ROLE OF DISTRACTION OSTEOGENESIS IN FACIAL DEFORMITY DUE TO TEMPORO-MANDIBULAR JOINT ANKYLOSIS

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In the partial fulfillment of the requirements for the degree

Of

MASTER OF DENTAL SURGERY

In

ORAL AND MAXILLOFACIAL SURGERY

By

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Under the guidance of

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BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

(Faculty of Babu Banarasi Das University)

BATCH: 2019-2022

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"ROLE OF DISTRACTION OSTEOGENESIS IN FACIAL DEFORMITY DUE TO TEMPORO-MANDIBULAR JOINT ANKYLOSIS "** is a bonafide and genuine research work carried out by me under the guidance of ***Prof. (Dr.) Hemant Gupta,*** Professor and Head, Oral and Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

LIST OF ANNEXURES

LIST OF ABBREVIATION

TMJ	**:**	**Temporomandibular Joint**
MIO	**:**	**Maximum interincisal opening**
SAD	**:**	**Simultaneous arthroplastic distraction**
OSAS	**:**	**Obstructive sleep apnea syndrome**
OHIP	**:**	**Oral health impact profile**
RCT	**:**	**Randomized controlled trial**
3DVSP	**:**	**3D virtual surgical planning**
TMJP	**:**	**Temporomandibular prosthesis**
OPD	**:**	**Out patient department**
SPSS	**:**	**Statistical package for social sciences**
SD	**:**	**Standard deviation**
PTV	**:**	**Pterygomandibular vertical plane**
PhW	**:**	**Pharyngeal wall**
CBCT	**:**	**Cone beam computed tomography**
OPG	**:**	**Orthopantomagram**
IOPAR	**:**	**Intra oral periapical radiographs**

ABSTRACT

INTRODUCTION : Temporomandibular joint ankylosis is a debilitating condition arising from fusion of the condyle to glenoid fossa ,resulting in limited movement of the mandible and associated with varying degree of esthetic and functional compromise. It is most commonly associated with trauma, local or systemic infection or systemic disease . Restoration of normal form and function can be challenging in such cases. Distraction osteogenesis is a surgical method in which bone formation is induced by separation of bony segments by means of an appliance in conjunction with an osteotomy. It offers lengthening of the mandible, providing space for correction of occlusal cant, midline shift, and facial asymmetry. The study was designed and aimed at evaluation and assessment of the functional and esthetic outcome in correction of facial asymmetry in temporomandibular ankylosis by distraction osteogenesis.

AIM AND OBJECTIVES : To study the efficacy of distraction osteogenesis in correction of facial deformity in patients suffering from TMJ ankylosis .

METHOD AND METHODOLOGY : This study consists of a 5 patients diagnosed with unilateral / bilateral TMJ ankylosis , who reported to the OPD of Oral and Maxillofacial Surgery , BBDCODS. Comprehensive clinical and cephalometric evaluation was done for all the patients to identify location and magnitude of Facial/skeletal deformaty . These patients were then subjected to distraction procedure under general anaesthesia before arthrectomy using intraoral or extraoral device. The therapeutic effect of Distraction was evaluated by the improvement in MIO, appearance and respiratory function after consolidation of Distraction and arthrectomy.

RESULTS : The results of this study confirm that there is significant rectification of facial esthetics, ramal height, mandibular length ,mouth opening , midline and airway correction in all cases**.**

CONCLUSION: Distraction osteogenesis is an effective tool for correction of facial deformity in patient with temporomandibular joint ankylosis. This treatment

procedure significantly restores and improves appearance, mouth opening, mandibular length, ramal height and airway.

KEYWORDS: Temporomandibular joint ankylosis, distraction osteogenesis, arthrectomy.

INTRODUCTION

Temporomandibular joint ankylosis is the fusion of the condyle to glenoid fossa resulting in limited movement of the mandible finally culminating into varying degree of functional and cosmetic debilitation. It is most commonly associated with trauma, local or systemic infection or systemic disease. If it occurs at a young age, it can affect the growth of the mandible, leading to micrognathia, retruded chin, reduced airway, compromised function and esthetics.

Unilateral TMJ ankylosis cases present with jaw asymmetry with or without retrognathia, while bilateral cases present with moderate to severe retrognathia leading to obstructive sleep apnoea. Optimally balanced restoration of form and function with provision for growth potential is often a challenge in such cases.

Treatment of TMJ ankylosis is a complex procedure as it not only involves releasing the joint but also correction of facial deformity and is often associated with high rates of relapse. Knowledge of etiology, pathophysiology, and mandibular biomechanics is fundamental for adequate treatment, which must be conducted early to achieve mandibular movement and prevent alterations in mandibular and maxillary

The mandibular condyle is considered an important agent in mandibular development due to its secondary cartilage.[2]Accordingly as mandibular dynamics are restricted in people who have not finished their craniofacial growth and development—vertical, sagittal, and transverse development of the mandible on the affected side will be stunted, generating a facial asymmetry, and often, compromising correct growth and maxillary development. Furthermore, airway obstruction results from the lack of mandibular development[3].

In growing patients, deformities of the mandible and maxilla may occur together with malocclusion. In classifying TMJ ankylosis in children, SAWHNEY[4] identified four different types:

Type 1 : There is minimal bony fusion, but extensive fibrous adhesions around the joint;

Type 2 : Has more bony fusion especially at the outer edge of the articular surface, but no fusion within the more medial area of the joint;

Type 3 : There is a bridge of bone between the mandible and the temporal bone;

Type 4 : The joint is replaced by a mass of bone.

Temporomandibular joint ankylosis can also be classified in the following ways: anatomically, as intracapsular or extracapsular; according to the tissue involved in the bone, as fibrous or fibro-osseous; and according to the extent of fusion, as complete or incomplete[5].

The primary objective for treatment of TMJ ankylosis is to increase mouth opening, correct the dento-facial deformity and prevent re-ankylosis. This is achieved by surgical release of the TMJ ankylosis by gap arthroplasty, inter-positional arthroplasty and/or total joint reconstruction.

Distraction osteogenesis can be used successfully before or after the release of the joint ankylosis, to correct secondary facial asymmetry. In the post-operative period, aggressive physiotherapy is the mainstay to prevent re-ankylosis [6]

Distraction osteogenesis is a technique where new bone formation is induced by gradual separation of bony segments by means of an appliance in conjunction with an osteotomy. Bone distraction was first introduced by Codvilla[7] nearly 100 years ago and subsequently popularized during the 1940s by Ilizarov[8,9], who developed a single-stage procedure to lengthen long bones without the use of grafting material.

The study was designed to determine objectively the effect of distraction in management of patients with temporomandibular joint ankylosis by clinical and radiological assessment along with cephalometry to provide a clinical correlation between the distraction procedure, the effective changes in the oro-pharyngeal dimensions, mandibular length, ramal height and the clinical outcome.

AIM AND OBJECTIVE

AIM :

- To study the efficacy of distraction osteogenesis in facial deformity of TMJ ankylosis.

OBJECTIVES

- To assess the following parameters in patients with TMJ ankylosis before and after the distraction and arthrectomy.
    1. Correction of facial asymmetry
    2. Airway
    3. Mouth opening
    4. Midline shift
    5. Cephalometric evaluations

- To compare preoperative and post operative findings.

REVIEW OF LITERATURE

Mario J. Imola, David D. Hamler, Gentry Thatcher and Khalid Chowdhury (2002)[10] conducted a 34 months study to review the preliminary results using distraction osteogenesis. 24 patients were treated with distraction osteogenesis during a period of 34 months. Outcomes were compared with previous anatomic abnormalities and functional deficits. Distraction achieved versus planned distraction based upon clinical status of functional abnormalities before and after treatment. Functional results included resolution or significant improvement of upper airway obstruction in 13 out of 14 patients and correction of corneal exposure for all 5 patients with pre-existing exorbitism.

Wang X, Wang XX, Liang C, Yi B et al (2003)[11] conducted a study for evaluation of the effect of distraction osteogenesis for correction of micrognathia which accompanies obstructive sleep apnea syndrome, a total of 28 patients with different severities of obstructive sleep apnea that underwent mandibular distraction osteogenesis

Emmanuela Nadal López, Pedro Luis Dogliotti, Mariana Saba et al (2004)[12] evaluated retrospectively 41 patients who underwent temporomandibular joint reconstruction during the last 10 years. Twenty were treated by costochondral graft, 15 by arthroplasty, and 6 by other surgical procedures, and they were excluded. Septic etiology was found in 54% cases. Follow-up was of at least 12 months of all cases. 75% of patients treated with bone graft required secondary surgery. Clinically, patients showed variable degrees of facial deformity and an unknown potential of mandibular growth following TMJ arthroplasty. The authors present their treatment protocol, which includes TMJ joint arthroplasty with temporal muscle interposition, and distraction osteogenesis in mandible, as a second procedure, to correct residual asymmetry or retrognathism if necessary.

Ko E W,Hung K F,Huang C S, Chen P K T (2004)[13]done a study to assess the effectiveness of multiplanar mandibular distraction by evaluating the treatment effect and 1-year stability, measuring changes on the affected and nonaffected sides, and evaluating correction of the occlusal plane and oral commissure cant. Eleven

patients aged 5 to 9.4 years (mean 6.7 years) who underwent unilateral multiplanar mandibular distraction were included, 10 with hemifacial microsomia and one temporomandibular joint ankylosis. Intermaxillary elastics were applied to intraoral dental devices during and after distraction until bony consolidation and occlusal interdigitation were achieved. Radiographs were taken and measured before distraction, after vertical distraction, after completion of distraction, and 1 year after treatment. Frontal facial photographs were obtained to analyze the changes in the position of the oral commissure. The facial profile was improved by sagittal mandibular advancement. Although the facial height increased 6.6 mm during vertical distraction,with a net gain of 5.8 mm in follow-up, the mandibular plane angle was maintained.The affected mandibular length increased 8.3 mm after distraction and remained unchanged after 1 year. Ramus height increased 12.7 mm after distraction and relapsed 3.8 mm at follow-up (30%). The affected body length demonstrated postoperative growth of 3.1 mm. Correction of the chin deviation was 9.8 mm after distraction and relapsed 1.6 mm (16.3%) after 1 year. Canting of the occlusal plane and oral commissure was corrected and remained stable. The 1-year follow-up revealed that the new sagittal jaw relation and mandibular body length were stable, and the achieved occlusal interdigitation was well maintained.

Rao K, Kumar S, Kumar V, Singh A, Bhatnagar S (2004)[3] conducted a study was to evaluate the use of distraction osteogenesis for simultaneous correction of the mandibular deformity.This study was done on six children with temporo-mandibular joint ankylosis and mandibular deformity. Uniaxial double pin distractors with Schanz pins were used in this study.The patients underwent simultaneous gap arthroplasty and mandibular osteotomy (retromolar) with distractor insertion. Distraction was started on the fifth post-operative day. The patients were put on dynamic temporo-mandibular joint exercises on the first post-operative day. All patients had a satisfactory mouth opening on follow-up. Satisfactory cosmetic correction of the mandibular deformity was also achieved in all these patients. Some degree of malocclusion resulted from treatment due to which the patients were placed on orthodontic treatment.

Strijen P J V , Breuning K H, Becking A G , Tuinzing D B (2004)[14] conducted a study to investigate mandibular stability after lengthening the mandible by means of distraction. Fifty patients (mean age, 14.7 years; range, 11.2 to 37.3 years) with Angle Class II mandibular hypoplasia were treated by bilateral distraction osteogenesis to lengthen the mandible. Patient were divided into a high-angle group, with a high mandibular angle (sella/nasionmandibular plane [SN-MP] _38°), and a normal-to-low mandibular angle group (SN-MP _38°). Clinical measurements and standardized cephalometric radiographs were taken just before operation; postdistraction at time of removal of the distraction devices, and 6 months and 1 year postoperatively. Analysis was performed by means of angle measurements: sella/nasion-maxilla point A (SNA), sella/nasionmandibular point B (SNB), and SN-MP. Eight of 14 high-angle patients showed a degree of relapse (57%), and only 3 of 36 patients showed relapse in the low/normal-angle group (8.3%). It can be concluded that high-angle patients are still at risk of relapsing and that distraction osteogenesis cannot prevent relapse in cases with a high mandibular plane angle. For low-angle patients, however, distraction is a safe and predictable procedure.

Ahmed O. Alyamani (2006)[15] conducted a study to evaluate the use if distraction osteogenesis in mandibular hypoplosia attributable to TMJ ankylosis and to present our protocol in surgical treatment with this relatively new therapeutic option. This study was done on seventeen patient with temporomandibular joint and mandibular deformity. Intra oral unidirectional bone born distractors were used in this study. Patient were categorized into three group; Group I underwent arthroplasty followed by distraction osteogenesis. Group II patients had simultaneous arthroplasty and distraction osteogenesis and Group III patient underwent distraction osteogenesis to relief upper airway obstruction followed by arthroplasty. All patient had a satisfactory mouth opening on follow-up and satisfactory correction of external facial appearance was achieved in all these patients. Some degree of malocclusion which were managed secondary by orthodontic treatment.

Sadakah AA, Elgazzar RF, Abdelhady AI (2006)[16] done a study to evaluate the feasibility of transoral bimaxillary distraction osteogenesis before releasing temporomandibular joint (TMJ) ankylosis using intraoral mandibular distractors.

Nine patients (5 males, 4 females) aged 14–35 (mean 19) years were included. A bilateral Le Fort I osteotomy was performed together with a mandibular osteotomy on the affected side(s). An intraoral distractor(s) was inserted in the lower jaw, followed by an intermaxillary fixation (IMF) to maintain preoperative dental occlusion. The distractor was activated, after a latency period of 5–7 days, 2 times daily by 0.5 mm. There followed a consolidation period of 6–8 weeks. TMJ ankylosis was then released via a periauricular incision, a gap arthroplasty was performed, and mandibular movement was established after removal of the IMF and distractor. Optimal results were achieved clinically and radiologically with minimal relapse and complications.Total mandibular elongation ranged from 17 to 25 mm (20.7 mm).Occlusal canting decreased to 08 in 7 patients and to 18 in 2 patients (mean 0.28).After a mean follow-up period of 17 months, a mean postoperative mouth opening of 34.7 mm was achieved (0.6 mm preoperatively) and no re-ankylosis was detected. Intraoral distraction of a deformed mandible and maxilla before releasing TMJ ankylosis is a feasible and perhaps advantageous technique.

Shehata E A A, Medra A M M (2006)[17] performed the DO to study the efficacy of modified simultaneous maxillary–mandibular distraction to correct facial asymmetry in patients with compensated occlusion and a canted occlusal plane. During the period January 1998–December 2003, 15 patients with facial asymmetry (8 male and 7 female, mean age 18 years) were treated using a modified technique of simultaneous maxillary–mandibular distraction. Their facial deformities were caused by hemicraniofacial microsomia (n = 6) or ankylosis of the temporomandibular joint (TMJ) (n = 9).The mean (range) gain in mandibular height was 16 (13–22) mm, and increase in elongation 14 (11–18) mm achieved over 11–22 days. Predicted movement on cephalometric analysis correlated closely with the actual distraction (mean accuracy 0.4 mm).Simultaneous bimaxillary distraction osteogenesis is a robust technique that provides the surgeon with the ability to correct facial asymmetry in patients with hemicraniofacial microsomia and those with facial deformity after ankylosis of the TMJ. A cephalometric prediction tracing made before distraction is a reliable guide to the actual distraction needed to correct the facial deformities in these patients.

Ananatanarayanan P,Narayanan V,Manikandhan R, Kumar D (2008)[18] done a study to evaluate the role of primary osteo-distraction prior to ankylosis release in pediatric patients, diagnosed with NDS secondary to temporomandibular joint (TMJ) ankylosis. Three patients in the age group of 8—12 years diagnosed with OSAS secondary to TMJ ankylosis underwent primary osteo-distraction for mandibular advancement.

They were evaluated pre- and post-operatively using radiographs, over night pulse oximetry, and subjective evaluation of their sleep patterns. All the three patients showed significant improvement in their saturation levels with a mean oxygen saturation of 94.66%. There was marked reduction in their snoring and sleep/awakening patterns. The mean advancement of the mandible in the three patients was 13.8 mm.Primary mandibular distraction is an effective method of correction of nocturnal desaturations during sleep in patients with TMJ ankylosis.

Gonzalez M, Egbert M, Guerrero C A, Sickels J E V (2008)[19] conducted a study For the purposes of this article, lengthening of the mandible is subdivided into vertical lengthening of the ramus as in patients with hemifacial microsomia and horizontal lengthening of the mandibular body as in patients with Pierre Robin syndrome. Unfortunately, many of the patients that present for treatment of mandibular deformities often have a combination of both vertical ramal deficiencies and horizontal body deficiencies. One of the cases presented includes an intrarch distraction of the body of the mandible illustrating how complex are some patients with skeletal discrepancies. The design of commercially available distractors may not satisfy the needs of an individual patient. This issue is addressed in greater detail elsewhere in this issue. Depending on the age of the patient and the complexity of the movement, a single vector or a multivector distractor may be needed. In very young patients or in individuals with complex movements, an external distractor may be necessary. As with orthognathic surgery, lengthening of the vertical aspect of the mandibular ramus is technically more difficult than lengthening the body of the mandible to correct sagittal deficiencies.

Yu H, Shen G, Zhang S, Wang X (2009)[20] conducted a study to evaluate the efficacy of simultaneous gap arthroplasty and distraction osteogenesis (DO) in the

treatment of unilateral ankylosis of the temporomandibular joint (TMJ) in patients with micrognathia. During the period January 2000-December 2006, 11 patients with unilateral ankylosis of the TMJ and micrognathia were treated with simultaneous gap arthroplasty, mandibular osteotomy, and implantation of a distractor. Mouth opening exercises were started on the first postoperative day and distraction on the fifth postoperative day. All patients had satisfactory mouth opening at follow-up, the mean (range) being 32.4 (28–37) mm in 13 to 58 months' follow-up. Mean length (range) of the mandibular body increased by DO was 12.4 (7–15) mm. Facial asymmetry was corrected and satisfactory occlusions achieved with the help of postoperative orthodontic treatment. We conclude that DO and gap arthroplasty can be used simultaneously in the treatment of patients with ankylosis of the TMJ and micrognathia.

Feiyun P, Wei L, Jun C, Xin X, Zhuojin S, Fengguo Y.(2010)[21] presented a study to evaluate the simultaneous correction of bilateral temporomandibular joint ankylosis with mandibular micrognathia using internal distraction osteogenesis (DO) with the help of a 3-dimensional craniomaxillofacial model technique.A total of 16 patients (age 18 to 43 years) with bilateral temporomandibular joint ankylosis and mandibular micrognathia were included in the present study. Obstructive sleep apnea and hypopnea syndrome was diagnosed in all patients preoperatively. Three-dimensional craniomaxillofacial models of the 16 patients were constructed using computed tomography and a rapid prototype technique. Simulation surgery and individual internal DO was performed on the models. The treatment included simultaneous DO of the mandibular body and transport DO for temporomandibular joint arthroplasty. The distraction was started on the seventh day after surgery. The distraction rate was 0.8 mm/day. The patients began active mouth opening postoperatively. Distracters were kept in place for 4 months after distraction completion and then removed. Polysomnography, cephalometry, and computed tomography were performed at 6 months postoperatively.The obstructive sleep apnea and hypopnea syndrome was cured, and the micrognathia was corrected in all patients. The average mouth opening increased from 4.6 mm preoperatively to 33.5 mm postoperatively. The average range of the sella-nasion-supramental angle increased from 68.7 degrees preoperatively to 77.6 degrees postoperatively. Bone

formation in the distraction gaps was observed. The follow-up period was 29.7 months (range 6 to 52). No complications or recurrence of temporomandibular joint ankylosis or micrognathia occurred in any patient during the follow-up period.

Elagazzar R F,Abdelhady Al, Saad KA, Elshaal M A et al (2010)[22] conducted a study reports the authors' experience in managing TMJ ankylosis in Delta Nile, Egypt (1995–2006) and compares the surgical modalities used. 101 patients (109 joints) were reviewed in this retrospective study. Pre- and postoperative assessment included history, radiological and physical examination, and mouth opening.The patients' age range was 2–41 years, 62% were female, and the follow up period ranged from 14 to 96 months. Average mouth opening was significantly increased from 5.3 mm pre-operatively to 32.9 mm 12 months postoperatively (P = 0.0001). Marked improvement in mouth opening was documented when the ramus-joint complex was reconstructed using distraction osteogenesis (34.7 mm),costochondral graft (34.4 mm) and Surgibone (34.6 mm). Gap arthroplasty showed least satisfactory mouth opening compared with other techniques (P = 0.001). Minor and major complications were encountered in 33% of cases, including 5% recurrence rate.

Rajkumar GC, Manjunath, Shashikala R, Veerendra KD (2011)[23] **c**onducted a study on patients with temporomandibular joint ankylosis commonly present with mandibular hypoplasia as a result of trauma to the temporomandibular joint, middle ear infection or due to various syndromes. There is a wide acceptance of the conventional osteotomies for treating temporomandibular joint ankylosis, but there are certain limitations pertaining to them. In order to overcome these limitations several new approaches with modifications have been introduced. One among these is the method of gradual bone elongation known as distraction osteogenesis. This process induces new bone formation along the vector of distraction force without requiring the use of a bone graft. This study was conducted on four patients (2 females and 3 males within the age group of 1630 years) in which 3 patients had bilateral temporomandibular joint ankylosis and one patient with unilateral temporomandibular joint ankylosis.. These patients underwent surgical correction of temporomandibular joint ankylosis and mandibular hypoplasia using distraction osteogenesis with extra-oral distraction device under general anesthesia. In this study

we have used extraoral device to achieve distraction more than 20 mm and to overcome the limitations of intra oral devices. This study concluded that distraction osteogenesis is the treatment of choice for the temporomandibular joint reconstruction and anterior linear advancement of the hypoplastic mandible in whom the mandibular

Zhu S, Li J, Luo E, Feng G et al (2011)[24] done a study for treatment of TM joint ankylosis on 24 adult patients. From January 2003 to December 2009, 24 adult patients (30 joints) with TMJ ankylosis and secondary deformities underwent TMJ reconstruction as the initial surgery, followed by orthodontic treatment and correction of secondary deformities as the second surgery. Clinical outcome was assessed based on oral function, radiography, and medical photography. Patients were followed up for a minimum of 12 months to a maximum of 32 months (mean,18.6 months). No relapse of TMJ ankylosis occurred in any patient during the follow-up period. Oral function and skeletal deformities were significantly improved in all patients. Satisfactory occlusion was achieved with the help of orthodontic treatment. Most of the patients were satisfied with the final outcome.

Sahoo NK, Tomar K, Kumar A, Roy ID.(2012)[25] Conducted a study to compare the outcome of reconstruction options adopted for the management of temporomandibular joint (TMJ) ankylosis.This retrospective cohort study consisted of a sample of patients with TMJ ankylosis diagnosed clinically and radiologically. Depending upon the reconstruction provided, the cases were divided into 2 groups. Group I includes the cases treated by excision of ankylosed mass and interposition of temporalis myofascial flap. In group II, the cases were treated by excision, temporalis myofascial flap interposition, and reconstruction of ramus condylar unit (RCU). Two different methods of reconstruction were used, costochondral graft (CCG) (group IIa) and distraction osteogenesis (group IIb). The outcome variables were range of jaw motion, overgrowth of CCG, reankylosis, and other complications. Data analyses included appropriate univariate and bivariate statistics.The average mouth opening achieved in both groups was 36 mm. Failure was observed in 3 patients, 1 from group I and 2 from group IIa. One case of bilateral ankylosis and 2 cases of unilateral ankylosis had recurrence. No overgrowth of CCG was observed.In cases with no or minimal mandibular deformity, interpositional arthroplasty with temporalis

myofascial flap is a good option without a second surgical wound. However, in younger patients, joint reconstruction with both costochondral graft and distraction osteogenesis of RCU is more appropriate and had similar results. The failure of treatment was due to noncompliance to postsurgical physiotherapy rather than the selection of reconstruction options.

Li J, Zhu S, Wang T, Luo E et al (2012)[26] performed a study to evaluate a staged treatment of TMJ ankylosis accompanied by micrognathia using arthroplasty, mandibular distraction osteogenesis, and advancement genioplasty. A total of 12 bilateral TMJ ankylosis patients with micrognathia (aged 17 to 27 years) underwent arthroplasty as the initial surgical procedure, followed by orthodontic treatment and correction of mandibular micrognathia by osteodistraction and advancement genioplasty as the second surgical procedure. The clinical results were evaluated by mouth opening, radiography, medical photography, and respiratory function.The patients were followed up for a minimum of 8 months to a maximum of 36 months. The TMJ ankylosis was released successfully in all the patients, showing an increase in average mouth opening from 3.3 mm preoperatively to 35.8 mm postoperatively. Micrognathia was corrected, and, remarkably, the obstructive sleep apnea and hypopnea syndrome was cured. Satisfactory occlusion was achieved with orthodontic treatment.

Karun V, Agarwal N, Singh V(2013)[27] conducted a study to guide the formation of the new bone to form a structural part of the distracted bone through distraction osteogenesis of 6 -8 weeks including 12 patients..The group under study included 6 female and 6 male patients with an average age of 5 years. The osteotomy site decided was proximal to the ante-gonial notch. The distractor vector was kept oblique for simultaneous lengthening of the mandibular body and ramus. Custom made stainless steel extra-oral (in 8 patients) and intra oral (in two patients) distraction devices from the Ortho Max Company, Baroda, India were used. In all patients, appreciable lengthening of mandible was achieved.

Gupta GM, Gupta P, Sharma A, Patel N, Singh A. (2013)[28] conducted a study for evaluation of functional and esthetic outcome after correction of mandibular

hypoplasia secondary to temporo-mandibular ankylosis treated by Distraction osteogenesis. The study included 14 patients with severe mandibular hypoplasia(mean age 18.64 years). Unilateral distraction was done in cases with just mandibular asymmetry, while bilateral distraction was done in cases with retrognathia with or without asymmetry .Mean distraction done was 14.2 mm. Functional outcome was evaluated based on individual score of parameters. Parameters of function like occlusion, airway and biting chewing had improved in all but one patient. Also, both patient and panel perceptions for esthetics had improved post distraction in all the cases.

Bansal V, Singh S, Garg N, Dubey P. (2014)[29] This clinical and radiographic study investigated the use of transport distraction osteogenesis in unilateral temporomandibular joint (TMJ) ankylosis patients. Six patients aged between 4 and 8 years were selected for the study; the mean preoperative maximal inter-incisal opening (MIO) was 3.5mm without lateral and protrusive mandibular movements. The ankylotic mass along with the posterior border of the ascending ramus was exposed via 'lazy-S' incision. A gap arthroplasty was performed, followed
by a 'reverse L' osteotomy on the posterior border of the ramus. In-house manufactured extraoral distraction devices were used for this prospective study. Follow-up clinical and radiographic evaluation was carried out for 13-27 months after completion of the activation period. After a mean follow-up of 19 months, the mean MIO was 29.1mm and the lateral and protrusive movements changed from none to slight. Cone beam computed tomography images of all patients showed remodelled neocondyle created by transport distraction osteogenesis with no statistically significant differences observed for average cancellous bone density, trabecular number, and trabecular spacing between the neocondyle of the operated side (test) and the condyle of the non-operated side (control). Neocondyle formation by transport distraction osteogenesis using the in-house distraction device is a promising treatment option for TMJ reconstruction in ankylosis patients.

Yadav R, Bhutia O, Shukla G, Roychoudhary A (2014)[30] done a study to evaluate the effects of distraction osteogenesis in management of obstructive sleep apnoea patients secondary to temporomandibular joints ankylosis. Fifteen patients were

included in study. Preoperatively the patients were worked up for polysomnography and CT scans. Only those patients with Apnoeaehypopnoea index >15 events/h denoting moderate to severe obstructive sleep apnoea were included in the study. Distraction osteogenesis was followed with 5 days latency period in adult patients and 0 days for children. Rate of distraction was 1 mm/day for adults and 2 mm/day for children till the mandibular incisors were in reverse overjet.After 3 months post distraction assessment was done using polysomnography and CT scan.TMJ ankylosis was released by doing gap arthroplasty after distraction osteogenesis. Post distraction improvement was seen in clinical features of OSA like daytime sleepiness and snoring. Epworth sleepiness scale improved from a mean of 10.25 to 2.25. Polysomnographic analysis also showed improvement in all cases with apnoeaehypopnoea index from 57.03 to 6.67 per hour. Lowest oxygen saturation improved from 64.47% to 81.20% and average minimum oxygen saturation improved from 92.17% to 98.19%.

Parmar S B, Utsav U. Bhatt, Dr. Shilpi U. Bhatt (2014)[31] conducted a study to correct facial asymmetry which can be corrected using Distraction Osteogenesis. The study was done to achieve lengthening of mandible in patients with mandibular deformities secondary to Temporo-mandibular joint ankylosis using intraoral distraction . The study included 10 patients,
six males and four females between age group of 14 – 21 years, all having unilateral temporo-mandibular joint ankylosis. Mandibular body osteotomy followed by fixation of intraoral distractor was done in all patients followed by intraoral distraction and consolidation of 6-8 weeks. The amount of distraction done ranged from 9mm to 13mm

Khan A, Fareed W M, Tandon P, Zafar M S (2015)[32] done a study which was to assess mono-planar distraction devices for the correction of various mandibular asymmetries in patients with unilateral temporomandibular joint ankylosis who developed restricted mouth opening and mandibular retrognathia. All patients were treated using one-stage distraction osteogenesis followed by temporalis fascia interpositional arthroplasty under general anesthesia. A significant increase in mandibular ramus and base length was observed. Although an increase in anterior

lower facial height was observed, it was not significant statistically. A decrease in posterior lower facial height and corpus was observed. Oblique distraction with angular osteotomy allowed lengthening of both the ramus and corpus, yielding satisfactory results and hence eliminating the need of secondary surgery. In conclusion, univector internal distractors are effective for correction of multi-planar mandibular deficiencies by optimizing its placement through meticulous planning.

Chellapa A L, Mehrotra D, Vishwakarma K, Mahajan N, and Bhutia D P (2015)[33] done a Study, planned to compare the treatment outcomes of pre-arthroplastic distraction (PAD) and simultaneous arthroplastic distraction (SAD) to establish the better treatment modality in terms of improvement in function and aesthetics.This prospective randomized experimental study included 20 children and adolescents suffering from facial deformity due to long standing unilateral TMJ ankylosis. They were randomly allocated to the two surgical groups with ten in each group.Both groups resulted in good facial symmetry and aesthetics. Initially, during the distraction period, mouth opening of SAD group scored less than that of PAD group but became comparable in 30 days. More pain at the distraction site and over the normal TMJ was observed in PAD group. The excursive movements were almost comparable in both the groups.We conclude that both procedures are effective in correcting the post-ankylotic deformity and improving function. Although PAD has better control over movement of the distracting segment, the contralateral TMJ may experience pain. SAD requires a shorter management period but is associated with a temporary decrease in function. Also, control of distraction may be difficult and chances of reankylosis are always there.

Xu J, Long X, Cheng AH, Cai H, Deng M, Meng Q. (2015)[34] done a study From 2006 to 2013, in which 18 patients with TMJ ankylosis were enrolled. All patients had clinical follow-up and detailed examination.All patients had satisfactory results postoperatively. The mean (range) mouth opening increased from 7.1 (0-18) to 32.1 (28-43) mm during 37 (6-81) months of follow-up period ($P < 0.01$). Facial asymmetry was corrected in all patients, and all patients had minimal postoperative scar perception of the preauricular incision.The Wuhan TMJ ankylosis protocol

provides a safe and effective treatment alternative in managing TMJ ankylosis, especially in young women who are anxious about perceptive extraoral scar.

Mehrotra D, Vishwakarma K, Chellapa A L ,Mahajan N. (2016)[35] conducted a study to evaluate the hard and soft tissue changes after pre-arthroplasty simultaneous maxillomandibular distraction osteogenesis for the correction of post-ankylotic dentofacial deformities. This prospective study included 10 patients with unilateral temporomandibular joint (TMJ) ankylosis who presented with a facial deformity and a maxillary cant. Informed patient consent was obtained for participation. Simultaneous maxillomandibular distraction was planned based on clinical and radiographic examinations. A horizontal mandibular osteotomy was performed in the ramus and the distractor device was fixed. A bilateral Le Fort I osteotomy was then performed and a four-hole straight plate was fixed on the contralateral zygomatic buttress to act as a fulcrum. After a latency period of 5 days, the distractor was activated twice daily by 0.5mm until the required vertical lengthening was achieved. Intermaxillary fixation was maintained during the entire distraction period. After a consolidation period of 8-12 weeks, the distractor was removed. All patients were followed up for a period of 12-24 months. A marked improvement in the facial asymmetry was noted in all cases. The occlusal cant and mandibular retrusion improved satisfactorily, and the average postoperative inter-incisal opening was 35.6mm. Pre-arthroplasty simultaneous maxillomandibular distraction offers a good treatment outcome, as it allows improvements in facial aesthetics as well as function.

Rossini G,Vinci B,Rizzo R, Pinho T. M. DaC, Deregibus A(2016)[36] conducted study to analyze the available evidence on the skeletal and soft tissue effects of mandibular distraction osteogenesis. A three point grading system was used to rate the methodological quality of the selected papers. Vertical and sagittal dimensions increased significantly, by a mean of 5-10mm ($P < 0.05$). 90 % correspondence between skeletal and soft tissue cephalometric points was observed. Significant skeletal relapse was reported, but it did not worsen the results of treatment.

Giraddi GB, Arora K, Sai Anusha AJ (2016)[37] conducted a study to evaluate the efficacy of simultaneous interpostional arthoplasty with distraction osteogenesis as a

single procedure and to give the patient acceptable functional rehabilitation with correction of the gross facial asymmetry. The study included 9 patients of Temporo-mandibular joint ankylosis with micrognathia were treated with interpositional arthroplasty and simultaneous DO and followed for a period of minimum 3 years. All the patients underwent osteotomy for DO. This was achieved by making an osteotomy in region of angle and placing a bone- borne unidirectional distractor after exposing via a submandibular incision. The results showed an increase in the mouth opening, length of the mandible and ramus height, correction o deviation, occlusion and midline shift. There was an overall improvement in the facial symmetry.

Zanaty O, El Metainy S, Abo Alia D, Medra A (2016)[38] aim of this study was to determine if there is a difference in Cormack and Lehane score before and after distraction osteogenesis in such patients, and to evaluate the airway changes and the respiratory outcome using polysomnography after mandibular distraction osteogenesis.This observational prospective study was carried out on 30 ASA II patients with micrognathia and TMJ ankylosis undergoing internal distraction osteogenesis. All patients were assessed with polysomnography before surgery and 6 month after surgery. Nasal intubation was done using a fiberoptic bronchoscope, then patients were subjected to the same anesthetic protocol. Direct laryngoscopy was attempted for the Cormack and Lehane grading after induction. The Cormack and Lehane grade was reassessed after facial symmetry was obtained on removal of the distractor.Mouth opening and Cormack and Lehane score improved significantly between the initial presentation for placement of mandibular distraction osteogenesis devices and on removal of the destructor under general anesthesia. Polysomnographic studies conducted after distraction confirmed the correction of airway obstruction in all patients: Improvement in Apnea–Hypopnea Index, mean difference (95% CI), 39.8 (38.8–40.9); the number of apneas per hour, mean difference, (95% CI) 41.1 (42.1–40.1); and oxygendesaturation-index mean difference (95% CI) 27.6 (28.3–26.8).Mandibular distraction osteogenesis improved laryngeal view.

Tomonari H, Takada H, Hamada T,Kwon S et al (2017)[39] described the case of a 16-year-old female patient with micrognathia, temporomandibular joint (TMJ)

ankylosis, and obstructive sleep apnea, who was treated with mandibular distraction osteogenesis (DO) combined with sliding genioplasty, using skeletal anchorage. They first performed interpositional arthroplasty, in which an interposition of fascia temporalis and surrounding fat tissue was inserted into the defect after bilateral condylectomy, increasing the maximum mouth opening from 5.0 to 32.0 mm. Subsequently, orthodontic treatment and advancement of the mandible were carried out by mandibular DO, using miniscrews and miniplates. Finally, sliding genioplasty was performed to bring the tip of the mandible forward. The total amount of mandibular advancement at the menton was 16.0 mm. An improved facial appearance and good occlusion were eventually achieved, and the apnea-hypopnea index decreased from 37.1 to 8.7. There was no obvious bone resorption or pain in the temporomandibular region, limited mouth opening (maximum mouth opening: 33.0 mm), myofascial pain or headache, downward rotation of the mandible, or lateral shift of mandibular position evident at 5 years and 6 months after mandibular DO.

Ul Haq M. E. et al (2017)[40] conducted a longitudinal study to assess the effectiveness of monoplanar mandibular distractor by evaluating the treatment effect and 1 year stability and evaluating correction of the occlusal plane and oral commissural cant. The study included 15 patients with severe mandibular deficiency. An intraoral monoplanar distractor was used to achieve independent horizontal distraction of the mandible. Amount of lengthening was determined with cephalograms and clinical observation. Cephalometric analysis revealed that ANB angle decreased from 13-6 , overjet of 15mm decreased to 4mm, corpus length increased from 49 – 67mm.. Satisfactory results from both aesthetic and functional standpoints were obtained by distraction osteogenesis of body of mandible.

Baskaran M, Arularasan S G, Divakar T K, Thirunavukkarasu R (2017)[41] conducted a study to assess the versatility of distraction osteogenesis in the treatment of micrognathia. The study included 4 patients (3 male and 1 female) with micrognathia of the mandible with the range of age 10 – 20 years. Osteotomy and placement of intraoral distractor done under general anaesthesia. The parameters assessed were ramus height, body length, hyo mental distance, posterior pharyngeal airway space, chin projection, facial asymmetry occlusion, midline shift pre and post

operatively. There was a significant improvement in all parameters observed in all patients.

Sharma R, Manikandhan R, Sneha P, Parameswaran A, Kumar JN, Sailer HF (2017)[42] conducted a study to describe the role of neocondyle distraction in TMJ ankylosis. The study included 5 patients (4 males and one female in the age range of 19 – 23 years, mean age 21.2). Neocondyle distraction was carried out in five patients with TMJ ankylosis following gap arthroplasty. Computed tomogram scans were taken before surgery and 1 year post distraction for surgical planning and postoperative assessment, respectively. The intraoral distractors (KLS Martin, Jacksonville, FL, USA) were used in this study. All five patients reported with adequate mouth opening and functional jaw movements. The procedure was well tolerated by all the patients. None of the patient underwent reankylosis following neocondyle distraction.

Zhang C, Li Y, Ye B, Liu Y et al (2017)[43] done a study to describe the authors' experience of bidirectional distraction osteogenesis for the treatment of mandibular deformities caused by TMJ ankylosis.Sixteen patients with TMJ ankylosis and severe secondary mandibular deformities were treated with bidirectional distraction osteogenesis and release of joint from January 2013 to December 2015. Clinical outcomes were assessed based on the oral function, radiography, and medical photography. No reankylosis was found during the follow-up period. Sufficient volume and density new bone had been formed after the consolidation period. All patients have maintained stable improvement in oral function during the follow-up period. Most of the patients achieved satisfactory outcomes.Bidirectional transport distraction osteogenesis technique is a good and effective therapeutic option in treatment of bilateral or unilateral TMJ ankylosis patients associated with mandibular micrognathia.

Chen K, Xiao D, Abotaleb B, Chen H, Li Y, Zhu S. (2018)[44] conducted a study to evaluate the accuracy of virtual surgical planning and 3-dimensional (3D) printed templates to guide osteotomy and distraction osteogenesis (DO) in the treatment of temporomandibular joint (TMJ) ankylosis and secondary mandibular deformity.Seven

consecutive patients diagnosed with TMJ ankylosis and mandibular deformities were included. A composite skull model was obtained with data from spiral computed tomography (CT) and laser scanning of the dental arch. A virtual surgical simulation was performed using Dolphin Imaging 11.7 Premium (Dolphin Imaging and Management Solutions, Chatsworth, CA). Then, the virtual plan was transferred to the operation using 2 surgical templates. These templates were designed by 3D printing using data from the virtual surgical simulation for guiding the osteotomy and the DO, respectively. The preoperative measurement and differences between the actual mandibular position and the virtual plan were analyzed.Postoperative radiographs, CT images, and quantitative analysis showed a clinically acceptable precision for the position of the mandible. The mean length of the mandible and the vertical height of the DO were 79.1 and 14.9 mm, respectively. With the 3D superimposition and linear measurement, the mean difference between the virtual plan and the actual results ranged from 0.64 ± 0.20 to 1.90 ± 0.85 mm. All patients obtained satisfactory changes in the facial profile and marked improvement in postoperative pharyngeal airway space and mouth opening.The results of this study showed that virtual surgical planning and 3D printed guiding templates facilitated treatment planning, an accurate osteotomy, repositioning of bony segments, and contouring of the mandibular border in the treatment of TMJ ankylosis and secondary mandibular deformity.

Qiao J, Yu B, Gui L, Fu X, Yen CK, Niu F et al (2018)[45] done a study provided IPA a new graft material sufficient to prevent recurrence, combined the modified protocol of performing DO 6 months after IPA, and evaluated its efficacy in treating TMJ ankylosis patients with MD.Six patients with unilateral TMJ ankylosis and MD were treated in the authors' study. The temporalis fascia flap and part of adjacent galea aponeurotica were filled the space after surgical release. Mouth-opening exercises started immediately post-IPA. Distraction osteogenesis was performed 6 months after IPA and had a 4-month consolidation. The maximum interincisal distance at preoperative, immediately post-.All patients had significant improvements in facial aesthetic, mouth-opening, and occlusion. No major complication or recurrence was observed at 3 to 4 years' follow-up. The mean maximum interincisal distance was 4.83 ± 2.79 mm preoperative and 35.67 ± 3.39 mm at the latest follow-

up. The mean distraction distance was 16.17 ± 5.98 mm. The body mass index improved from 17.33 ± 0.64 kg/m preoperative to 18.75 ± 0.60 kg/m before DO.Temporalis fascia flap and adjacent galea aponeurotica as new graft materials are recommended for IPA. The modified staged treatment proved to be reliable and effective to prevent recurrence, improve mandibular length and final occlusion.

Peacock ZS, Salcines A, Troulis MJ, Kaban LB (2018)[46] done a retrospective cohort study of children to assess the fate of the permanent teeth in and adjacent to the regenerate in pediatric patients who underwent mandibular distraction osteogenesis (DO) and 2) to compare the postoperative growth of the distracted mandible with age- and gender-matched controls.Children who underwent mandibular DO during the primary or mixed dentition period and before completion of somatic growth (boys aged ≤14 years and girls aged ≤12 years) at Massachusetts General Hospital from 1996 to 2014. From the DO registry, patients were selected who had complete clinical and radiographic records and at least 1 year of follow-up. Patients with disorders of dental development (eg, ectodermal dysplasia) were excluded. Panoramic radiographs were used to assess changes in morphology, eruption, and orientation of the dentition. Standardized digital lateral cephalograms were used to assess the mandible (sella-nasion-B point, mandibular unit length, ramus height, body length) preoperatively, at the end of distraction, at 1 year after device removal, and at longest follow-up.A total of 118 patients of all ages in the registry underwent some form of DO during the study period. For assessment of the effects on dentition, 26 subjects, who had 36 osteotomies and distraction wounds, met the inclusion criteria. In this sample, 22 of 26 subjects (85%) had 52 adverse effects in 38 of 90 permanent teeth (42.2%) assessed. Cephalometric measurements indicated that there was net mandibular growth at longest follow-up, after a period of skeletal relapse from the end of distraction to 1 year after device removal; however, only 2 of 25 subjects (8%) regained a growth rate in the vector of DO that matched or exceeded normal age- and gender-matched controls.Net growth of the mandible occurs after DO but at a slower rate and lesser magnitude than that of age- and gender-matched controls.

Jiang Y, Huang Y, Ye B,Li Y, Zhu S (2018)[47] done a retrospective study which described the authors' experience in the treatment of temporomandibular joint (TMJ) ankylosis with dentofacial deformities in 18 pediatric patients during a 4-year period. These patients underwent different types of arthroplasty with condylar reconstruction, simultaneously with treatment of dentofacial deformities. Re-ankylosis was confirmed if maximal incisal opening (MIO) was <20 mm. Clinical outcomes were evaluated in terms of oral function, radiography, and medical photography. Patients were followed up for a mean time of 24.8 months. No infections, re-ankylosis, or permanent facial nerve damage were found during the hospitalization or follow-up period. All patients achieved significant improvements in MIO and oral function. The dentofacial deformities in most patients were improved to varying degrees. The results provided more useful information for the management of the pediatric patients with TMJ ankylosis and secondary dentofacial deformities. Early treatment and close follow-up play an important role in the management of these patients.

Andrade NN, Mathai PC, Ganapathy S, Aggarwal N, Rajpari K, Nikalje T (2018)[48] done pre-arthroplastic mandibular distraction osteogenesis [DO] to increase the PAS and resolve the underlying OSA prior to releasing the ankylosis.Twenty-five cases of TMJ ankylosis with micrognathia and OSA were included in this prospective observational sleep study. They were further divided into a paediatric group [14 subjects] and an adult group [11 subjects]. All cases presented with a history of onset of ankylosis during childhood [before the completion of craniofacial growth] as result of which there was a lack of forward growth of the mandible. Subjects included in our study underwent initial DO of the mandible followed by a second procedure for distractor removal and ankylosis release. Questionnaires, lateral cephalograms and sleep studies were taken pre-operatively (T0), immediate post-distraction to the desired length (T1) and 12 months post the distractor removal and ankylosis release (T2). The parameters studied were PAS width, apnoea hypopnea index [AHI], O2 saturation, mouth opening and mandibular advancement.The paediatric group variables were as follows: mean PAS width which increased from 3.5 mm [T0] to 9 mm[T2], mean AHI which decreased from 48.04 [T0] to 3.60 [T2], mouth opening which increased from 4.5 mm [T0] to 34 mm [T2] and mean O2 saturation which increased from 89.86% [T1] to 96.88% [T2]. The adult group variables were as

follows: mean PAS width which increased from 5 mm[T0] to 11mm[T2], mean AHI which decreased from 31.45 [T0] to 1.43 [T2], mouth opening which increased from 5 mm [T0] to 34 mm [T2] and mean O2 saturation which increased from 92.01% [T0] to 96.84% [T2]. Statistical analysis revealed that DO of the mandible significantly improved OSA by increasing the PAS which was evident by the lower AHI score. Mouth opening was also significantly improved post ankylosis release and maintained at the T2 interval. Ten subjects followed up beyond the T2 interval [mean 28 months post ankylosis release] and their data also revealed positive compliance towards physiotherapy, adequate mouth opening and maintenance of normal AHI. Pre-arthroplastic mandibular

Khan M N, **Asim M A, Shah I (2018)**[49] proposed the management of obstructive sleep apnea syndrome associated with severe micrognathia.They presented comprehensive management of a case of OSAS associated with post temporomandibular joint ankylosis severe micrognathia. Various surgical treatment methods including DO and conventional orthognathic surgical procedures were employed in management of this patient of obstructive sleep apnea. Both functional and esthetic complaints of the patient were addressed, and we achieved exceptional results at the end of treatment.

Zhang W,Yang X, Zhang Y , Zhao T , Jia J , Chang S et al (2018)[50] conducted study to evaluate the effect of the sequential treatment of temporomandibular joint ankylosis with secondary deformities by distraction osteogenesis. They retrospected 40 patients with temporomandibular joint ankylosis, whose age varied from 9 to 53 years old (average 24.5 years old). Among of them, 11 patients were diagnosed as unilateral temporomandibular joint ankylosis, 29 were diagnosed as bilateral joint ankylosis. OSAHS was found in 27 patients. All patients underwent distraction osteogenesis as the initial surgery, followed by arthroplasty. The orthognathic treatment was performed along with or after the arthroplasty. The therapeutic effect was evaluated by the improvement of MIO, appearance and respiratory function. After the treatment procedure was ended, all patients' mouth

opening and appearance were improved remarkably, and the symptom of snoring disappeared. The patients were followed up for 4 to 72 months (average 20.5), only 4 patients were recurrent, and needed further surgical treatment.

Bi RY, Luo XT, Jiang N, Zhu SS, Li YF (2018)[51] conducted study on Seventeen patients who underwent spiral computed tomographic (CT) scans before and after DO. After treatment, the overall posterior airway space was enlarged in all three sections of the airway (oropharyngeal, glossopharyngeal, and laryngeal). They compared rates of change in the airway among the sections using 2-dimensional and 3-dimensional assessments, and found that the rate of change in 3-dimensional assessment of volume was significantly higher than that in the 2-dimensional (62% compared with 34%).They also found that the higher 3-dimensional rate of change came from changes in the oropharyngeal and glossopharyngeal sections, while there was no significant difference between the 2- and 3-dimensional rates of change in the laryngeal section. Because the laryngeal section had the most robust enlargement after DO in both the overall area of the posterior airway space (increased by 54%) and volume (increased by 73%), we concluded that 3-dimensional assessments were more sensitive to smaller changes in the airway space during the operation. This suggests that 3-dimensional assessments are preferable in the prediction and evaluation of the effects of DO on the posterior airway space.

Fariña R,Canto L, Gunckel R, Alister J P, Uribe F (2018)[52] done a study with primary goal of treatment is to resolve the functional and morphological disorders. Pre- and posttreatment clinical and cephalometric registries were conducted in 15 patients with temporomandibular joint ankylosis over a 10-year period (2002–2012). All the patients underwent complete removal of the ankylotic block, gap arthroplasty, and ipsilateral coronoidectomy. Distraction osteogenesis was performed on 12 patients.Fifteen patients, 8 female and 7 male, ranging from 3 to 30 years of age, were included in this study. The posttreatment follow-up period ranged from 3 to 13 years.The mean preoperative maximum mouth opening was 3 ± 1.7 mm, and the mean postoperative maximum mouth opening was 36 ± 6.5 mm. The labial inclination with respect to the true horizontal decreased considerably (6.2° ± 2.3° preoperative to 1° ± 1.6° postoperative). A correction of the mandibular deviation

was measured at the symphysis with respect to the facial midline (8° ± 2° preoperative to 2° postoperative). Finally, the height ratio of both mandibular rami (the healthy side and the affected side) decreased considerably (1.27 ± 0.05 preoperative to 1.07 ± 0.06 postoperative).Reankylosis only occurred in 2 patients, who were then successfully treated by means of gap arthroplasty.The therapeutic algorithm proposed in the present work provides favorable functional and morphological results. Early and aggressive functional physiotherapy is essential to minimize the risk of reankylosis.

Anchlia S, Vyas S, Dayatar RG, et al. (2019)[53] done a prospective single-centre study on 43 joints in 25 adult patients with TMJ Ankylosis aimed at providing a single-staged management plan of ankylosis release, RCU reconstruction and extended advancement centering genioplasty. Interpositional arthroplasty was done using temporalis myofascial flap, abdominal dermis fat or buccal fat pad. RCU reconstruction was done either by vertical ramus osteotomy or L osteotomy.Follow-up ranged from 12 to 20 months (mean 14.4). Average mouth opening at maximum follow-up was 34.36 mm with re-ankylosis in no case. Cephalometric parameters showed increase in point P to Pog, decrease in N perpendicular to Pog, angle N-A-Pog, Cg-ANS to Cg-Menton, neck-chin angle and labiomental angle. N-PAS increased, and average 50% improvement in AHI was seen in all patients with OSA. Most common complications involved transient paraesthesia of temporal and zygomatic branches of facial nerve.Based on the findings of the above study, we propose treatment guidelines for treatment of TMJ ankylosis in adult patients with AHI < 20.

Dharmendra Kumar MG, Narayanan V, Manikandan R1 et al (2019)[54] conducted a study to evaluate the role of primary osteo-distraction prior to ankylosis release in patients, diagnosed with sleep apnoea, facial asymmetry, and reduced quality of life secondary to temporo-mandibular joint ankylosis. The study included 10 patients in the age group of 13 – 40 years with TMJ ankylosis underwent primary osteo-distraction for mandibular advancement. In cases of bilateral TMJ ankylosis, the amount of distraction achieved post-operatively was 68.33 _ 3.51 ($P < 0.05$) and in cases of unilateral TMJ ankylosis it was 91.15 _ 5.08 ($P < 0.05$). In all the ten

cases TMJ ankylosis with sleep apnoea, there was significant improvement in the airway and Epworth Sleep Scale ($P < 0.05$). There was significant improvement of quality of life among these patients' pre- and post-operatively.

Ma Y,Huang Y ,Zhu S, Li Y(2019)[55] conducted a study to Explore the use Of simultaneous arthroplasty And distraction Osteogenesis in the treatment of children with ankylosis of the temporomandibular joint (TMJ) and secondary mandibular deformities. Between January 2012 and December 2016, 17 children (7 boys and 10 girls, mean (range) age 7 (4–12) years) were treated. Preoperatively, the mean (range) maximal incisal opening was 1.4 (0–5) mm. Distraction began after five to seven days at a rate of 0.5 mm twice daily, and the distractor was removed three to five months after the completion of distraction. The mean (range) follow-up time after removal was 29.6 (16–45) months, and the distance of distraction was 14.4 (10–18) mm. After treatment, all patients had satisfactory outcomes, a good facial profile, alignment of the midline lower incisor, and a level occlusal plane. The mean (range) maximum incisal opening reached 35.7 (31–41) mm. Bone formation across the distraction gap was good. The mean minimum axial area of the airway increased from 61.4 mm to 96.4 mm ($p < 0.01$). No patients had a recurrence of ankylosis during follow up. Our results suggest that simultaneous arthroplasty and distraction osteogenesis is feasible in this group.

Hassan SAE, Mohamed FI (2019)[56] done a retrospective study to evaluate the short-term and long-term skeletal and soft-tissue stability after MDO with or without genioplasty, as well as the stability of the achieved maximum inter-incisal opening (MIO) in patients with mandibular hypoplasia secondary to TMJ ankylosis. Twenty patients with mandibular hypoplasia secondary to TMJ ankylosis were managed by a two-stage surgical protocol, gap arthroplasty as the first stage, followed by MDO. The patients were analyzed for skeletal and soft-tissue stability as well as the maintenance of the achieved MIO. Lateral cephalograms were evaluated at four time intervals: pre-distraction (T1), after a consolidation period with or without genioplasty (T2), after one year following consolidation (T3), and at the longest follow-up (T4). Statistical analyses compared the skeletal and soft-tissue changes at different intervals in every group.All the ankylosed joints except three were treated

with gap arthroplasty without costochondral graft. The MIO was increased from 8.2 ± 2.1 mm preoperatively to 40.2 ± 1.7 mm postoperatively. After the consolidation period, MIO decreased to 23 ± 6.5 mm. The patients were instructed to restart active physiotherapy after removal of the distractors to regain the pre-distraction MIO, which was maintained during the short-term follow-up. The mean follow-up period was 8.5 ± 1.5 years. At the end of the follow-up, two patients showed recurrence of ankylosis. Cephalometric analysis revealed great improvements in the hard- and soft-tissue structures after MDO with or without genioplasty. Several significant long-term relapses could be observed in all groups; however, they did not reach their pre-operative values. TMJ ankylosis leads to severe, multidirectional mandibular hypoplasia, which is significantly corrected with the MDO. The MDO provides a stable short-term improvement in the facial esthetics at the first postoperative year, but a significant relapse occurs during the long term follow-up. Nevertheless, a satisfied facial esthetic is maintained for up to seven to 12 years postoperatively. During the activation period, the MDO minimizes the gained MIO after release of ankylosis, but the MIO is successfully restored with physiotherapy.

Singh H, Mishra S, Srivastava D, Kapoor P, Sharma P, Chandra L (2019)[57] reported a case which describes the encouraging results of systematically sequenced and staged therapeutic approach adopted for successful rehabilitation of an adult patient with asymmetric Class II dentofacial deformity with mandibular micrognathia secondary to unilateral TMJ ankylosis. Concurrent gap arthroplasty and bilateral distraction of mandibular body were performed during the first operation for functional restoration of mandibular movements and correction of mandibular micrognathia and associated asymmetry. After 13 months of post-distraction orthodontic treatment, Le Fort I osteotomy for inferior repositioning and sagittal advancement of maxilla was performed during the second operation, in conjunction with adjunctive alloplastic reconstruction of inferior border of mandible for optimization of facial aesthetics. Postsurgical orthodontic detailing facilitated achievement of stable, balanced interdigitation. The total active treatment period was 29 months. After treatment, both the skeletal disharmony and the functional stability were significantly improved with establishment of functional occlusion. The morphological and functionally acceptable results were reasonably well-maintained

during three-year follow-up. The merits of mandibular osteodistraction vs. conventional mandibular orthognathic surgery and the potential advantages of staged surgical approach are discussed.

Srivastava D, Luthra P, Mishra S, Chandra L, Sharma S et al (2019)[58] presented a case series on Technique of Dual Distraction for Correction of Unilateral Temporomandibular Joint Ankylosis With Facial Asymmetry.We present the cases of 7 patients with unilateral TMJ ankylosis and facial asymmetry of various grades who have been treated using gap arthroplasty and simultaneous dual distraction. Considerable debatehas surrounded the sequencingof TMJ release and distraction osteogenesis; however, the simultaneous approach has recently become popular. The use of a single distractor simultaneously with TMJ release has been widely reported. However, one disadvantage with this technique is that the proximal condylar segment remains unstable. Dual distraction is a newer technique which we have proposed as a single-stage approach for the correction of TMJ ankylosis and facial asymmetry and to address the problems resulting from the use of a single distractor. Results: After treatment, all the patients showed a mouth opening ranging from 35 to 50 mm and satisfactory facial symmetry. Dual distraction is a promising technique in the correction of facial asymmetry.

Vignesh U, Mehrotra D, Bhave S M, Singh PK et al (2020)[59] done a study to evaluate the success of distraction osteogenesis in temporomandibular joint (TMJ) ankylosis patients with facial deformities. Study Design. QoL and the Oral Health Impact Profile (OHIP) were prospectively studied in 42 consecutive patients with facial deformities, planned for maxillofacial distraction osteogenesis, using 2 validated questionnaires, the Orthognathic Quality of Life Questionnaire and OHIP-14. Patients who had undergone any previous surgeries were excluded. Results. Among these patients, 16 were female, 26 male; mean age was 14.98§4.88 years, and all had prearthroplastic distraction. The shortening in the mandible was in the proportion 29:01:12 in the body, ramus, and ramus-body, respectively. Mean QoL scores before and after distraction were 68.52§9.50 and 26.62§3.51; and mean OHIP scores before and after distraction were 33.88§6.26 and 15.36§2.54, a highly significant difference ($P < .001$) suggesting improvement. Significant improvement

was identified on all QoL and OHIP questions after distraction (P < .01). The postdistraction overall mean QoL score among patients with extraoral or intraoral distractor did not have a significant difference (P = .32), but facial appearance in the bilateral distraction group; jaw function and overall well-being in the multivector distraction group; and facial appearance, jaw function, and overall well-being in maxillomandibular distraction group had significant improvements (P < .05). Conclusions. Distraction osteogenesis considerably improves oral health and health-related QoL in patients with TMJ ankylosis with facial deformities.

Xia L,Zhang Y, An J, Chen S, He Y (2020)[60] conducted a study which aimed to evaluate the remodeling of condyles reconstructed by transport distraction osteogenesis (DO) in patients with temporomandibular joint (TMJ) ankylosis. Twenty-one patients with 26 affected joints were followed up for 34.1 ± 13.3 months. Patients who had undergone gap arthroplasty and TMJ reconstruction by DO were included.Computed tomography images were obtained preoperatively (T0), upon completing distraction (T1), upon removal of the distraction device (T2), and >2 years postoperatively (T3). The following were measured: mandibular ramus height, distance between gonion and Frankfurt plane (GoeFN), condylar width, and condyleeramus angulation.Of the 21 patients, one showed re-ankylosis, while five exhibited anterior open bite. From T1 to T3, the total amount of resorption of ramus height reached up to 8.2 ± 4.6 mm ($p < 0.001$), in comparison with a total distraction length of 13.8 ± 4.1 mm; the mean resorption rate was 59.4%. Similarly, GoeFN decreased by 6.2 ± 4.0 mm ($p < 0.001$).Our findings indicated that DO combined with gap arthroplasty was an effective method for the treatment of TMJ ankylosis to improve MMO.

Ramly E P, Yu J W, Eisemann B S, Yue O et al (2020)[61] presented an institutional experience treating congenital and acquired temporomandibular joint (TMJ) ankylosis, detailing outcomes and potential risk factors of recurrence. Retrospective chart review identified patients with TMJ ankylosis (1976–2019). Clinical records, operative reports, and imaging studies were reviewed for demographics, surgical operations, and ankylosis including maximal interincisal opening (MIO) and re-ankylosis. Forty-four TMJs with bony ankylosis were identified in 28 patients (mean

age at any initial mandibular surgery: 3.7; range:0–14 years). Follow-up was 13.7_5.9 years. Sixteen (57.1%) patients had bilateral ankylosis; 27(96.4%) had syndromes. Nine patients had congenital ankylosis, 16 had iatrogenic ankylosis (4.5_3.7 years from initial distraction osteogenesis or autologous mandibular reconstruction) referred from outside institutions in 6 instances, and 3 had post-infectious ankylosis. Patients having their first mandibular operation at a younger age had more frequent reoperations for recurrent TMJ ankylosis, although this did not reach statistical significance. Mean improvement in MIO was 21.4_7.3 mm. Ankylosis recurred in 21 (75%) patients. Five patients with congenital TMJ ankylosis required gastrostomy and remained at least partially dependent. Five patients had tracheostomy at the time of TMJ ankylosis surgery: 2 were eventually decannulated and 3 required repeat tracheostomy after ankylosis recurrence and remained tracheostomy-dependent.

Chugh A, Mehrotra D,Yadav P K (**2021**)[62] done a systemic review on the study to generate evidence towards the role of DO in TMJa, evaluate its efficiency and develop an algorithm for use of DO in TMJ. The research question was formulated using the PICOS statement for reporting guidelines in systematic reviews, where the efficiency of DO was evaluated in terms of mouth opening, correction of facial deformity and asymmetry, airway correction, and its long term effects.1130 articles reported DO as a treatment modality for TMJ ankylosis, of which 32 prospective studies, 16 retrospective and 2 RCTs were included in the study. DO was used for mandibular distraction in 45 studies and for simultaneous maxillamandibular distraction in only five studies. An algorithm for use of DO in TMJa was developed. Although DO has proven its application in TMJ ankylosis cases, its best use is for correction of obstructive sleep apnoea. Relapse causing loss of posterior ramal height is a concern after transport DO. Prearthroplastic DO appears to best correct mandibular deformity. A maxillomandibular deformity requires simultaneous maxillomandibular distraction. However, a metanalysis is still awaited for effectiveness of DO in TMJ ankylosis.

Albert D, Muthusekhar M R (2021)[63] conducted a systematic review to compare the effectiveness of various sequences of DO in the management of TMJ ankylosis with

micrognathia/and obstructive sleep apnea syndrome (OSAS).A comprehensive online and manual search of English language literature with no date restrictions was done on March 2020. Inclusion criteria were case series and prospective and retrospective studies involving adult/paediatric human subjects with unilateral/bilateral TMJ ankylosis and micrognathia/OSAS treated with DO.Of 73 studies identified, only 10 were included in the qualitative synthesis. The outcomes assessed were as follows: maximum mouth opening (MMO), posterior airway space (PAS), polysomnography variables, reankylosis, mandibular length, and chin and mandible position. All the included studies showed high risk of bias. MMO and mandibular length increased, chin and mandibular position improved by the end of treatment in all the three sequences, and polysomnography variables and PAS significantly improved in PrAD compared to PAD and improved in SAD compared to baseline. Reankylosis was significantly less in PrAD. More well-designed studies comparing the three sequences of DO should be carried out to arrive at a consensus.

Dowgierd K, Pokrowiecki R, Kulesa Mrowiecka M, Dowgierd M, Woś J, Szymor P et al (2022)[64] presented a protocol for the treatment of ankylosis of the temporomandibular joints that assumes earlier intervention with the assistance of 3D virtual surgical planning (3DVSP) and custom biomaterials for better and safer surgical outcomes. Thirty-three patients were treated due to either uni- or bilateral temporomandibular ankylosis. Twenty individuals received temporomandibular prosthesis, whereas seventeen required simultaneous 3D virtual surgical/planned orthognathic surgery as the final correction of the malocclusion. All patients exhibited statistically significant improvements in mouth opening (from 1.21 ± 0.74 cm to 3.77 ± 0.46 cm) and increased physiological functioning of the mandible. Gap arthroplasty and aggressive rehabilitation prior to temporomandibular prosthesis (TMJP) placement were preferred over costochondral autografts. The use of 3DVSP and custom biomaterials enables more precise, efficient and safe procedures to be performed in the paediatric and adolescent population requiring treatment for temporomandibular ankylosis.

MATERIAL AND METHOD

Study Design

A prospective, randomized, single center study was performed in patients with TMJ ankylosis. Patients participated in the study as per inclusion criteria, reporting to the out-patient department (OPD) of Oral and Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Lucknow.

Inclusion criteria

- Patients diagnosed with unilateral or bilateral TMJ ankylosis.
- Age ranges below 18 years with facial asymmetry.

Exclusion criteria

- Patients with severe bone disorders
- Subjects with any underlying systemic disease or compromised immunity.
- Patients not willing to participate in the study.

Materials Required

Materials and Equipments Used in the study with specifications and Company :

- Stainless steel miniature Distraction device with bicortical screws.
- Mouth mirror and probe
- Metallic scale
- Perisosteal elevator – Howarth and Molts
- Tissue holding forcep
- Suture cutting scissors
- Needle holder
- B. P. handle and blade
- Micromotor and handpiece
- Saw
- osteotomes
- Dental Bur kit
- Disposable syringes
- Other surgical instruments

METHODOLOGY

Mandibular Distraction was done under General anaesthesia using either extra oral submandibular incision or intraoral vestibular incision. Osteotomy was done with the help of saw / bur. Unrestricted movements of bone segments upon activation of distraction was verified and wound closed.

- Latency period of 3 – 5 days was allowed for soft callous formation following distraction of 0.5 mm twice a day.
- Consolidation period of 8 – 10 weeks was allowed for callous maturation after completion of distraction.
- Ankylosis was released in a separate operative procedure either before or after completion of distraction.
- The exposure of the joint was done by Alkayat - Bramley incision followed by arthrectomy / interpositional arthroplasty.
- All patients were subjected to post-operative physiotherapy.

ASSESSMENT PARAMETERS –

All patients diagnosed with unilateral / bilateral TMJ ankylosis, willing to participate in the study were subjected to distraction procedure under general anaesthesia either before or after arthrectomy using intraoral or extraoral device. Patient will be assesed in following parameters.

1. Correction of facial asymmetry based on :
   a) patient perception
   b) panel perception :

score of 1- 3 was assigned where 1 = unsatisfactory, 2 = satisfactory and 3 = excellent.

2. Midline correction , measured in millimeters.
3. Airway: evaluations were done on the basis of pre and post operative lateral cephalograph, measured in millimeters.
4. Mouth opening : Inter-incisal ,measured in millimeters , both pre and post operatively.
5. Cephalometric evaluation : Pre and Post operative lateral cephalograph, PA cephalograph.

Statistical Analysis

The data was recorded in a preformed case/sheet, according to the parameters mentioned and were tabulated and statistical analysis was carried out using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software.

The following statistical tools was employed for the present study:

- **MEAN**
- **STANDARD DEVIATION**
- **CHI SQUARE TEST**

1. **Chi-square test:** This test was performed to evaluate whether there was a significant difference in frequency of events in one group from that in another. The following formula was used to calculate the proportion.

Chi square test:

$$\chi^2 = \sum \frac{(O - E)^2}{E}$$

Where O = Observed frequency

E = Expected frequency

2. Mean: Mean was calculated as the central tendency of a group using the following formula:

$$\overline{X} = \frac{\Sigma X}{N}$$

37

Where ΣX = summation of values

n = number of samples

1. **Standard Deviation**: Most frequently used, measure of dispersion, denotedby S.D. and was calculated as:

$$SD = \sqrt{\frac{\Sigma (X - \bar{X})^2}{n}}$$

S.D. = Standard Deviation

X = Individual value for the parameter

$\bar{X}$ = Arithmetic mean

N = Number of observations

2. **Student 't' test:** To test between equality of two mean:

$$t = \frac{\bar{x}_1 - \bar{x}_2}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}}$$

X_1 = Mean 1

X_2 = Mean 2

SD_1 = Standard deviation 1

SD_2 = Standard deviation 2

n_1 = Number of values in group 1

n_2 = Number of values in group 2

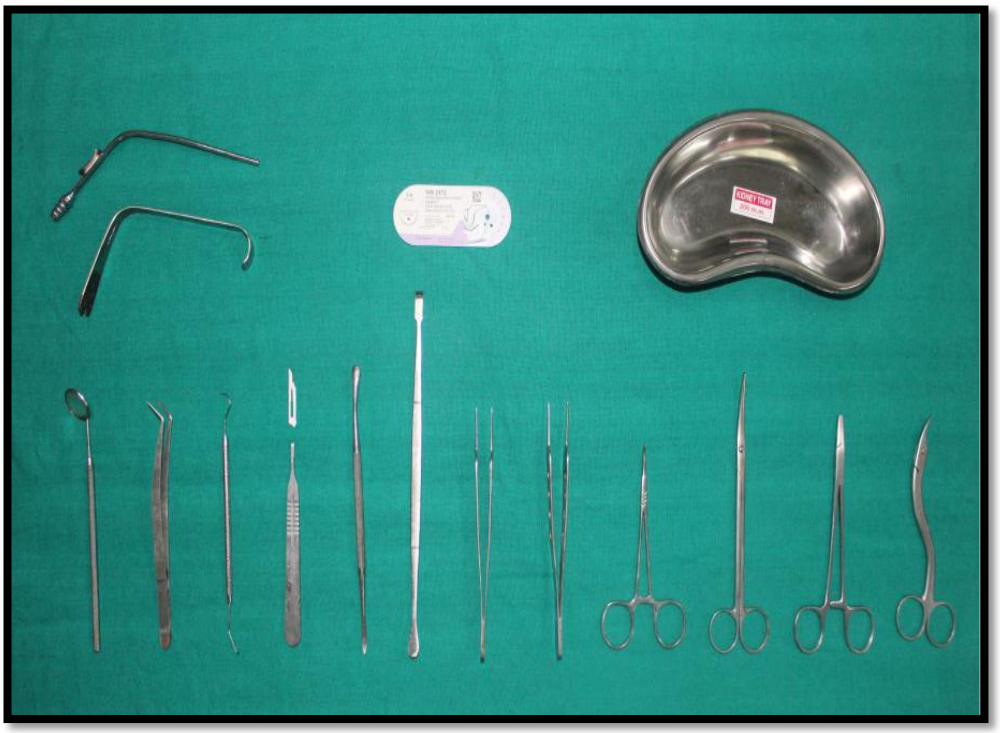
Blood investigations -

BT, CT, Hb%, ESR, TLC, DLC, HbsAg, Blood sugar, HIV, S.Urea, S.Creatinine,

Radiographic investigations - OPG, IOPAR, Lateral Cephalogram, PA view

PHOTOGRAPHS

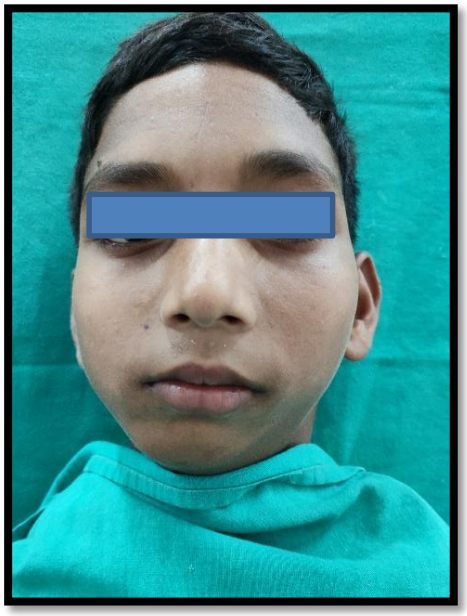
ARMAMENTARIUM

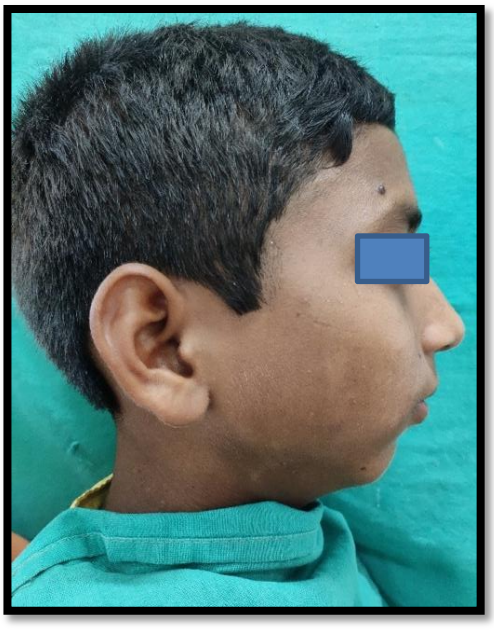


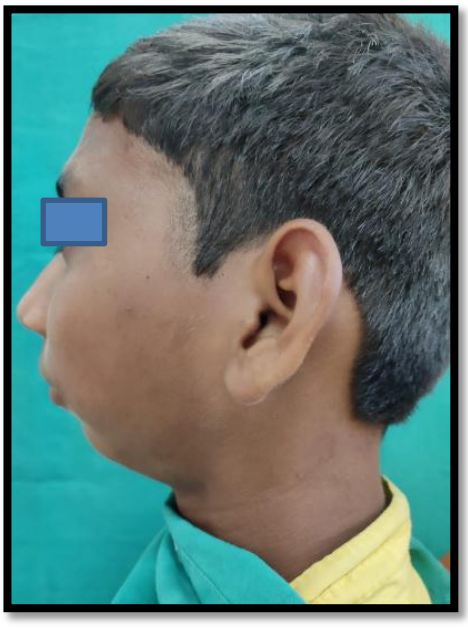
DISTRACTOR DEVICE

CASE 1

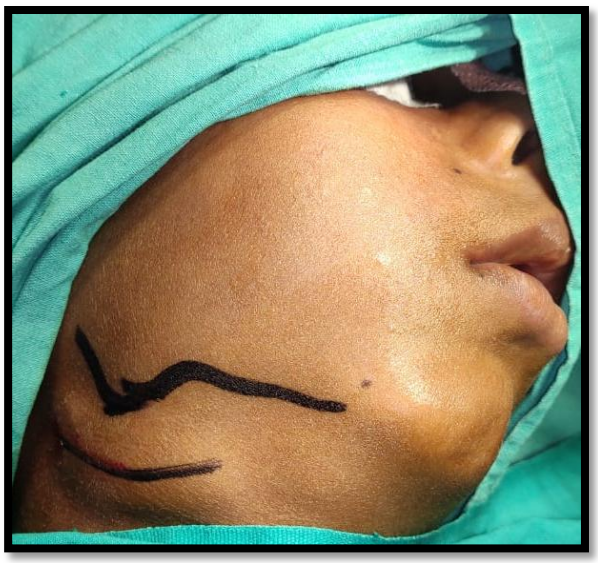
PRE-OPERATIVE PHOTOGRAPHS



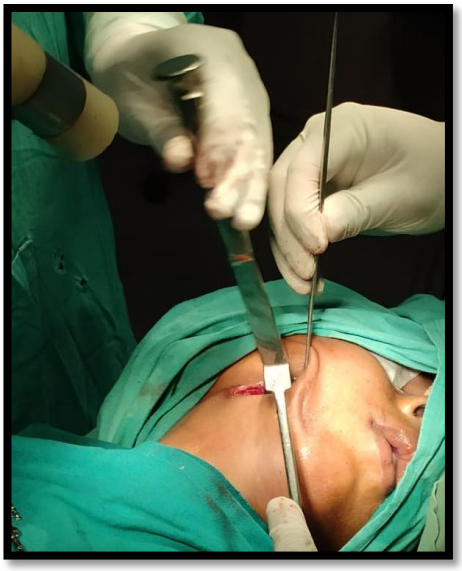




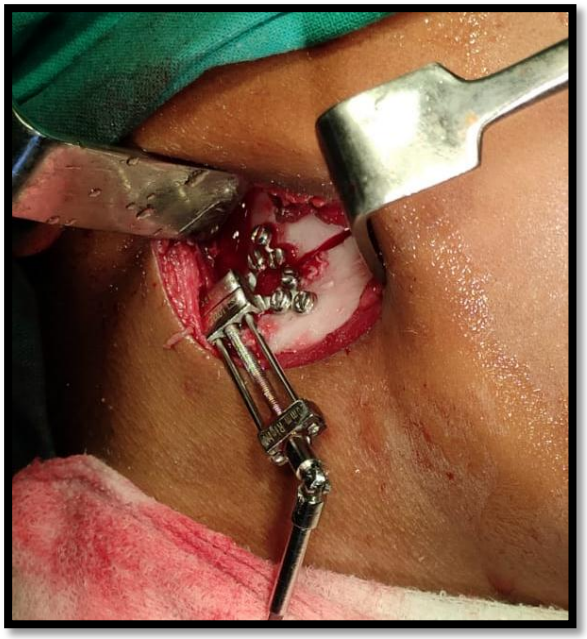
INTRA-OPERATIVE PHOTOGRAPHS



Incision Marking



Osteotomy

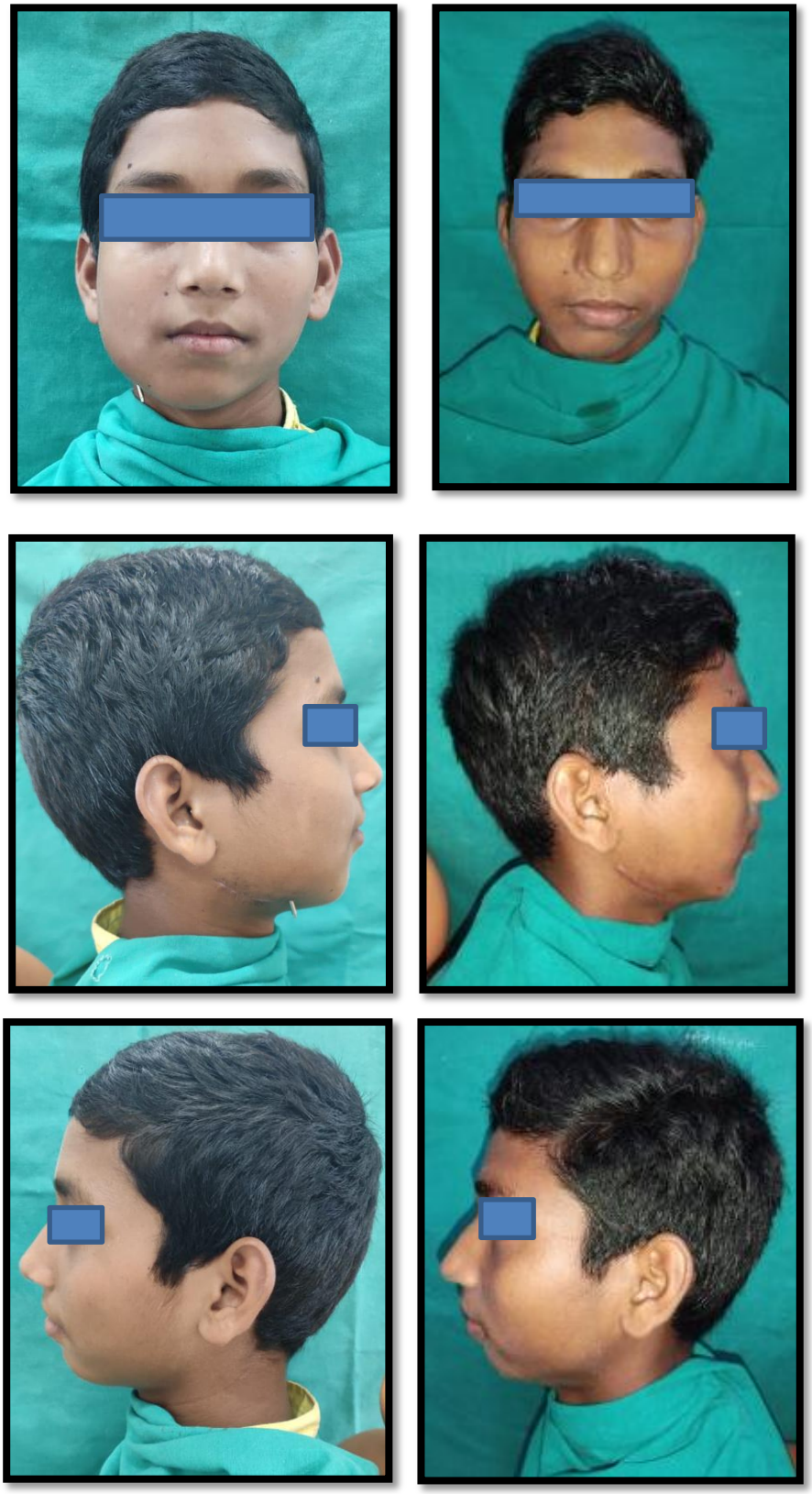


Placement Of Distractor

Arthrectomy And Removal Of Distractor Done

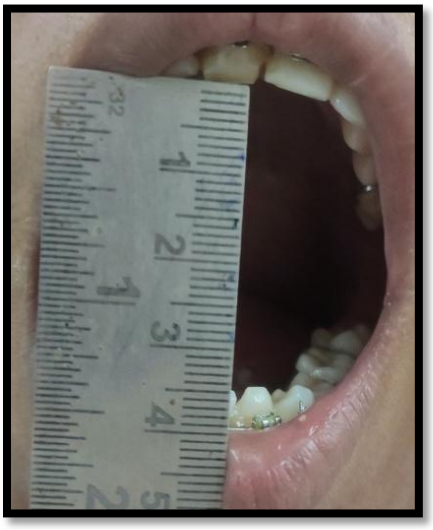
POST-OPERATIVE PHOTOGRAPHS

After 3 Months **After 6 Months**



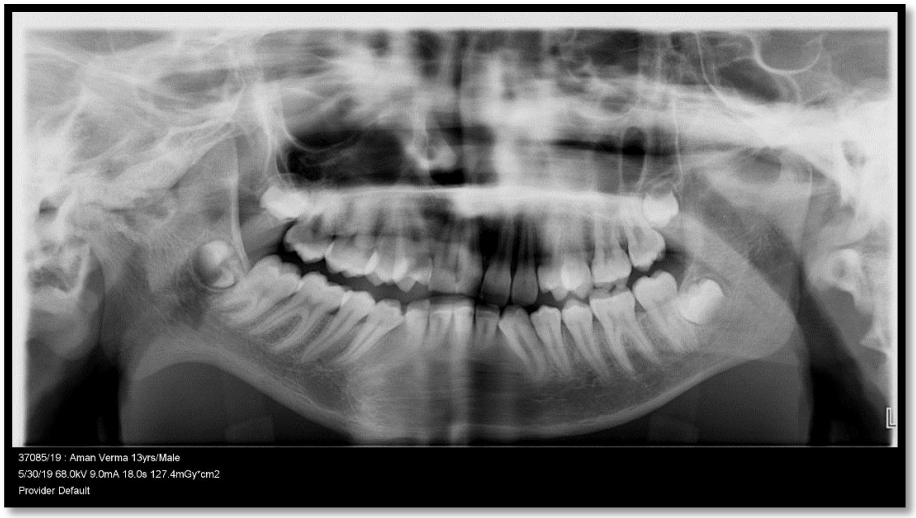
MOUTH OPENING

Pre-Operative MIO 5MM

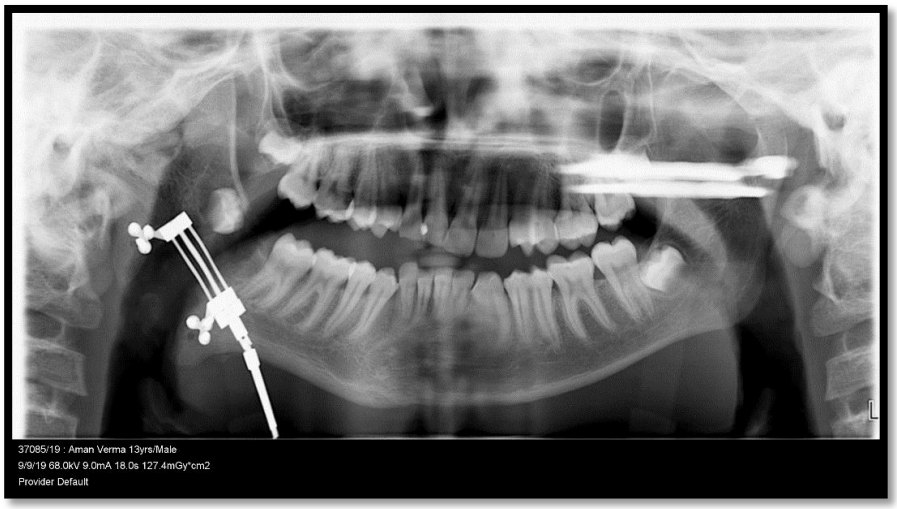


Post-Operative MIO 36 MM

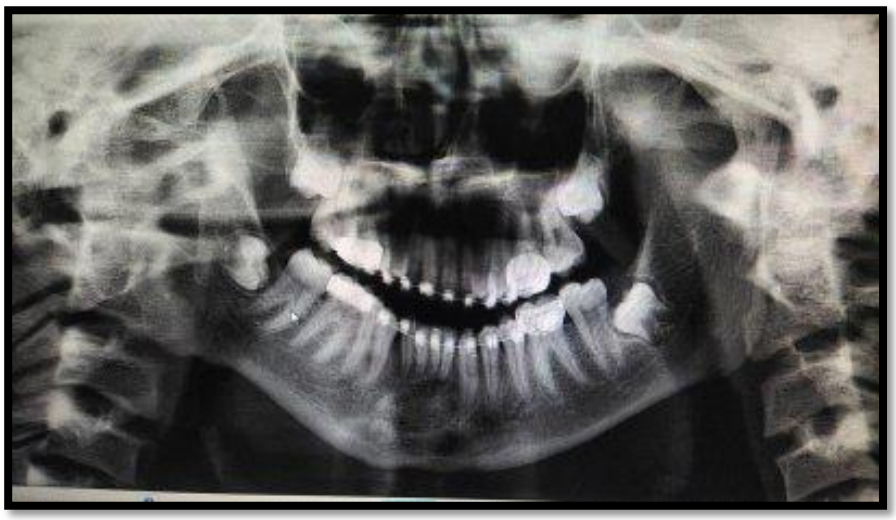
RADIOGRAPHS



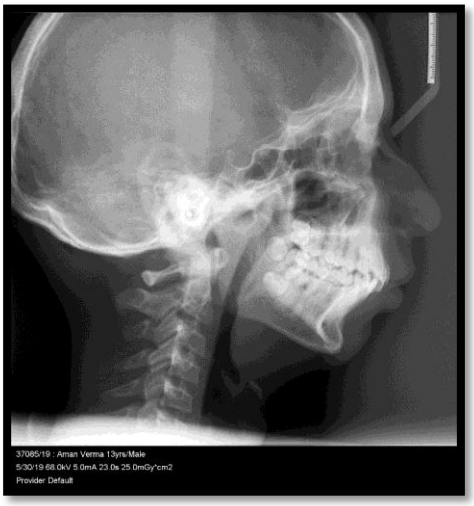
Pre-Operative OPG



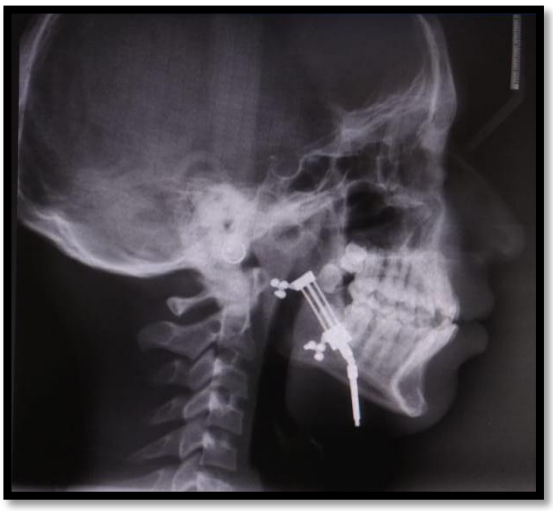
Post-Operative OPG After 3 Months



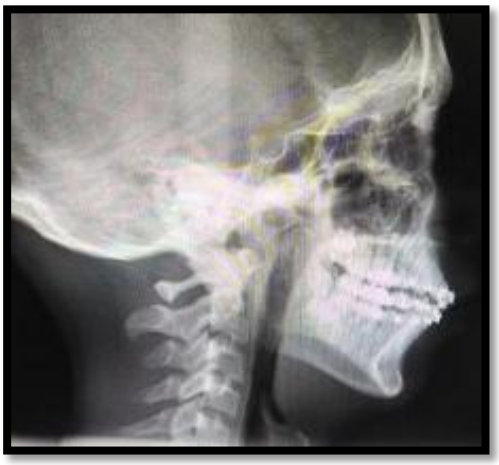
Post-Operative OPG After Six Months

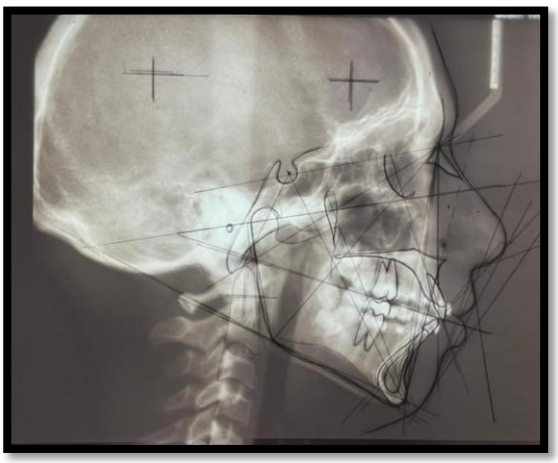


Pre-Operative Lateral Cephalogram



Cephalogram Post-Operative Lateral Cephalogram After 3 Months

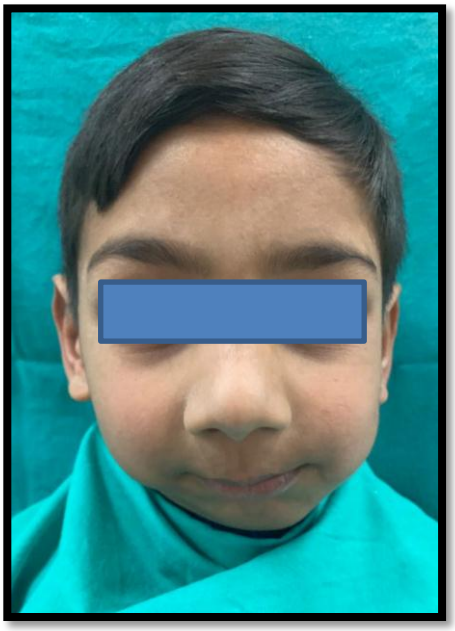


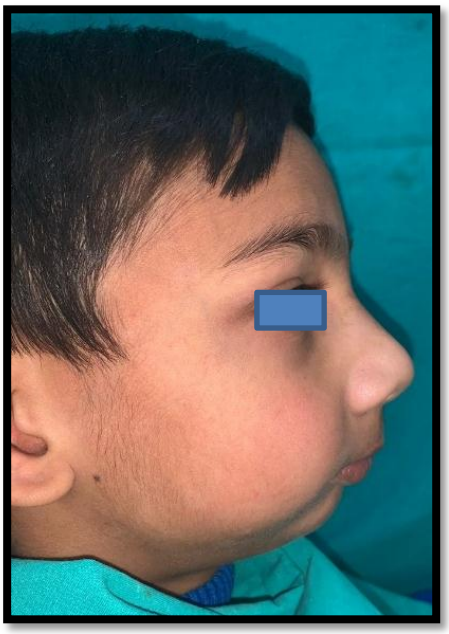


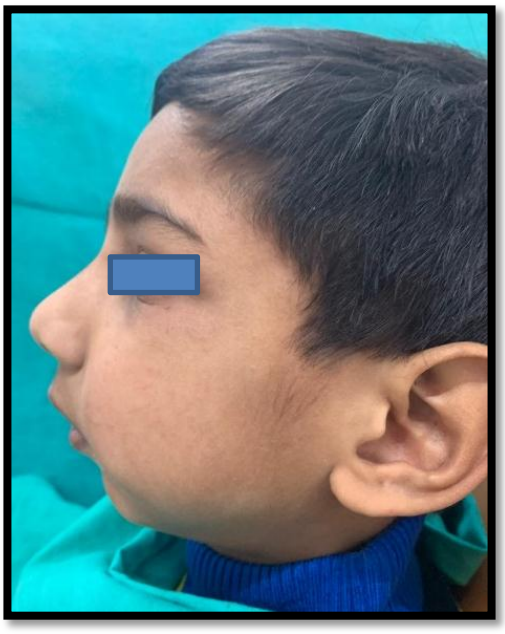
Post –Operative Lateral Cephalogram After 6 Months

CASE 2

PRE-OPERATIVE PHOTOGRAPHS

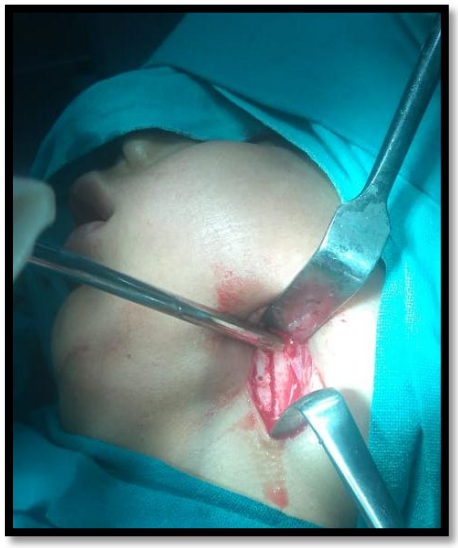




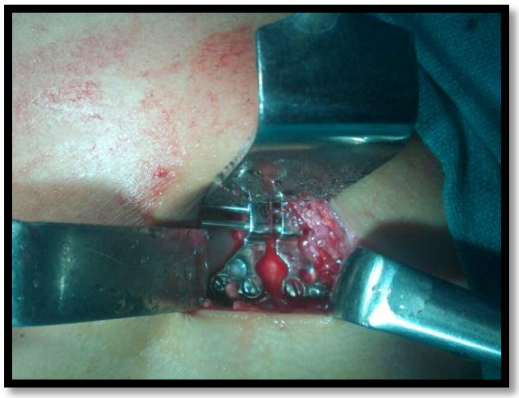


INTRA-OPERATIVE PHOTOGRAPHS

STAGE 1

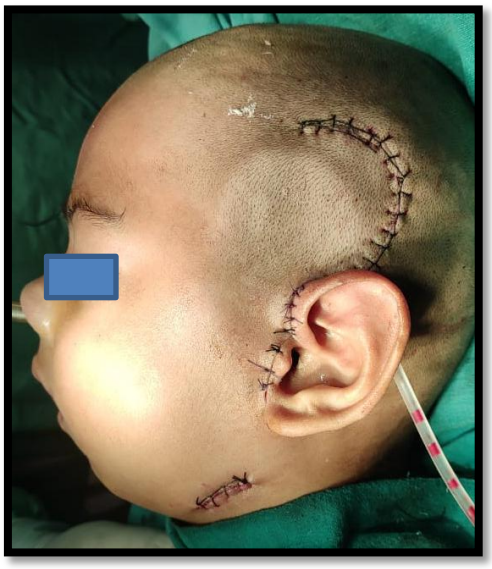


Osteotomy

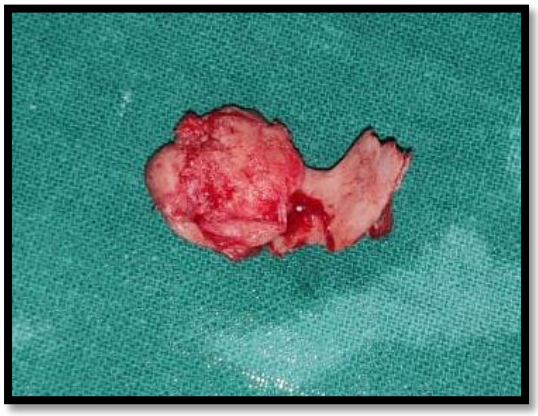


Distractor Placement

STAGE 2

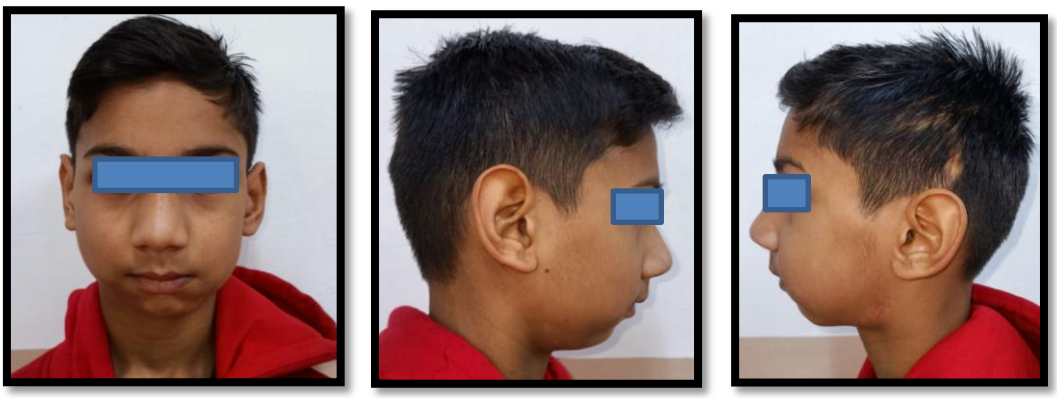


Arthrectomy and Distractor Removal Done

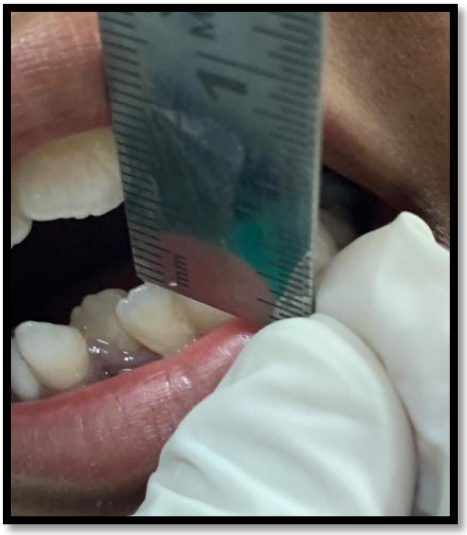


Resected Ankylotic Mass

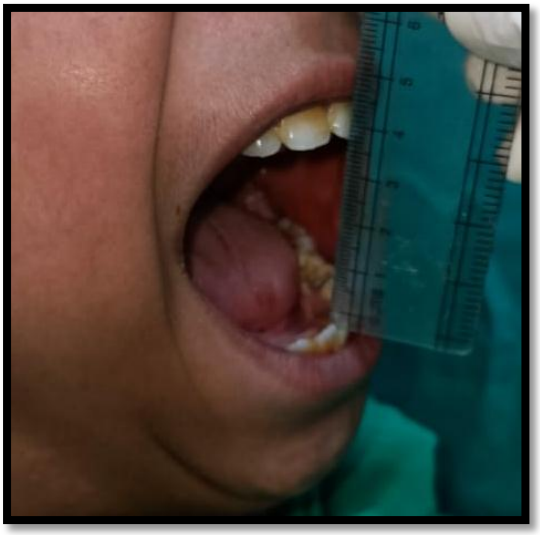
POST-OPERATIVE PHOTOGRAPHS



MOUTH OPENING

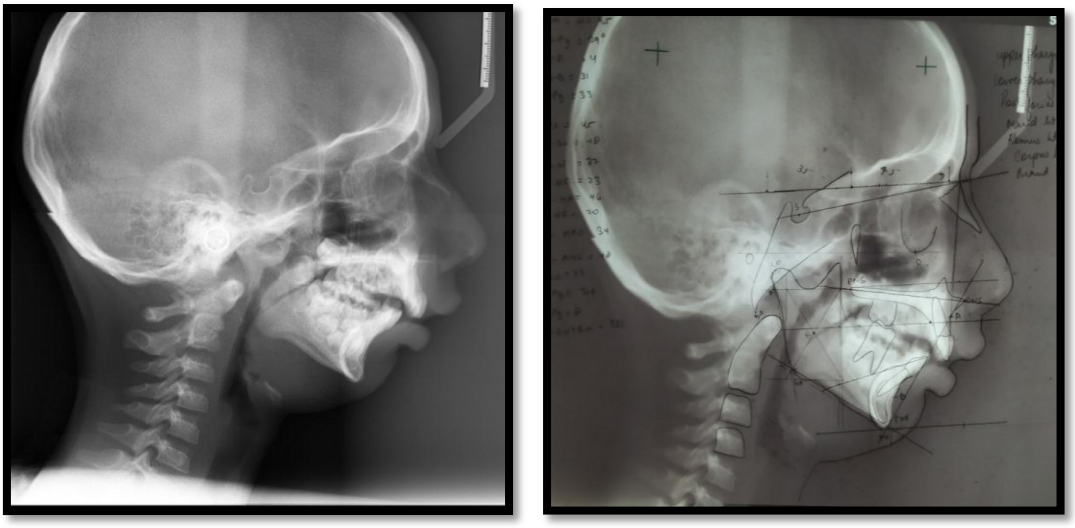


Pre-Operative MIO 7 MM

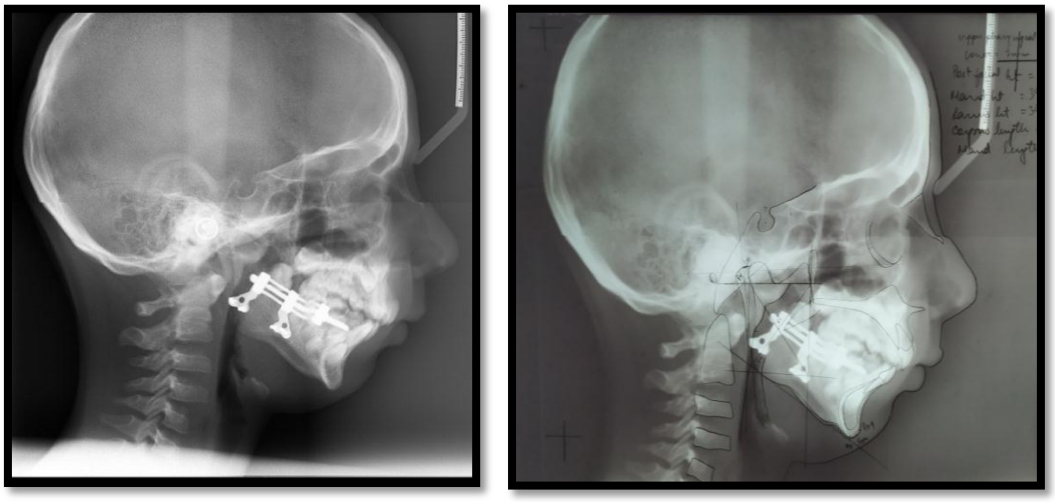


Post-Operative MIO 38 MM

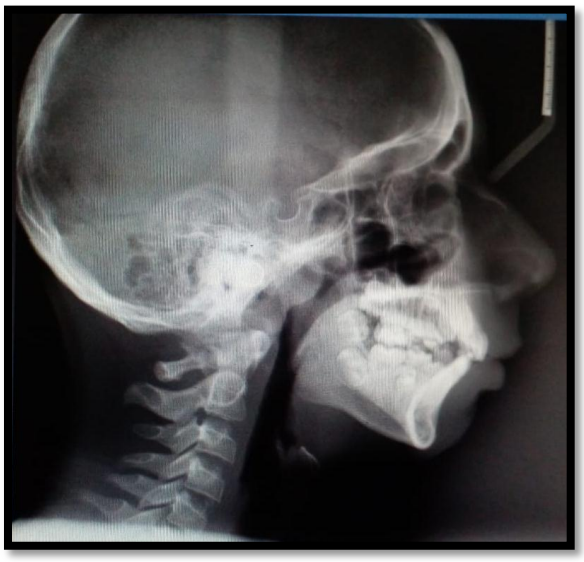
RADIOGRAPHS



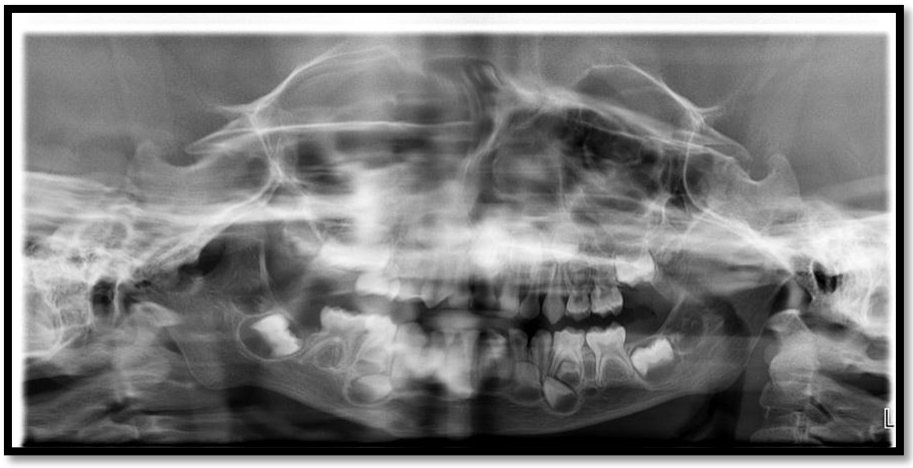
Pre-Operative Lateral cephalogram



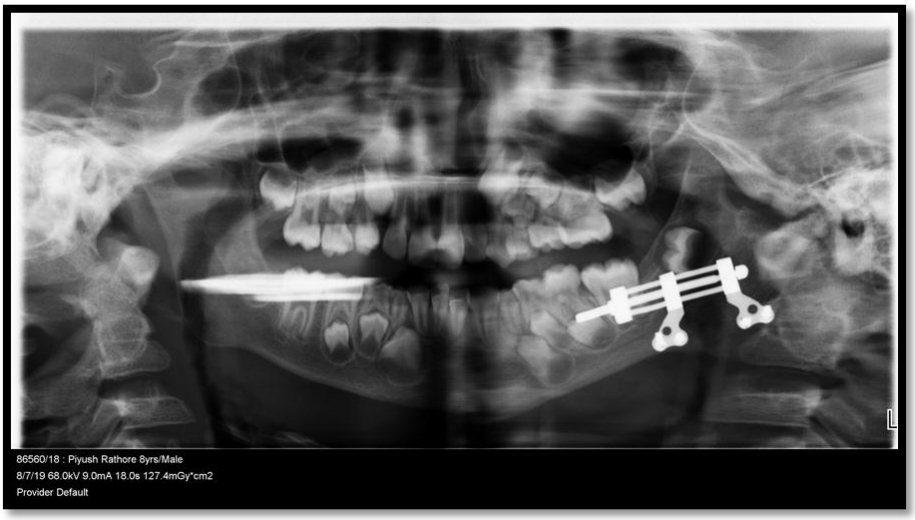
Post-Operative Lateral Cephalogram After 3 Months



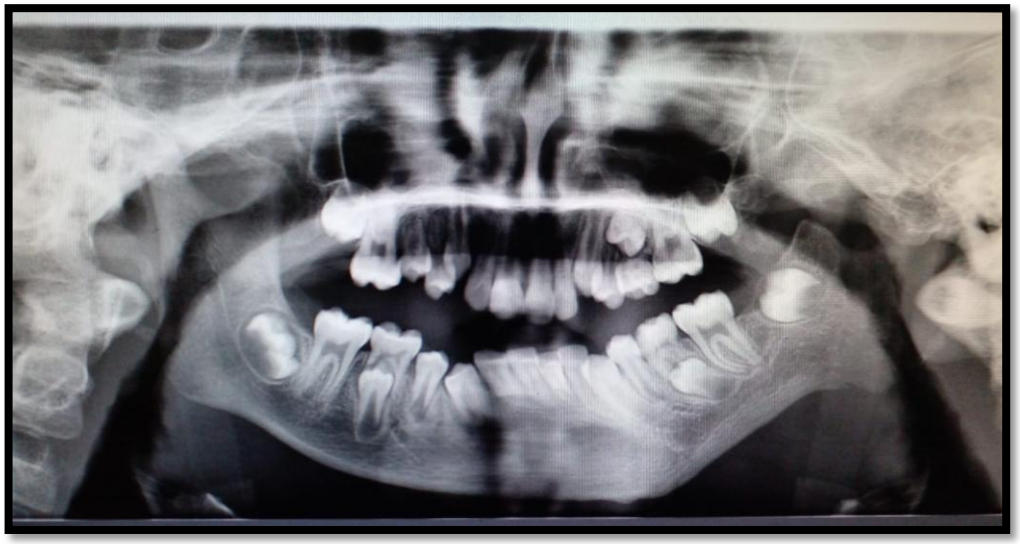
Post-Oprative Lateral Cephalogram after 6 Months



Pre-Operative OPG



Post-Operative OPG After 3 Months



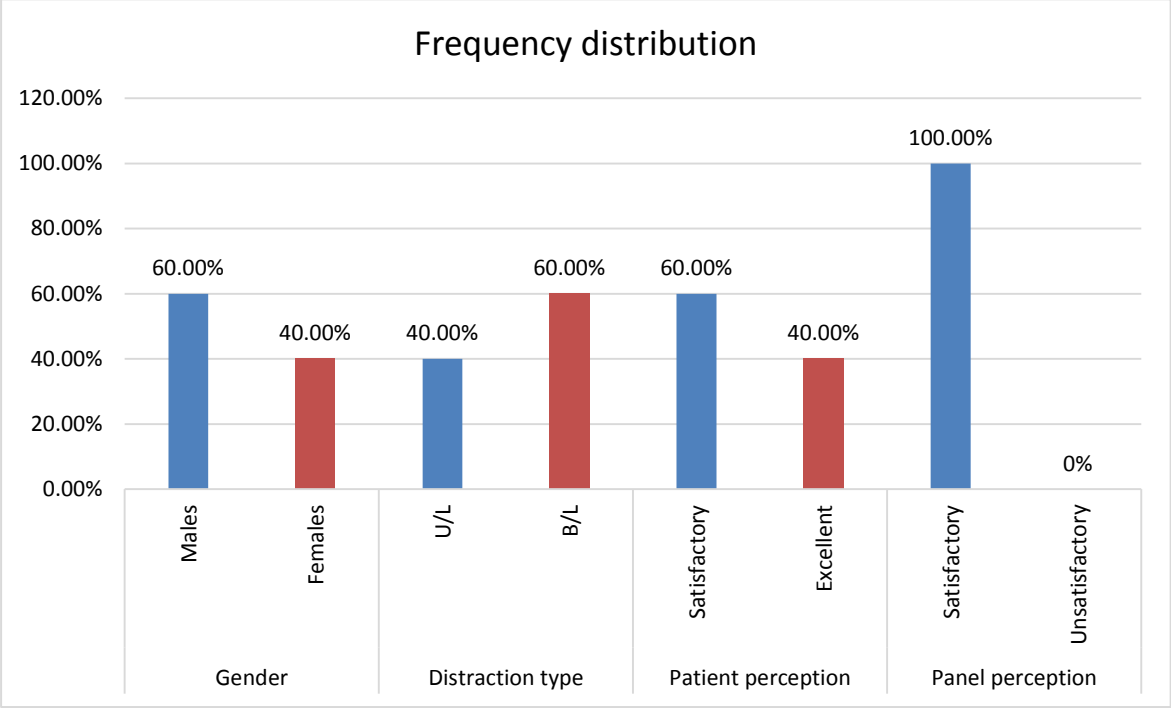
Post-Operative OPG after 6 Months

RESULT AND OBSERVATION

Table 1 : Sociodemographic profile of study population, Type of Distraction and Perceptions of Patients & Panel

		Frequency	Percent
Gender	Males	3	60.0%
	Females	2	40.0%
Distraction type	U/L	2	40.0%
	B/L	3	60.0%
Patient Perception	Satisfactory	3	60.0%
	Excellent	2	40.0%
Panel Perception	Satisfactory	5	100.0%
Age of Study participants		Mean =13.4	SD=3.78

The study population was comprised of 60% males & 40% females. Among all, 40% had U/L type of distraction, and remaining 60% had B/L type of distraction. Among all, 60% gave their response as satisfactory and 40% gave their response as excellent. Among panel members, all gave satisfactory response.

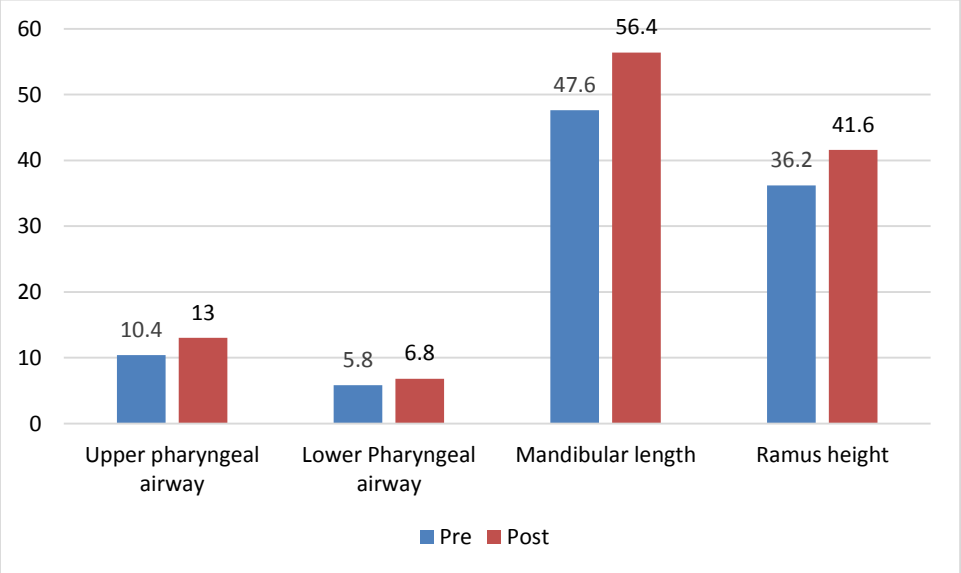


GRAPH 1. FREQUENCY DISTRIBUTION

Table 2: Sociodemographic profile of study Upper and Lower Pharyngeal airway, Mandibular length, Ramus height

		Mean	N	Std. Deviation	Mean Difference	P value
Upper pharyngeal airway	Pre	10.4000	5	2.40832	-2.60000±0.8944	0.039, S
	Post	13.0000	5	1.58114		
Lower Pharyngeal airway	Pre	5.8000	5	1.30384	-1.00000±4.0000	0.498, NS
	Post	6.8000	5	3.96232		
Mandibular length	Pre	47.6000	5	7.50333	-8.80000±1.30384	0.039, S
	Post	56.4000	5	6.54217		
Ramus height	Pre	36.2000	5	3.34664	5.40000±2.79285	0.042, S
	Post	41.6000	5	4.50555		

Comparison of upper pharyngeal space, lower pharyngeal space, mandibular length & Ramal height, from pre to post was done using Paired t test. It was found that, there was a statistically significant increase in Upper pharyngeal space, mandibular length & Ramal height. No statistically significant difference could be found in lower pharyngeal airway, from pre to post.

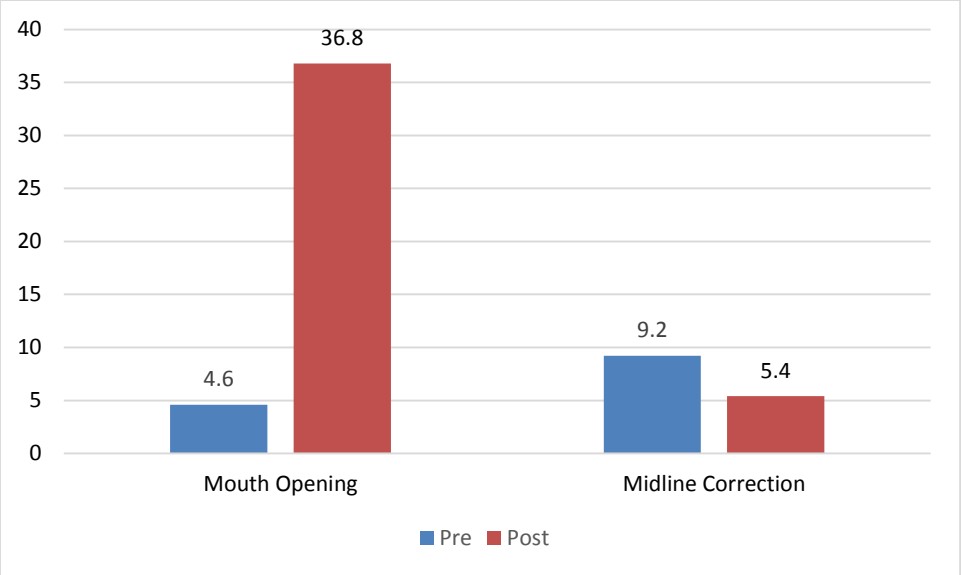


GRAPH 2 : Comparison of upper pharyngeal space, lower pharyngeal space, mandibular length & Ramal height, from pre to post was done using Paired t test.

Table 3: Sociodemographic profile of study: Mouth Opening, Midline Correction

		Mean	N	Std. Deviation	Mean Difference	P value
Mouth Opening	Pre	4.6000	5	1.51658	-32.2000±1.09545	0.038, S
	Post	36.8000	5	1.30384		
Midline Correction	Pre	9.2000	5	3.49285	3.80000±1.30384	0.042, S
	Post	5.4000	5	2.88097		

Comparison of mouth opening & midline correction, from pre to post was done using Paired t test. It was found that, there was a statistically significant increase in mouth opening, from pre to post. The midline correction was achieved significantly from pre to post.



Graph 3: Comparison of mouth opening & midline correction, from pre to post was done using Paired t test.

DISCUSSION

Patients with TMJ ankylosis suffer from various functional and esthetic facial deformities. It is characterized by retrognathic mandible; chin deviation towards the affected side, limitation of mandibular movements, obstructive sleep apnea syndrome, facial muscle atrophy and occlusal plane cant [19].

Greater the duration of ankylosis, more is the severity of hypoplasia accompanied with severe functions and esthetics compromises .

Carlson [65] classified the surgical procedures for release of the ankylosed condyle into 3 groups: condylectomy, gap arthroplasty and interpositional arthroplasty. Kaban et al.,1990 [66] presented a treatment protocol. This surgical protocol, with some modifications, has been used widely for the treatment of mandibular hypoplasia associated with ankylosis. Sagittal split osteotomy, genioplasty, and LeFort I osteotomy in adult have been described as auxiliary procedures [67,68] for correction of dento-skeletal deformities after release of the joint.

There are different surgical modalities for the treatment of temporomandibular joint ankylosis including gap arthroplasty, interpositional anthroplasty (costo-chondral graft interposition). Most authors consider pedicle temporal muscle flap as an adequate interposition cover to the temporomandibular joint [69,70] to prevent reoccurrence .Reconstruction of the joint with costochondral graft have a list of potential problem such as unpredictability of the growth pattern, high incidence of re-ankylosis, possibility of resorption or infection, possible separation of the cartilage from the bone and occasional fractures. Furthermore, the morbidity of the donor site must be considered such as the possibility of developing a pneumothorax [71]

Management of ankylotic mass was done by using the modified Kaban's protocol as suggested which includes :

A. Aggressive resection(gap arthroplasty with resection of deformed condyle mass between the roof of glenoid fossa and ramus to create a gap of 1.5 cm to prevent re-ankylosis);
B. Ipsilateral coronoidectomy on affected side ;
C. Contralateral coronoidectomy when steps 1 and 2 do not result in maximum incisal opening greater than 35 mm ;

D. Lining of the TMJ with temporalis muscle with or without fascia to maintain the vertical height of the resected ankylotic mass,
E. Early mobilization of jaws and aggressive physiotherapy done after 7 days to 10 days for 15 days.

Relapse is more accentuated in micrognathic patients presenting with the typical ‘‘Bird face’’ deformity, having deficient soft tissue of the lower third of the face and at the neck, absence of the neck angle and shortened suprahyoid muscles. Ankylosis release and costochondral graft reconstruction continues to be used as the standard procedures to treat TMJ ankylosis. The complications associated with these procedures are excessive and unpredictable growth or the necrosis and resorption of the costochondral graft.

If conventional mandibular advancement by osteotomies and bone grafts is performed in these type of patients, the muscles and the tight skin envelop results in compromised esthetics and relapse , whereas with bone distraction all the tissues from skeleton to skin are simultaneously elongated with optimal esthetic results [72] .
The other disadvantages of conventional osteotomy procedures are:
A. Surgical neurosensory complication,
B. Condylar resorption, post-operative relapse,
C. Bone graft failure, bone graft donor site morbidity and
D. Bone formation by secondary healing.

To overcome these problems distraction osteogenesis becomes the treatment of choice for the reconstruction of temporomandibular joint and mandibular hypoplasia[23]

Distraction osteogenesis to the maxillofacial region has caused a therapeutic revolution in the cases of mandibular hypolpasia associated with ankylosis and offers new method of treatment in these patients [73]. Arthrectomy can be combined with distraction osteogenesis of the mandibular body; it is believed that this combination of treatment is a quicker and easier than costochondral graft, reducing operating time and risk of blood transfusion. Papageorge and Apostolidis 1999 [74] reported similar result in their study in which they performed Distraction osteogenesis for mandibular lenghtening in conjunction with a condylectomy and arthroplasty in young patient

with severe bony tmj ankylosis. They reported satisfactory correction of facial asymmetry and no re-occurrence over a period of 15 months.

Furthermore, avoiding donor site morbidity as well as intermaxillary fixation , results in reduction in post operative discomfort , hospital stay and treatment cost. There is no uniform consensus on whether arthropalsty and distraction osteogenesis must be performed as one or two staged procedures.

Distraction osteogenesis begins with the development of a reparative callus between the edges of two bone segments divided by a low-energy osteotomy. After the callus has initially formed, a distraction force is applied to these bone segments which gradually pulls them apart. Gradual incremental separation of bone segments places the callus under tension; this aligns the inter segmentary gap tissues parallel to the direction of distraction. Ilizarov and other investigators demonstrated excellent bone regenerate formation and a favorable soft tissue response with a rate of distraction of 1 mm per day performed at a highly fractionated, continuous rhythm.[75] After the desired amount of bone length is achieved, the distraction force is discontinued. The newly formed bone (distraction regenerate) then undergoes maturation and remodeling until it becomes undistinguishable from the residual host bone. Clinically, distraction osteogenesis consists of five sequential periods:

1. Osteotomy;
2. Latency, (the duration from bone division to the onset of traction)
3. Distraction, the time when gradual traction is applied and distraction regenerate is formed;
4. Consolidation, the period that allows maturation and conicalization of the regenerate after traction forces are discontinued; and
5. Remodeling, which extends from the initial application of full functional loading to the completion of regenerate bone remodeling.

The two major strengths of distraction osteogenesis in the mandibular reconstruction are the ability to provide strong bone with excellent blood supply and the ability to provide effective expansion of the soft tissue envelope called distraction histogenesis. By this technique elongation of the mandible is done using corticotomies at the angle of the mandible that preserves the integrity of the nerve and vascular supply. Ideally, the distraction vectors must lie parallel to the occlusal plane to prevent open bite from being produced during elongation.[67]This holds true

especially for anteroposterior distraction after the growth has ceased. In the growing adolescents, lateral open bite is of limited concern because of the maxillary dentoalveolar compensation with ongoing growth. An angle between the long axis of the distractors and the maxillary occlusal plane should range from 30 to 40.[77]

When vertical lengthening is planned an angle between the long axis of the distractor and the maxillary occlusal plane can range from 45 to 90.[78] Oblique vector is chosen to produce both vertical and horizontal advancement. The bilateral distractors should not be convergent, to avoid any strain on the temporomandibular joints. The position of the pin placement will determine the distraction vector. The distraction vector is different in each patient according to the grade of mandibular hypoplasia.

This approach enables the reconstructive team, through a minimally invasive procedure, to manage patients with severe mandibular hypoplasia with excellent and predictable functional and aesthetic outcomes[23.]

Both intraoral and extraoral distraction techniques have their advantages and limitations.

The advantage of intraoral distraction is that it is less bulkier, hidden in oral cavity, there is greater patient compliance and no extraoral scaring [79]

Intra oral distraction has limitations such as: placement of distraction device is technically difficult, difficulty in maintaining oral hygiene, placement of intraoral device at the time of placement may lead to injuries to unerupted tooth, roots of erupted teeth, wound dehiscence and second surgical procedure required to remove the distractor [23 ,79]

The advantages of extra oral distraction osteogenesis are: hardware is easy to place, lesser chances of infection, easier to maintain oral hygiene, mandible lengthening more than 20 mm is feasible, multiplanar and bi-directional devices are largely successful in lengthening the mandible. The disadvantage of extraoral distraction osteogenesis are: device looks bulkier to the patient, depressed pin scars along the pin tracts and pin tract infections are a possibility [23].

In the present study, an intraoral distractor with an extraoral approach was used. This aided in gaining advantages of both intraoral and extraoral distractors, while simultaneously reducing the limitations of each technique. With the use of intraoral distractor, the size of distractor reduced in size which in turn was more

acceptable by patient than the bulkier extraoral counterparts. Also due to the hidden nature of distractor, patient acceptance increased. The advantages of easy placement, better vector control, easy activation and good oral hygiene by patient were achieved. The hidden scars in neck crease and shadow of mandible to place the distractor eliminated the pin tract scars of intraoral distractors which are rarely acceptable to patient. Also, good coverage of oral mucosa was achieved when the distractor was applied through extraoral technique as compared to intraoral placement of distractor. This in turn also reduced the incidence of mucosal dehiscence. Trauma to the teeth also was not seen as better control was present at the time of surgery and distractor placement due to good accessibility.

Many authors usually start with Mandibular DO, followed by gap arthroplasty ([16]Sadakah Et al., 2006; [80] Shang et al., 2012;[81]Zhanget al., 2018). The reason for this selection is that the ankylosed TMJ acts as a fixed point that pushes the mandible in a forward direction. Gonzalez[19] .suggested that for cases of TMJ ankylosis,two-stage surgeries should be performed. During the first stage, ramal and corpus lengthening should be achieved, which allows the clinician a predictable mandibular ramus and vertical augmentation and mandibular lengthening and the second stage surgery is planned once the consolidation is completed, which consists of freeing of TMJ ankylosis by arthrectomy. Following this protocol, there is a better control of distraction segments as the immobile joint denoted to the foundation that might move the mandible in the forward direction, instead of the retrogressive direction[82)]

This avoids pressure against the new surgically created joint, and allows active physiotherapy after releasing the joint. These findings are in accordance with the current study where horizontal and vertical advancement yielded separately to optimum results with enhanced chin prominence. In addition, performing arthroplasty before distraction may carry the risk of re-ankylosis. However, up to now there has been no consensus on whether distraction should be done at the time of arthroplasty. Some authors prefer to do the procedures simultaneously, but López et al.[12] suggested that the mandibular DO should be done after the arthroplasty as the growth potential of the mandible would be known only when the ankylosis had been relieved. Bartlett et al.[83] reported that DO is a valuable aid in the treatment of the problematic child with congenital proliferative ankylosis of the TMJ. Interim DO, before

definitive arthroplasty, can provide a static open bite that prevents progressive deformity and its associated functional disturbances. The mandibular lengthening obtained by gradual distraction can result not only in expansion of the mandibular bony tissue but in proportional and harmonic modification of the muscles and the surrounding soft tissues. The forces produced by the distractor on the mandible are similar to physiological forces during mandibular development. McCormick et al.[84]noticed that the distraction spur operates on the affected condyles, and causes an

Distraction, therefore, seems to have beneficial effects not only on the harmony of the craniofacial complex but also on temporomandibular articulation. By reestablishing correct function of the soft and skeletal tissues, it is possible to regain the normal potential growth of the mandible. Clinical variables potentially determining the success of distraction osteogenesis include[85]:

a) meticulous planning and skillful execution of corticotomy (low-energy bone division with maximum preservation of osteo- genic tissues);
b) proper orientation of the distraction appliance relative to the anatomic axis of the mandible, occlusal plane and to the desired direction of distraction;
c) stable fixation of the bone segments, and; adequate distraction protocols (involving duration of latency period, rate and rhythm of distraction, and duration of consolidation period) to predictability achieve the desired outcome.

The results of this study confirm the findings that there was a significant rectification of facial aesthetics, oro-pharyngeal airway width, mandibular length, ramal height and mouth opening in the patients with TMJ ankylosis after distraction of mandible with distractor device. Furthermore, there was significant improvement of quality of life among these patient's pre- and post-operatively. No evidence of re-ankylosis was observed in any patients during the study period.

The mean age of our patients was 13.4 years. It was concluded that a positive facial appearance plays an important role in improving the professional and private life of patients aged 20-30 years. This does not conflict with the fact that those patients are not only looking for improvement in their facial esthetics but also looking for improvement in their jaw function, which is considered their prime concern, especially in developing countries.

Qualitative evaluation of the functional and esthetic outcomes were also carried out in this study. On analyzing the data it was found that the parameters of

function like occlusion, airway and biting-chewing had improved in all patient. Mouth opening was maintained by all the patients. The parameters for esthetics taken were patients' and panel's perception. The patients' opinion (pre and post distraction photographs) as parameters were taken since esthetics is an individual perception and it is of utmost importance how an individual feels about his or her looks. On the other hand the specialists' opinion as panel perception was also taken into account as they could judge the pre and post distraction esthetics changes professionally. On evaluation it was found that both patient and panel perceptions for esthetics had improved post distraction in all the cases.

border of upper and lower incisors with a measuring scale. Grummons analysis in PA cephalogram was used to check for asymmetry correction and length required to distract the mandible for asymmetry correlation. Dharmendra et al conducted a study in 2018 in patients with TMJ ankylosis for amount of midline correction, took the postero-anterior radiograph by using Grummon's analysis pre- and post-operatively with a mean of 83.14 _ 5.98 and 91.15 _ 5.08 which was found to be statistically significant ($P < 0.05$). A uniform standardized PA cephalograms were taken to determine mandibular morphology correction according to Grummon's analysis in TMJ ankylosis in order to compare the deficit of the affected side of mandibular growth to the non -affected side.[54] The amount of correction is calculated by measuring the area of triangle formed by three points in the PA view, such as condylion(Co), antegonial notch(Ag) and menton(Me). Deviation of the chin was measured in degrees by the angle formed by the skeletal midline (vertical line in the middle of the base of the cristagalli apophysis) and the straight line that connects the center of the chin to the skeletal midline in the frontal x-ray. COGS analysis was done to determine the height of the ramus by measuring the distance in millimeters between the articular angle(Ar) and the gonial angle(Go) (total ramus height) and mandibular body length by measuring the linear distance between gonion(Go) and pogonion(Pg) in the pre and post operative lateral cephalogram x-ray.

Susan Abd El-Hakim Hassan conducted a study in 2019 on 20 pateints to evaluate the short-term and long-term skeletal and soft-tissue stability after MDO with or without genioplasty, as well as the stability of the achieved maximum inter-incisal opening (MIO) in patients with mandibular hypoplasia secondary to TMJ ankylosis. The patients were analyzed for skeletal and soft-tissue stability as well as

the maintenance of the achieved MIO. The cephalometric analysis revealed a great improvement in the hard- and soft-tissue structures after MDO in all groups. In addition, there was a significant increase in the length of the corpus of the mandible (GoePg), ramus height, and lower facial height (ANSeMe)[56].

The patients were also compared , pre distraction and immediate post-consolidation using lateral cephalograms to determine changes in their oro-pharyngeal airway space and dimensions following mandibular distraction. The airway dimensions were first measured using McNamara analysis[86](1984) utilizes measurements in relation to the upper pharynx and lower pharynx. The upper pharyngeal width is measured from a point on the posterior outline of the soft palate to the closet point on the posterior pharyngeal wall, while the lower pharyngeal width is measured from the intersection of the posterior border of the tongue and the inferior border of the mandible to its corresponding closet point on the posterior pharyngeal wall. The oro-pharyngeal airway space was then traced on the lateral cephalogram using the following radiographic points—Sella (S), Nasion (N), Frankfurt Horizontal (FH), and Pterygomandibular Vertical Plane (PTV)[87.] A line connecting the posterior nasal spine and anterior tubercle of the atlas defined as the superior border of the posterior airway space (PAS), while the line drawn across the median glosso-epiglotic fold parallel to FH defined the inferior border of the PAS. The posterior border of the PAS was defined as the posterior pharyngeal wall (PhW) and the anterior border was defined as the posterior tongue outline and the PTV. The anteroposterior PAS dimension was measured as a line connecting the most posterior point of the tongue (TB) and PhW drawn parallel to FH. The tracings were then super-imposed on a grid and the area involved was manually measured. The results of the comparison revealed statistically significant improvement in pharyngeal airway post distraction, in this study.

Our findings are consistent with the results of P. ananatanarayana et al in 2007, who conducted a study to evaluate the role of primary osteo-distraction prior to ankylosis release in pediatric patients, diagnosed with NDS secondary to temporomandibular joint (TMJ) ankylosis. All the three patients underwent a thorough radiographic evaluation using lateral and frontal cephalograms.They were evaluated for oro-pharyngeal airway patency using McNammara's airway analysis and by Grummon's analysis for planning the quantum and vector of distraction. All

the post-operative lateral cephalograms showed a significant increase in the oro-pharyngeal airway[18].

Postoperative physiotherapy included gradual intraoral bilateral insertion of wooden spatulas (2-mm thick); 10 spatulas (20 mm) immediately after the surgery, followed by daily in number until an optimal mouth opening was attained. Little discomfort was experienced by most of our patients during the physiotherapy process.

All patients were followed-up at three months interval for a period of atleast two years.

CONCLUSION

Within the scope and limitations of this study, following conclusions can be drawn:

- Distraction Osteogenesis is effective method for correction of facial asymmetry and mandibular lengthening.
- Pre-release distraction osteogenesis appears to be a better option for correction of ankylosis related skeletal deformity of the mandible;
- Vector planning (using cephalometric evaluations) is of vital importance during placement of distractor device while performing surgery, to achieve desired lengthening in desired direction.
- Comparison of pre and post operative cephalometric analysis provides an useful insight into planned and achieved results
- The following parameters improved significantly post-operatively :
    - Facial asymmetry
    - Airway
    - Mouth opening
    - Skeletal and dental midline

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ANNEXURES

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

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

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

IEC Code: 14 **BBDCODS/03/2020**

Title of the Project: Role of Distraction Osteogenesis in Facial Deformity due to Temporo-Mandibular Joint Ankylosis.

Principal Investigator: Dr. Shiwangi Yadav **Department:** Oral & Maxillofacial Surgery

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

Type of Submission: New, MDS Project Protocol

Dear Dr. Shiwangi Yadav,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 18[th] March, 2020.

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

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.

The comments were communicated to PI thereafter it was revised.

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

Forwarded by:

Lakshmi Bala 18/03/20

(Dr. Lakshmi Bala)
Member-Secretary
IEC

Member-Secretary
Institutional Ethics Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

(Dr. B. Rajkumar)
Principal
BBDCODS

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

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

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Role of Distraction Osteogenesis in Facial Deformity due to Temporo-Mandibular Joint Ankylosis"** submitted by **Dr Shiwangi Yadav** Post graduate student from the **Department of Oral & Maxillofacial Surgery** as part of MDS Curriculum for the academic year 2019-2022 with the accompanying proforma was reviewed by the Institutional Research Committee present on **19th December 2019** at BBDCODS.

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

Prof. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

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

Guardian Information Document (GID)

1. **Study Title**

   Role of distraction osteogenesis in facial deformity due to temporomandibular joint ankylosis.

2. **Invitation Paragraph**
   -Your child is being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. **What is the purpose of the study?**
   To study the efficacy of Distraction Osteogenesis in correction of facial deformity due to T.M. Joint ankylosis

4. **Why have I been chosen?**
   Your child has been chosen for this study as you have fulfilled the desired inclusion criteria for the diseased condition.

5. **Do I have to take part?**
   Your child's participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you still are free to withdraw at any time and without giving a reason.

6. **What will happen to me if I take part?**
   Your child will be involved in my study for 12 months. As your child has facial abnormality, he/she will be treated for the correction of this diseased condition. The procedure includes Osteotomy preparation for distractor placement, which is a major surgical procedure. The study is being conducted to improvise the outcome of the procedure and lessen your child's problems.

7. **What do I have to do?**
Your child can have your regular lifestyles as usual and to follow the required visiting schedule to the centre for the investigation of the study.

8. **What is the procedure that is being tested?**
It's a major surgical procedure carried out in mandible under general anaesthesia to perform the osteotomy for the placement of distractor intraorally followed by the latency, distraction & consolidation period of 3-4 months.Then a follow up for the evaluation of post treatment changes.

9. **What are the interventions for the study?**
There are no such interventions, risks and adverse effects related to the study.There is clinical benefit to the volunteer as he/she will receive the distractor.

10. **What are the side effects of taking part?**
There are no side effects to the patients of this study.

11. **What are the possible disadvantages and risks of taking part?**
There are no disadvantages and risks for being as part of the study.

12. **What are the possible benefits of taking part?**

As we get the desired results after the distraction, your child will be able to perform normal functions of mouth and appearance will be more pleasing.

13. **What if new information becomes available?**
I additional information becomes available during the course of the research you will be told aboutthese and you are free to discuss it with your researcher and decide accordingly.

14. **What happens when the research study stops?**
As the study will run for about 12 months, after that your child has to visit the department as per the requirement. Moreover, if at all the study stops before the stipulated time due to unavoidable circumstances, this will be explained to you.

15. **What if something goes wrong?**
If any adverse event occurs, or something goes wrong during the study, the complaints will be handled by the competent person reporting to the institution and IEC. Cost to be hear by the person undertaking the study and personal interest towards treatment in severe adverse event.

16. **Will my taking part in this study be kept confidential?**
Yes, it will be kept confidential.

17. **What will happen to the results of the research study?**
The result of the study will be published in the indexed journal. Your identity will be kept confidential in case of any report/ publications.

18. Who is organizing the research?
This research study is organized by the Dept. of Oral & Maxillofacial Surgery.

19. Will the results of the study be made available after study is over?
Yes, only the data obtained will be published.

20. Who has reviewed the study?
The study has been reviewed by and approved by the Head of the department, guides, co-guides and IEC of the institution.

21. Contact for further information

Dr. Shiwangi Yadav
MDS, Dept. of Oral & Maxillofacial Surgery,
E- mail : shiwangi67@gmail.com
Contact no. 9696464294

Dr.Lakshmi Bala,
Member Secretary, IEC
bbdcods.iec@gmail.com

Signature of PI.....

Name.....

Date.....

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज
(बाबू बनारसी दास विश्वविद्यालय का एक घटक संस्थान)
बी.बी.डी.सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत)

संरक्षक सूचना दस्तावेज (GID)

1- अध्ययन शीर्षक

टेम्पोरोमैंडिबुलर संयुक्त एंकिलोसिस के कारण चेहरे की विकृति में विकर्षण ओस्टोजेनेसिस की भूमिका

2- आमंत्रण अनुच्छेद?

आपके बच्चे को एक शोध / परीक्षण अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है। इससे पहले कि आप तय करें कि आपके लिए यह समझना महत्वपूर्ण है कि शोध / अध्ययन क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने और दोस्तों, रिश्तेदारों और अपने इलाज करने वाले चिकित्सक / परिवार के डॉक्टर से चर्चा करें। हमसे पूछें कि क्या ऐसा कुछ है जो स्पष्ट नहीं है या यदि आप अधिक जानकारी चाहते हैं। यह निर्णय लेने के लिए समय लें कि आप हिस्सा लेना चाहते हैं या नहीं।

3- अध्ययन का उद्देश्य क्या है?

टी. एम. की वजह से चेहरे की विकृति के सुधार में विकृति ऑस्टियोजेनेसिस की प्रभावकारिता का अध्ययन करना। संयुक्त एंकिलोसिस

4-मुझे क्यों चुना गया है?

आपके बच्चे को इस अध्ययन के लिए चुना गया है क्योंकि आपने रोगग्रस्त स्थिति के लिए वांछित समावेश मानदंडों को पूरा किया है।

5- क्या मुझे भाग लेना है?

शोध में आपके बच्चे की भागीदारी पूरी तरह से स्वैच्छिक है। यदि आप करते हैं, तो आपको यह दिया जाएगा रखने के लिए सूचना पत्र और सहमति फॉर्म पर हस्ताक्षर करने के लिए कहा जाएगा। अध्ययन के दौरान आप अभी भी किसी भी समय और बिना कारण बताए वापस लेने के लिए स्वतंत्र हैं।

6- अगर मैं भाग लेता हूं तो मेरे साथ क्या होगा?

आपका बच्चा 12 महीने तक मेरे अध्ययन में शामिल रहेगा। जैसा कि आपके बच्चे में चेहरे की असामान्यता है, उसे इस रोग की स्थिति के सुधार के लिए उपचारित किया जाएगा। प्रक्रिया में डिस्ट्रेक्टर प्लेसमेंट के लिए ओस्टियोटॉमी तैयारी शामिल है, जो एक प्रमुख सर्जिकल प्रक्रिया है। प्रक्रिया के परिणाम को सुधारने और आपके बच्चे की समस्याओं को कम करने के लिए अध्ययन किया जा रहा है

7- मुझे क्या करना है ?

आपके बच्चे की हमेशा की तरह आपकी नियमित जीवनशैली हो सकती है और अध्ययन की जांच के लिए केंद्र में आवश्यक दौरा कार्यक्रम का पालन करना चाहिए।

8- परीक्षण की जा रही प्रक्रिया क्या है?

यह 3-4 महीने के विलंबता, व्याकुलता और समेकन की अवधि के बाद अव्यवस्था की नियुक्ति के लिए अस्थिभंग प्रदर्शन करने के लिए सामान्य संज्ञाहरण के तहत अनिवार्य में किया गया एक प्रमुख शल्य प्रक्रिया है। पोस्ट उपचार परिवर्तनों के मूल्यांकन के लिए एक अनुवर्ती कार्रवाई करें।

9- अध्ययन के लिए हस्तक्षेप क्या हैं?

अध्ययन से संबंधित इस तरह के हस्तक्षेप, जोखिम और प्रतिकूल प्रभाव नहीं हैं। स्वयंसेवक को नैदानिक लाभ है क्योंकि वह विचलित कर देगा।

10- भाग लेने के दुष्प्रभाव क्या हैं?

इस अध्ययन के कोई दुष्प्रभाव नहीं हैं।

11- भाग लेने के संभावित नुकसान और जोखिम क्या हैं?

अध्ययन का हिस्सा होने के लिए कोई नुकसान और जोखिम नहीं हैं।

12- भाग लेने के संभावित लाभ क्या हैं?

जैसा कि हम ध्यान भंग होने के बाद वांछित परिणाम प्राप्त करते हैं, रोगी मुंह के सामान्य कार्यों को करने में सक्षम होगा और उपस्थिति अधिक प्रसन्न होगी।

13- क्या होगा अगर नई जानकारी उपलब्ध हो जाए?

मुझे अतिरिक्त जानकारी उपलब्ध होजा ती है अनुसंधान के दौरान आपको इनके बारे में बताया जाएगा और आप अपने शोधकर्ता के साथ इस परचर्चा करने और उसके अनुसार निर्णय लेने के लिए स्वतंत्र हैं।

14- शोध अध्ययन बंद होने पर क्या होता है?

जैसा कि अध्ययन लगभग 12 महीनों तक चलेगा, उसके बाद आपको आवश्यकतानुसार विभाग का दौरा करना होगा।इसके अलावा, अगर सभी अध्ययन अपरिहार्य परिस्थितियों के कारणनिर्धारित समय से पहले रुक जाते हैं, तो यह आपको समझाया जाएगा।

15- क्या होगा अगर कुछ गलत हो जाए?

यदि कोई प्रतिकूल घटना होती है, या अध्ययन के दौरान कुछ गलत हो जाता है, तो शिकायत को सक्षम व्यक्ति द्वारा संस्था और आई.ई.सी.को रिपोर्ट किया जाएगा। गंभीर प्रतिकूल घटना में उपचार के प्रति अध्ययन और व्यक्तिगत हित को ध्यान में रखते हुए व्यक्ति द्वारा सुनने की लागत।

16- क्या इस अध्ययन में मेरा हिस्सा गोपनीय रखा जाएगा?

हां इसे गोपनीय रखा जाएगा।

17- शोध अध्ययन के नतीजों का क्या होगा?

अध्ययन के परिणामों का उपयोग मानक प्रत्यारोपण के साथ लघु प्रत्यारोपण की नैदानिक सफलतादर की तुलना करने के लिए किया जाएगा। किसी भी रिपोर्ट / प्रकाशन के मामले में आपकी पहचान गोपनीय रखी जाएगी।

18- शोध का आयोजन कौन कर रहा है?

यह शोध अध्ययन मौखिक और मैक्सिलो फेशियल सर्जरी विभाग,शैक्षणिक संस्थान (BBDCODS) द्वारा आयोजित किया जाता है।

19 क्या अध्ययन के परिणाम अध्ययन के बाद उपलब्ध कराए जाएंगे?

हाँ।

20- अध्ययन की समीक्षा किसने की है?

अध्ययन की समीक्षा विभाग के प्रमुख, मार्गदर्शक, सह-मार्गदर्शक और आई.ई.सी.द्वारा अनुमोदित की गई है।

21- अधिक जानकारी के लिए संपर्क करें

डॉ. शिवांगी यादव

एम.डी.एस,

मौखिक और मैक्सिलो फेशियल सर्जरी विभाग

ई- मेल: shiwangi67@gmail.com

संपर्क नंबर- 9696464294

डॉ. लक्ष्मी बाला,

सदस्य सचिव, आ.ई.ईसी.

bbdcods.iec@gmail.com

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ-227,105

पीआई का हस्ताक्षर .....

नाम .....

दिनांक.....

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

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

Child Information Document

Study title: — Role of distraction osteogenesis in facial deformity due to temporomandibular ankylosis

Introduction

To assess the pre-operative and post operative findings on the basis of some parameters in patients with TMJ ankylosis before and after the distraction and arthrectomy

We invite you to participate in this study

What will you have to do?

To participate in this research study, you will be interviewed/ examined by.....

.....and if found to fulfill pre-specified criteria, you will be eligible to be enrolled in this research study.

Since you are in the age group of 8-18 years we ask your accompanying parent / guardian will also sign a similar form called as the Parent Informed Consent Form.

List all procedures, which will be employed in the study. Point out any that are considered experimental/or otherwise, and explain technical and medical terminology in simple, nontechnical & direct language.

In addition, to record the same parameters daily your parent / guardian will also be provided with a diary where they will enter the same findings accordingly. You will have to tell them about your symptom and they will mark accordingly in the diary

Risks and discomforts

There is no foreseen significant risk / hazard to your health, if you wish to participate in the study. If you follow the directions of the ..... in charge of this study and you are injured due to any procedure given under the study plan, the Sponsor will pay for the medical expenses for the treatment of that injury.

Benefits

If you participate in the study you will receive .....If you appear to have any acute illness .....you will be offered free treatment for those visits in accordance with local standard medical care. You will not be offered free treatment for chronic diseases or conditions not related to study procedures.

Your participation in the study may help others, because this participation will help us determine if the study drug/procedure is safe.

Confidentiality

Your existing medical records may be accessed; personal health information about you may be collected and processed by study investigators for the purpose of performing the study. Information about you will be collected and stored in files with an assigned number, and not directly with your name. All documents related to the study will only be accessed by the study investigator, sponsor, the Ethics Committee and the Regulatory authority.

Your parent / guardian will have the right to access personal information about you at any time with the study doctor and the right to correct this personal information. Your parent / guardian can take away your authorization to collect process and disclose data about you at any time.

Right to refuse or withdraw

You do not have to take part in this research if you do not wish to do so. You may stop participating in the research at any time you wish. The study investigator may decide to withdraw you from the study if he/she considers it is in your best interest

You will be informed of important new findings developed during the course of the study so you will be able to consider your participation in the study in light of new information

Parents responsibilities

It is the responsibility of your parent / guardian to come along with you to the centre during the study period for all the visits unless you withdraw or are prematurely discontinued from the study. It is also your responsibility and your parent / guardian to report any expected or unexpected reactions (side effects) that you notice during the study period.

We expect your co-operation throughout the study.

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

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

बाल आश्वासन प्रपत्र

अध्ययन का शीर्षक : टेम्पोरोमैंडिबुलर संयुक्त एंकिलोसिस के कारण चेहरे की विकृति में विकर्षण ओस्टोजेनेसिस की भूमिका।

अध्ययन संख्या :

विषय का पूरा नाम :

जन्म तिथि o आयु

पता :

मैं - अपनी पसंद की मुफ्त शक्ति का प्रयोग कर रहा हूं, जिससे मैं अध्ययन में भाग लेने के लिए अपनी सहमति देता हूं

अध्ययन के उद्देश्य और किए जाने वाले कार्य की प्रकृति के बारे में ,o उपस्थित चिकित्सक द्वारा मुझे मेरी संतुष्टि के लिए सूचित किया गया है। मुझे पता है कि यदि मेरे माता-पिता / अभिभावक को किसी भी परीक्षण संबंधी चोट से पीड़ित होने पर उपचार का खर्च वहन नहीं करना पड़ता है, जिसका उक्त परीक्षण दवा के साथ संबंध है। मुझे परीक्षण के दौरान किसी भी समय परीक्षण से बाहर निकलने के अधिकार के बारे में पता है, ऐसा करने के लिए कारण दिए बिना

अध्ययन प्रतिभागी का हस्ताक्षर दिनांक

अध्ययन प्रतिभागी का नाम

साक्षी तिथि का हस्ताक्षर दिनांक

साक्षी का नाम

उपस्थित चिकित्सक तिथि पर हस्ताक्षर दिनांक

उपस्थित चिकित्सक का नाम

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

Child Assent Form

Study Title Role of distraction osteogenesis in facial deformity due to TMJ Ankylosis.
Study Number _____
Subject's Full Name _____
Date of Birth/Age _____
Address _____
_____

I _____, exercising my free power of choice, hereby give my consent for participation in the study entitled: " ..... "

I have been informed, to my satisfaction, by the attending physician, about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any trial related injury, which has causal relationship with the said trial drug. I am also aware of right to opt out of the trial, at any time during the course of the trial, without having to give reasons for doing so

Signature of the study participant _____ Date: _____
Name of the study participant _____

Signature of the Witness _____ Date _____
Name of the Witness _____

Signature of the attending Physician _____ Date: _____
Name of the attending Physician

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:……..

Signatory's Name…… Date……

Signature of the Investigator…… Date……..

Study Investigator's Name..... Date……..

Signature of the witness…… Date……..

Name of the witness……

Received a signed copy of the PID and duly filled consent form

Signature/thumb impression of the subject or legally Date……..

Acceptable representative

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

शिशु सहमति पत्र

मैं _____ में भाग लेने के लिए अपनी सहमति प्रदान करता हूँ। मुझे इस अध्ययन के हेतु और उसमे की जाने वाली प्रक्रिया के बारे में चिकिस्तक द्वारा बता दिया गया है। मुझे पता है कि अध्ययन सम्बन्धी किसी हानि जिसका अध्ययन की दावा से सम्बन्ध है उसका खर्च मेरे माता पिता अथवा अभिवाहक को नहीं वहां करना है। मुझे यह भी पता है कि मैं इस अध्ययन से किसी समय बिना कोई कारण बताये बाहर हो सकता हूँ।

अध्ययन में भाग लेने वाले का नाम और हस्ताक्षर
_____दिनांक_____

गवाह के हस्ताक्षर _____दिनांक _____

गवाह का नाम _____

चिकिस्तक का नाम और हस्ताक्षर_____दिनांक_____

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

Consent Form (English)

Title of the Study …….

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

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

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

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज

(बाबू बनारसी दास विश्वविद्यालय)

बीबीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत)

सहमति प्रपत्र (हिंदी)

अध्ययन का शीर्षक ……..

स्टडी नंबर……..
विषय का पूरा नाम …….
जन्म तिथि/आयु ……
विषय का पता…….
फोन नंबर। और ई-मेल पता ……
योग्यता ……
व्यवसाय: छात्र / स्वरोजगार / सेवा / गृहिणी / अन्य (कृपया उपयुक्त के रूप में टिक करें)
विषय की वार्षिक आय……
नाम और नामांकित व्यक्ति (ओं) और विषय के साथ उसका संबंध (के प्रयोजन के लिए) मुकदमे से संबंधित मौत के मामले में मुआवजा)।

1. **मैं पुष्टि करता हूं कि मैंने प्रतिभागी सूचना दस्तावेज दिनांक . को पढ़ और समझ लिया है ……..उपरोक्त अध्ययन के लिए और प्रश्न पूछने का अवसर मिला है। या मुझे अन्वेषक द्वारा अध्ययन की प्रकृति के बारे में बताया गया है और मुझे प्रश्न पूछने का अवसर मिला है।**
2. **मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और बिना किसी दबाव के स्वतंत्र इच्छा के साथ दी गई है और मैं बिना कोई कारण बताए और अपनी चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किए बिना किसी भी समय वापस लेने के लिए स्वतंत्र हूं।**
3. **मैं समझता हूं कि परियोजना के प्रायोजक, प्रायोजक की ओर से काम करने वाले अन्य, नैतिकता समिति और नियामक प्राधिकरणों को वर्तमान अध्ययन और किसी भी आगे के शोध के संबंध में मेरे स्वास्थ्य रिकॉर्ड को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी। इसके संबंध में आयोजित किया जा सकता है, भले ही मैं परीक्षण से हट जाऊं। हालांकि, मैं समझता हूं कि तीसरे पक्ष को जारी या प्रकाशित किसी भी जानकारी में मेरी पहचान प्रकट नहीं की जाएगी।**
4. **मैं इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं, बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्यों के लिए हो।**

5. **मैं भविष्य के शोध के लिए संग्रहीत नमूने (दांत/ऊतक/रक्त) के उपयोग की अनुमति देता हूं। हाँ नही** [ ]
लागू नहीं [ ]
6. **मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं। मुझे जटिलताओं और दुष्प्रभावों के बारे में समझाया गया है, यदि कोई हो, और उन्हें पूरी तरह से समझ लिया है। मैंने प्रतिभागी/स्वयंसेवक के मुझे दिए गए सूचना दस्तावेज को भी पढ़ और समझ लिया है।**

विषय/कानूनी रूप से स्वीकार्य प्रतिनिधि के हस्ताक्षर (या अंगूठे का निशान):……..
हस्ताक्षरकर्ता का नाम……. **तारीख** ……**।**
अन्वेषक के हस्ताक्षर …… **तारीख**……..
अध्ययन अन्वेषक का नाम …… **तारीख**……..
गवाह के हस्ताक्षर…… **तारीख**……..
गवाह का नाम ……
पीआईडी की एक हस्ताक्षरित प्रति और विधिवत भरे हुए सहमति फॉर्म विषय के हस्ताक्षर/अंगूठे का निशान या कानूनी रूप से दिनांक……..

स्वीकार्य प्रतिनिधि

CASE SHEET

DATE:-

OPD NO.:-

PATIENT NAME:-

AGE/SEX:-

FULL PERMANENT POSTAL ADDRESS:-

TELEPHONE NO.:-

CHIEF COMPLAINT:-

FAMILY HISTORY:-

PERSONAL HISTORY:-

HABITS:-

HISTORY OF PAST ILLNESS:-

HISTORY OF PRESENT ILLNESS:-

PAST DENTAL HISTORY:-

SYSTEMIC EXAMINATION:-

LOCAL EXAMINATION:-

INVESTIGATIONS & RECORDS:-

Hb gram%-

RBC count-

PCV-

ESR-

B.T.

C.T.

TLC-

DLC- POLY- MONO-

LYMPHO- EASN.-

Platelet count-

HbSAg-

HIV- I

- II

Blood urea-

Serum creatinine-

DIAGNOSIS:-

TREATMENT:-

PRE-OPERATIVE RECORD

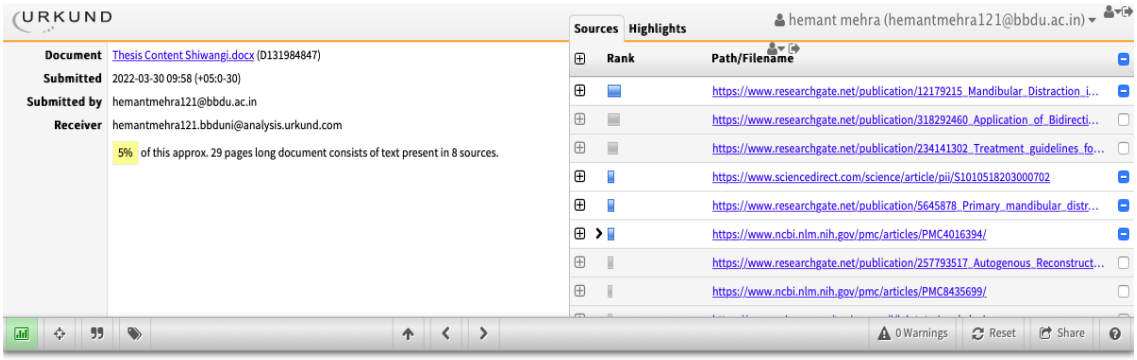
PHOTOGRAPHS ,OPG,LATERAL CEPHALOGRAM,PA VIEW

INTRA-OPERATIVE RECORD

PHOTOGRAPHS, MIO MEASUREMENT

POST-OPERATIVE RECORD

PHOTOGRAPHS, OPG, LATERAL CEPHALOGRAM,PA VIEW



TMJ. Interim DO, before definitive arthroplasty, can provide a static open bite that prevents progressive deformity and its associated functional disturbances.

The mandibular lengthening obtained by gradual distraction can result not only

in expansion of the mandibular bony tissue but in proportional and harmonic modification of the muscles and the surrounding soft tissues.

The forces produced by the distractor on the mandible are similar to physiological forces during mandibular development. McCormick et al.84noticed that the distraction spur operates on the affected condyles, and causes an increase in volume and optimization of the space orientation.

Distraction, therefore, seems to have beneficial effects not only on the harmony of the craniofacial complex but also on temporomandibular articulation. By reestablishing correct function of the soft and skeletal tissues, it is possible to regain the normal potential growth of the mandible. Clinical variables potentially determining the success of distraction osteogenesis include89 85 [25]:

a. meticulous planning and skillful execution of corticotomy (low-energy bone division with maximum preservation of osteo- genic tissues);

b. proper orientation of the distraction appliance relative to the anatomic axis of the mandible, occlusal plane and to the desired direction of distraction;

c. stable fixation of the bone segments, and; adequate distraction protocols (involving duration of latency period, rate and rhythm of distraction, and duration of consolidation period) to predictability achieve the desired outcome.

The results of this study confirm the findings that there was a significant rectification of facial aesthetics, oro-pharyngeal airway width, mandibular length, ramal height and mouth opening in the patients with TMJ ankylosis after distraction of mandible with distractor device. Furthermore, there was significant improvement of quality of life among these patient's pre- and post-operatively. No evidence of re-ankylosis was observed in any patients during the study period.