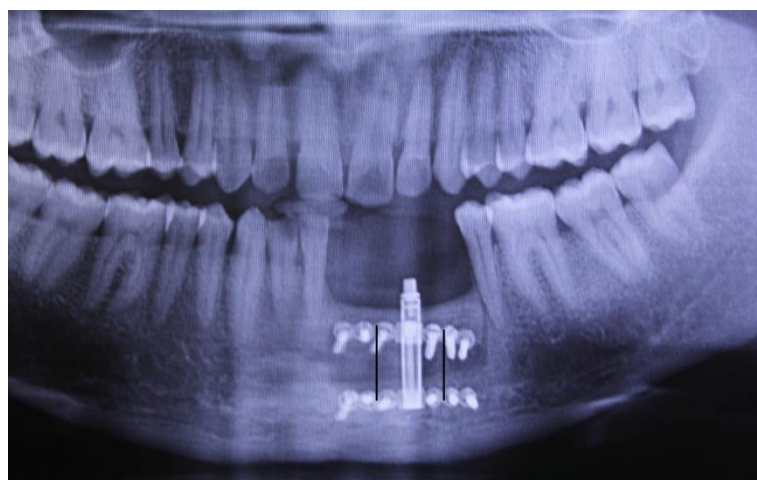
Completion of distraction Intra Oral view



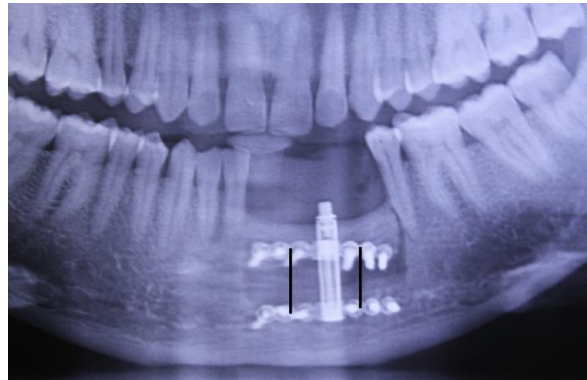
Completion of consolidation Intra Oral view



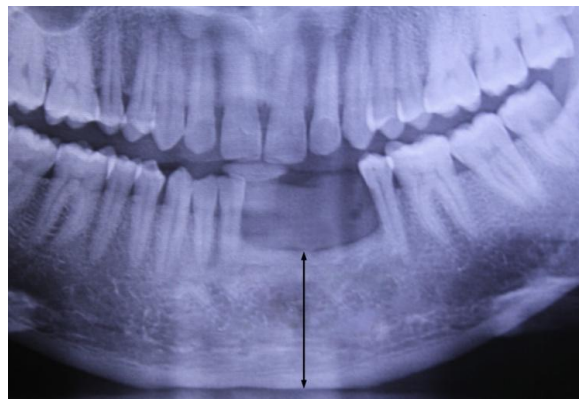
Completion of distraction OPG



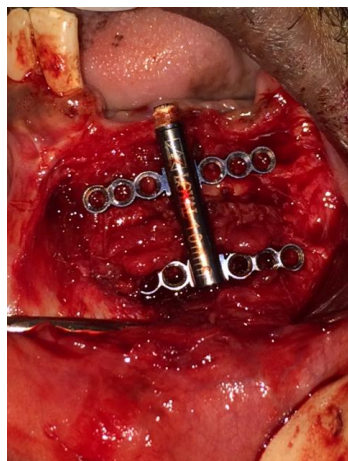
Completion of consolidation OPG



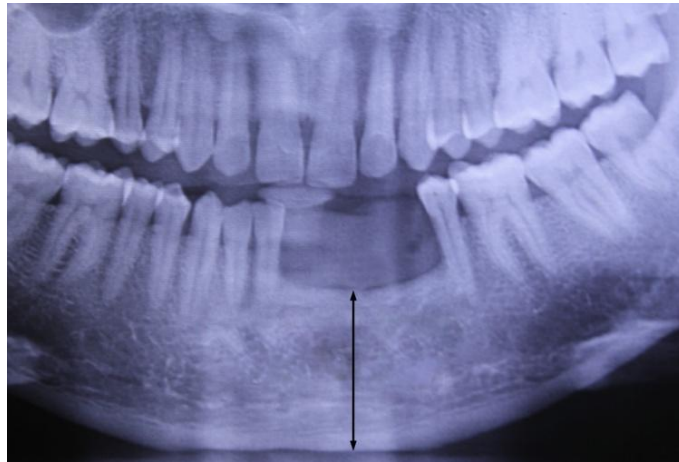
Device Removal OPG



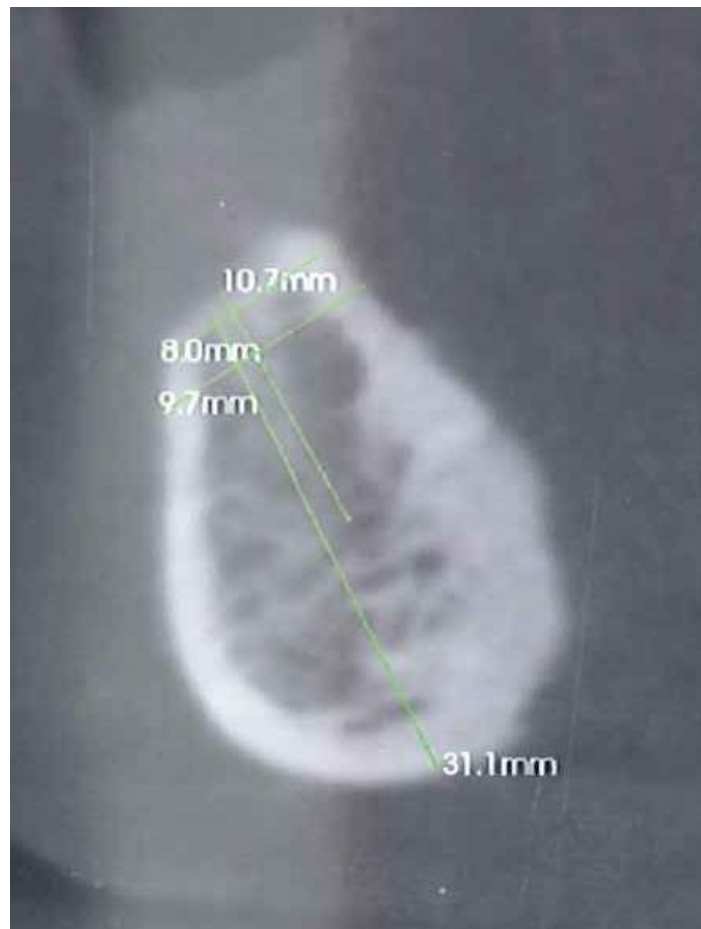
Device Removal



OPG 6 Months



CBCT 6 Months



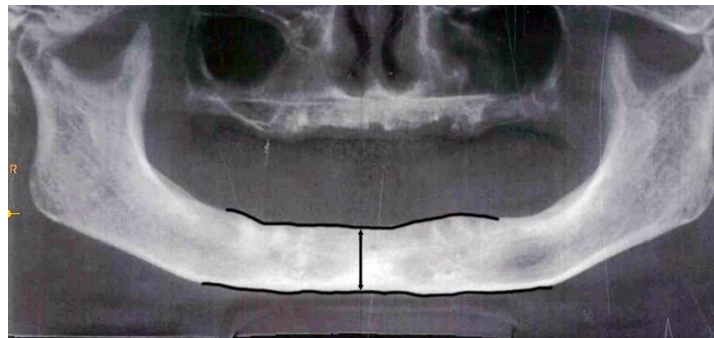
Case - 2

Pre Op Photo

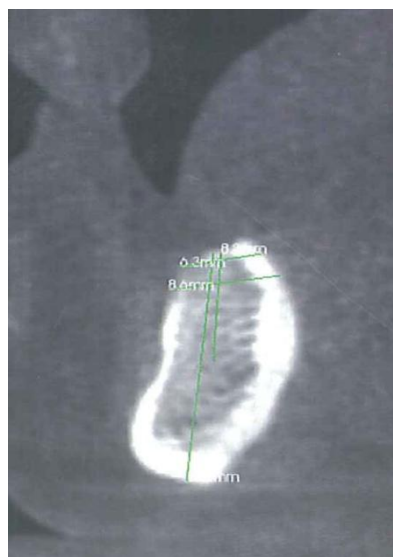
Intra Oral View



Pre- Op OPG



Pre op CBCT



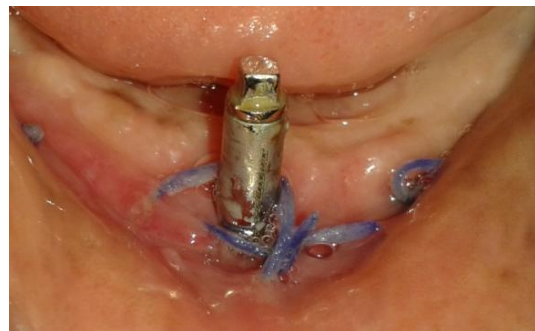
Osteotomy cut



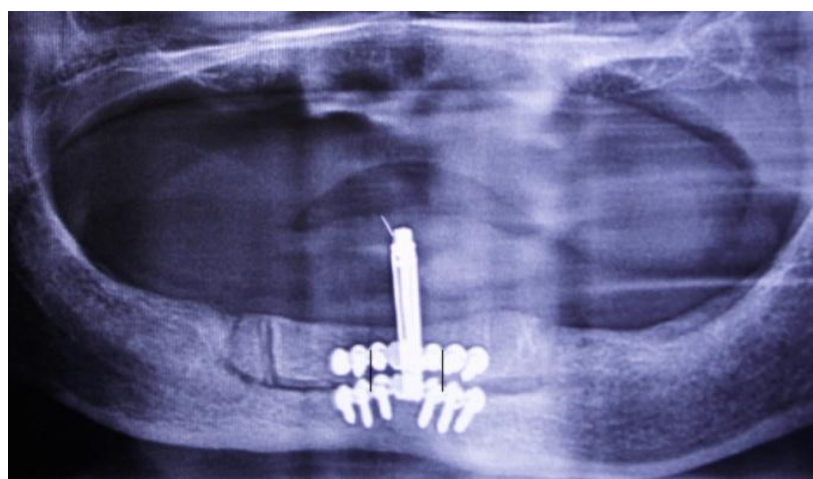
Device Fixed



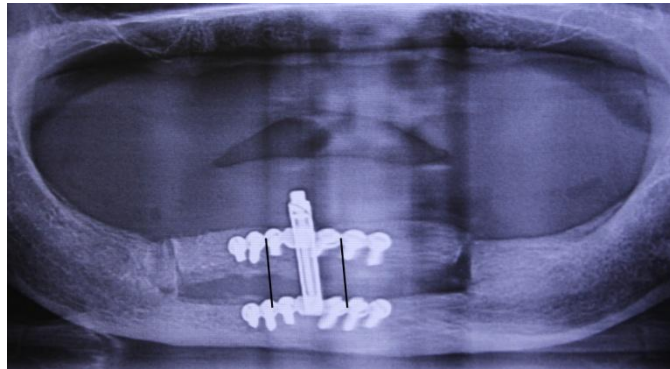
At the latency Intra Oral



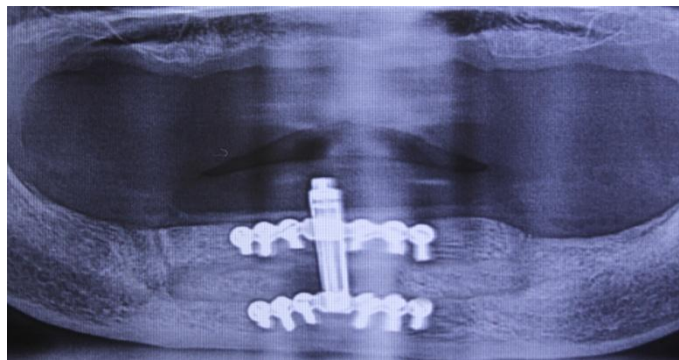
At the latency OPG



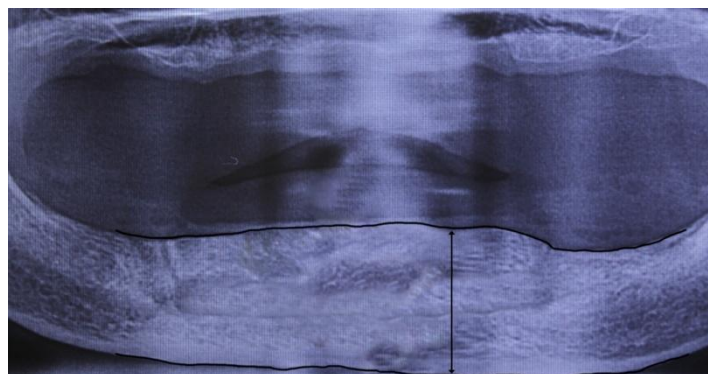
Completion of distraction OPG



Completion of consolidation OPG



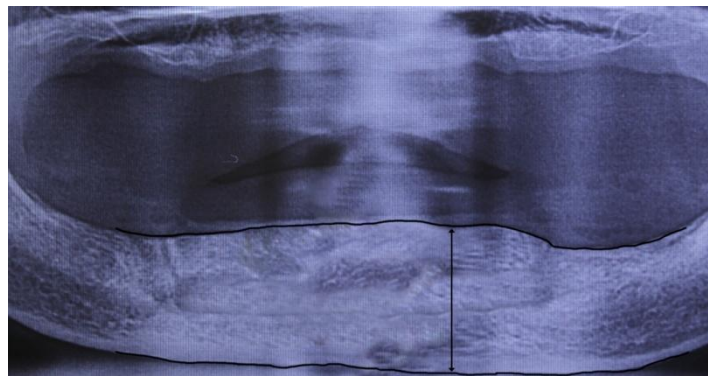
Device Removal OPG



Device Removal Intra Oral



OPG 6 Months



Post Op CBCT 6 Months



Case - 3

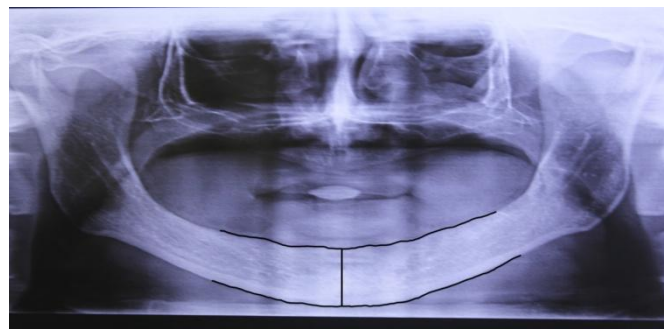
Frontal View



Intra Oral View



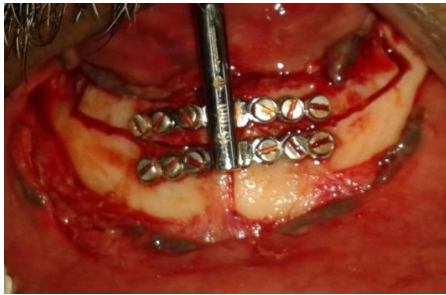
Pre- Op OPG



Pre op CBCT



Osteotomy cut with device fixed



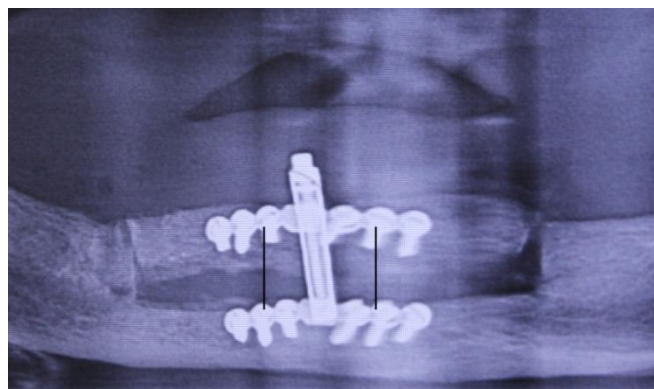
At the latency Intra Oral



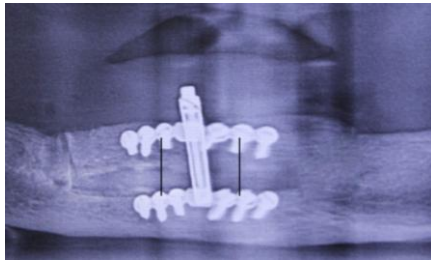
Completion of distraction Intra Oral (Dehiscence and plate exposure)



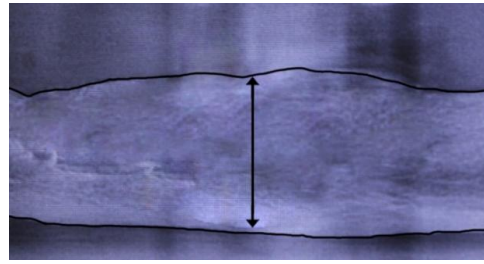
Completion of distraction OPG



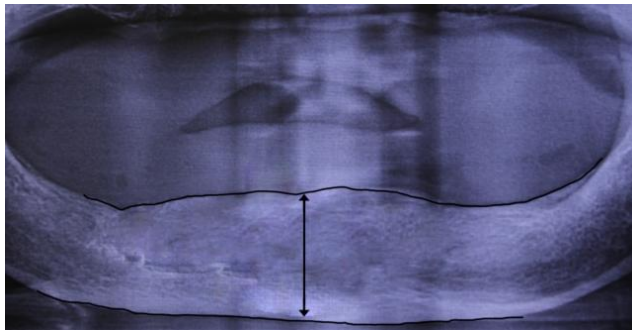
Completion of consolidation



OPG Device Removal OPG



OPG 6 Months

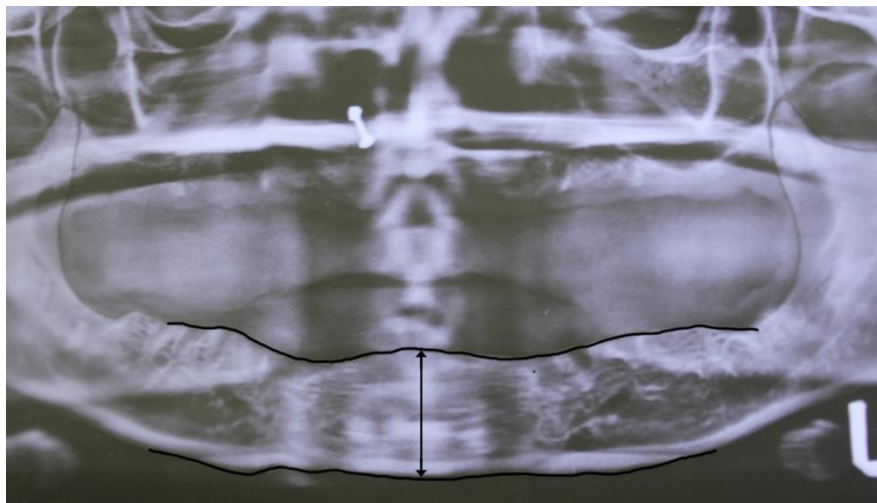


CBCT 6 Months



Case - 4

Pre- Op OPG



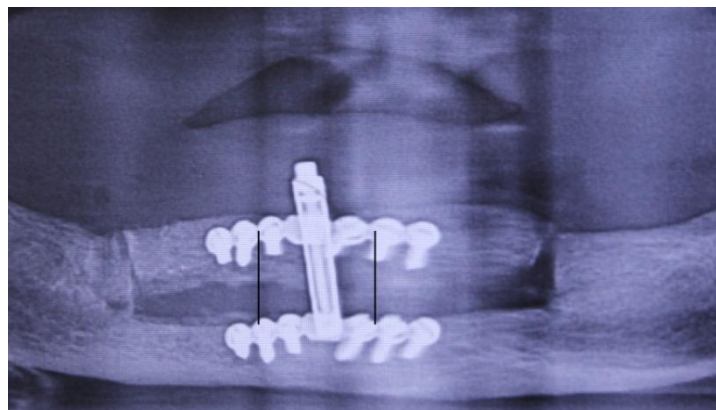
Pre op CBCT



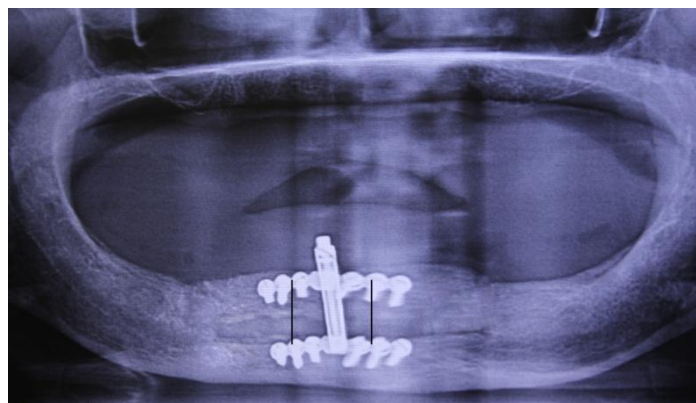
Osteotomy cut with device fixed



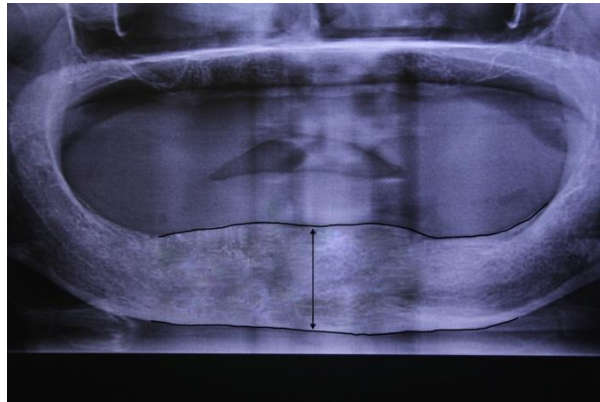
Completion of distraction OPG



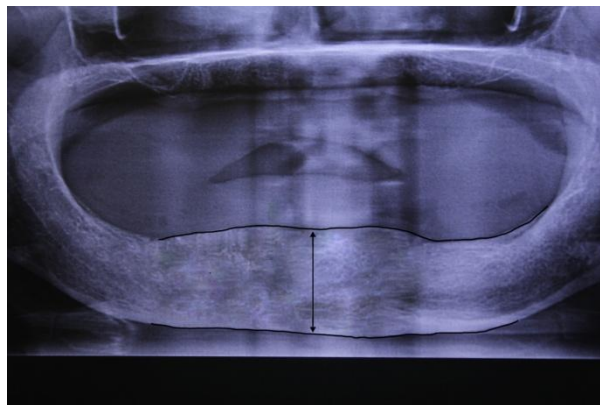
Completion of consolidation OPG



Device Removal OPG



OPG 6 Months

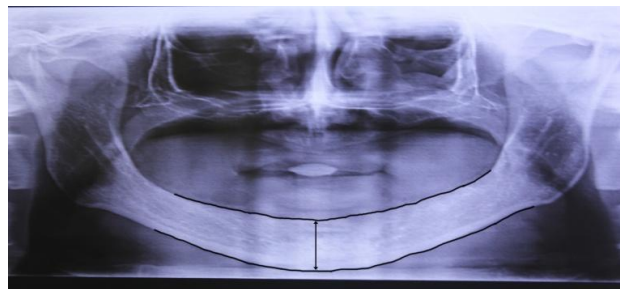


CBCT 6 Months



Case - 5

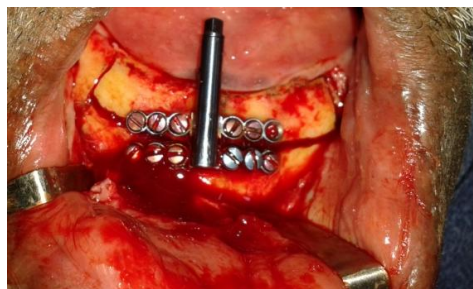
Pre- Op OPG



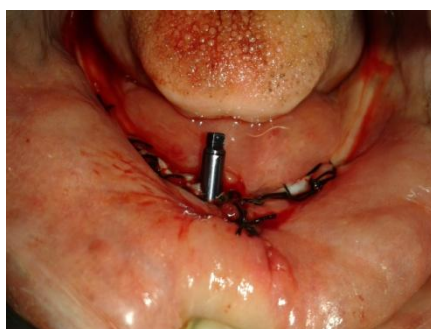
Pre op CBCT



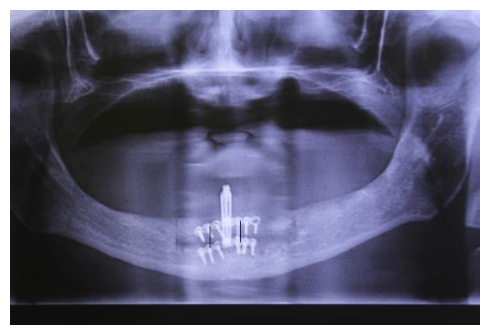
Osteotomy cut with Device fixation



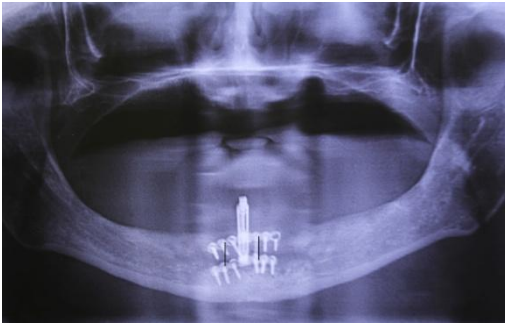
At the latency Intra Oral



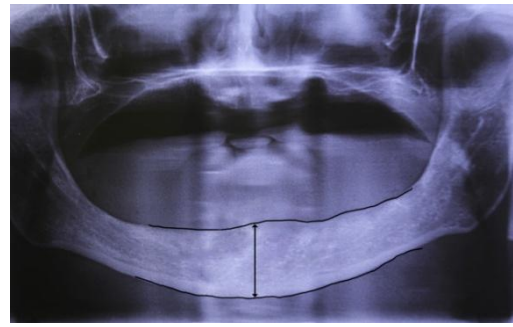
Completion of distraction OPG



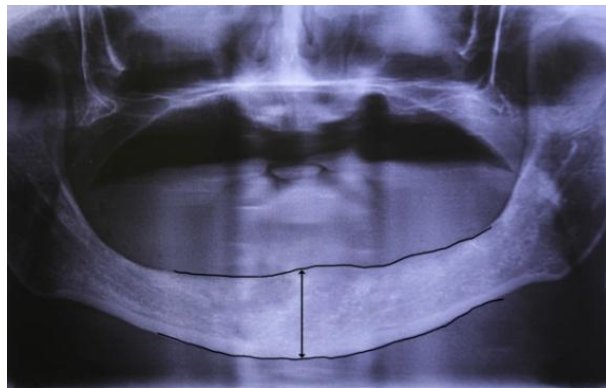
Completion of consolidation OPG



Device Removal OPG



OPG 6 Months



CBCT



In this study, five patients with decreased vertical alveolar bone height were included. One patient had partially edentulous alveolar defect due to marginal mandibulectomy done for a benign tumour in the anterior region. The remaining four patients had vertically deficient alveolar ridges due to total extraction of teeth. All these five patients underwent alveolar bone augmentation using Distraction Osteogenesis for increasing the vertical height. All the patients were subjected to intra oral, distraction device for vertical augmentation of atrophied alveolar ridges in the anterior mandibular region.

Pre operative CBCT and OPG were taken for evaluation of the residual alveolar bone height in the anterior mandibular region. The alveolar bone height to be augmented was estimated in each patient from the OPG and CBCT. Based on the amount of distraction to be done the distraction device was selected. Distraction device was placed in the osteotomised segments with the preplanned vector orientation.

Postoperatively, the distraction protocol was followed. Radiographs were taken periodically at the end of **the latency phase**, during **distraction phase** to check for the active movement of the device and at the end of the **consolidation phase**. The distraction was evident clinically and radiographically.

In this study, all the patients radiologically showed evidence of bone regenerate formation at the distraction site. In one of the patient during the consolidation period on routine radiological examination device breakage was

noted. Patient was placed on soft diet and advised to be more careful. The device breakage did not substantially affect the formed bone regenerate and the patient completed the entire period of consolidation.

Immediate postoperative complications

The incidence of complication was very minimal, except for a haematoma in one patient observed during the first postoperative day and it was managed conservatively which resulted in spontaneous resolution. The third case complained of unilateral paresthesia on the right side near the mental region probably due to the retraction at the time of the surgery, post operatively the paraesthesia was treated with vitamin B and the patient had complete recovery.

During distraction

Clinical and radiological observation were made during the active lengthening of the alveolar bone with distraction device. Activation was considerably painless in four patients, however one patient complained of pain and tension during the first 10 minutes following the activation. For all the patient's, the rythm of distraction was maintained to two times a day, maintaining the rate of 1mm / per day. The maximum distraction done for each patient is 10mm. Antibiotics and analgesics were prescribed for a period of five days. One of the patient complained of pain in the distraction site for which the antibiotics and analgesics were continued for seven days.

Wound dehiscence occurred in one of the patients during the distraction phase and was managed with local application of chlorhexidine gel (0.2%) which

resulted in gradual healing. In one patient, the anchor segment was found broken during the routine radiological examination during the consolidation period, the distractor was left in the same position through the end of the consolidation period.

The design of the distractor device was selected such that, there was no interference of the activation arm with the opposing maxillary alveolar mucosal region in all the five patients. The clinical results of this study were satisfactory with negligible complications. In all the patients distraction of the alveolar bone were evident clinically and radiographically by the formation of bone regenerate. At the end of the consolidation phase, all the patients were subjected to radiological examination (orthopantomogram) and the height of the bone regenerate formed were measured. The distraction devices were removed under local anesthesia and the bone height gained was recorded intraoperatively with the sterile digital vernier caliper. Haemostasis obtained, wound sutured with 3-0 vicryl. Patient advised antibiotics and analgesics.

Pre operative and post operative OPG were compared and the amount of alveolar bone height gained was measured. The vertical bone gain ranges from 8.6 mm to 9mm with mean of 8.8 mm. post operative CBCT was taken at the end of the sixth month in all the case, and the pre and post operative values were compared, the height of the bone regenerate formed was recorded. Post consolidation period reveals adequate mineralisation of the distraction regenerate in all the five patients. OPG and CBCT findings show a clear evidence of the vertical augmentation of the transport segment and revealed the gain in the quantum of alveolar bone height.

Chart – 1:

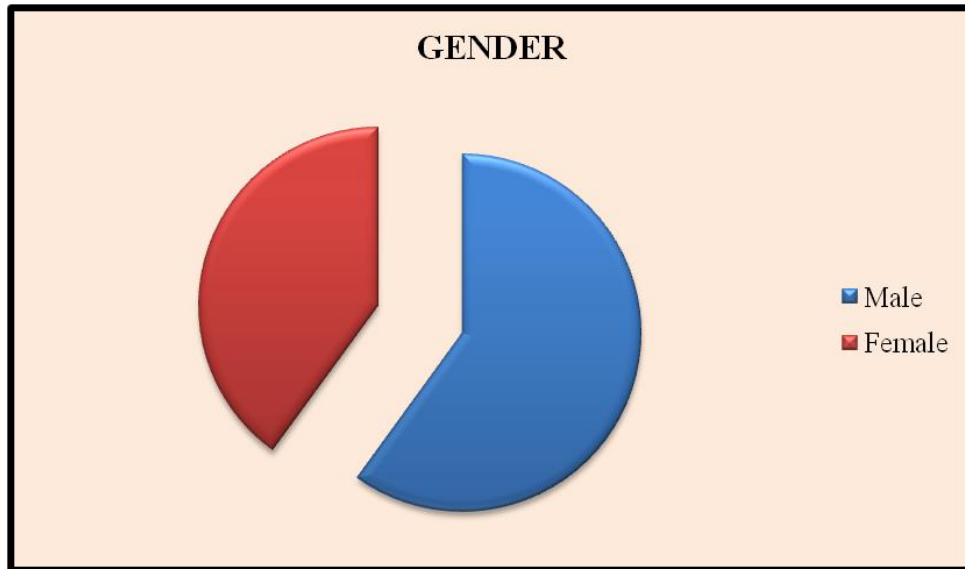


Table – 2: LATENCY PHASE (1-7 days)

Patient	Age/sex	Hematoma	Neurosensory disturbances	Pain	Interference of activation arm with opposing arch	Oral hygiene status
Case 1	34/m	No	No	No	No	Good
Case 2	39/f	No	No	No	No	Good
Case 3	45/m	Yes	Yes	No	No	Good
Case4	46/f	No	No	No	No	Good
Case 5	43/m	No	No	No	No	Good

Chart- 2: LATENCY PHASE

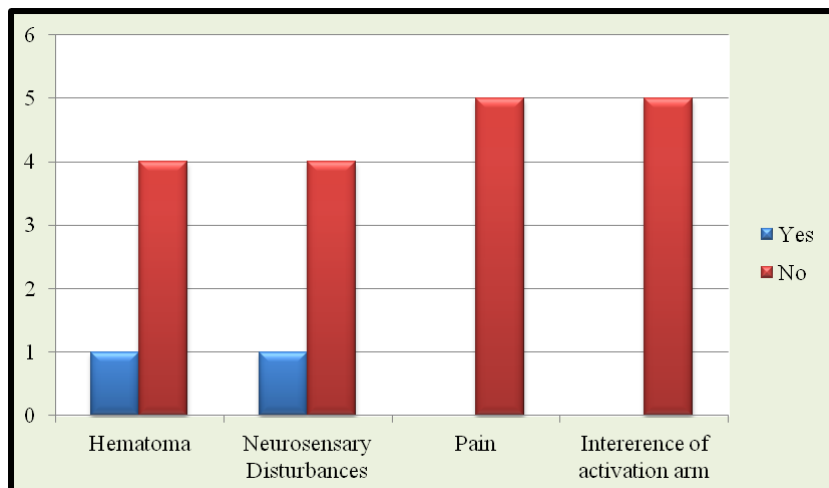
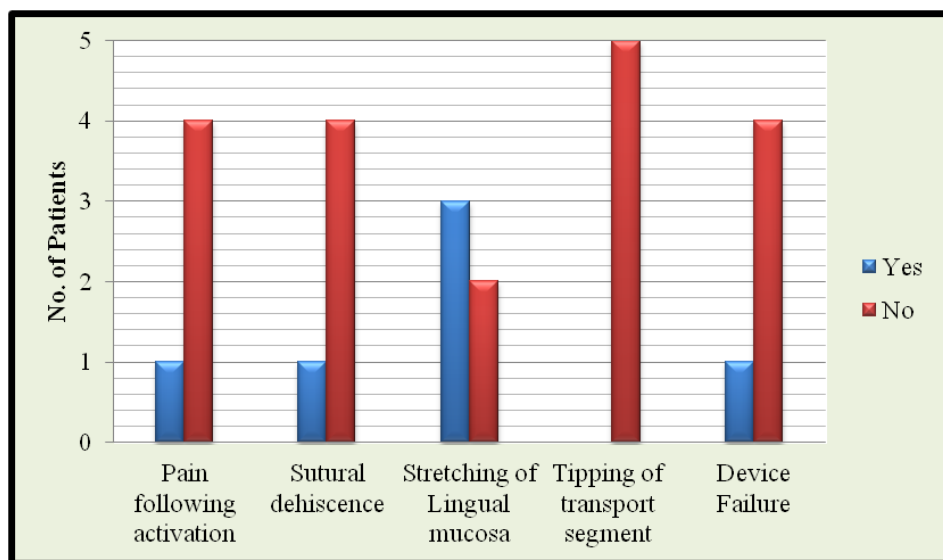


Table – 3: DURING DISTRACTION PHASE (8- 18 days)

Patient	Age / sex	Pain following activation	Sutural dehiscence	Stretching of lingual mucosa	tipping of transport segment	Device failure
Case 1	34/m	No	No	yes	No	Yes
Case 2	39/f	No	No	yes	No	No
Case 3	45/m	No	Yes	No	No	No
Case 4	46/f	yes	No	yes	No	No
Case 5	43/m	No	No	No	No	No

Chart – 3: DURING DISTRACTION PHASE



**Table – 4: HEIGHT OF THE DISTRACTION
REGENERATE OBTAINED (mm)**

Case	Age /sex	Diagnosis	Site	plan	Latency Period (days)	Distraction period (days)	Regenerate height (mm)
Case 1	34/ m	Partially edentulous defect- marginal mandibulectomy	Anterior mandible	D.O	7	10	10
Case 2	39/f	Completely edentulous Alveolar defect due to atrophy	Anterior mandible	D.O	7	9	9.5
Case 3	45/ m	Completely edentulous alveolar defect due to atrophy	Anterior mandible	D.O	7	10	7.8
Case 4	46/f	Completely edentulous alveolar defect due to atrophy	Anterior mandible	D.O	7	10	9
Case 5	43/ m	Completely edentulous alveolar atrophy	Anterior mandible	D.O	7	10	8

Table – 5: POST DISTRACTION PHASE (19-40 days)

Patient	Age/sex	Pain	Infection	Plate exposure	Device stability	Oral hygiene
Case 1	34/m	No	No	No	Moderate	Good
Case 2	39/f	No	No	No	Good	Good
Case 3	45/m	No	No	Yes	Good	Good
Case 4	46/f	No	No	No	Good	Good
Case 5	43/m	No	No	No	Good	Good

Table – 6: ORTHOPANTOMOGRAPHIC EVALUATION

Patient	Age/sex	Preop height from basal bone to crest (mm)	Bone height from the basal bone to the crest at the end of the activation (mm)	Bone height from the basal bone to crest at the end of the consolidation (mm)	Clinical intra op bone gain (mm)	Bone height from the basal bone to the crest during six months Follow up (mm)
Case 1	34/m	21	31	31	10	31
Case 2	39/f	20	29.5	29.5	9.5	29.5
Case 3	45/m	19	26.8	26.8	7.8	26.8
Case 4	46/f	21	30	30	9	30
Case 5	43/m	19	27	27	8	27
MEAN		20	28.86	28.86	8.86	28.86

Chart – 4: ORTHOPANTOMOGRAPHIC EVALUATION

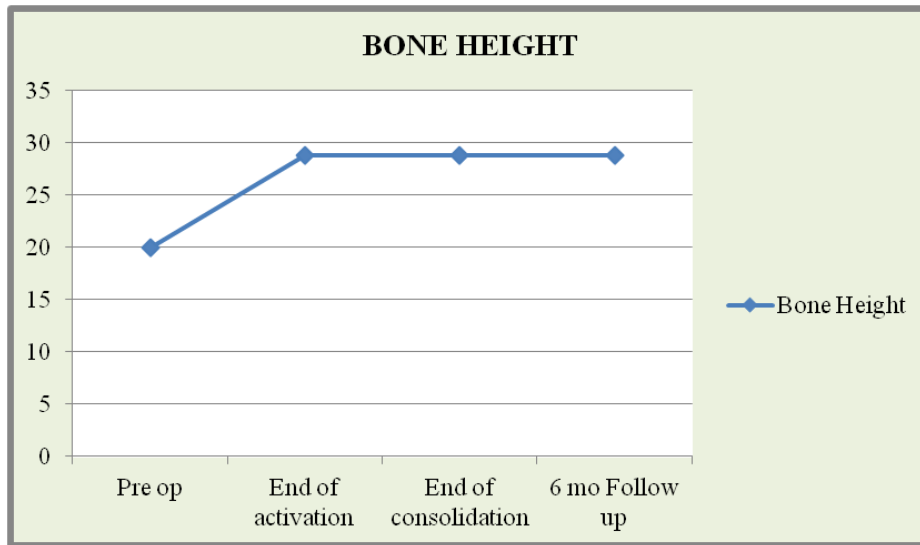


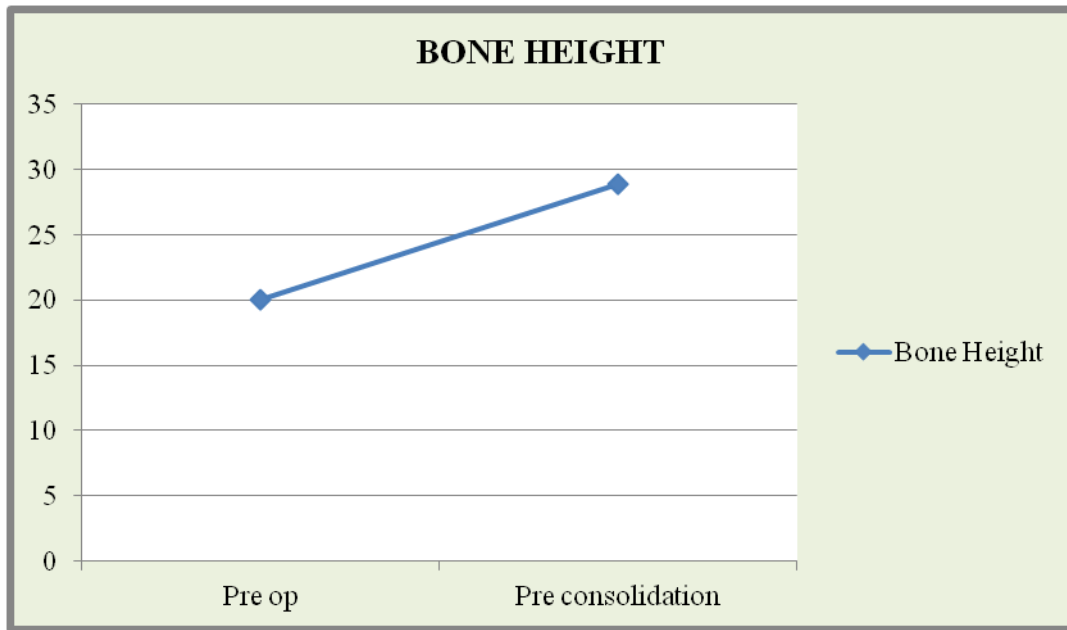
Table – 7: CBCT EVALUATION

Patient	Age/sex	Pre operative bone height	Post consolidation bone height	Bone height obtained
Case 1	34/m	21 mm	31 mm	10 mm
Case 2	39/f	20 mm	29.5 mm	9.5 mm
Case 3	45/m	19 mm	26.8 mm	7.8 mm
Case 4	46/f	21 mm	30 mm	9.5mm
Case 5	43/m	19 mm	27 mm	8 mm
MEAN		20 mm	28.86 mm	8.86 mm

Mean bone height gain = mean post consolidation bone height - mean pre op bone height .

$$28.8 \text{ mm} - 20 \text{ mm} = 8.8 \text{ mm.}$$

Chart – 5: CBCT EVALUATION



Deficiency of the alveolar bone height jeopardises the anatomic landmarks required for the efficient full mouth rehabilitation. In a vertically deficient alveolar ridge the musculature namely genioglossus, mylohyoid, buccinator comes apparently more superficial and obliterate the buccal and lingual sulci.

In order to establish the near normal height of the alveolar ridge a variety of surgical procedures were advocated by many surgeons, including onlay bone grafts¹, vertical guided bone regeneration, and alveolar distraction osteogenesis. Restoration of such vertically deficient alveolar ridge poses a challenging task and is possible with the extended application of the callus distraction principles of the Ilizarov's unique DistractionOsteogenesis. DO is defined as the regeneration of bone between vascularised bone surfaces that are separated by gradual distraction.⁶

Distraction Osteogenesis allows the simultaneous augmentation of soft and hard tissues and is considered to be a useful technique. Rachmiel⁸ et al reported that distraction osteogenesis induces skeletal distraction, and the augmentation of soft tissues and bone trabeculae was observed 6 weeks after the completion of distraction osteogenesis.

In preprosthetic surgery, vertical distraction of the alveolar bone was recently developed as an alternative to the complex augmentation techniques

with either free autogenous bone transplants¹⁴, allografts in association with GBR procedures, xenogenic materials, alloplastic bone substitutes.²

Comparing the alternative modalities^{1-4,12} of restoring the alveolar architecture, distraction osteogenesis has the advantages¹⁰ of;

- No donor site morbidity,
- Reducing the risk of bonegraft necrosis and resorption compared to non vascularised free bone grafts (because the transport segment retains its periosteal blood supply).
- No foreign body reactions.
- Obtaining proportional and harmonic modification of the muscles and the surrounding soft tissues.
- Controlling the direction and amount of bone augmentation.
- Shortening the duration and hospitalization .
- Less invasiveness.
- Reducing the possibility of relapse with no bone grafting.

Alveolar distraction devices were used to provide gradual, controlled coronal transport of a mobilised alveolar segment in a stable , incremental manner. When the desired position of the bone segment was achieved , the device was left in place serving as a fixation device to allow the transformation of callus into bone in the distraction zone. The revolution and development of the distraction devices^{8,18,22,17,32} provided numerous possibilities of alveolar ridge augmentation.

The surgical procedure involving the augmentation of the deficient alveolar ridge requires an osteotomy to divide the bone. Distraction procedure constitutes latency period for the fibrous callus formation. Activation produces distraction force on the fibrous callus to form the distraction regenerate. Once the traction force is terminated, the regenerate is allowed to consolidate and the device is removed. For a successful distraction osteogenesis, the blood supply to the bone fragments plays a vital role⁶.

Currently, there are three distraction systems available for the vertical distraction osteogenesis. They are

1. Central application device⁷ (LEAD SYSTEM, Leibinger Endosseous Alveolar Distraction system).
2. Eccentric application device¹⁰ (TRACK distractor by Martin, Tuttlingen, Germany).
3. Distraction by an implant²³ (DIS-SIS distraction implant and ACE dental implant system, Brockton, MA).

In the present study, we used the eccentric application Intra oral (extra osseous) distractors made up of stainless steel with transport and basal plates which were fixed with the help of 1.5mm screws.

Osteotomy

- Defined as” a low energy osteotomy of the cortex preserving the local blood supply to both the periosteum and medullary canal.”
- First, the labial corticotomy was made. Then using the fine osteotome the lingual cortex was fractured preserving the intact lingual periosteum.

- Discontinuity of the bone segments triggers an evolutionary process of bone repair known as “fracture healing” which involves recruitment of osteoprogenitor cells, followed by cellular modulation or osseointegration and establishment of an environmental template for osseointegration.

Latency period⁶

- Latency is “the time following the osteotomy when initial fracture healing bridges the cut bone surface prior to initiating distraction”
- To optimise the response of osteogenic tissue to distraction, a latency period has been suggested for early callus formation (mesenchymal tissue reaction).
- Different latency periods have been suggested in clinical studies and animal experiments. We followed a latency period of 7 days in all the five patients and on the eighth post-operative day, we started distraction.

Rate of Distraction

- Rate is “the number of millimetres per day at which the bone surfaces are stretched”.
- Ilizarov⁸ principles stressed the importance of one mm of distraction rate per day for optimal results.
- Quality and quantity of the newly formed bone increases when distraction is performed continuously at a rate of 1mm/day.
- We followed the rate of 1mm/day in all the five patients in our study according to the principles of Ilizarov⁶

Rhythm of Distraction

- “ It is the number of distractions per day usually in equally divided increments to the total rate”
- The force of distraction should ideally be applied as a continuous rhythm, yet dividing the bone advancement into twice daily or four times daily application is more practical for the patient.
- Mc Carthy et al ³⁹(1992) suggested rhythm of distraction from two (0.5mm) or four (0.25mm) times a day.
- In this study,0.5mm twice daily rhythm was followed for distraction.

Consolidation³⁶

All the patients in our study were followed with the same distraction protocol of latency phase, distraction phase and consolidation phases for augmenting the vertically deficient alveolar ridges in the mandibular anterior region.

Alveolar Distraction Osteogenesis has numerous advantages in the treatment of the dento alveolar bone defects , however its extended application shall be carefully monitored due to the complications related to surgical techniques and devices.

The first detailed study of ADO complications was conducted by Enislidis et al³⁰, who classified complications as major or minor during all distraction protocols. The possibility of bleeding from the floor of the mouth during

osteotomy procedures has been reported to be minimal (Uckan et.al.,2002), in the review of literature. In this study the intra operative complications of profuse intraoral bleeding was not encountered, since osteotomes were used instead of bur or saw to complete the lingual osteotomy line. For better hemostasis and comfortable results, an ultrasonic osteotome or laser may be used.

Post operatively, extraoral hematoma was reported in one patient during latency period (1-5 days) and the clinical condition was managed conservatively which resulted in spontaneous resolution.

In mandible, the vertical osteotomies should not compromise the continuity or damage the neurovascular structures. In this study, the osteotomies were carried out at a distance of 5mm from the mental foramen. This method should not be applied in a very atrophic mandible to avoid the fracture. In order to prevent a fracture or resorption of the alveolar transported segment, care should be taken not to make it too small. The transported segment should be atleast 5mm in height for connection with the plate and screws.

In one patient temporary paresthesia²⁴ was found unilaterally on the right side and treated conservatively which resulted in spontaneous resolution within 6 - 8 weeks, the parasesthesia is probably due to manipulation of the anterior segment near the mental nerve and or due to the retraction during the surgical procedures which coincides with the study reported by Gaggl et al ⁴²(1999).

Most of the complications²⁵⁻³¹ were reported during the phase of distraction and were managed competently. Some studies have reported that the patients experienced pain during distraction. The intensity of the pain depends on the distraction rate, ratio and amount (Zaffe et al.,2002; Chiapasco et al.,2004;Saulasic et al.,2005;Froum et al., 2008). To overcome this pain, the frequency of the activation might be increased or the rate of activation might be reduced overall. In this study, one patient experienced pain for 10 mins following the activation due to tension and managed to avoid the pain by prescribing analgesics prior to the activation.

In this study, the sutural dehiscence was seen in two patients where crestal incision were made, probably due to the presence of edema occurring during distraction as a result of the tension and sharp bone edges. To avoid the dehiscence the crestal incision is modified and a paragingival incision was placed in three patients. The crestal attached gingiva was intact and the device existed through a button hole and no dehiscence was reported thereafter.

Gabriele et al in their study reported device fracture due to improper adaptation and recommended that the distractor should be oriented to allow parallel and diverging action toward the osteotomy cut. In this study device failure occurred in one patient during the consolidation phase. Device was kept in the same position, allowing the distraction regenerate to consolidate. Patient was advised to be on soft diet with limited movements of the jaw and restricted mouth opening.

Another utmost complication is the inappropriate direction of distraction which can be evident showing lingual tipping of the transport segment due to the lingual pull exerted by the genioglossus musculature^{37,38}. In this study the osteotomised transport segment moved in the desired vector. No such tipping of the transport segment reported in all the five cases in this study, as reported in the literature.

Most serious complication of Distraction Osteogenesis is the fracture of the mandible. In this study, fracture of the residual bone segment was not encountered because of the presence of the sufficient residual basal bone thickness. The cases were also selected by strictly following the selection criteria.

Patient compliance during the entire treatment period is essential and thus careful patient selection and adequate motivation is of utmost importance. In this study all the five patient were very co-operative during the entire study period.

Routine radiographs were taken periodically to evaluate the efficiency of the distraction osteogenesis. After following a consolidation period the devices were removed. OPG and CBCT images revealed good quantum of lamellar bone of a mean height of 8.8 mm without any major complications such as neurosensory disturbances.

From this study, it is evident that the application of the distraction force at a rate of 1mm per day with the rhythm of 0.5mm twice activation per day with the strict adherence to the distraction protocol resulted in the regeneration of the alveolar bone with sufficient soft tissue mucosa simultaneously.

In this study, the minor complications encountered were managed competently. This shows the efficiency of the distraction osteogenesis and its advantages over the other reconstructive modalities influencing its versatile application in the craniomaxillofacial region .

Augmentation of the defects in the dento alveolar region has proved to be a challenging and complicated endeavour because the deformity involves deficiencies in both the bone and mucosal tissues. Distraction Osteogenesis with its versatility has revolutionalized the surgical reconstruction of the various anatomical structures of the head & neck region.

Distraction Osteogenesis is a technique that induces bone generation through the so called tension –stress effect through the gradual distraction of osteotomised bone fragments⁶.

The surgical procedure involving the augmentation of the deficient alveolar ridge requires an osteotomy to divide the bone. Distraction procedure constitutes latency period for the fibrous callus formation. Activation produces distraction force on the fibrous callus to form the distraction regenerate. Once the traction force is terminated, the regenerate is allowed to consolidate and the device is removed.

Distraction Osteogenesis has proved to be safe and effective due to its unique advantages like low risk, no donor site morbidity, simple manipulation, high curative rates, simultaneous gain in the volume of soft tissues, less resorption of the crestal bone because the crestal bone remains cortical, less relapse with stable results to achieve the better esthetic and functional status, hence distraction is superior to the other bone augmentation procedures⁸.

Being a sensitive procedure, Distraction Osteogenesis requires careful planning and execution following the vector principle. It is important to place the distraction device in a correct distraction vector in order to avoid a labial deficiency of the augmented alveolar bone segment.

In all the five patients, as a result of the distraction process, the segment of the mature bone is transported vertically into the alveolar ridge defect in order to lengthen the crest for prosthetic reconstruction. From the results of this study it has been observed that distraction osteogenesis is the optimal choice for surgically augmenting the vertically deficient alveolar ridges.

In conclusion, Distraction Osteogenesis is a versatile, valuable and safe method for the vertical augmentation of the alveolar ridges in the anterior mandibular region. However to ascertain and consolidate the efficacy of the surgical procedure a larger sample with a long term follow up is essential.

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CASE SHEET

**AUGMENTATION OF ALVEOLAR RIDGES OF THE
PARTIALLY/COMPLETELY EDENTULOUS ANTERIOR
MANDIBULAR REGION BY DISTRACTION OSTEOGENESIS**

PATIENT'S NAME : _____

AGE/ SEX : _____

PATIENT'S

IDENTIFICATION NO : _____

CONTACT ADDRESS : _____

CONTACT No : _____

INSTITUTION : TN Govt. Dental College & Hospital,
Chennai - 600 003.

CENTRE : Dept. of Oral & Maxillofacial Surgery,
TN. Govt. Dental College and Hospital,
Chennai - 600 003

CHIEF COMPLAINT:

HISTORY OF THE PRESENTING ILLNESS:

CLINICAL FINDINGS:

INVESTIGATIONS:

DIAGNOSIS:

TREATMENT : Alveolar Ridge Augmentation

Procedure followed : Alveolar Distraction Osteogenesis

FOLLOW UP

1. Distraction Protocol
2. 6 Months Follow up

NAME OF THE INVESTIGATOR :

SIGNATURE OF INVESTIGATOR :

INFORMED CONSENT

× INFORMED CONSENT

- × "AUGMENTATION OF ALVEOLAR BONE HEIGHT IN PARTIALLY & COMPLETELY EDENTULOUS JAW WITH DISTRACTION OSTEOGENESIS"
 - ×
 - × Patient's Identification No: _____ Patient's Name: _____
 - × Patient's DOB: _____
 dd mm yyyy
 - × I confirm that I have read and understood the Information Sheet for the above study. I have had the opportunity to ask questions and all my questions and doubts have been answered to my complete satisfaction.
 - × I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.
 - × I understand that the Clinical study personnel, the Ethics Committee and the Regulatory Authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I understand that my identity will not be revealed in any information released to the third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study.
 - × I agree not to withhold any information about my health from the investigator and will convey the same truthfully.
 - × I agree to take part in the above study and to comply with the instructions given during the study and to faithfully co-operate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or wellbeing or any unexpected or unusual symptoms.
 - × **I am aware that my deficient alveolar ridge can be treated by using distraction device and screws. I was explained about the surgical methods (under local or general anesthesia) of treatment and the methods to be employed to record the progress of my treatment during the follow-up period. I was also informed about the side effects of this surgical procedure and I hereby consent to participate in this study.**
 - × I consent to give my medical history, undergo complete physical examination and diagnostic tests including hematological, biochemical and urine examination etc.
 - × Signature / Thumb Impression: _____ Place: _____ Date: _____
 - × Patient's Name & Address: _____
 - × Signature of the Investigator: _____ Place _____ Date _____
 - × Study Investigator's Name: _____
 - × Institution: _____
 - × * Signature of the Witness: _____ Place _____ Date _____
 - × * Name & Address of the Witness _____
 - × *Mandatory for uneducated patients (Where thumb impression has been provided above).
 - ×
 - ×
-

சுய ஒப்புதல் படிவம்
ஆய்வு செய்யப்படும் தலைப்பு
திசை திருப்பும் எனும்பு விலக்க முறையில் பகுதியாக மற்றும் முற்றிலும் பல் உதிர்ந்த வாய்
தாடை பற்குழி எனும்பு உயரம் அதிகரித்தல்

ஆராய்ச்சி நிலையம் : அரசு பல் மருத்துவக் கல்லூரி
 சென்னை - 600 003

பங்கு பெறுபவரின் பெயர் :
 பங்கு பெறுபவரின் எண் :
 பங்கு பெறுபவரின் பிறந்த தேதி : _____ / _____ / _____
 தேதி மாதம் வருடம்

அறுவை சிகிச்சை சம்பந்தமாக நான் மேலே கூறப்பட்ட தகவல் படிவத்தை முழுமையாக படித்துப் பார்த்தேன். நான் இது தொடர்பான அனைத்து கேள்விகளுக்கும் நிறைவான பதில்கள் பெற்றேன்.

இந்த ஆய்வில் எனது பங்கு தன்னிச்சையானது என்றும் எந்த நேரத்திலும் இந்த ஆய்வில் இருந்து சட்ட உரிமைகள் பாதிக்கப்படாமல் விலகிக் கொள்ளாளாம் என்பதை அறிவேன்.

மருத்துவ ஆய்வு அதிகாரிகள், எனது சிகிச்சை தொடர்பான பதிவேடுகளை பார்வையிட சம்மதிக்கிறேன் (ஆய்வில் இருந்து நான் விலகினாலும்). எனது அடையாள குறிப்புகள் மூன்றாவது நபருக்கு தெரிவிக்கப்படமாட்டாது என்று புரிந்து கொண்டேன்.

இந்த ஆய்வு அறிக்கைகளை பயன்படுத்தவும், வெளியிடவும், நான் சம்மதிக்கிறேன். ஆய்வாளர் எனது மருத்துவக் குறிப்புகளை வெளியிட தடையாக இருக்கமாட்டேன் என உறுதியளிக்கிறேன்.

நான் ஆய்வு குழுவிற்கு முழு ஒத்துழைப்பு அளிப்பேன் என்றும் எனது உடல்நிலையில் ஏதேனும் உபாதைகள் ஏற்பட்டால் அதனை உடனே ஆய்வாளருக்கு தெரிவிப்பேன் என்று உறுதியளிக்கிறேன்.

பொது மயக்க மருத்துவ முறையிலோ/ பகுதி உணர்வுகற்றல் மூலமாகவோ எனது பற்குழி எனும்பு குறைப்பாட்டை எனும்பு திசைத்திருப்பும் சாதனம் பொருத்தி அறுவை சிகிச்சை செய்யப்படுகிறது என்பதை நான் அறிந்துகொண்டேன். இந்த அறுவை சிகிச்சை முறையில் ஏற்படும் அனைத்து பக்கவிளைவுகளையும் மருத்துவர் மூலம் அறிந்து கொண்டு இந்த ஆய்விற்கு என்னை உட்படுத்திக் கொள்கிறேன்.

நான் எனது மருத்துவ குறிப்புகளை தரவும், மேலும் முழு உடல் பரிசோதனைக்கும் இரத்தம், சிறுநீர் மற்றும் உயிர் வேதியியல் நோய் அறிதல் சோதனைகளுக்கும் முழுஒப்புதல் அளிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம் இடம்..... தேதி.....
 கட்டைவிரல் ரேகை
 பங்கேற்பவரின் பெயர் மற்றும் விலாசம்
 ஆய்வாளரின் கையொப்பம் இடம்..... தேதி.....
 ஆய்வாளரின் பெயர்