ROLE OF DISTRACTION OSTEOGENESIS IN CORRECTION OF OBSTRUCTIVE SLEEP APNOEA IN TEMPORO-MANDIBULAR JOINT ANKYLOSIS PATIENTS

Dissertation Submitted to

BABU BANARASI DAS UNIVERSITY LUCKNOW, UTTAR PRADESH.

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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BATCH: 2021-2024

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"ROLE OF DISTRACTION OSTEOGENESIS IN CORRECTION OF OBSTRUCTIVE SLEEP APNOEA IN TMJ ANKYLOSIS PATIENTS"** is a bonafide work carried out by me, under the guidance of **Dr. Hemant Gupta**, Professor & Head, Department of Oral & Maxillofacial surgery, Babu Banarasi Das College of Dental sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

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ACKNOWLEDGEMENT

My first and foremost thanks to God.

The teacher is the remover of darkness, the guidance of a teacher removes the obscures the light of awareness. Guidance in a proper direction is necessity for any form of success in life. I would like to begin by expressing my heart-felt gratitude to my teacher, advisor, my Guide ***Prof. (Dr.) Hemant Gupta, Professor and Head, Department of Oral & Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Lucknow,*** *for his constant guidance and support, without which I could not have completed this dissertation. I consider myself to be extremely privileged to have been his student. I express my sincere and deep sense of gratitude and appreciation to sir. Thank you sir for being so patient with me throughout my post graduate journey.*

I would now like to thank, my co guide ***Dr. Hemant Mehra, Reader Department of Oral & Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Lucknow****. He is a person who is always caring, helpful in every aspect, the one who always supports his students in every difficult situation.*

My deepest gratitude to, ***Dr. Rashmi Agarwal, Reader, Department of Oral & Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Lucknow****. Thank you so much ma'am for your constant help and support. Without your support I could not have completed my thesis.*

I want to thank ***Dr. Ankit Gangwar, Reader, Department of Oral & Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Lucknow*** *for his support and encouragement.*

I am also very thankful to ***Dr. Ashish Uppal, Senior Lecturer, Department of Oral & Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences,***

Lucknow *for being cooperative always. Without his cooperation this dissertation would have been lot more difficult. I am sincerely thankful.*

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I want to thank ***Dr.Ishita Srivastava, Senior Lecturer, Department of Oral & Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Lucknow****for her constant support.*

I also want to thank ***Dr.Sobia Afreen, Senior Lecturer, Department of Oral & Maxillofacial Surgery, Babu Banarasi Das College of Dental Sciences, Lucknow****for her constant support.*

Now, it's the time to remember my seniors Dr. Rajatava Paria , Dr. Piyush Raj Dhari and Dr. Shahanika Yadav. We have spent some quality time under them. I sincerely thank them for their constant support and guidance from the the very beginning till today. Thanks for all support and sweet memories.

I like to place special thanks to my loving juniors Dr.Shiwangi Kumari, Dr.Shivankar Tyagi, Dr.Jaya Mahato, Dr.Sarvagya Singh, Dr.Vineet Vaibhav and Dr.Aditya Narayan for their cooperation and assistance in completion of this work.

My heartfelt thanks to Dr. Abhijeet Humne & Dr. Pallavi Rai as my batchmates and friend. We have all been there for one another and have taught ourselves and each other on important topics, academically as well as personally. Also, for easing out the difficult situations by their timely advice and reminders, for making me laugh and cheerful environment everytime. As we started this journey together, no one can understand this journey better.

I extend my heartfelt gratitude to my best friend Dr. Dikshita Das for her unwavering support and invaluable assistance throughout the challenging journey of crafting this dissertation. Thank you for being the pillar of strength and inspiration that made this achievement possible.

I couldn't have reached this far without my family. My mere words will never match the extent of affection I received from them. I express my love and warmest gratitude to my father Mr. Nasir Shaikh, my mother Mrs Nigaar Parvin. I want to thank my sister, Dr. Mishba Shaikh as I felt myself luckiest to have sister like her. I thank them all for their understanding, constant support, selfless love and encouragement that they have always provided me. They stood by me through all my ups and downs. I dedicate this piece of work to them.

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It is my duty to express my sincere thanks to the non-teaching staff Nankan Bhaiya, Haider bhaiya, shivam and nursing staff. I am thankful to all those, who helped me and provided their cooperation that made me complete my work. My apologies to those I have unintentionally omitted. My sincere thanks to my Patients who were the most important part of my thesis. I want to thank them for their patience and co-operation. Thank you everyone for being a part of my life and making it worth living.

Dr. Shaikh Marufhusain

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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**
OSAS	**Obstructive sleep apnoea syndrome**
NCPAP	**Nasal continuous positive airway pressure**
MMA	**Maxillomandibular advancement**
IMF	**Intermaxillary fixation**
DO	**Distraction osteogenesis**
CCG	**Costochondral graft**
RCU	**Ramus condylar unit**
MDO	**Mandibular distraction osteogenesis**
PAS	**Posterior airway space**

MPH	**Mandibular plane hyoid**
AHI	**Apnoea hypopnea index**
Qol	**Quality of Life**
PrAD	**Pre-arthroplastic distraction osteogenesis**
PAD	**Post-arthroplastic distraction osteogenesis**
SAD	**Simultaneous arthroplastic distraction osteogenesis**
MCDO	**Mandibular distraction osteogenesis**
ESS	**Epworth sleepiness scale**
IA	**Interpositional arthroplasty**
BIRD	**Bilateral Internal Ramus Distraction of the mandible**
PSQI	**Pittsburgh sleep quality index**
CFM	**Craniofacial macrosomia**
BT	**Bleeding time**
CT	**Clotting time**
CBC	**Complete blood count**

Background of the study :- Obstructive sleep apnoea is identified as repetitive and intermittent upper airway collapse or narrowing during sleep. Skeletal advancement through maxillomandibular surgery remains the most effective surgical treatment for OSA but is radical with certain relapse rate. Distraction osteogenesis of mandible is a single-jaw surgical treatment alternative to bi-jaw surgeries having lesser complications.

Aim: To evaluate the effects of distraction osteogenesis in management of obstructive sleep apnoea patients secondary to temporomandibular joints ankylosis.

Methods: Five patients were included in this study. Preoperatively the patients were worked up for polysomnography and CT scans. Only those patients with Apnoea-hypopnoea index >15 events/h denoting moderate to severe obstructive sleep apnoea were included. 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 interpositional arthroplasty after distraction osteogenesis.

Results: Post distraction improvement was seen in clinical features of OSA like daytime sleepiness and snoring. Polysomnographic analysis also showed improvement in all cases with apnoea-hypopnoea index from 40.80 to 2.80 per hour. Oxygen desaturation index improved from 38.26 to 2.50 per hour. Cephalometric analysis showed improvement in all parameters. Upper pharyngeal airway pace improved from 9.40 to 12.40 mm. Lower pharyngeal airway space improved from 5.60 to 9.60 mm. Mandibular length increased from 51.20 to 59.20 mm. Ramal height increased from 37.80 to 43.20 mm and mouth opening improved from 5.80 to 37.80 mm.

Conclusion: Distraction osteogenesis is a stable and beneficial treatment option for temporomandibular joint ankylosis patients with obstructive sleep apnoea.

Keywords: Temporomandibular joint ankylosis, distraction osteogenesis, arthroplasty, obstructive sleep apnea.

Ankylosis of the temporomandibular joint is an intracapsular union of the disc-condyle complex to the temporal articular surface that restricts mandibular movements, including the fibrous or bony fusion between condyle, disc, glenoid fossa, and eminence.[1] Trauma is the most frequent cause of TMJ ankylosis followed by local or systemic infection and diseases including ankylosing spondylitis, rheumatoid arthritis, and psoriasis.[2]

Normal airway depends upon several factors like oral (lower) and nasopharyngeal (upper) airways, appearance of face, absence of TMJ pathology (TMJ ankylosis), normal TMJ function, mouth opening of 35-55 mm, mandibulohyoid distance (6.5cm), normal morphology and growth of mandible and maxilla and neck appearance.[3] TMJ ankylosis is a disabling condition as it affects all factors relating normal airway[4].

Patients with TMJ ankylosis develop obstructed or reduced oropharyngeal (upper) and nasopharyngeal (lower) airways[5], severe maxillomandibular dysplasia, convex profile, reduced mandibulohyoid distance, decreased chin to neck angles etc[6]. Decreased mouth opening causes serious problems in mastication, digestion, speech, appearance, and hygiene.[7] Overall it disturbs facial and mandibular growth, leads to acute compromise of the upper and lower airway invariably resulting in physical and psychological disability.[6,8]

Diagnosis of TMJ ankylosis is usually made by clinical examination and imaging studies, such as plain films, orthopantomograms, computed tomography (CT) scans, MRI, and three dimensional reconstruction.[6]

The management goal in TMJ ankylosis is to improve the patient's stomatognathic function, correct associated facial deformity, decrease pain, and prevent reankylosis. Various surgical modalities have been proposed to manage TMJ ankylosis including gap arthroplasty, interpositional arthroplasty, and total joint reconstruction. Autogenous tissues, such as ear cartilage, temporalis muscle flap, dermis, fat, and bone, have been used. Alloplastic materials, such as Proplast Teflon and Silastic have also been used, but with high failure rates.[9-12]

Obstructive sleep apnoea is characterized by episodes of complete collapse of the airway or partial collapse with an associated decrease in oxygen saturation or arousal from sleep. This disturbance results in fragmented, nonrestorative sleep. Obstructive sleep apnoea occurs as a common disorder in children born with congenital craniofacial deformities as well as in male adults .[16-18] Surgical treatment is indicated in the cases with high apnoea-hypopnoea Index. Although soft tissue surgery like uvulopalatopharyngoplasty offers success in treating OSA in selected cases, bone surgery is often required in congenital/developmental anomalies of the craniofacial complex. Maxillomandibular advancement has been shown to be highly effective in improving OSA conditions.[19] Conventional orthognathic procedures have been the workhorse for advancing the craniomaxillofacial and mandibular complex at multilevels. The principle is to create a well controlled fracture at specific anatomical region to allow repositioning of the jaw segment in a planned position. In OSA cases, advancing the jaw bone could enlarge the posterior airway three dimensionally and reduce the collapsibility of the soft tissue such as the tongue or soft palate[14] , thus helping in patients of OSAS.

Distraction osteogenesis is a novel surgical technique that involves lengthening the jawbone to treat obstructive sleep apnoea syndrome. The procedure involves making a small cut in the lower jawbone and attaching a metallic distractor device. The jawbone is then gradually lengthened by distraction osteogenesis along with histodistraction of soft tissue which shifts the attached tissues like the tongue forward, thereby freeing the airway.

Distraction osteogenesis is a method of generating new bone following a corticotomy or an osteotomy and gradual distraction. The method is based on the tension-stress principle proposed by Ilizarov.[13,14] The gradual bone distraction creates mechanical stimulation which induces biological responses and consequently bone regeneration. This is accomplished by a cascade of biological processes which may include differentiation of pleuripotent cells, angiogenesis, osteogenesis, and bone mineralization. In facial bones, the method

was proved to be predictable in animal studies with the generation of new bone and was later used in clinical practice.[15]

Distraction osteogenesis consists of four steps. In the first phase, called the "osteotomy/surgical phase", the bone is cut, either partially, only through the hard exterior, or completely, and a device is fitted which will be used in the next phases. In the second phase, the latency period, which lasts generally seven days, the appliance is not activated and early stages of bone healing are allowed. In the third phase, the "distraction phase", the device, which is mounted to the bone on each side of the cut, is used to gradually separate the two pieces, allowing new bone to form in the gap. When the desired or possible length is reached, which usually takes three to seven days, a *consolidation phase* follows in which the device keeps the bone stable to allow the bone to fully heal. After the consolidation phase, the device is removed in a second surgical procedure.[1]

The use of distraction osteogenesis in oral and maxillofacial surgery offers several advantages over conventional orthognathic and bone grafting procedures, and therefore has became increasingly popular in the last two decades especially for severe bone deficiency such as deficient maxilla, midface, deficient hypoplastic mandible and deficient alveolar bone prior to implants placement.

The study was designed objectively to determine the effect of distraction osteogenesis in management of obstructive sleep apnoea in patients with temporomandibular joint ankylosis by clinical and radiological assessment along with cephalometry and polysomnography.

AIM – To study the efficacy of distraction osteogenesis in management of obstructive sleep apnoea.

OBJECTIVES –

1. Comparison of preoperative & postoperative upper and lower pharyngeal airway space, ramal height, mandibular length on a lateral cephalogram.
2. Evaluation of polysomnography preoperatively and postoperatively.
3. Comparison of mouth opening preoperatively and postoperatively.

Prinsell J.R (1999)[20] conducted a study to determine the efficacy of maxillomandibular advancement (MMA) surgery, with a description of several innovations, as a site-specific treatment of obstructive sleep apnoea syndrome (OSAS) in 50 patients with disproportionate velo-orohypopharyngeal anatomy. Patients were referred for MMA evaluation when applicable conservative therapies such as nasal continuous positive airway pressure (nCPAP) were not tolerated, refused, or unsuccessful. Case selection was based primarily on the sites of disproportionate upper airway anatomy. MMA consisted of a Lefort I osteotomy, bilateral sagittal split ramus osteotomies, and a new modified procedure called an anterior inferior mandibular osteotomy with indirect hyoid suspension. Some patients also received concomitant adjunctive nonpharyngeal procedures. He concluded that MMA is highly successful and safe and may be a definitive primary single-staged surgical treatment of selected OSAS cases with diffusely complex or multiple sites of disproportionate velo-orohypopharyngeal anatomy.

Bell RB, Turvey T.A (2001)[21] assessed the clinical outcomes of children with medically refractory OSA who were treated with a variety of procedures to advance the maxillofacial skeleton. The records of eight children with OSA were reviewed. Six children had identifiable syndromes associated with micrognathia, one child had mandibular ankylosis, and one child was nonsyndromic. They concluded that skeletal advancement can be an effective treatment for medically refractory OSA in children. Success, however, is dependent not only on skeletal position but also on neuromuscular adaptation. Bronchoscopy is the most valuable diagnostic and predictive tool.

Denny AD , Talisman R , Hanson PR , Recinos RF (2001)[22] conducted a study to measure changes in the airway cross-sectional area of paediatric patients with micrognathia and obstructive airway symptoms after treatment by mandibular distraction. The measurements obtained were correlated with the clinical outcomes. Ten patients, ranging in age from 3 months to 8 years, underwent measurement and distraction. Eight patients were under 30 months of age. All patients had retrognathia of greater than 8 mm and obstructive airway symptoms while awake that had resulted in tracheostomy, repeated apnoea

monitor triggering, or abnormal sleep study. Cephalometric analysis was performed pre-treatment and post-treatment by distraction. The effective airway space was defined with the following boundaries: a horizontal line from the tip of the odontoid to the velum, the uvula tip to the tongue base along the shortest line, the tongue base down to the base of the epiglottis, and the horizontal line to the posterior pharynx. These lines were traced for each cephalogram, the outline was digitized, and the area was calculated by computer. The range of distraction was 8 to 22 mm; the mean effective airway increase was 67.5 percent, with a range of 26 to 120 percent. Measurable airway increase occurred in all patients who underwent distraction, and all patients showed clinical improvement. Mandibular distraction seems to provide a consistent change in tongue base position that improves obstructive airway symptoms by increasing measured effective airway space. The potential for mandibular distraction exceeds the simple correction of malocclusion also by eliminating soft-tissue obstruction of the micrognathic airway. Airway improvement is independent of the syndrome diagnosed. They concluded that mandibular distraction osteogenesis may be useful to avoid or decannulate existing tracheostomy in infants with micrognathia.

Wang X, Wang XX, Liang C, Yi B and Li Z.L (2002)[23] conducted a study to evaluate the effect of distraction osteogenesis in correction of micrognathia accompanying obstructive sleep apnoea syndrome on 28 patients. A total of 51 distraction devices were placed for bilateral distraction in 23 patients and for unilateral distraction in five patients. The mean age of patients was 21.2 years. Each patient was evaluated preoperatively and postoperatively with cephalometry and polysomnography. The authors concluded that mandibular distraction osteogenesis is an effective method for correcting micrognathia accompanying obstructive sleep apnoea syndrome. Compared with other current routine surgical procedures, it has many advantages, such as low risk, simple manipulation, high curative rate, low relapse rate, and stable result. It is presently the most effective method for the treatment of this difficult and complicated disorder.

Prinsell J.R (2002)[24] presented a retrospective review of several published case series with inclusion criteria of 20 or more patients who underwent MMA and

received documented preoperative and postoperative diagnostic polysomnography. Protocols of MMA as a primary vs. secondary operation, with and without adjunctive procedures in a site-specific approach, were compared and discussed. He concluded that MMA is a highly successful and potentially definitive primary single-staged surgery that may result in a significant reduction in OSAS-related health risks, as well as financial savings for the health care system. The diagnosis and management of OSAS requires a multidisciplinary team approach, including a working relationship between the dentist and sleep physician. General dentists and dental specialists who participate in the management of snoring and OSAS cases should have some knowledge of basic sleep medicine.

Lopez E.N and Dogliotti P.D (2004)[25] evaluated retrospectively 41 patients who underwent temporomandibular joint reconstruction during the last 10 years. 20 patients were treated by costochondral graft, 15 patients by arthroplasty, and 6 patients by other surgical procedures. 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 concluded that their treatment protocol, which includes TMJ joint arthroplasty with temporal muscle interposition, and distraction osteogenesis in mandible, as a second procedure can be used to correct residual asymmetry or retrognathism if necessary.

Ko EW, Hung KF, Huang CS, Chen PK (2004)[26] conducted 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 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 was 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 analyse 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 AK, Bhatnagar SK (2004)[27] conducted a study 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. 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.

Steinbacher DM, Kaban LB, Troulis MJ (2005)[28] conducted a study to evaluate mandibular lengthening by distraction osteogenesis (DO) to achieve decannulation of micrognathic children with “permanent” tracheostomies. Total 5 children, aged 2 to 14 years, who received a tracheostomy between ages 2 and 36 months for airway obstruction were included in this study. All patients underwent bilateral mandibular distraction using semiburied, unidirectional devices. The authors concluded that mandibular advancement by DO is a potentially viable treatment option for tracheostomy-dependent children with upper airway obstruction secondary to micrognathia.

Sadakah AA, Elgazzar RF, Abdelhady AI (2006)[29] performed a study to evaluate the feasibility of transoral bimaxillary distraction osteogenesis before releasing temporomandibular joint (TMJ) ankylosis using intraoral mandibular distractors. Nine patients aged 14–35 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 followed by a consolidation period of 6–8 weeks. TMJ ankylosis was then released via a preauricular incision, 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. The study concluded that intraoral distraction of a deformed mandible and maxilla before releasing TMJ ankylosis is a feasible and perhaps advantageous technique.

Shehta EAA, Medra AMM (2006)[30] performed a study to evaluate 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 were treated using a modified technique of simultaneous maxillary–mandibular distraction. Their facial deformities were caused by hemicraniofacial microsomia or ankylosis of the temporomandibular joint (TMJ).The mean (range) gain in mandibular height was 16 mm, and increase in elongation 14 mm achieved over 11–22 days. Predicted movement on cephalometric analysis correlated closely with the actual distraction.The author derived to a conclusion that simultaneous bimaxillary distraction osteogenesis is a robust technique that provides the surgeon with the ability to correct facial asymmetry in patients with hemi craniofacial 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 patients.

Lin SY, Halbower AC, Tunkel DE, Vanderkolk C (2006)[31] conducted a study to evaluate the long-term benefits of mandibular distraction on sleep-related

upper airway obstruction in young children with mandibular hypoplasia. Five children with upper airway obstruction from craniofacial anomalies were treated with mandibular distraction, with a minimum follow-up of 12 month. They concluded that most children who undergo mandibular distraction for upper airway obstruction associated with mandibular hypoplasia demonstrate significant clinical improvement of obstructive sleep apnoea. However, those children who continue to have symptoms of sleep-disordered breathing after surgery should undergo polysomnography for evaluation of persistent obstructive sleep apnoea.

Ravindran C, Ramkumar S, Nandakumar N (2006)[32] presented a case of obstructive sleep apnoea syndrome due to mandibular hypoplasia resulting from a TMJ ankylosis, which was treated with distraction osteogenesis of the mandible. They found that the use of distraction osteogenesis for the treatment of obstructive sleep apnoea is a novel and ground breaking concept and can also be a successful alternative to other surgical options. It simultaneously advances both the soft and hard tissues, in the process corrects the functional as well as the aesthetic aspects of the deformity.

Lu Xiaofeng, Tang Yousheng, Shen Guofang, Zhu Ming, Li Qingyun, Qiu Weiliu (2008)[33] conducted a study to apply the treatment of DO for the pa tients of OSAHS with craniomaxillofacial deformities, in which 58 patients of OSAHS with craniomaxilloman dibular deformities were examined by PSG and cephalometric analysis with age ranging from 4 to 22 years. There were 36 patients suffering from TMJ ankylosis with micrognathia, 6 cases in micrognathia, 5 cases of first and second bronchial arch syndrome, 8 cases maxilla hypoplasia, and 3 cases Crouzon syndrome. They were treated by osteotomy of mandible body and/or ramus, Le fort I or Le fort III osteotomy and DO. Advanced distance was from 12 to 40 millimetres. They were evaluated by PSG and cephalometric analysis postoperatively with mean duration of follow up of 2.5 years. The authors found that the patients had better profile and the narrow upper airway was relieved with AHI dropping from 69.6 pre-operatively to 3.3 post-operatively. They concluded that DO is a good treatment method for the patients of OSAS with micrognathia, especially for the patients with severe craniomaxillomandibular deformities.

Genecov DG, Barceló CR, Steinberg D, Trone T, Sperry E (2009)[34] conducted a study to evaluate the long-term success of mandibular distraction osteogenesis in patients with mandibular airway obstruction syndrome (MAOS). Bilateral distraction osteogenesis of the mandible was performed in 67 patients, 26 patients did not have any prior surgical treatment, and 41 patients already had a tracheotomy. The distraction devices used were internal in 33 and external in 34 of 67 patients. The distraction protocol consisted of a 24-hour latency period and then a 1-mm/d activation period. The mean activation period was 19.4 days, the mean consolidation period was 73 days, and the mean length of distraction achieved was 22 mm. They concluded that distraction osteogenesis of the mandible provides an excellent treatment for micrognathia and airway obstruction in patients younger than 6 years who do not respond to conservative treatment. It prevents the need for tracheostomy and allows for early decannulation in patients who previously underwent tracheostomy and is consistent with the improvement of feeding and prevention of gastroesophageal and laryngeal refluxes.

Feiyun P, Wei L, Jun C, Xin X, Zhuojin S, Fengguo Y (2009)[35] performed 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 with bilateral temporomandibular joint ankylosis and mandibular micrognathia were included. Obstructive sleep apnoea and hypopnea syndrome was diagnosed in all patients preoperatively. Threedimensional 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 with distraction rate of 0.8 mm/day. The patients began active mouth opening postoperatively. Distracters were kept in place for 4 months and then removed. Polysomnography, cephalometry, and computed tomography were performed at 6 months postoperatively. They noticed that obstructive sleep apnoea and hypopnea syndrome was cured, and the

micrognathia was corrected in all the 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 to 77.6 degrees. Bone formation in the distraction gaps were observed. The follow-up period was 29.7 months. No complications or recurrence of temporomandibular joint ankylosis or micrognathia occurred in any patient during the follow-up period.

Rajkumar GC, Manjunath, Shashikala R, Veerendra KD (2011)[36] conducted a study on patients with temporomandibular joint ankylosis who commonly present with mandibular hypoplasia as a result of trauma to the temporomandibular joint, middle ear infection or due to various syndromes. This process induces new bone formation along the vector of distraction force without requiring the use of a bone graft. 4 patients in which 3 patients had bilateral temporomandibular joint ankylosis and one patient with unilateral temporomandibular joint ankyloses were included who underwent surgical correction of temporomandibular joint ankylosis and mandibular hypoplasia with distraction osteogenesis using extra-oral distraction device to achieve distraction of more than 20 mm. This study concluded that distraction osteogenesis is the treatment of choice for temporomandibular joint reconstruction and anterior linear advancement of the hypoplastic mandible in whom the mandibular advancement is highly difficult to be achieved by the conventional osteotomy procedures. The relapse rate over a period of 5 year is very minimal.

Brevi BC, Toma L, Magri AS, Sesenna E (2011)[37] performed a study using orthognathic technique of mandibular osteodistraction to achieve 1 to 2 cm advancements in Forty-four patients who were affected by severe OSAS. They concluded that the mandibular distraction technique is a good option in cases that require a large degree of mandibular advancement, because it decreases damage to the inferior alveolar nerve, decreases temporomandibular problems, and allows gradual monitoring of the esthetic result. The DO technique allows a larger advancement, almost double that of traditional procedures, and gradual development of esthetic changes. Larger advancements should guarantee

immediate and improved results and stability of the modifications as patients age and/or gain weight.

Sahoo NK, Tomar K, Kumar A, Roy ID (2012)[38] Compared the outcomes of reconstruction options adopted for the management of temporomandibular joint (TMJ) ankyloses by conducting a retrospective cohort study which consisted of a sample of patients with TMJ ankylosis diagnosed clinically and radiologically and depending upon the reconstruction provided, the cases were divided into 2 groups. Group I included 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. 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. It was found that in cases with no or minimal mandibular deformity, interpositional arthroplasty with temporalis myofascial flap was a good option without a second surgical wound. However, in younger patients, joint reconstruction with both costochondral graft and distraction osteogenesis of RCU was more appropriate and had similar results. The failure of treatment may be due to noncompliance to postsurgical physiotherapy rather than the selection of reconstruction options.

Jaspers GW, Booij A, de Graaf J, de Lange J (2012)[39] assessed the long-term effects of Maxillomandibular advancement (MMA) on OSAS by means of AHI in polysomnography and Epworth Sleepiness Scale (ESS). The study was a retrospective cohort study with a normal follow-up protocol. They concluded that MMA is promising in aspects of AHI and ESS reduction and larger long-term cohort studies of MMA are needed to confirm these clinical outcomes.

Gupta GM, Gupta P, Sharma A, Patel N, Singh A (2013)[40] 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. 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 showed improvement in all except for one patient. Also, both patient and panel perceptions for esthetics had improved post distraction in all the cases.

Khan M.Z, Ahmed A and Shah A.H (2013)[41] reported a 2-year follow-up of a female patient with Micronesia and OSAS secondary to unilateral TMJ ankylosis of the right side. The treatment involved vertical ramus osteotomy, coronoidectomy and external distraction osteogenesis of her mandible. After the treatment of micrognathia oropharyngeal airway space was increased, patient was followed up for 2 years and the results remained uneventful. They concluded that DO is a safe, effective and rapid technique to treat OSA related to micrognathia particularly in cases that require a large degree of mandibular advancements.

Yadav, R, Bhutia O, Shukla, G and Roychoudhury A (2013)[42] evaluated 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. They concluded that Distraction osteogenesis is a stable and beneficial treatment option for temporomandibular joint ankylosis patients with obstructive sleep apnoea.

Tahiri Y, Viezel-Mathieu A, Aldekhayel S, Lee J, Gilardino M (2013)[43] reviewed effectiveness of distraction osteogenesis in the treatment of airway obstruction in pediatric patients with mandibular hypoplasia. Studies involving isolated distraction of the pediatric mandible (younger than 18 years) with descriptive reporting of airway changes were included. Extracted data included demographics, initial diagnosis, distractor type, distraction protocol,

predistraction and postdistraction airway status, and complications. Seventy-four articles met the inclusion criteria, resulting in 711 patients with craniofacial abnormalities who underwent mandibular distraction osteogenesis. Mean age at the time of distraction was 18.1 months. They concluded that in addition to its positive effect on facial appearance, mandibular distraction osteogenesis is an effective procedure for the treatment of airway obstruction associated with congenital craniofacial defects involving mandibular hypoplasia in appropriately selected patients.

Lam DJ et al (2014)[44] conducted a study to assess the rate and predictors of surgical success and complications among (1) patients who underwent maxillary distraction osteogenesis prior to other airway procedures (MDO first), and (2) patients who required an initial tracheotomy and were subsequently treated with MDO (tracheostomy first). They concluded that Mandibular distraction osteogenesis has a high rate of success in avoiding tracheostomy. Patients who required tracheostomy before MDO had a lower success rate in achieving decannulation and a higher rate of complications. However, these patients also had a higher rate of syndromic diagnoses and associated comorbidities. Patients with Goldenhar syndrome have a decreased likelihood of surgical success.

Nurliza A et al (2015)[45] described a case of a four year old girl who presented with mandibular hypoplasia in anterior-posterior direction secondary to left TMJ ankyloses which was further complicated with presence of severe trismus, adenoid hyperplasia grade III and moderate obstructive sleep apnoea. They performed two stages of surgical intervention which were bilateral mandibular distraction osteogenesis via submandibular approach followed by left condylectomy and gap arthroplasty with interpositional myofascial temporalis flap 4 months later. They concluded that mandibular distraction osteogenesis is effective in treating mandibular deformity and relieving symptoms of OSA. The sterolithography model played an important role in surgical planning and multidisciplinary approach was crucial for optimum surgical correction of this maxillofacial deformity.

Mehrotra D, Vishwakarma K, Chellapa A L ,Mahajan N. (2016)[46] 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. 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. They concluded that pre-arthroplasty simultaneous maxillomandibular distraction offers a good treatment outcome, as it allows improvements in facial aesthetics as well as function.

Tsui W, Yang Y, Cheung L and Leung YY (2016)[47] conducted a systematic review to answer the clinical question "What are the effectiveness of mandibular distraction osteogenesis (MDO) and its complications to treat patients with obstructive sleep apnoea syndrome (OSAS)?".A systematic search including a computer search with specific keywords, reference list search, and manual search were done. Relevant articles on MDO were assessed and selected in 3 rounds for final review based on 5 predefined inclusion criteria and followed by a round of critical appraisal. Different types of distraction and their treatment outcomes of OSAS were recorded with standardized form and analyzed. This systematic review showed that MDO was effective in resolving OSAS in adults with retrognathic mandible. MDO also showed promising results in infants or children with OSAS. From the results of this systematic review they recommended to define the criteria of success or cure for OSAS surgery in children and infants. They also recommended setting up randomized controlled

trials to compare MDO with traditional maxillomandibular advancement surgery for OSAS patients and to provide a better evidence on the success and complication rates of the techniques.

Kumari P et al (2017)[48] conducted a study to evaluate the changes in posterior airway space (PAS) and mandibular plane hyoid (MPH) distance following mandibular advancement using distraction osteogenesis (DO). Twenty-five consecutively operated patients of mandibular hypoplasia who underwent mandibular advancement using distraction with at least 12 months follow-up were included in the study. The study group comprised 15 males and 10 females with an age range of 15–30 years. The authors concluded that statistically significant changes were achieved in MPH and SNB. Although change in PAS was statistically insignificant, it may have clinical applications, especially in the field of Phase II surgical management of obstructive sleep apnoea.

Baskaran M, Arularasan SG, Divakar TK, Thirunavukkarasu R (2017)[49] assessed the versatility of distraction osteogenesis in the treatment of micrognathia. The study included 4 patients with micrognathia of the mandible with the age range 10 – 20 years. Osteotomy and placement of intraoral distractor done was under general anaesthesia. The parameters assessed were ramus height, body length, hyoid 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.

Tomonari H, Takada H, Hamada T, Kwon S, Sugiura T and Miyawaki S (2017)[50] described the case of a 16-year-old female patient with micrognathia, temporomandibular joint (TMJ) ankylosis, and obstructive sleep apnoea, who was treated with mandibular distraction osteogenesis (DO) combined with sliding genioplasty, using skeletal anchorage. The study concluded that Mandibular DO using skeletal anchorage with intermaxillary elastics is useful for preventing extrusion of the upper and lower anterior teeth, thereby preventing rotation of the mandible. In addition, mandibular DO combined with sliding genioplasty is effective at improving both dentofacial deformities and impaired respiratory function.

Balaji SM (2017)[51] reported a case of a 3-year-old boy who was struggling with severe retrognathic chin and OSA causing hypopneic episodes and snoring. He was successfully treated by bilateral mandibular distraction. The author found that DO is a powerful tool for surgical reconstruction of complex jaw deformities. The goal of treatment in infants with severe micrognathia is to focus on breathing and feeding and to optimize growth and nutrition. It appears to be the superior method of reconstruction technique when performed correctly and effectively lengthens the jaws without the use of grafts.

Zhang C, Li Y, Ye B, Liu Y, Bao C, Zhu S (2017)[52] described 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 new bone density had been formed after the consolidation period. All patients had maintained stable improvement in oral function during the follow-up period. Most of the patients achieved satisfactory outcomes. Bidirectional transport distraction osteogenesis technique proved to be a good and effective therapeutic option in treatment of bilateral or unilateral TMJ ankylosis patients associated with mandibular micrognathia.

Zhang W et al (2017)[53] evaluated the effects of the sequential treatment of temporomandibular joint ankylosis with secondary deformities by distraction osteogenesis on 40 patients with temporomandibular joint ankyloses. The treatment procedure led to improved mouth opening and appearance and the symptom of snoring disappeared. The patients were followed up for 4 to 72 months, 4 patients showed recurrence, and needed further surgical treatment. They concluded that the sequential treatment of temporomandibular joint ankylosis with secondary deformities by distraction osteogenesis, arthroplasty and orthognathic surgery could achieve satisfactory and stable result.

Andrade NN, Mathai PC, Ganapathy S, Aggarwal N, Rajpari K, Nikalje T (2018)[54] performed 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. Patients 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. 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. The authors concluded that pre-arthroplastic mandibular DO is a successful modality for treatment of OSA in TMJ ankylosis patients with stable results at 12 months. By resolving the narrow airway and OSA, compliance towards physiotherapy was improved thus reducing the risk of re-ankylosis in the long term.

Chen K, Xiao D, Abotaleb B, Chen H, Li Y, Zhu S. (2018)[55] 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. 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 analysed. 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.

Bi RY, Luo XT, Jiang N, Zhu SS, Li YF (2018)[56] 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.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 and volume. The authors 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.

Kumar D et al (2019)[57] 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 temporomandibular joint ankylosis. The study included 10 patients in the age group of 13 – 40 years with TMJ ankylosis who underwent primary osteo-distraction for mandibular advancement. The amount of distraction achieved post-operatively was more in cases of unilateral TMJ ankylosis compared to bilateral TMJ ankylosis. In all the ten cases of TMJ ankylosis with sleep apnoea, there was significant improvement in the airway and Epworth Sleep Scale. There was significant improvement of quality of life among these patients and post-operatively.

Yu X, Wang J, Hou S, Zeng R (2019)[58] reported a case of a 4-year paediatric patient with early-onset bilateral TMJ ankylosis and severe secondary micrognathia, as well as obstructive sleep apnoea syndrome. They found that TMJ management with simultaneous mandible distraction is an effective method to improve mandibular movement restrictions, airway obstructions and micrognathia and patients with childhood onset require early surgical treatments to avoid secondary malformations. However, poor compliance with post-surgical physiotherapy is likely to lead to a limited range of motion following surgery.

Ma Y, Huang Y,Zhu S and Li Y(2019)[59] 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 with age range 4–12 years were treated. Preoperatively, the mean maximal incisal opening was 1.4 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 follow-up time after removal was 29.6 months, and the distance of distraction was 14.4 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 maximum incisal opening reached 35.7 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. No patients had a recurrence of ankylosis during

follow up. The results suggested that simultaneous arthroplasty and distraction osteogenesis is feasible in this age group.

Kandamani J (2020)[60] conducted a review to find a scientific evidence based background for the mandibular distraction osteogenesis in treatment of temporomandibular ankylosis. A literature search using google scholar and science direct was made using the following terms: ankylosis, temporomandibular joint, distraction. The inclusion criteria for the review consisted of: controlled clinical trials, retrospective studies, case reports, and follow-up studies. The author concluded that distraction osteogenesis of mandible in the first phase and followed by release of ankylosis (with gap or inter-positional arthroplasty) in the second phase operation or Release of ankylosis (with gap or inter positional arthroplasty) followed immediately by distraction osteogenesis, either of these two techniques can be carried out considering its own advantages and disadvantages and the treatment planning should be sequenced according to individual needs depending on the age at diagnosis and expertise available, goal should be focussed on achieving the highest inter incisal distance possible and immediate relieve of the narrow posterior airway space through release of the ankylosis. Also intensive mouth opening physiotherapy is mandatory to achieve and maintain an acceptable inter incisal distance.

Vignesh U, Mehrotra D, Bhave S M and Singh PK (2020)[61] performed a study to evaluate the success of distraction osteogenesis in temporomandibular joint (TMJ) ankylosis patients with facial deformities. 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 OHIP14. All the patients had prearthroplastic distraction. Significant improvement was identified on all QoL and OHIP questions after distraction. The post distraction overall mean QoL score among patients with extraoral or intraoral distractor did not have a significant difference, 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. The study concluded that distraction osteogenesis considerably improves oral health and health related QoL in patients with TMJ ankylosis with facial deformities.

Kamath AT, Kudva A, Singh A (2020)[62] presented a case of a patient with the triad of TMJ ankylosis, retrognathia, and OSA who underwent DO for correction of OSA followed by bilateral TMJ reconstruction with stock alloplastic prostheses on the distracted mandible, along with genioplasty to correct retrogenia. They concluded that in patients with concomitant TMJ ankylosis and OSA, the sequencing of surgery and the preferred treatment modality to correct the deformity has been a matter of debate and the use of stock alloplastic TMJ prostheses to correct TMJ ankylosis following mandibular distraction for the correction of mandibular retrognathia and OSA provided a successful outcome for this patient one-year post surgery. One-year post-surgery, the patient demonstrated stability and a good maximum incisal opening.

Xia L, Zhang Y, An J, Chen S, He Y (2020)[63] conducted a study which aimed to evaluate the remodelling 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. Patients who had undergone gap arthroplasty and TMJ reconstruction by DO were included. Computed tomography images were obtained preoperatively, upon completing distraction, upon removal of the distraction device, and >2 years postoperatively. The following were measured: mandibular ramus height, distance between gonion and Frankfurt plane, condylar width, and condyle ramus angulation. Of the 21 patients, one showed re-ankylosis, while five exhibited anterior open bite. They concluded that DO combined with gap arthroplasty was an effective method for the treatment of TMJ ankylosis to improve MMO.

Albert D, Muthusekhar M R (2021)[64] conducted a systematic review to compare the effectiveness of various sequences of DO in the management of TMJ ankylosis with micrognathia/and obstructive sleep apnoea syndrome (OSAS). 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. 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 pre-arthroplastic distraction osteogenesis (PrAD) compared to post-arthroplastic distraction osteogenesis (PAD) and improved in simultaneous arthroplastic distraction osteogenesis (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.

Agarwal S.S , Sahoo N.K , Datana S , Bhandari S.K (2021)[65] conducted a study to evaluate the efficacy of mandibular corpus distraction osteogenesis (MCDO) in the management of obstructive sleep apnoea (OSA) secondary to temporomandibular joint (TMJ) ankyloses. 15 patients comprehensively managed for severe OSA secondary to TMJ ankylosis with combined orthodontics and were studied objectively by comparing apnoea–hypopnea index (AHI) scores and airway parameters, and subjectively by Epworth sleepiness scale (ESS) survey at pretreatment (T0) and 1-year postsurgery (T1). Change in skeletal parameters at T1 was evaluated by comparison of sella-nasion-point A (SNA), sella-nasion-point B (SNB), and point A-nasionpoint B (ANB) angles. Change in AHI per millimeter advancement was also calculated. They concluded that MCDO is an effective modality for the treatment of severe OSA secondary to TMJ ankylosis.

Vanmathi V.K, Parasuraman V and Ramya Vanmathi R (2021)[66] presented a case describing the management of unilateral bony re-ankylosis of temporomandibular joint after the failure of a costochondral graft in an eight-year-old girl. They performed simultaneous gap arthroplasty and distraction osteogenesis to separate the ankylotic mass and lengthen the ramus-condyle unit and concluded that the management of bony ankylosis of TMJ with facial asymmetry and retrognathia can be effectively managed by simultaneous gap arthroplasty and distraction as a single-stage treatment procedure. Also,

effective postoperative care at an early stage, intense physiotherapy, and rigorous long term followup are essential to prevent reoccurrence of TMJ ankylosis.

Chugh A, Mehrotra D, Yadav P K (2021)[67] performed a systemic review to generate evidence towards the role of DO in TMJ ankylosis, 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 maxillomandibular distraction in only five studies. An algorithm for use of DO in TMJ ankylosis was developed. They concluded that 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, pre-arthroplastic DO appears to best correct mandibular deformity and a maxillomandibular deformity requires simultaneous maxillomandibular distraction.

Purohit S, Datarkar A, Bhawalkar A, Dawre S and Pardiwala A.F. (2021)[68] conducted a study to evaluate the sequential treatment of patients with temporomandibular joint ankylosis and secondary deformities by distraction osteogenesis and subsequent arthroplasty or orthognathic surgery on 15 patients with age ranging from 18 to 28 years diagnosed with unilateral temporomandibular joint ankylosis. All the 15 patients were first treated with distraction osteogenesis followed by interpositional arthroplasty of TMJ. They concluded that distraction osteogenesis followed by arthroplasty and corrective orthognathic surgery when required can provide good results in temporomandibular joint ankylosis patients with good facial features, stable occlusion, adequate mouth opening and reduction in obstructive sleep apnoea syndrome.

Upadya VH, Bhat HK, Rao BHS, Reddy SG (2021)[69] reviewed studies comparing various classifications and surgical techniques for the treatment of temporomandibular joint ankylosis. PubMed, EBSCO, Web of Science, and Google Scholar were searched using a combination of keywords. Articles related to classification, resection-reconstruction of the temporomandibular joint, and management of airway obstruction were considered and categorized based on the objective. They concluded that Interpositional arthroplasty (IA) results in better maximal incisal opening compared to gap arthroplasty, with no significant difference in recurrent rates and that distraction osteogenesis (DO) is emerging as a popular technique for the restoration of symmetry and function as well as for relieving airway obstruction. IA, with a costochondral graft, is recommended in growing patients and may be combined with or preceded by DO in cases of severe airway obstruction. Alloplastic total joint replacement combined with fat grafts and simultaneous osteotomy procedures are gaining popularity. A custom-made total joint prosthesis using CAD/ CAM can efficiently overcome the shortcomings of stock prostheses.

Rubio-Bueno P (2021)[70] conducted a study to investigate the usefulness of Bilateral Internal Ramus Distraction of the mandible (BIRD) to cure OSA. Study design was of an interventional (surgical) one-arm trial of OSA patients assessed before and 12 months after BIRD. All patients were evaluated by pre- and post-operative polysomnography and three-dimensional scans. The amount of skeletal advancement, percentage of upper airway volume increase and postoperative value of mandibular occlusal plane were the predictor variables. Changes in the apnoea-hypopnoea index (AHI), oxygen desaturation index (ODI), and percentage of time with saturation under 90% (TC90) were the main outcome variables. The author concluded that lengthening the mandibular ramus by distraction osteogenesis to cure OSA appeared to be more effective and safer when compared to other surgical protocols, especially in very severe cases with initial AHI>50/h. Titration of the mandibular advancement weekly using respiratory polygraphy allows better healing control and customization of the skeletal advancement, enhancing the aesthetic result.

Zhang YF et al. (2022)[71] performed a study to compare the treatment effect of distraction osteogenesis and maxillomandibular advancement for severe

obstructive sleep apnoea hypopnea syndrome patients and to guide clinical decisions about treatment of OSAHS. The preoperative and postoperative data of 37 patients were collected in which cephalometry, polysomnography (PSG), Pittsburgh sleep quality index (PSQI) and Epworth sleepiness scale (ESS) scores were analysed. With propensity score matching method, the treatment effect of MMA and DO was analysed and compared. They concluded that for severe OSAHS patients, distraction osteogenesis showed a better therapeutic effect compared to that of MMA.

Ma LK et al (2023)[72] conducted a study to evaluate the effect of mandibular distraction osteogenesis (MDO) on respiratory function in Craniofacial macrosomia (CFM) patients with obstructive sleep apnoea (OSA) according to polysomnography (PSG).They retrospectively analysed patients with CFM who underwent PSG before surgery and after completion of mandible distraction. The Paediatric Sleep Questionnaire (PSQ) was used to assess patients' signs and symptoms related to OSA. They concluded that MDO can improve OSA-related symptoms in CFM patients. In addition, respiratory function was improved in most patients after MDO, based on PSG. CFM patients, especially those with OSA, can benefit from MDO.

Dholabhai P, Anchlia S, Dhuvad J, Bhatt U, Nakrani A, Kania J (2023)[73] conducted a study to evaluate the efficacy of simultaneous TMJ ankylosis (TMJA) release with uniplanar mandibular distraction in the management of facial deformity, improvement in function and obstructive sleep apnoea in growing patients. Ten patients in the age group of 5-15 years with unilateral/bilateral TMJA and mild to moderate OSA and short body length but ramus height within normal limits were treated with simultaneous ankylosis release and uniplanar mandibular distraction osteogenesis. Clinical, radiographic, and OSA parameters were evaluated and followed up for 1 year. They concluded that simultaneous TMJA release with uniplanar mandibular Distraction osteogenesis may be recommended as the treatment of choice in growing patients with mild to moderate OSA and facial deformity, as it causes simultaneous correction of micrognathia, facial asymmetry, OSA and prevents the need for an additional surgery.

Eligibility criteria

Inclusion criteria

- Patients with unilateral or bilateral TMJ ankylosis who are diagnosed with obstructive sleep apnoea.
- Age ranging between 12-45 years with mandibular hypoplasia.

Exclusion criteria

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

Materials Required

Armamentarium:-

- Mouth mirror, tweezer and probe
- Metallic scale
- B. P. handle no. 3 with blade no. 15
- Howarth and Molts periosteal elevator
- Dissecting scissor
- Retractors
- Micromotor and handpiece
- Dental Bur kit
- Oscillating bone saw
- Osteotomes
- Disposable syringes
- Stainless steel miniature Distraction device with bicortical screws.
- Tissue holding forcep
- Suture- 3-0 vicryl and 3-0 mersilk
- Needle holder
- Other surgical instruments

METHODOLOGY

Study Design

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

Method –

- 5 patients were included in the study.
- Routine laboratory and radiological investigations, Informed/written consents, preanesthetic evaluation was done for all the patients.
- The patients were prepared as per the routine aseptic protocol and under laryngoscopic assisted intubation, general anesthesia was administered.
- Preoperative mouth opening, polysomnography and lateral cephalometric analysis was recorded.

Mandibular Distraction was done under general anaesthesia using either extra oral submandibular incision or intraoral vestibular incision. The **submandibular incision** (Risdon approach) was placed 1.5 to 2 cm inferior to the mandible to reduce the risk of neuropraxia of the marginal mandibular nerve**.**

The **mandibular vestibular** incision was placed 3 to 5 mm inferior to the mucogingival junction extending posteriorly over the external oblique ridge, traversing mucosa, submucosa, buccinator muscle, buccopharyngeal fascia, and periosteum. The incision is usually no more superior than the occlusal plane of the mandibular teeth to help prevent herniation of the buccal fat pad into the surgical field and also spare the buccal artery and nerve.

Osteotomy was done with the help of saw / bur. Distractor device was placed and fixed with titanium screws. 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 after completion of distraction and consolidation.
- The exposure of the joint was done by Alkayat - Bramley incision followed by arthrectomy / interpositional arthroplasty with temporalis fascia.
- All patients were subjected to post-operative physiotherapy.

PARAMETERS ASSESSED :-

Patients for surgery were selected irrespective of sex, religion or socio-economic status. The parameters assessed are-

1. Correction of obstructive sleep apnoea based on polysomnography
2. Cephalometric evaluation : Airway- Upper and lower pharyngeal airway
   Mandibular length
   Ramal height
3. Mouth opening: Inter-incisal, measured in millimetres, both pre and post operatively.

STATISTICAL ANALYSIS

The data for the present study was entered in the Microsoft Excel 2007 and analyzed using the SPSS statistical software 23.0 Version. The descriptive statistics included mean, standard deviation frequency and percentage. The level of the significance for the present study was fixed at 5%.

The intragroup comparison was done using the Wilcoxon Sign Rank test depending upon the normality of the data. The Shapiro–Wilk test was used to investigate the distribution of the data and Levene's test to explore the homogeneity of the variables.

Mean

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

Where:

$\overline{X}$ = the data set mean

$\sum$ = the sum of

X = the scores in the distribution

N = the number of scores in the distribution

Range

$$range = X_{highest} - X_{lowest}$$

Where:

$X_{highest}$ = largest score

X_{lowest} = smallest score

Variance

$$SD^2 = \frac{\Sigma(X - \overline{X})^2}{N}$$

The simplified variance formula

$$SD^2 = \frac{\Sigma X^2 - \frac{(\Sigma X)^2}{N}}{N}$$

Where:

SD^2 = the variance

$\sum$ = the sum of

X = the obtained score

$\overline{X}$ = the mean score of the data

N = the number of scores

Standard Deviation (N)

$$SD = \sqrt{\frac{\Sigma(X - \overline{X})^2}{N}}$$

The simplified standard deviation formula

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

Where:

SD = the standard deviation

$\sum$ = the sum of

X = the obtained score

$\overline{X}$ = the mean score of the data

N = the number of scores

Wilcoxon Sign Rank test

The **Wilcoxon signed-rank test** is a non-parametric statistical hypothesis test used either to test the location of a set of samples or to compare the locations of two populations using a set of matched samples. When applied to test the location of a set of samples, it serves the same purpose as the one-sample Student's *t*-test. On a set of matched samples, it is a paired difference test like the paired Student's *t*-test (also known as the "*t*-test for matched pairs" or "*t*-test for dependent samples"). Unlike the Student's *t*-test, the Wilcoxon signed-rank test does not assume that the data is normally distributed. On a wide variety of data sets, it has greater statistical power than the Student's *t*-test and is more likely to produce a statistically significant result. The cost of this applicability is that it has less statistical power than the Student's *t*-test when the data is normally distributed.

The test is named for Frank Wilcoxon (1892–1965) who, in a single paper, proposed both it and the rank-sum test for two independent samples. The test was popularized by Sidney Siegel (1956) in his influential textbook on non-parametric statistics. Siegel used the symbol T for the test statistic, and consequently, the test is sometimes referred to as the **Wilcoxon *T*-test**.

1. Compute $|X_1|, \ldots, |X_n|$.
2. Sort these quantities. Define $R_1, \ldots, R_n$ so that $0 < |X_{R_1}| < |X_{R_2}| < \cdots < |X_{R_n}|$.
3. Let sgn denote the sign function: $\operatorname{sgn}(x) = 1$ if $x > 0$ and $\operatorname{sgn}(x) = -1$ if $x < 0$. The test statistic is the *signed-rank sum* T:

$$T = \sum_{i=1}^{N} \operatorname{sgn}(X_i) R_i.$$

4. Produce a p-value by comparing T to its distribution under the null hypothesis.

Activ
Go to

Blood investigations - BT, CT, CBC (Hb%, ESR, TLC, DLC) Blood sugar, S. Urea, S. Creatinine.

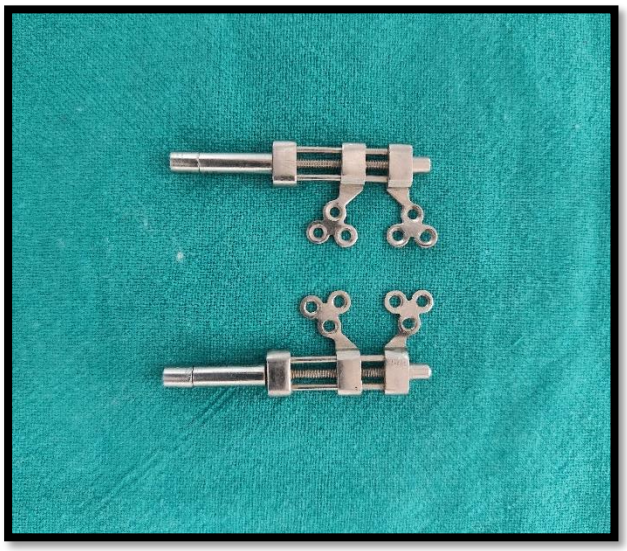
Viral markers – HbsAg, HIV 1&2, HCV.

Radiographic investigations - OPG, IOPAR, Lateral Cephalogram, PA Chest.

Sleep study- Polysomnography

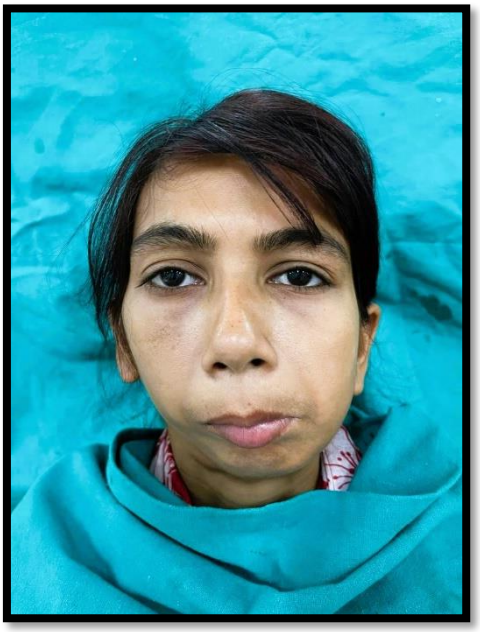
PHOTOGRAPHS

ARMAMENTARIUM



Distractor Device

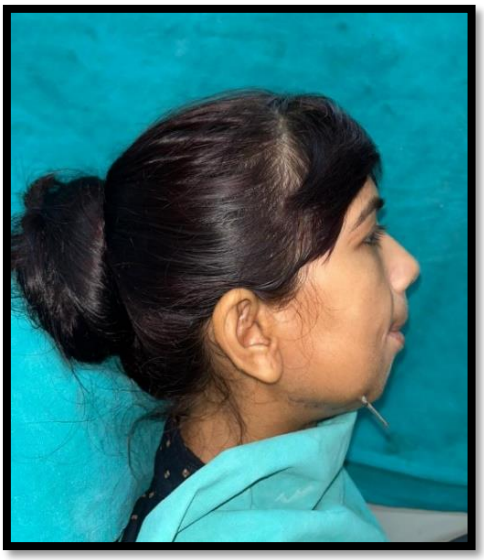
PRE-OPERATIVE PHOTOGRAPHS



STAGE 1 SURGERY

INTRA-OPERATIVE PHOTOGRAPHS

POST-OP 3 MONTHS



STAGE 2 SURGERY

INTRA-OPERATIVE PHOTOGRAPHS

Incision Marking

Flap Reflection

Ankylotic Mass

Interpositioning of temporalis fascia

Closure

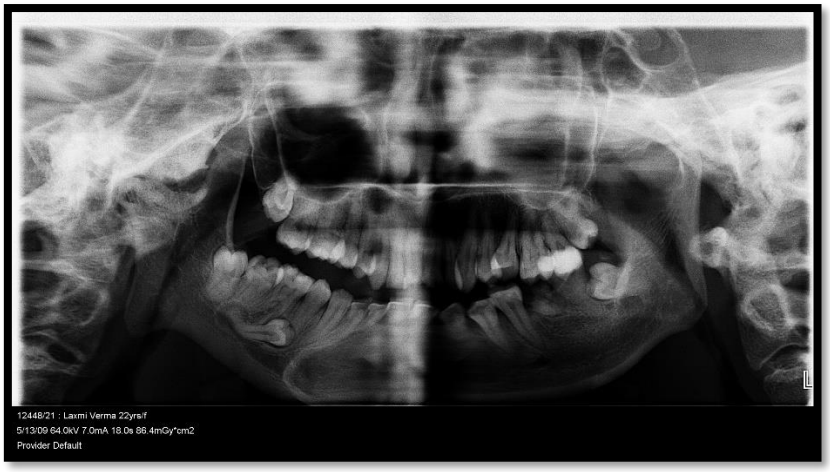
POST-OPERATIVE 3 MONTHS

MOUTH OPENING

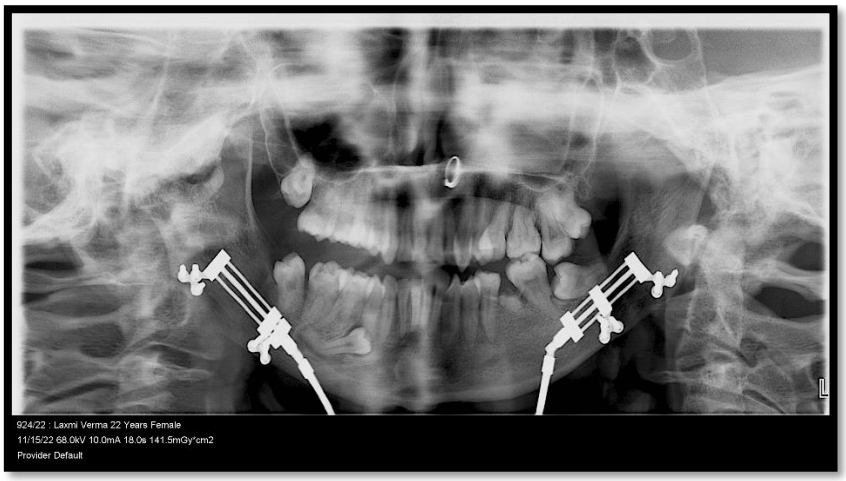
Pre-Operative MIO 11 mm

Post-Operative MIO 37.5 mm

RADIOGRAPHS



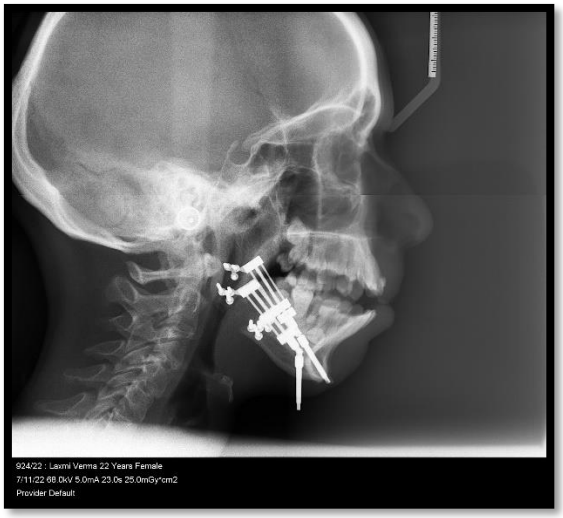
Pre-Operative OPG



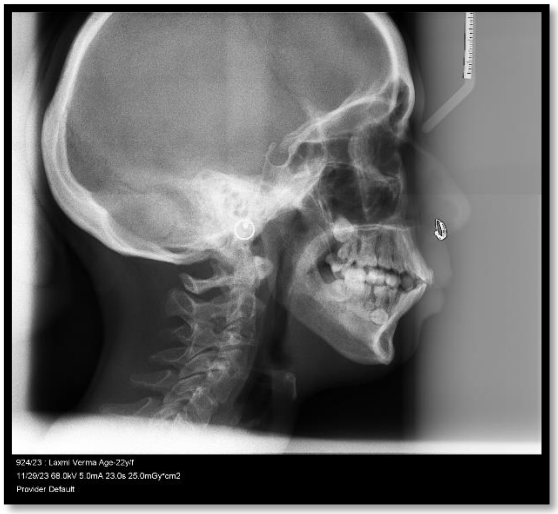
Post-Operative OPG After 3 Months

Post-Operative OPG After 1 Year

Pre-Operative Lateral Cephalogram



Post-Operative Lateral Cephalogram After 3 Months



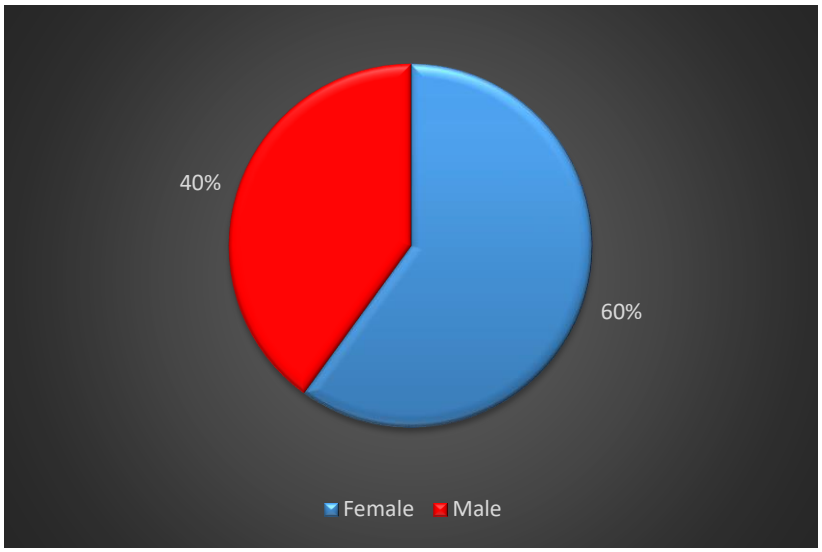
Post –Operative Lateral Cephalogram After 1 Year

GENDER DISTRIBUTION OF STUDY SUBJECTS

Table 1. Gender distribution

	N	Percentage	Mean Age
Female	03	60%	16.33
Male	02	40%	14.50

Based on the gender distribution 60% were females and 40% were males. The mean age of the females was 16.33 years and mean age of the males was 14.50 years.



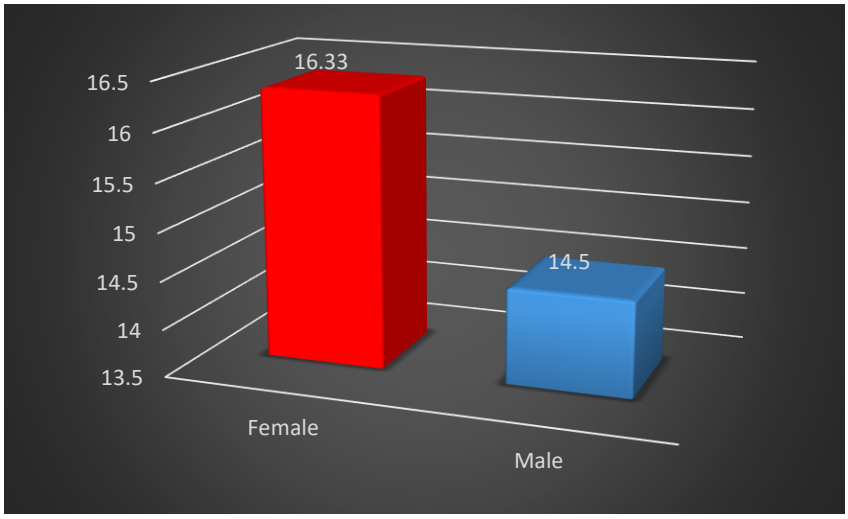
Graph 1. Gender Distribution

AGE DISTRIBUTION OF STUDY SUBJECTS

Table 2. Age Distribution

	Mean Age	Std Deviation	Std Error
Female	16.33	1.21	0.324
Male	14.50	1.67	0.367

The mean age of the females was 16.33 years (sd=1.21) and mean age of the males was 14,50 years (sd=1.67)



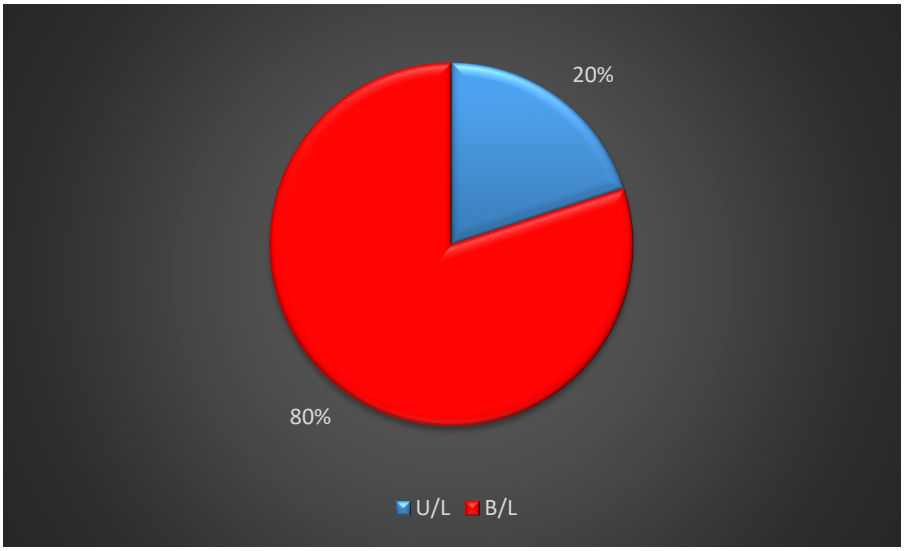
Graph 2. Age distribution

DISTRIBUTION BASED ON TYPE OF DISTRACTION

Table 3. Distribution based on type of distraction

	N	Percentage
U/L	01	20%
B/L	04	80%

Based on type of distraction, 20% had undergone U/L distraction and 80% had undergone B/L distraction.



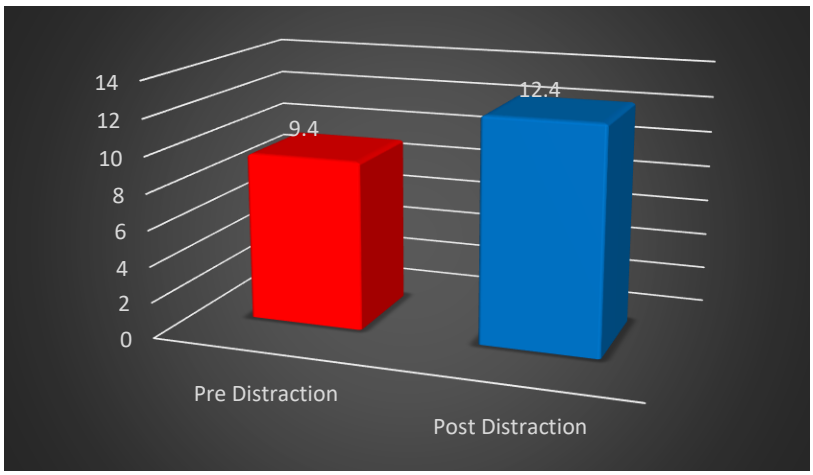
Graph 3. Distribution based on type of distraction

INTRAGROUP COMPARISON OF CEPHALOMETRIC EVALUATIONS BETWEEN PRE AND POST DISTARCTION VALUES

Table 4. Comparison of upper pharyngeal airway space pre & post distraction

	Mean	Std. Deviation	Minimum	Maximum	Z value	P value
Pre Distraction	9.4000	2.60768	7.00	13.00	2.123	0.042 (Sig)
Post Distraction	12.4000	1.67332	11.00	15.00		

The mean upper pharyngeal airway space at predistraction was 9.40 and at post distraction was 12.40. The intragroup comparison between the pre and post distraction values was done using the Wilcoxon Sign Rank test and the difference was found to be statstitically significant between pre and post values. There was a significant increase in the values of upper pharyngeal airway space from pre distraction level after the distraction.

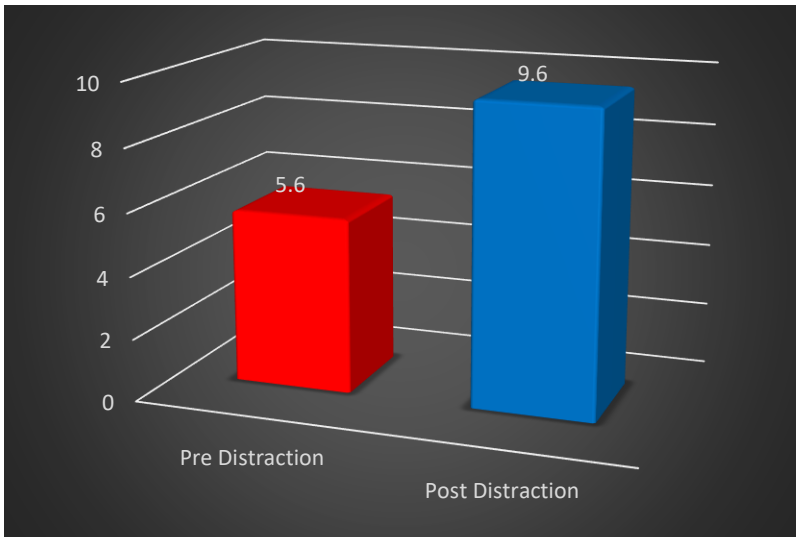


Graph 4. Comparison of upper pharyngeal airway pre & post distraction

Table 5. Comparison of lower pharyngeal airway space pre & post distraction

	Mean	Std. Deviation	Minimum	Maximum	Z value	P value
Pre Distraction	5.6000	1.51658	4.00	7.00	2.031	0.041 (Sig)
Post Distraction	9.6000	1.51658	8.00	12.00		

The mean lower pharyngeal airway space at the predistraction was 5.60 and at the post distraction was 9.60. The intragroup comparison between the pre and post distraction values was done using the Wilcoxon Sign Rank test and the difference was found to be statstitically significant between pre and post values. There was a significant increase in the values of lower pharyngeal airway space from pre distraction level after the distraction.

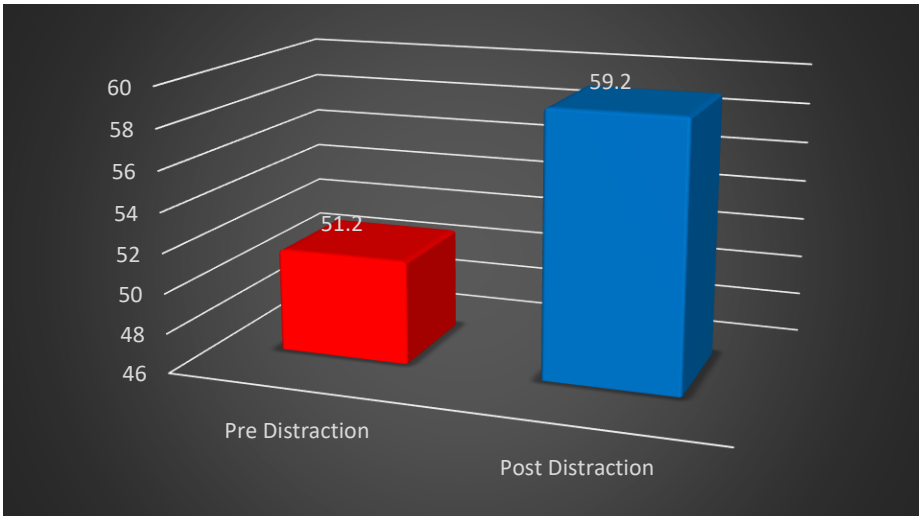


Graph 5.Comparison of lower pharyngeal airway pre & post distraction

Table 6. Comparison of mandibular length pre & post distraction

	Mean	Std. Deviation	Minimum	Maximum	Z value	P value
Pre Distraction	51.2000	5.06952	46.00	58.00	2.158	0.039 (Sig)
Post Distraction	59.2000	4.81664	54.00	66.00		

The mean mandibular length at the predistraction was 51.20 and at the post distraction was 59.20. The intragroup comparison between the pre and post distraction values was done using the Wilcoxon Sign Rank test and the difference was found to be statstitically significant between pre and post values. There was a significant increase in the values of mandibular length from pre distraction level after the distraction.

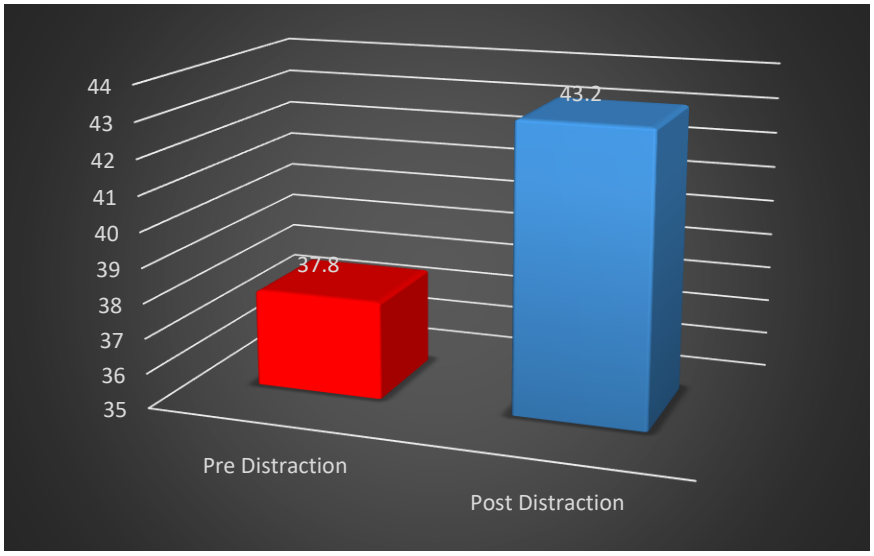


Graph 6. Comparison of mandibular length pre & post distraction

Table 7. Comparison of ramal height pre & post distraction

	Mean	Std. Deviation	Minimum	Maximum	Z value	P value
Pre Distraction	37.8000	2.68328	34.00	40.00	2.034	0.049 (Sig)
Post Distraction	43.2000	4.32435	37.00	48.00		

The mean ramal height at the predistraction was 37.80 and at the post distraction was 43.20. The intragroup comparison between the pre and post distraction values was done using the Wilcoxon Sign Rank test and the difference was found to be statstitically significant between pre and post values. There was a significant increase in the values of ramal height from pre distraction level after the distraction.



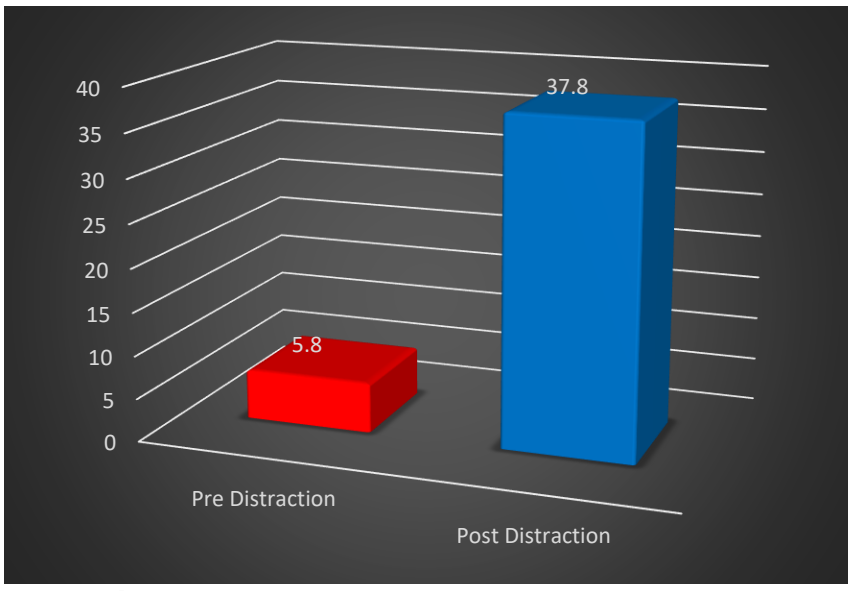
Graph 7. Comparison of ramal height pre & post distraction

INTRAGROUP COMPARISON OF MOUTH OPENING BETWEEN PRE AND POST DISTARCTION VALUES

Table 8. Comparison of mouth opening pre & post distraction

	Mean	Std. Deviation	Minimum	Maximum	Z value	P value
Pre Distraction	5.8000	2.77489	3.00	10.00	-2.132	0.001 (Sig)
Post Distraction	37.8000	1.48324	36.00	40.00		

The mean Mouth opening at the predistraction was 5.80 and at the post distraction was 37.80. The intragroup comparison between the pre and post distraction values was done using the Wilcoxon Sign Rank test and the difference was found to be statstitically significant between pre and post values. There was a significant increase in the values of mouth opening from pre distraction level after the distraction.



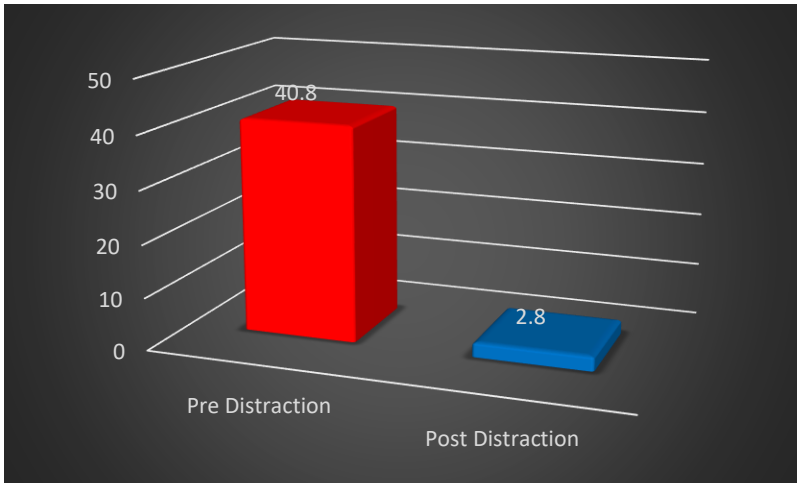
Graph 8. Comparison of mouth opening pre & post distraction

INTRAGROUP COMPARISON OF POLYSOMNOGRAPHY EVALUATION BETWEEN PRE AND POST DISTARCTION VALUES

Table 9. Comparison of AHI pre & post distraction

	Mean	Std. Deviation	Minimum	Maximum	Z value	P value
Pre Distraction	40.8000	7.98123	32.00	52.00	- 2.023	0.043 (Sig)
Post Distraction	2.8000	.83666	2.00	4.00		

The mean AHI at the predistraction was 40.80 and at the post distraction was 2.80. The intragroup comparison between the pre and post distraction values was done using the Wilcoxon Sign Rank test and the difference was found to be statstitically significant between pre and post values. There was significant decrease in the values of AHI from pre distraction level after the distraction.

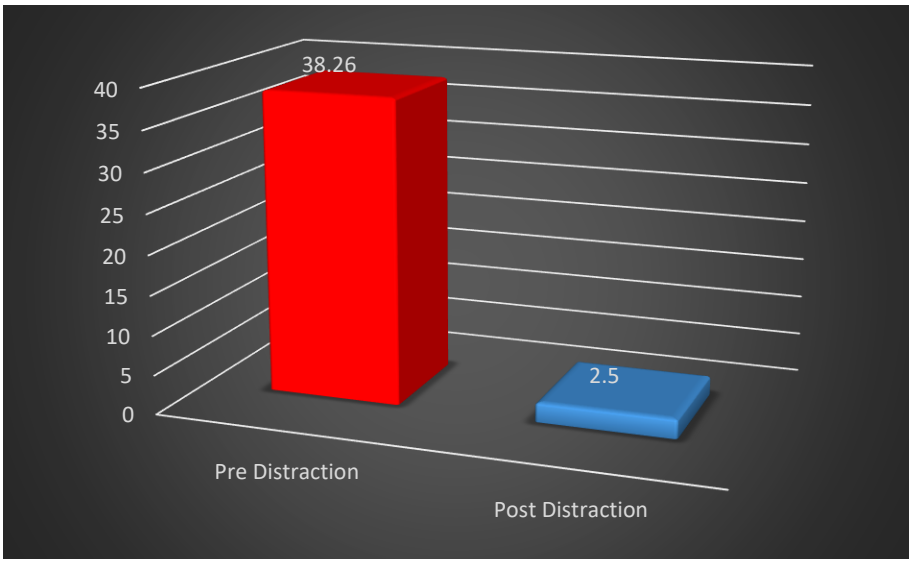


Graph 9. Comparison of AHI pre & post distraction

Table 10. Comparison of ODI pre & post distraction

	Mean	Std. Deviation	Minimum	Maximum	Z value	P value
Pre Distraction	38.2600	4.13981	34.00	43.00	-2.023	0.043 (Sig)
Post Distraction	2.5000	.60828	1.80	3.20		

The mean ODI at the predistraction was 38.26 and at the post distraction was 2.50. The intragroup comparison between the pre and post distraction values was done using the Wilcoxon Sign Rank test and the difference was found to be statstitically significant between pre and post values. There was significant decrease in the values of ODI from pre distraction level after the distraction.



Graph 10. Comparison of ODI pre & post distraction

In the past, oral and maxillofacial surgeons were consulted for patients with obstructive sleep apnoea only when other methods of treatment such as continuous positive airway pressure, dental appliances and soft tissue operations, failed. With time, the high level of success achieved by maxillomandibular advancement to enlarge the skeleton and thereby expand the soft tissue airway has made sleep medicine physicians and OSA patients to consult oral and maxillofacial surgeons more frequently and at an earlier stage in the treatment.

Obstructive sleep apnoea is a sleep-related breathing disorder defined as absence of breathing for 10 seconds or more despite an effort to breathe.[74] OSA affects almost 1 billion people globally, with 425 million adults aged 30-69 years having moderate to severe OSA. The increasing prevalence of OSA is related to the rising rates of obesity. It has been reported that there is a genetic component as some risk factors, including obesity and upper airway soft tissue structure that are genetically inherited.[75]Successful treatment of OSA can be achieved by a variety of medical and surgical modalities. Because of the magnitude, morbidity and potential instability of standard surgical techniques for large expansions of the facial skeleton, the use of distraction osteogenesis (DO) as a minimally invasive alternative has become an important treatment modality.[76]

Sleep-related reduced ventilatory drive and neuromuscular combined with anatomic risk factors are likely to play a significant role in upper airway obstruction during sleep. The anatomic factors that promote pharyngeal narrowing include large neck circumference, soft tissue, bone, or vessels. Many of these structures can lead to increased surrounding pressure of the upper airway resulting in pharyngeal collapsibility and/or insufficient space to accommodate the airflow in a portion of the upper airway during sleep. In addition, the upper airway muscle tone plays a role as when it decreases, a repetitive total or partial airway collapse results. The most common cause of OSA in adults is obesity and advancing age. The severity of OSA decreases with age when adjusting for BMI.[77]

Anatomic Factors contributing to OSA are micrognathia, retrognathia, facial elongation, mandibular hypoplasia, adenoid and tonsillar hypertrophy, inferior displacement of the hyoid. Nonanatomic risk factors include central fat distribution, obesity, advanced age, male gender, supine sleeping position and pregnancy.[77]

DO is an alternative for acute bone lengthening in situations requiring large movements not attainable by standard osteotomies, acute lengthening, and bone grafting. Advancements of 20 mm or more without a bone graft, the associated donor site morbidity, scarring, and potential for infection can be achieved. Soft tissue seems to grow linearly along lines of tension, and skin, muscles, nerves, and vascular tissue are generated, not stretched.[78] Resistance to advancement by the soft tissue envelope is decreased by this process of distraction histogenesis.[79]

The advantage with DO is obvious, especially for severe midface hypoplasia and micrognathia where the stretched soft tissue envelope contributes to relapse after traditional osteotomies, acute lengthening, and bone grafts. Scarring from previous operations (cleft lip and palate repair, uvulopalatopharyngoplasty, orthognathic surgery) or radiation therapy may limit amount of advancement possible by standard orthognathic surgical procedures. These patients are ideal candidates for DO.

DO requires patient understanding and cooperation.[80] Failure to follow the prescribed activation can result in inappropriate vector of distraction, inadequate regenerate formation and even dismantling of the distractor. With bimaxillary DO, a prolonged period of maxillomandibular fixation is necessary, affecting speech, alimentation, and social interaction. During the process of distraction, patients may experience pain, problems sleeping, and disturbances of recreational activities.[81]

In this study the cause of the retrognathic mandible in all patients was post traumatic, long standing, temporomandibular joint ankylosis which is fusion of the condyle to the temporal bone leading to retarded growth of the mandible. In severe retrognathia the space available for the tongue is diminished and as the tonicity of muscles decreases during sleep the tongue falls back which causes obstruction of the upper airway, resulting in episodes of apnoea. Repeated bouts

of transient hypoxaemia occur leading to high sympathetic nervous system activity which results in complications like hypertension, angina, stroke, myocardial infarction and cardiac failure.[82]

The age range of patients in this study was 11-20 years. The mandibular condyles in children are more prone to intra-capsular fractures due to trauma or surgical manipulation because they have a broad head and a relatively narrow neck.[83] Moreover, paediatric condyles have a high regenerative and remodeling capacity, which significantly increases the likelihood of ankylosis after trauma, or re-ankylosis after surgery.[84]

Distraction osteogenesis was performed in all patients before the release of the TMJ ankylosis, because if TMJ ankylosis is released before doing distraction osteogenesis than the already diminished posterior airway space will be further compromised and will pose problems in the post operative period (tracheostomy may be needed). In all the cases a linear distractor was used for lengthening the mandible as the only movement required was in the horizontal ramus. After distraction TMJ arthrectomy was done with interpositional arthroplasty and later on genioplasty was performed to improve the facial esthetics.

According to the present study, there is more female predilection, which is similar to several other hospital-based studies[85] in literature but this result is also contradictory to many studies as they state the reason that male do more outdoor activities as compared to females.[84] In this study, females had a high prevalence of TMJ ankylosis as compared to males, which may be due to the difference in the anatomy of condyle and differences in their hormonal level. Increasing serum levels of estrogen and progesterone with increasing grade of severity of TMDs suggest a role of these hormones as etiological factors for TMDs.[86]

Signs and symptoms of TMDs are four times more common among women, who seek specialized treatment for this disease three times more frequently than men. Despite the fact that the low prevalence of TMDs in men has not been completely elucidated yet, the presence of higher testosterone levels may be a plausible explanation.[87]

There is the hypothesis that the presence of estrogen receptors in women's TMJ changes metabolic functions increasing ligament laxity. Estrogen also increases susceptibility to painful stimuli by modulating the limbic system. Although researchers do not share the same opinion, studies in humans have shown that painful symptoms increase by 30% among patients on menopause treatment with estrogen replacement therapy and by 20% in women using oral contraceptives.[87]

Polymorphism in the estrogen receptor has been shown to be correlated to the intensity of pain, facial axis angle and mandibular body length in patients who suffer from TMJ osteoarthritis. However, despite these studies, until recently no direct evidence has been found that links female reproductive hormones to TMJ disease or that defines the mechanisms by which these hormones may cause TMJ disease. A recent study has shown that estrogens and relaxin could contribute to the degeneration of cartilage homeostasis by disrupting TMJ and inducing activation of metalloproteinases that degrade cartilage matrix macromolecules (collagen and proteoglycans).[87]

In this study, all cases were found in 11–20 year old age group, and this finding is similar with that of various studies[88,89] that stated TMJ ankylosis is commonly seen in children and young adults.

In this study, bilateral TMJ ankylosis (80%) was more prevalent as compared to unilateral TMJ ankylosis (20%). According to the literature, unilateral cases tended to show better clinical outcomes than bilateral cases. TMJ ankylosis cases could present as a bilateral or unilateral lesion based on the number of joints affected. Most of the patients presented with bilateral TMJ ankylosis. The high prevalence of bilateral TMJ ankylosis might be due to the trauma (falling) mechanism that could result in mandibular symphysis fracture which, in turn, produces a higher chance of osteogenic potential bone fragments in the condylar process.[90]

The amount of mandibular advancement required in this study was more than 1.5 cm (mean 2.2 cm) and in such cases distraction osteogenesis would be considered as the better option rather than standard osteotomies. Advancement

was carried out after a latency period of 5 days in adults and 0 day for children. The rate of distraction was 1 mm/day for adults and 2 mm/day for children until the mandibular incisors were in reverse overjet or edge to edge position.[91]

The results of this study confirm the findings that there was a significant rectification of oro-pharyngeal airway width, mandibular length, ramal height, mouth opening, AHI index and ODI index 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 reankylosis was observed in any patients during the study period.

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[92](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, and Pterygomandibular Vertical Plane[93]. A line connecting the posterior nasal spine and anterior tubercle of the atlas defined as the superior border of the posterior airway space , 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 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 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 pre and post distraction comparison

revealed statistically significant improvement in pharyngeal airway post distraction, in this study.

The mean upper pharyngeal airway space increased from predistraction 9.40 to post distraction 12.40 . There was a significant increase in the values of upper pharyngeal airway space.

The mean lower pharyngeal airway space at the predistraction was 5.60 which increased to 9.60 post distraction. There was a significant increase in the values of lower pharyngeal airway space.

COGS analysis was done to determine the height of the ramus by measuring the distance in millimeters between the articular angle 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 which showed significant increase.

The mean mandibular length at the predistraction was 51.20 and at the post distraction was 59.20 . There was a significant increase in the values of mandibular length from pre distraction level after the distraction.

The mean ramal height at the predistraction was 37.80 and at the post distraction was 43.20 . There was a significant increase in the values of ramal height from pre distraction level after the distraction.

The mean Mouth opening at the predistraction was 5.80 and at the post distraction was 37.80 . There was a significant increase in the values of mouth opening.

Polysomnography refers to a systematic process used to collect physiologic parameters during sleep. A polysomnogram is a procedure that utilizes electroencephalogram, electro-oculogram, electromyogram, electrocardiogram, and pulse oximetry, as well as airflow and respiratory effort, to evaluate for underlying causes of sleep disturbances. PSG is considered to be the gold standard for diagnosing sleep-related breathing disorders, which include obstructive sleep apnoea, central sleep apnoea, and sleep-related hypoventilation/hypoxia.[94]

In our study polysomnography for all patients was done both preoperatively and postoperatively in which all the patients were having severe OSA. Improvement in mean apnoea-hypopnoea index was seen in all cases. The mean AHI at the predistraction was 40.80 and at the post distraction was 2.80 . There was significant decrease in the values of AHI from pre distraction level after the distraction. This shows that advancement of mandible increases space for tongue and prevents fall back during sleep, thus reducing the episodes of apnoea and hypopnoea. This is in correlation with a study.[95]

The mean ODI at the predistraction was 38.26 and at the post distraction was 2.50 . There was significant decrease in the values of ODI from pre distraction level after the distractionImprovement in desaturation in turn reduces the chances of transient hypoxaemia and thus reduces chances of complications associated with obstructive sleep apnoea

We noted that improvement in facial profile, snoring and daytime sleepiness can be achieved by distraction osteogenesis in retrognathic patients and in patients like those in the present study, where the amount of advancement needed is more than 10 mm, distraction osteogenesis can be considered as it causes tension across the osteotomy and induces bone formation and histogenesis of blood vessels, muscles, nerves, cartilages, ligaments, skin and mucosa.[96,97,98] Thus there is less chance of relapse as compared to orthognathic surgery.

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

I. Moderate to severe obstructive sleep apnoea secondary to temporomandibular joint ankylosis can be successfully treated by distraction osteogenesis of the mandible.
II. Improvement in posterior airway space and facial profile can be achieved by doing distraction osteogenesis in retrognathic patient secondary to temporomandibular joint ankylosis associated with obstructive sleep apnoea.
III. Upper and lower pharyngeal airways space improved significantly in the post distraction phase.
IV. Mandibular length and ramal height increased significantly after distraction osteogenesis.
V. There was significant improvement in the mouth opening post operatively.
VI. Apnoe-Hypopnoea index and oxygen desaturation index improved significantly in post distraction phase.

1. Long X, Li X, Cheng Y, et al. Preservation of disc for treatment of traumatic temporomandibular joint ankylosis. Journal of Oral and Maxillofacial Surgery. 2005;63(7):897–902.
2. Kaban LB, Perrott DH, Fisher K. A protocol for management of temporomandibular joint ankylosis. Journal of Oral and Maxillofacial Surgery. 1990;48(11):1145–1151.
3. FIRDOS T, MURAD N, WAHID A, NAUSHEN N, ISLAM Z. Airway Impairment in Patients with TMJ Ankylosis - A Comparative Study. Pakistan Journal of Medical & Health Sciences Vol. 7 No. 02 APR – JUN (2013)
4. Ukwas A, Elshik M, Elbialy M. TMJ Ankylosis in Children: A Case Report and Literature Review. Case Rep Dent. 2023 Jan 5; 2023:6474478.
5. Anchlia, S. (2021). Temporomandibular Joint Ankylosis. In: Bonanthaya, K., Panneerselvam, E., Manuel, S., Kumar, V.V., Rai, A. (eds) Oral and Maxillofacial Surgery for the Clinician. Springer, Singapore.
6. Spijkervet FK, de Bont LG, Boering G. Management of pseudoankylosis of the temporomandibular joint: report of cases. J OralMaxillofac Surg 1994; 52:1211–7.
7. Sawhney CP. Bony ankylosis of the temporomandibular joint: follow-up of 70 patients treated with arthroplasty and acrylic spacer interposition. Plast Reconstr Surg 1986; 77(1):29–40.
8. He D, Yang C, Chen M, et al. Traunatic temporomandibular joint ankylosis: our classification and treatment experience. J Oral Maxillofac Surg 2011; 69:1600–7.
9. Wolford LM, Henry CH, Nikaein A, et al. The temporomandibular joint alloplastic implant problem. In: Sessle BJ, Bryant PS, Dionne RA, editors. Temporomandibular disorders and related pain conditions. Seattle (WA): IASP Press; 1995. p. 443–7.
10. Wolford LM. Temporomandibular joint devices: treatment factors and outcomes. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1997;83:143–9.

11. Wolford LM, Cottrell DA, Henry CH. Temporomandibular joint reconstruction of the complex patient with the Techmedica custom-made total joint prosthesis. J Oral Maxillofac Surg 1994;52:2–10.
12. Henry CH, Wolford LM. Treatment outcomes for TMJ reconstruction after Proplast-Teflon implant failure. J Oral Maxillofac Surg 1993;51:352–8.
13. Ilizarov GA. The tension-stress effect on the genesis and growth of tissues. Part I. The influence of stability of fixation and soft-tissue preservation. Clin Orthop Relat Res. 1989;238:249–81.
14. Ilizarov GA. The tension-stress effect on the genesis and growth of tissues: Part II. The influence of the rate and frequency of distraction. Clin Orthop Relat Res. 1989;239:263–85.
15. Rachmiel A, Shilo D. The use of distraction osteogenesis in oral and maxillofacial surgery. Ann Maxillofac Surg. 2015 Jul-Dec;5(2):146-7.
16. Young T, Palta M, Dempsey J, et al. The occurrence of sleep-disordered breathing among middle-aged adults. N Engl J Med 1993; 328:1230–1235.
17. Bearpark H, Elliott L, Grunstein R, et al. Snoring and sleep apnoea. A population study in Australian men. Am J Respir Crit Care Med 1995; 151:1459–1465.
18. Ip MS, Lam B, Lauder IJ, et al. A community study of sleep-disordered breathing in middle-aged Chinese men in Hong Kong. Chest 2001; 119:62–69.
19. Holty JE, Guilleminault C. Maxillomandibular advancement for the treatment of obstructive sleep apnoea: a systematic review and meta-analysis. Sleep Med Rev 2010; 14:287–297.
20. Prinsell JR. Maxillomandibular advancement surgery in a site-specific treatment approach for obstructive sleep apnea in 50 consecutive patients. Chest. 1999 Dec;116(6):1519-29.
21. Bell RB, Turvey TA. Skeletal Advancement for the Treatment of Obstructive Sleep Apnea in Children. The Cleft Palate Craniofacial Journal. 2001;38(2):147-154.
22. Denny AD, Talisman R, Hanson PR, Recinos RF. Mandibular distraction osteogenesis in very young patients to correct airway obstruction. Plastic and Reconstructive Surgery. 2001 Aug;108(2):302-311.

23. Liang, C., Wang, X., Yi, B., Li, Z., Wang, X. and Chen, B. (2002) Distraction osteogenesis for treatment of tem-poromandibular joint ankylosis. Zhonghua Yi Xue Za Zhi, 25, 807-809.
24. Prinsell JR. Maxillomandibular advancement surgery for obstructive sleep apnea syndrome. J Am Dent Assoc. 2002 Nov;133(11):1489-97; quiz 1539-40.
25. López EN, Dogliotti PL. Treatment of temporomandibular joint ankylosis in children: is it necessary to perform mandibular distraction simultaneously? J Craniofac Surg. 2004 Sep;15(5):879-84; discussion 884-5.
26. Ko EW, Hung KF, Huang CS, Chen PK. Correction of facial asymmetry with multiplanar mandible distraction: a one-year follow-up study. Cleft Palate Craniofac J. 2004 Jan;41(1):5-12.
27. Rao K, Kumar S, Kumar V, Singh AK, Bhatnagar SK. The role of simultaneous gap arthroplasty and distraction osteogenesis in the management of temporo-mandibular joint ankylosis with mandibular deformity in children. J Craniomaxillofac Surg. 2004 Feb;32(1):38-42.
28. Steinbacher DM, Kaban LB, Troulis MJ. Mandibular advancement by distraction osteogenesis for tracheostomy-dependent children with severe micrognathia. J Oral Maxillofac Surg. 2005 Aug;63(8):1072-9.
29. Sadakah AA, Elgazzar RF, Abdelhady AI. Intraoral distraction osteogenesis for the correction of facial deformities following temporomandibular joint ankylosis: A modified technique. Int J Oral Maxillofac Surg. 2006;35:399–406.
30. Shehta EAA, Medra AMM. Modified bimaxillary distraction osteogenesis: A technique to correct facial asymmetry. Br J Oral Maxillofac Surg 2006;45:471-7
31. Lin SY, Halbower AC, Tunkel DE, Vanderkolk C. Relief of upper airway obstruction with mandibular distraction surgery: Long-term quantitative results in young children. Arch Otolaryngol Head Neck Surg. 2006 Apr;132(4):437-41.

32. Ravindran C, Ramkumar S, Nandakumar N. Management of obstructive sleep apnea through distraction osteogenesis of the mandible: A case report. Sri Ramachandra J Med. 2006;1:37–8.
33. Xiaofeng L, Yousheng T, Guofang S, Ming Z, Qingyun L, Weiliu Q. Part 1: Distraction osteogenesis for the patients of OSAS with craniomaxillomandibular deformities. Journal of Oral and Maxillofacial Surgery. 2008 Aug 1;66(8):14.
34. Genecov DG, Barceló CR, Steinberg D, Trone T, Sperry E. Clinical experience with the application of distraction osteogenesis for airway obstruction. The Journal of Craniofacial Surgery. 2009 Sep;20 Suppl 2:1817-1821.
35. Feiyun P, Wei L, Jun C, Xin X, Zhuojin S, Fengguo Y. Simultaneous correction of bilateral temporomandibular joint ankylosis with mandibular micrognathia using internal distraction osteogenesis and 3-dimensional craniomaxillofacial models. J Oral Maxillofac Surg. 2010;68:571–577.
36. Rajkumar GC, Manjunath, Shashikala R, Veerendra KD (2011) Distraction osteogenesis in the management of temporomandibular joint ankylosis. Int J Clin Dent Sci 2:22–26
37. Brevi BC, Toma L, Magri AS, Sesenna E. Use of the mandibular distraction technique to treat obstructive sleep apnea syndrome. J Oral Maxillofac Surg. 2011 Feb;69(2):566-71.
38. Sahoo NK, Tomar K, Kumar A, Roy ID. Selecting reconstruction option for TMJ ankylosis: a surgeon's dilemma. J Craniofac Surg. 2012;23(6):1796–1801.
39. Jaspers GW, Booij A, de Graaf J, de Lange J. Long-term results of maxillomandibular advancement surgery in patients with obstructive sleep apnoea syndrome. Br J Oral Maxillofac Surg. 2013 Apr;51(3):e37-9.
40. Gupta G.M., Gupta P., Sharma A., Patel N., Singh A. Evaluation of functional and esthetic outcome after correction of mandibular hypoplasia secondary to temporomandibular ankylosis treated by distraction osteogenesis. J Maxillofac Oral Surg. 2014;13(2):152–158

41. Khan M.Z, Ahmed A and Shah A.H (2013). "Management of obstructive sleep apnea and facial asymmetry by distraction osteogenesis of mandible". Pak Armed Forces Med J. 63 (2): 292–295
42. Yadav, R., Bhutia, O., Shukla, G., & Roychoudhury, A. (2014). Distraction osteogenesis for management of obstructive sleep apnoea in temporomandibular joint ankylosis patients before the release of joint. Journal of cranio-maxillo-facial surgery : official publication of the European Association for Cranio-Maxillo-Facial Surgery, 42 5, 588-94 .
43. Tahiri Y, Viezel-Mathieu A, Aldekhayel S, Lee J, Gilardino M. The effectiveness of mandibular distraction in improving airway obstruction in the pediatric population. Plastic and Reconstructive Surgery. 2014 Mar;133(3):352e-359e.
44. Lam DJ, Tabangin ME, Shikary TA, Uribe-Rivera A, Meinzen-Derr JK, de Alarcon A, Billmire DA, Gordon CB. Outcomes of mandibular distraction osteogenesis in the treatment of severe micrognathia. JAMA Otolaryngol Head Neck Surg. 2014 Apr;140(4):338-45.
45. Nurliza, A., Hariri, F., Nurlizat, A., Haririz, F., Rahmanz, Z.A., Jabarr, M., Nordinl, R., Bustamana, A., & Nabilt, S. Mandibu lar distraction osteogenesis for obstructive.
46. Mehrotra D, Vishwakarma K, Chellapa AL, Mahajan N. Pre-arthroplasty simultaneous maxillomandibular distraction osteogenesis for the correction of post-ankylotic dentofacial deformities. Int J Oral Maxillofac Surg 2016;45:820-7
47. Tsui WK, Yang Y, Cheung LK, Leung YY. Distraction osteogenesis as a treatment of obstructive sleep apnea syndrome: A systematic review. Medicine. 2016 Sep;95(36):e4674.
48. Kumari P, Roy SK, Roy ID, et al. Changes in posterior airway space and mandibular plane hyoid distance following mandibular advancement DO. Annals of Maxillofacial Surgery. 2016 Jul-Dec;6(2):182-189.
49. Baskaran M, Arularasan SG, Divakar TK, Thirunavukkarasu R. Treatment of Micrognathia by Intraoral Distraction Osteogenesis: A Prospective Study. Ann Maxillofac Surg. 2017 Jan-Jun;7(1):37-44.

50. Tomonari H, Takada H, Hamada T, Kwon S, Sugiura T, Miyawaki S. Micrognathia with temporomandibular joint ankylosis and obstructive sleep apnea treated with mandibular distraction osteogenesis using skeletal anchorage: a case report. Head Face Med. 2017 Nov 10;13(1):20.
51. SM, Balaji. (2017). Bilateral pediatric mandibular distraction for micrognathia with temporomandibular joint ankylosis and sleep apnea. Indian Journal of Dental Research. 28. 588. 10.4103/ijdr.IJDR_412_17.
52. Zhang C, Li Y, Ye B, Liu Y, Bao C, Zhu S (2017) Application of bidirectional distraction osteogenesis for the treatment of mandibular micrognathia caused by temporomandibular joint ankylosis. J Craniofac Surg 28(6):1502–1507
53. Zhang W, Yang X, Zhang Y, Zhao T, Jia J, Chang S, Liu Y, Yu B, Chen Y, Ma Q (2018) The sequential treatment of temporomandibular joint ankylosis with secondary deformities by distraction osteogenesis and arthroplasty or TMJ reconstruction. Int J Oral Maxillofac Surg 47(8):1052–1059.
54. Andrade NN, Mathai PC, Ganapathy S, Aggarwal N, Rajpari K, Nikalje T. Pre-arthroplastic mandibular distraction osteogenesis for the correction of OSA in TMJ ankylosis: a prospective observational study of 25 cases. Oral Maxillofac Surg. 2018 Dec;22(4):409-418.
55. Chen K, Xiao D, Abotaleb B, Chen H, Li Y, Zhu S. Accuracy of virtual surgical planning in treatment of temporomandibular joint ankylosis using distraction osteogenesis: comparison of planned and actual results. J Oral Maxillofac Surg. 2018; 76(11), 2422.e1-2422-2520.
56. Bi RY, Luo XT, Jiang N, Zhu SS, Li YF. Change in the posterior airway after mandibular distraction osteogenesis in patients with ankylosis of the temporomandibular joint: a retrospective study. Br J Oral Maxillofac Surg. 2018; 56(6):525–530
57. Dharmendra Kumar MG, Narayanan V, Manikandan R, et al. Role of extra oral monofocal distractor device in the correction of the facial asymmetry, sleep apnoea, and quality of life associated with TMJ ankylosis. Journal of Stomatology, Oral and Maxillofacial Surgery. 2019 Jun;120(3):203-210.
58. Yu X, Wang J, Hou S, Zeng R. Mandibular distraction osteogenesis in the treatment of pediatric temporomandibular joint ankylosis with micrognathia

and obstructive sleep apnea syndrome: A case report with 4-year follow-up. Exp Ther Med. 2019 Dec;18(6):4888-4892.

59. Ma Y, Huang Y, Zhu S, Li Y. Simultaneous arthroplasty and distraction osteogenesis for the treatment of ankylosis of the temporomandibular joint and secondary mandibular deformities in children. Br J Oral Maxillofac Surg. 2019 Feb;57(2):135-139
60. Kandamani J. (2020) Mandibular Distraction Osteogenesis in Treatment of Temporomandibular Ankylosis: A Review. Journal of Maxillofacial and Oral Surgery. 19(4): 529-535.
61. Vignesh U, Mehrotra D, Bhave SM, Singh PK. Quality of life after distraction osteogenesis in TMJ ankylosis patients. Oral Surg Oral Med Oral Pathol Oral Radiol. 2020
62. Kamath AT, Kudva A, Singh A. Bilateral temporomandibular joint reconstructions with stock alloplastic prostheses on a distracted mandible - A case report. Cranio. 2022 Jul;40(4):365-372.
63. Xia L, Zhang Y, An J, Chen S, He Y. Evaluating the remodeling of condyles reconstructed by transport distraction osteogenesis in the treatment of temporomandibular joint ankylosis. J Craniomaxillofac Surg. 2020 May;48(5):494-500.
64. Albert D, Muthusekhar M R. Controversies in the management of temporomandibular joint ankylosis using distraction osteogenesis - A systematic review. Ann Maxillofac Surg 2021;11:298-305
65. Agarwal SS, Datana S, Sahoo NK, Bhandari SK. Evaluation of Airway Dimensions Following Mandibular Setback with Surgery-First Orthognathic Versus Conventional Orthognathic Approach. J Maxillofac Oral Surg. 2021 Jun;20(2):296-303.
66. Vanmathi, Vasantha & Parasuraman, Varalakshmi & Vanmathi, Ramya. (2021). Simultaneous Gap Arthroplasty and Distraction Osteogenesis in the Management of Unilateral Bony TMJ Reankylosis – A Case Report. International Journal of Medical and Dental Sciences. 10. 1945-1951. 10.18311/ijmds/2021/25916.

67. Chugh A, Mehrotra D, Yadav PK. A systematic review on the outcome of distraction osteogenesis in TMJ ankylosis. Journal of Oral Biology and Craniofacial Research. 2021 Oct-Dec;11(4):581-595.
68. Purohit, S., Datarkar, A.N., Bhawalkar, A., Dawre, S., & Pardiwala, A.F. (2021). An Algorithm for Facial Asymmetry Correction in Adult TMJ Ankylosis Patients - A Clinical Study.
69. Upadya VH, Bhat HK, Rao BHS, Reddy SG. Classification and surgical management of temporomandibular joint ankylosis: a review. J Korean Assoc Oral Maxillofac Surg. 2021 Aug 31;47(4):239-248.
70. Rubio-Bueno P, Hernando G, Capote-Moreno A, Landete P, Wix R, Peñaloza A, Rocío E, Zamora E, Soriano JB, Naval-Gías L. A one-arm surgical trial of obstructive sleep apnea (OSA) patients before and 12 months after Bilateral Internal Ramus Distraction of the mandible (BIRD). Sleep Med. 2021 Apr;80:57-65.
71. Zhang YF, Zhang ZR, Tan ZJ, Yu B, Dai TQ, Liu FW, Kong L, Tian L, Cai BL. [A retrospective controlled study on the treatment effect of distraction osteogenesis and maxillomandibular advancement for severe obstructive sleep apnea hypopnea syndrome patients]. Zhonghua Kou Qiang Yi Xue Za Zhi. 2022 Sep 9;57(9):907-913. Chinese.
72. Ma LK, Zhang ZY, Tang XJ, Xu X, Feng S, Zhao SB, Shu KY, Liu BY, Zang TY, Liu W. Respiratory outcome of mandibular distraction osteogenesis on obstructive sleep apnea in craniofacial microsomia: A retrospective study. J Craniomaxillofac Surg. 2023 Jun;51(6):355-359.
73. Dholabhai P, Anchlia S, Dhuvad J, Bhatt U, Nakrani A, Kania J. Simultaneous TMJ Ankylosis Release with Uniplanar Mandibular Distraction Osteogenesis for Correction of Facial Deformity and Obstructive Sleep Apnoea in Growing Patients: A Pilot Study. J Maxillofac Oral Surg. 2023 Jun;22(2):333-343.
74. Kushida CA, Littner MR, Morgenthaler T, Alessi CA, Bailey D, Coleman Jr J, et al: Practice parameters for the indications for polysomnography and related procedures: an update for 2005. Sleep 28(4): 499e521, 2005 April
75. Surani S, Taweesedt P. Obstructive Sleep Apnea: New Perspective. Medicina (Kaunas). 2022 Dec 29;59(1):75.

76. Steinbacher DM, Kaban LB, Troulis MJ. Mandibular advancement by distraction osteogenesis for tracheostomy-dependent children with severe micrognathia. J Oral Maxillofac Surg 2005;63:1072
77. Slowik JM, Sankari A, Collen JF. Obstructive Sleep Apnea. [Updated 2022 Dec 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023
78. Castano FJ, Troulis MJ, Glowacki J, et al. Proliferation of masseter myocytes after distraction osteogenesis of the porcine mandible. J Oral Maxillofac Surg 2001;59:302–7.
79. Ilizarov GA. The tension-stress effect on the genesis and growth of tissues. Part I. The influence of stability of fixation and soft-tissue preservation. Clin Orthop Relat Res 1989;249–81.
80. Tselnik M, Pogrel A (2000) Assessment of the pharyngeal airway space after mandibular setback surgery. J Oral Maxillofac Surg 58:282–285.
81. Primrose AC, Broadfoot E, Diner PA, et al. Patients' responses to distraction osteogenesis: a multi-centre study. Int J Oral Maxillofac Surg 2005;34:238–42.
82. Somers VK, White DP, Amin R, Abraham WT, Costa F, Culebras A, et al: Sleep apnoea and cardiovascular disease: an American Heart Association/American College of Cardiology Foundation scientific statement from the American Heart Association Council for High Blood Pressure Research Professional Education Committee, Council on Clinical Cardiology, Stroke Council, and Council on Cardiovascular Nursing. J Am Coll Cardiol 52(8): 686e717, 2008 Aug 19
83. Ramly E. P., Yu J. W., Eisemann B. S., et al. Temporomandibular joint ankylosis in pediatric patients with craniofacial differences: causes, recurrence and clinical outcomes. The Journal of Craniofacial Surgery . 2020;31(5):1343–1347.
84. Güven O., Keskin A. Remodelling following condylar fractures in children. Journal of Cranio-Maxillofacial Surgery . 2001;29(4):232–237.
85. Erol B, Tanrikulu R, Görgün B. A clinical study on ankylosis of the temporomandibular joint. J Cranio Maxillofac Surg. 2006;34:100–6.

86. Patil, Santosh & Yadav, Nidhi & Mousa, Mohammed & Alzwiri, Abdalwhab & Kassab, Mohamed & Sahu, Rohit & Chuggani, Satish. (2015). Role of female reproductive hormones estrogen and progesterone in temporomandibular disorder in female patients. Journal of Oral Research and Review. 7. 41. 10.4103/2249-4987.172492.
87. Chisnoiu AM, Picos AM, Popa S, Chisnoiu PD, Lascu L, Picos A, Chisnoiu R. Factors involved in the etiology of temporomandibular disorders - a literature review. Clujul Med. 2015;88(4):473-8.
88. Abb as I, Jamil M, Jehanzeb M, Ghous SM. Temporomandibular joint ankylosis: Experience with interpositional gap arthroplasty at Ayub Medical College Abbottabad. J Ayub Med Coll Abbottabad. 2005;17:67–9.
89. Belmiro C, Ricardo V, Rafeal V. Treatment of TMJ ankylosis. Oral Med Oral Pathol Oral Radiol. 2005;11:66–9.
90. Mekonnen D, Gizaw A, Kebede B. Temporomandibular Joint Ankylosis among Patients at Saint Paul's Hospital Millennium Medical College, Ethiopia: A 9-Year Retrospective Study. Int J Dent. 2021 Feb 17;2021:6695664.
91. Hollier Jr LH, Higuera S, Stal S, Taylor TD: Distraction rate and latency: factors in the outcome of pediatric mandibular distraction. Plast Reconstr Surg 117(7): 33e36, 2006 Jun
92. McNamara JA (1984) A method of cephalometric evaluation. AJO86:449–469
93. Tselnik M, Pogrel A (2000) Assessment of the pharyngeal airway space after mandibular setback surgery. J Oral Maxillofac Surg 58:282–285.
94. Rundo JV, Downey III R. Polysomnography. Handbook of clinical neurology. 2019 Jan 1;160:381-92.
95. Wang X, Wang XX, Liang C, Yi B, Lin Y, Li ZL: Distraction osteogenesis in correction of micrognathia accompanying obstructive sleep apnoea syndrome. Plast Reconstr Surg 112(6): 1549e1557, 2003 Nov
96. Aronson J, Harrison B, Boyd CM, Cannon DJ, Lubansky HJ, Stewart C: Mechanical induction of osteogenesis: preliminary studies. Ann Clin Lab Sci 18: 195e203, 1988

97. Aronson J, Harrison BH, Stewart CL, Harp Jr JH: The histology of distraction osteogenesis using different externalfixators. Clin Orthop Relat Res 241: 106e116,1989

98. Aronson J, Good B, Stewart C, Harrison B, Harp J: Preliminary studies of mineralization during distraction osteogenesis. Clin Orthop Relat Res: 43e49, 19

BABU BANARASI DAS UNIVERSITY
BBD COLLEGE OF DENTAL SCIENCES, LUCKNOW

BBDCODS/IEC/09/2022 Dated: 16th September, 2022

Communication of the Decision of the Xth Institutional Ethics Sub-Committee Meeting

IEC Code: 19

Title of the Project: Role Of Distraction Osteogenesis In Correction Of Obstructive Sleep Apnoea In TMJ Ankylosis Patient.

Principal Investigator: Dr Shaikh Marufhusain **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 Shaikh Marufhusain,

The Institutional Ethics Sub-Committee meeting comprising following members was held on 15th September, 2022.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry
2.	Dr. Praveen Singh Samant Member	Prof. & Head, Department of Conservative Dentistry & Endodontics
3.	Dr. Jiji George Member	Prof. & Head, Department of Oral Pathology & Microbilogy
4.	Dr. Amrit Tandan Member	Professor, Department of Prosthodontics and Crown & Bridge
5.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics & Dentofacial Orthopaedics

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:

Prof. Dr. Puneet Ahuja
Principal
BBD College of Dental Sciences
BBD University, Lucknow

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

Lakshmi Bala 16/09/22

Dr. Lakshmi Bala
Member-Secretary
Institutional Ethics Sub-Committee (IEC)
BBD College of Dental Sciences
BBD University, Lucknow

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

BABU BANARASI DAS UNIVERSITY

BBD COLLEGE OF DENTAL SCIENCES, LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Role Of Distraction Osteogenesis In Correction Of Obstructive Sleep Apnoea In TMJ Ankylosis Patient"** submitted by **Dr Shaikh Marufhusain** Postgraduate student in the **Department of Oral & Maxillofacial Surgery** for the Thesis Dissertation as part of MDS Curriculum for the academic year 2021-2024 with the accompanying proforma was reviewed by the Institutional Research Committee in its meeting held on **14th September, 2022** 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. Dr. Puneet Ahuja
Chairperson

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

Dr. Mona Sharma
Co-Chairperson

Babu Banarasi Das College of Dental Sciences

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

PARTICIPANT INFORMATION DOCUMENT

1. **Study Title**

   ROLE OF DISTRACTION OSTEOGENESIS IN CORRECTION OF OBSTRUCTIVE SLEEP APNEA IN TMJ ANKYLOSIS PATIENT.

2. **Invitation Paragraph**

   You are 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 management of obstructive sleep apnea.

4. **Why have I been chosen?**

   You have been chosen for the study as you are fulfilling the required criteria for the study.

5. **Do I have to take part?**

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

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

   You will have to come multiple times before and after surgery for follow up as and when required.

7. **What do I have to do?**

   There will be certain changes made in the dietary intake with few other precautionary measures and you will be expected to follow that.

8. **What is the procedure that is being tested?**

   Role of distraction osteogenesis in correction of obstructive sleep apnea in tmj ankylosis patient.

9. **What are the interventions for the study?**

   Distraction osteogenesis will be done in TMJ ankylosis patient to correct obstructive sleep apnea. Distractors will be placed at ankylosis side and will be removed after consolidation phase followed by TMJ arthrectomy.

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10. What are the side effects of taking part?

Although there are no reports of serious side effects of the procedure but the participants may have minimum side effects of the drugs like nausea and post operative vomiting. If anything happens during the procedure we have skilled personnel and specialized equipments to manage any emergency.

If the participants suffers any other symptoms postoperatively, the guardian should immediately talk to the doctor.

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

There are no disadvantages of taking part in the study, there can be minimum side effects of the drugs.

12. What are the possible benefits of taking part?

Release of the TMJ ankylosis increasing facial esthetics and functional efficiency.

13. What if new information becomes available?

If additional information becomes available during the course of the research you will need to tell the patient about this. States:

-Sometimes during the course of a research project, new information becomes available about the research being studied. If this happens, your researcher will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your researcher/investigator will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

Nothing will happen to the participants.

15. What if something goes wrong?

the problem/complain will be handled by HOD or the IRC. If something serious happen the institute will take care of the problem.

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?

18. Who is organizing the research?

the research is being done in the department of Oral and Maxillofacial Surgery, BBDCODS. The research is self funded. The participants will have to pay for procedural charges as given by the institution.

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

Yes

20. Who has reviewed the study?

The HOD and the members of IRC/ IEC of the institution have reviewed and approved the study.

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21. Contact for further information

Dr. Maruf Hussain Shaikh
Department of Oral & Maxillofacial Surgery.
Babu Banarasi College of Dental Sciences.
Lucknow-226028
Mob: 8840768448

Dr. Laxmi Bala
Member Secretary of Ethics Committee of the Institution
Babu Banarasi College of Dental Sciences.
Lucknow
Email: bbdcods.iec@gmail.com

Signature of PI……

Name……..

Date……..

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज
(बाबू बनारसी दास विश्वविद्यालय)
बीबीडी सिटी, फैजाबाद रोड, लखनऊ – 227105 (भारत)

1. **अध्ययन शीर्षक**

   टीएमजे एंकिलोसिस रोगी में ऑब्सट्रक्टिव स्लीप एपनिया के सुधार में डिस्ट्रैक्शन ओस्टियोजेनेसिस की भूमिका।

2. **आमंत्रण पैराग्राफ**

   आपको एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है। निर्णय लेने से पहले आपके लिए यह समझना महत्वपूर्ण है कि शोध क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय निकालें और यदि आप चाहें तो मित्रों, रिश्तेदारों और अपने इलाज करने वाले चिकित्सक/पारिवारिक चिकित्सक के साथ इस पर चर्चा करें। हमसे पूछें कि क्या कुछ ऐसा है जो स्पष्ट नहीं है या यदि आप अधिक जानकारी चाहते हैं।

3. **अध्ययन का उद्देश्य क्या है?**

   ऑब्सट्रक्टिव स्लीप एपनिया के प्रबंधन में व्याकुलता अस्थिजनन की प्रभावकारिता का अध्ययन करना।

4. **मुझे क्यों चुना गया है?**

   आपको चुना जाता है क्योंकि आप अध्ययन के मानदंडों को पूरा करते हैं।

5. **क्या मुझे भाग लेना है?**

   यह आपको तय करना है कि भाग लेना है या नहीं। यदि आप भाग लेने का निर्णय लेते हैं, तो आपको यह सूचना पत्रक रखने के लिए दिया जाएगा और सहमति प्रपत्र पर हस्ताक्षर करने के लिए कहा जाएगा। यदि आप भाग लेने का निर्णय लेते हैं, तब भी आप किसी भी समय और बिना कोई कारण बताए वापस लेने के लिए स्वतंत्र हैं।

6. **यदि मैं भाग लेता हूँ तो मेरा क्या होगा?**

   जरूरत पड़ने पर फॉलो-अप के लिए आपको सर्जरी से पहले और बाद में कई बार आना होगा।

7. **मुझे क्या करना होगा?**

   कुछ अन्य एहतियाती उपायों के साथ आहार सेवन में कुछ बदलाव किए जाएंगे और आपसे इसका पालन करने की अपेक्षा की जाएगी।

8. **किस प्रक्रिया का परीक्षण किया जा रहा है?**

   टीएमजे एंकिलोसिस रोगी में ऑब्सट्रक्टिव स्लीप एपनिया के सुधार में व्याकुलता ओस्टोजेनेसिस की भूमिका।

9. अध्ययन के लिए क्या हस्तक्षेप हैं?

ऑब्सट्रक्टिव स्लीप एपनिया को ठीक करने के लिए टीएमजे एंकिलोसिस रोगी में डिस्ट्रेक्शन ओस्टोजेनेसिस किया जाएगा। डिस्ट्रेक्टर्स को एंकिलोसिस की तरफ रखा जाएगा और समेकन चरण के बाद टीएमजे आर्थ्रेक्टोमी के बाद हटा दिया जाएगा।

10. भाग लेने के दुष्प्रभाव क्या हैं?

हालांकि प्रक्रिया के गंभीर दुष्प्रभावों की कोई रिपोर्ट नहीं है, लेकिन प्रतिभागियों को मतली और पोस्ट ऑपरेटिव उल्टी जैसी दवाओं के न्यूनतम दुष्प्रभाव हो सकते हैं। यदि प्रक्रिया के दौरान कुछ भी होता है तो हमारे पास किसी भी आपात स्थिति को प्रबंधित करने के लिए कुशल कार्मिक और विशेष उपकरण हैं।

यदि प्रतिभागियों को ऑपरेशन के बाद कोई अन्य लक्षण दिखाई देते हैं, तो अभिभावक को तुरंत डॉक्टर से बात करनी चाहिए।

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

अध्ययन में भाग लेने के कोई नुकसान नहीं हैं, दवाओं के न्यूनतम दुष्प्रभाव हो सकते हैं।

12. भाग लेने के संभावित लाभ क्या हैं?

TMJ एंकिलोसिस का विमोचन चेहरे के सौंदर्यशास्त्र और कार्यात्मक दक्षता को बढ़ाता है।

13. क्या होगा यदि नई जानकारी उपलब्ध हो जाती है?

कभी-कभी एक शोध परियोजना के दौरान, अध्ययन किए जा रहे शोध के बारे में नई जानकारी उपलब्ध हो जाती है। यदि ऐसा होता है, तो आपको इसके बारे में सूचित किया जाएगा और अध्ययन में होने वाले परिवर्तनों के बारे में सूचित किया जाएगा। आप अध्ययन के बीच में हटने के लिए स्वतंत्र हैं। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपसे एक अद्यतन सहमति फॉर्म पर हस्ताक्षर करने के लिए कहा जा सकता है।

14. जब शोध अध्ययन बंद हो जाता है तो क्या होता है?

यदि अध्ययन निर्धारित समय से पहले समाप्त / बंद हो जाता है, तो इसका कारण रोगियों को समझाया जाएगा।

15. अगर कुछ गलत हो जाए तो क्या होगा?

यदि कोई गंभीर प्रतिकूल घटना होती है, या अध्ययन के दौरान कुछ गलत हो जाता है, तो बीबीडीसीओडीएस ओपीडी में क्षेत्र में विशेषज्ञता रखने वाले डॉक्टरों द्वारा शिकायतों का निपटारा किया जाएगा।

16. क्या इस अध्ययन में मेरे भाग लेने को गोपनीय रखा जाएगा?

आपका नाम, पता या कोई व्यक्तिगत या अन्य जानकारी बीबीडीसीओडी के बाहर साझा नहीं की जाएगी।

17. शोध अध्ययन के परिणामों का क्या होगा?

अध्ययन के परिणामों का उपयोग 4 विभिन्न प्रकार के माउथवॉश की प्रभावशीलता का मूल्यांकन और तुलना करने के लिए किया जाएगा। किसी भी परिणाम/रिपोर्ट/प्रकाशन में प्रतिभागियों की पहचान का खुलासा नहीं किया जाएगा।

18. शोध का आयोजन कौन कर रहा है?

यह शोध अध्ययन शैक्षणिक संस्थान (BBDCODS) द्वारा आयोजित किया जाता है।

BBDCODS

19. क्या अध्ययन समाप्त होने के बाद अध्ययन के परिणाम उपलब्ध कराए जाएंगे?

यदि रोगी चाहे तो अध्ययन का परिणाम उसे उपलब्ध कराया जाएगा।

20. अध्ययन की समीक्षा किसने की है?

संस्थान के एचओडी/आईआरसी/आईईसी ने अध्ययन की समीक्षा की और उसे मंजूरी दी।

21. अधिक जानकारी के लिए संपर्क करें

डॉ. मारुफ हुसैन शेखी

ओरल और मैक्सिलोफेशियल सर्जरी विभाग।

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ-226028

भीड़: 8840768448

डॉ लक्ष्मी बाला,

संस्था की आचार समिति के सदस्य सचिव,

पता: बाबू बनारसी दास विश्वविद्यालय, फैजाबाद रोड, आतिफ विहार,

लखनऊ, यूपी। 226028

ईमेल: bbdcods.iec@gmail.com

पं. का नाम -

पता -

ईमेल -

टेलीफोन नंबर। -

पीआई के हस्ताक्षर .....

नाम.....

तारीख.....

प्रतिभागी को सूचना पत्र की एक प्रति और हस्ताक्षरित सहमति प्रपत्र दिया जाएगा।

अध्ययन में भाग लेने के लिए धन्यवाद।

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow-226028

Child information document

Study title: —Role of distraction osteogenesis in correction of obstructive sleep apnoea in TMJ ankylosis patients.

Introduction

To assess the pre operative and post operative findings on basis of some parameters in patients with obstructive sleep apnoea before and after distraction osteogenesis.

We invite you to participate in this study.

What will you have todo?

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 beprovided with a diary where they will enter the same findings accordingly. You will haveto 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 helpus 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 : टीएमजे एंकिलोसिस रोगियों में अवरोधक स्लीप एपनिया के सुधार में व्याकुलता ओस्टोजेनेसिस की भूमिका

ओस्टोजेनेसिस की भूमिका।

अध्ययन संख्या :

विषय का पूरा नाम :

जन्म तिथि ० 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 ,० 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_____
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

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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.....

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 चिकित्सक 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 _____

चिकित्सक का नाम और हस्ताक्षर _____ दिनांक _____

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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.....

PLEADS

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

सहमति पत्र

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

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

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

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

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

हॉ [ ] नही [ ] अनउपयुक्त [ ]

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

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

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

अध्ययन अन्वेषक का नाम .....

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

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

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

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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

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Submission Information

Author Name	Shaikh Maruf Husain
Title	ROLE OF DISTRACTION OSTEOGENESIS IN CORRECTION OF OBSTRUCTIVE SLEEP APNOEA IN TEMPORO-MANDIBULAR JOINT ANKYLOSIS PATIENTS
Paper/Submission ID	1412836
Submitted by	amarpal.singh056@bbdu.ac.in
Submission Date	2024-02-08 15:08:33
Total Pages	13
Document type	Dissertation

Result Information

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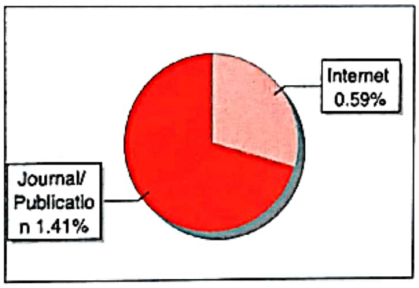

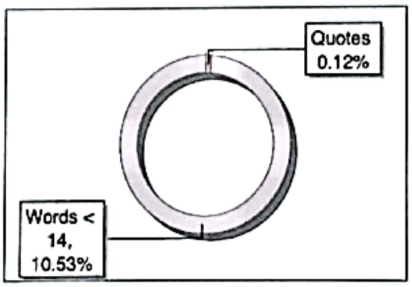

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