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DISTRACTION OSTEOGENESIS IN SEVERE UPPER AIRWAY OBSTRUCTION DUE TO MANDIBULAR MICROGNATHIA (A RANDOMIZED CLINICAL TRAIL)

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ABSTRACT

INTRODUCTION: Distraction Osteogenesis (DO) is a good solution solving respiratory distress when other proceduresare failed in severe micrognathia. it is an alternative treatment correcting mandibular hypoplasia. In this study, distraction with a dynamic osteosynthesis system (MD-DOS) for gradual lengthen the mandible with severe hypoplasia. Latency period was seven days. Distraction was performed three times daily for 14 days with rate 0.33 mm. Retention was nine weeks. The mandible had been elongated improving the air way and relive of obstruction.

AIM OF THE STUDY: Evaluation of airway improvement following mandibular distraction osteogenesis in pediatric population with mandibular micrognathia with severe upper airway obstruction.

MATERIALS AND METHODS: Twenty patients aged from 5 month and 5 years (mean age is 3.86 years) with micrognathia and sever airway obstruction had been treated with mandibular distraction osteogenesis (MDO). All patients had been evaluated by a multidisciplinary team. Indications for surgery included frequent apneic episodes with severe desaturation (70%). The study treats patients with congenital anomalies as congenital ankylosis, Pierre Robin sequence (PRS), Hemifacial microsomia, Treacher Collins syndrome and Goldenhar syndrome. Detection of airway obstruction correction were done by comparing pre-operative and post-operative sleep lab study (polysomnography).

RESULTS: Cephalometric radiograph, OPG and CT get data for planning the mandibular osteotomy and distractor application for mandibular lengthening and restoring the airway with accepted variable complications on 20 patients age from 5 months to 5 years.

CONCLUSIONS: Mandibular distraction osteogenesis is a valuable treatment for severe airway obstruction due to mandibular hypoplasia when other procedures are failed .

KEYWORDS: Mandibular micrognathia, Airway obstruction, distraction osteogenesis.

RUNNING TITLE: Mandibular osteogenesis for mandibular elongation to improve the airway.

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INTRODUCTION

Distraction osteogenesis (DO) is a biomechanical process of bone tissue formation, where the distraction forces which act between the bone segments effect the biological potential of the bone by forming a callus of determined length and height. It is preceded by osteotomy or subperiosteal osteotomy and followed by fixation of the distractor on the segments and their gradual lengthening of bone and soft tissue or both.[(1)]

First distraction osteogenesis as a mean of elongation in long bones was described by Ilizarov (1952, 1988, 1992).[(2)] By time it involved several other bones rather than short and flat bones till it reaches the skull bones (maxilla, mandible and cranium) to correct craniomaxillofacial defect which may be congenital or acquired.[(3)]

The distractor is a device that allows expansion in one or more directions that has some sort of attachment to the bone, teeth or both. Submerged distractors have a part that emerges through the mouth or transcutaneous.[4] Non submerged are extraoral and attached directly to the bone or teeth.[5]

The design differed according to the anatomical site and needs to be corrected whether for both jaws (upper or lower) or specific jaw segments. The action of distraction is unidirectional, bidirectional, or multidirectional (distraction in length, height, and width). Unidirectional is intraoral distractors while multidirectional is extraoral distractors. (6)

Distractors can be designed for the lower jaw, the upper jaw or for specific jaw segments. According to the direction of the vector of distraction forces they can be unidirectional, bidirectional or multidirectional (distraction in length, height and width). As a rule intraoral distractors are unidirectional, while extraoral distractors are bidirectional or multidirectional.[6]

Indications of DO in mandible include: Unilateral distraction of the ramus, angle, or posterior body as in hemifacial microsomia. Bilateral advancement of the body for severe micrognathia, particularly in infants and children with severe airway obstruction . Vertical distraction of alveolar segments to correct an uneven occlusal plane or to facilitate implantation into edentulous zones. Horizontal distraction across the midline to correct cross bite deformities or to improve arch form. Transport distraction to generate a neo-condyle and temporomandibular joint in patients with severe joint ankyloses. Reconstruction of posttraumatic deformities (midfacial retrusion or mandibular collapse). Insufficient alveolar height and/or width (Maxillary or mandibular alveolar distraction). Reconstruction of oncologic and/or aggressive cystic jaws defects.

In our work there are several congenital craniofacial syndromes that may require distraction, these include Congenital unilateral and bilateral condylar ankylosis , Pierre Robin sequence (PRS) , Hemifacial microsomia , Treacher Collins syndrome , Goldenhar syndrome , Nager syndrome and Velocardiofacial syndrome. [7,8]

The features of PRS were first described by Robin[9] and include micrognathia, gloss ptosis and respiratory distress. Robin later revised the characteristics of the syndrome and included cleft palate as an additional factor that could be present. A wide range of clinical manifestations exists, but the main clinical problems faced by clinicians include upper airway obstruction and feeding difficulties.[10]

It is clear that not every child with mandibular hypoplasia displays airway obstruction.[11,12] Some patients may present an adequate airway when awake, but the obstruction may arise during feeding or sleeping when the pharyngeal muscle tone decreases. Thus, management regimes differ depending on the degree of upper airway obstruction.[13] Current treatments of mandibular hypoplasia with airway obstruction include non-surgical (prone positioning, nasopharyngeal tube/stenting, prolonged intubation), or surgical options (tongue-lip adhesion, tracheotomy, mandibular distraction osteogenesis).

Recently, in neonates and children mandibular distraction osteogenesis has been popularized in the literature and it is now widely accepted as the procedure of choice in the early management of airway obstruction due to craniofacial disproportion.[14,15]

AIM OF THE STUDY

The aim of this study is:

Primary outcome

To evaluate the airway improvement following mandibular distraction osteogenesis in pediatric population with unilateral or bilateral micrognathia associated with severe upper airway obstruction.

Secondary outcome

Detect amount of relapse after consolidation.

MATERIAL AND METHODS

This trail included twenty pediatric patients aged from 5 months to 5 years old, suffered from airway problems secondary to bilateral or unilateral mandibular micrognathia. Participants were recruited from Cranio-Maxillofacial and Plastic Surgery Department in Faculty of Dentistry Alexandria University.

Ethical approval was granted by the Research Ethics Committee, Faculty of Dentistry, Alexandria University. All participants signed an informed consent prior to the commencement of the study.

Inclusion criteria

Syndromic and non-syndromic, mandibular hypoplasia causing presence of tracheostomy both or without, failure of non-surgical methods to treat airway obstruction, and severe breathing difficulty with respiratory distress with episodes of severe desaturation (oxygen saturation below 70% - respiratory rate higher than 60/min).

Exclusion criteria

Central apnea that was dependent on other levels of airway impairment, such as laryngomalacia/ tracheomalacia, and previous surgical procedures.

Materials

KLS Martin Semibeird distractor (Gebrüder Martin GmbH & Co. KG, Tuttlingen, Germany was used. **(Figure 2)**

Preoperative evaluation

Preoperative assessment of all patients had been submitted for clinical examination, routine laboratory investigations, and Computed tomography scans with 3D-dimensional reconstruction evaluating the posterior airway space (PAS), mandibular morphology, and remainder of the craniofacial skeleton. Furthermore, the CT scan will

help in detecting the relationship of the posterior and inferior border of the mandible to plane osteotomy and detect the vector of distraction. In addition to ultrasound investigations for any associated congenital anomalies like congenital heart diseases, Sleep lab studies (polysomnography) which is technique of recording, analyzing, and interpreting multiple simultaneous physiologic parameters during sleep is performed to determine if the breathing pattern has central (neurological) or obstructive (functional) episodes. (18)

Before surgery, all details of the procedures were explained to the child parents and instructions about fasting before the surgical intervention were given to the patients and or guardians and patients were referred to the pediatric dentistry department for oral care. The instructions must be followed to gain the most benefit with the least complications.

Operative technique

All patients underwent the surgical procedure under general anesthesia. The patients had been treated with a bilateral intra-oral mandibular semibeird distractor with an external arm to facilitate activation by parents by KLS-Martin LP manufactures a miniaturized intraoral mandibular distractor with a flexible arm that exits percutaneously capable of 30 mm of distraction. The patients had been received general anesthesia using either a pre-existing tracheotomy or oral intubation with the help of fiber optic in case of difficult intubation due to narrowing of air-way passage. Extra-oral submandibular incision was done 2 cm below the inferior margin of the mandible, at the angle area (Risdon incision). (19) Blunt dissection to the marginal border of the mandible with subperiosteal dissection of the masseter muscle had been performed. Osteotomy line had been marked on the mandible outer cortex the device had been correctly positioned and fixed with mono cortical self-drilling screws. (20)

The planned osteotomy line had been performed either (21) horizontal cut in the ramus in case of short ramus, vertical cut in the body in case of retracted mandible, or oblique at the body/ramus junction in case of short ramus and retracted mandible. Phases of distractions osteogenesis are first phase is the latency period in which hematoma formation occurs following osteotomy which is later replaced by granulation tissue. Second phase is progressive increase of bone gap with osteogenesis at the margin of distraction gap. Third phase is extension of osteogenesis to the center of the gap during consolidation phase. Forth phase is the maturation of the ossification in the distraction chamber in late consolidation period. Fifth phase is the bone remodeling and continuity of alveolar canal after completion of distraction osteogenesis. (22,23) **(Figure 1)**

The steps had been repeated on the other side if needed. After the device removal, we completed the osteotomy line using a cutting bur, saw or piezo technique, and rotational force was applied using chisel. Careful manipulation during chisel application after osteotomy to preserve the neurovascular bundle. The devices had been re-inserted and fixed to their site on the mandible by the same screw holes and had been checked carefully for detection of accurate stability. The distractors had been fixed by screws. **(Figure 2)** Extension rods had been used in all patients. Distractors had been activated in the field during surgery to ensure the complete osteotomy. The tunnel had been done for the activation bar to exist

Complications of distraction osteogenesis are divided into 3 groups of complications including intraoperative complications according to the surgical procedure such as mal-fracture, incomplete fracture, nerve damage, excessive bleeding, and problems related to the device such as fracture and placement instability. In addition to intra-distraction complications that occur during distraction such as pain, malnutrition, infection, premature consolidation, and device problems, while post-distraction complications include problems arising during splinting and after distractor removal such as malunion, relapse, and persistent nerve damage. (16,17)

The null hypothesis of this study is just one group of patients 20 in number one problem need to be solved which is severe upper air way obstruction no comparison.

from the skin. The masseter muscle had been repositioned and sutured to the internal pterygoid muscle with resorbable sutures size (5.0). Finally closure by prolene suture with a drain.

Distraction protocol and postoperative assessment (24)

The patient was admitted to the ICU immediately after recovery from anesthesia to maintain airway passage and deal with any complications that may occur after the operation.

Distraction had been initiated following a latency period of 24 hours if without tracheostomy and 5 days if the patient had a tracheostomy with a rate of 1mm/day.

The patient had been discharged from the hospital after training the parents on how to activate the distractor.

Follow-up phase:

Patients were followed immediately after the operation, after 2 months, after 6 months, and finally, after 1 year. Postoperative evaluation will be made at the end of the consolidation period. In order to evaluate the efficacy of distraction, besides comparison of preoperative and postoperative airway areas, bone distraction will also be compared with its reflection on airway distance.

Airway improvement evaluation by pre-operative and post-operative sleep lab study comparison by Apnea Hypopnea Index (AHI), Respiratory

Disturbance Index (RDI), Oxygen Desaturation Index (ODI).
Activation will be stop when the endpoint will be obtained: symptoms and signs of airway obstruction solved, PAS and maxillomandibular relationship will be improved and tracheotomy, if present can be removed. Distraction will be continued until a slight overcorrection is reached and will be removed after 2 months.

RESULTS

Immediately after the operation, after 2 months, after 6 months, and finally after 1 year. Airway evaluation: The distance between the posterior pharyngeal wall and the base of the tongue was measured to calculate the cross-sectional area of the airway using the preoperative and postoperative CT, and compared pre-operative and post-operative sleep lab study to detect correction of airway obstruction by Apnea Hypopnea Index (AHI) Normal less than < 5 event/hour. (25) Respiratory Disturbance Index (RDI) is Normal less than < 5 events/hour. Oxygen desaturation index (ODI) At sea level the normal range is usually 96-97%. All these data collected and compared by sleep lab study (polysomnography) before and after. This chart showing the recovery of the air way passage that airway had been dilated during the first two months then show minimal relapse especially after distractor removal. **(Graph 1)**
Activation had been stopped when the endpoint had been obtained: signs and symptoms of airway obstruction were solved, PAS and the maxillomandibular relationship had been improved, and tracheotomy if present, it could be removed. Distraction had been continued until a slight overcorrection was reached and had been removed after 2 months. Postoperative evaluation had been made at the end of the consolidation period. Evaluate distraction efficacy, compare between preoperative and postoperative airway, also compare between bone distraction and reflection on airway distance. Removal of distractor after 3 months to decrease the possibility of relapse acting as a bone retainer.

Cases presentation

Case (1)

Male patient with Hutchinson-Gilford progeria Syndrome 4 years in age.

- **Pre-operative:** Lateral view show convex profile due to sever mandibular hypoplasia.
- **Syndrome is associated with**: Mild cardiac anomalies as Aortic, tricuspid, and pulmonary valves regurgitation.
- Heavy loud frequent snoring during sleeping due to sever air way obstruction (obstructive sleep apnea).
- Comparison of air way correction by Apnea hypopnea index (AHI) show improvement of numbers of apnea per hour from sever 43 to be normal less than 5 times. **(Figure 3)**

Case (2)

Another boy 1.5 years with Sox 9 gene mutations and the Pierre-Robin sequence.

- Tracheostomy required in preoperative pictures because to severe airway obstruction brought on by mandibular hypoplasia.
- respiratory discomfort and significant airway blockage are symptoms of severe mandibular micrognathia.
- Past history of complete cleft palate with previous successful surgery.
- **The sleep lab study** : demonstrate severe obstruction since there are more than 30 apnea episodes per hour. Efficiency of the sleep lab test was 93%, compared to 71% before distraction, and the number of episodes per hour was fewer than 5, as opposed to 37 before distraction.
- **Radiograph after distraction:** showing a clearly expanded oropharynx compared to its previous tight state. **(Figure 4)**

Case (3)

Another one is 5 years old girl with Goldenhar syndrome complain mainly from esthetic problem and mild airway obstruction systemically free with mild degree of scoliosis with study lab almost normal. **(Figure 5)**

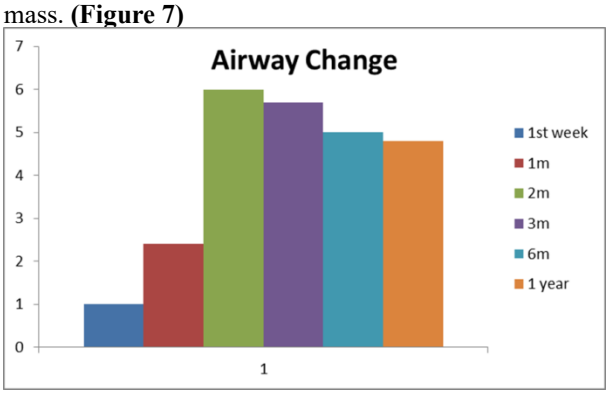
Case (4) Another case 5 years old girl with Pierre Robin sequence with variable degree of craniofacial stenosis with microcephaly admitted 7 days in NICU at birth due to breathing difficulties.
Complains of air way obstruction specially during sleeping with loud snoring, complete cleft palate and esthetic unacceptable facial profile and food and fluid regurgitation. Treated by bilateral mandibular distraction. **(Figure 6)**

Case (5)

Another case 4 years old Girl complain of

- Airway obstruction.
- Unacceptable lateral profile.
- Heavy snoring.

She had previous operated to release the ankylotic mass. **(Figure 7)**



Graph (1):

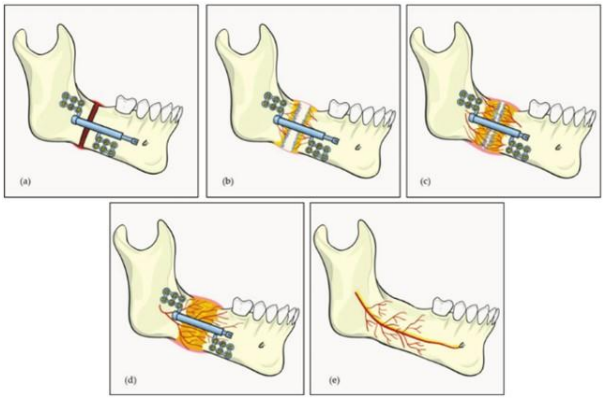


Figure (1): (A) Latency period in which hematoma formation occurs following osteotomy which is later replaced by granulation tissue. (B) During distraction period, bone gap is progressively increased with osteogenesis at the margin of distraction gap. (C) Osteogenesis extend to the Centre of the gap during consolidation phase. (D)Maturation of the ossification in the distraction chamber in late consolidation period. (E) Bone remodeling and continuity of alveolar canal after completion of distraction osteogenesis.

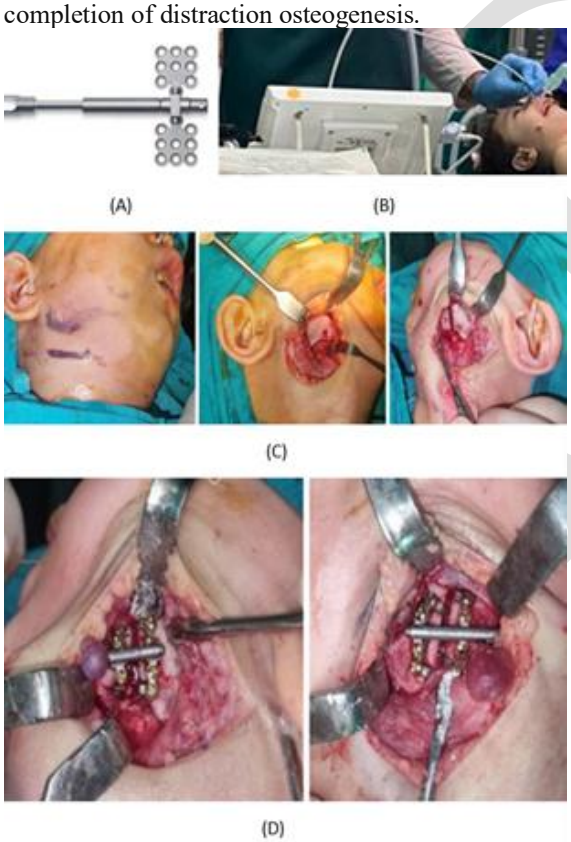


Figure (2): (A) KLS Martin Semibuired distractor. (B) Fiberoptic intubation (C) Surgery (D) After application of distractors bilaterally.

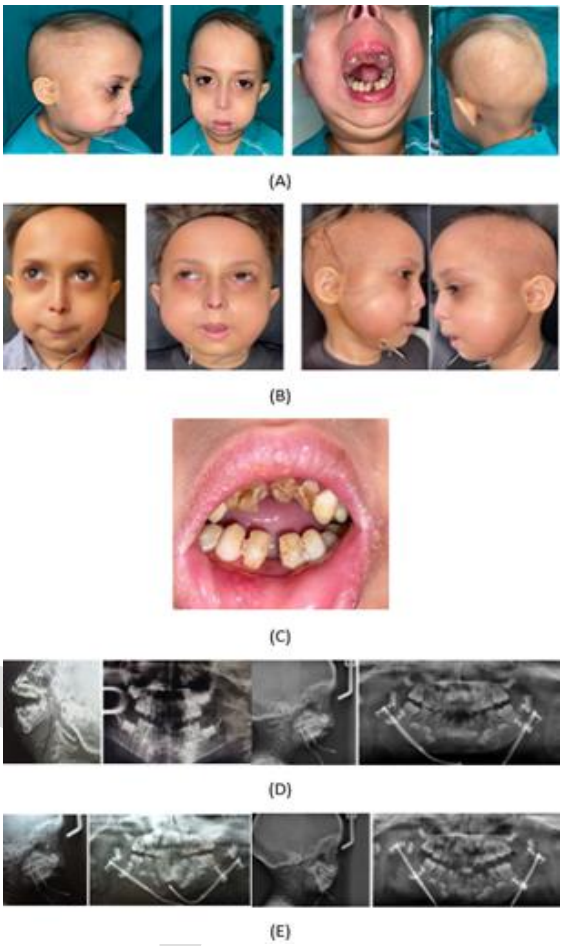


Figure (3): (A) Sever micrognathia with prominent scalp veins, narrow face with prominent eyes, peaked nose, restriction of mouth opening with bad oral hygiene due to mouth breathing, mouth opening during sleeping and macrocephaly with scanty hair and hair loss. (B) Photographs show the distraction site with mild inflammation with lateral view photographs show improvement of lateral profile after mandibular distraction. (C) Intraoral photographs show anterior open bit with multiple carious teeth. (D) Lateral view shows severe oropharyngeal obstruction with small lower jaw, OPG show Delayed eruption and immediate Post operative. (E) Week after distraction and after complete distraction.

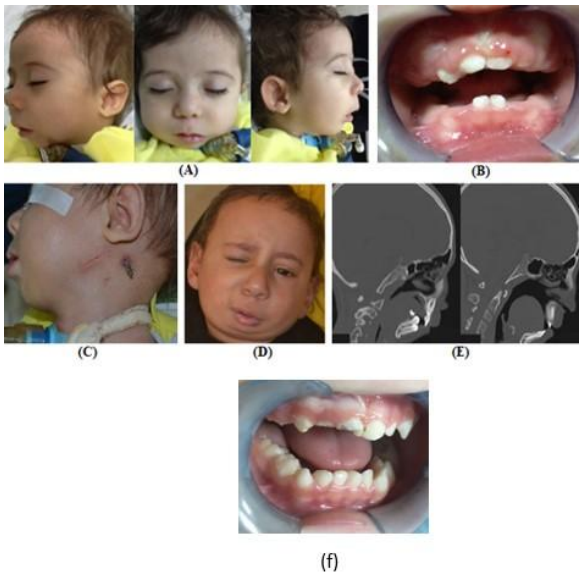


Figure (4): (A) Preoprative photograph showing severe airway blockage required a tracheostomy. (B) intraoral photograph showing limited mouth opening. (C) The distractor's arm and the surgery's submandibular scar are visible below the ear. (D) Left side facial nerve affected. (E) Radiographs showing a clearly expanded oropharynx compared to its previous tight state. (F) intraoral photograph showing improvement of mouth opening.

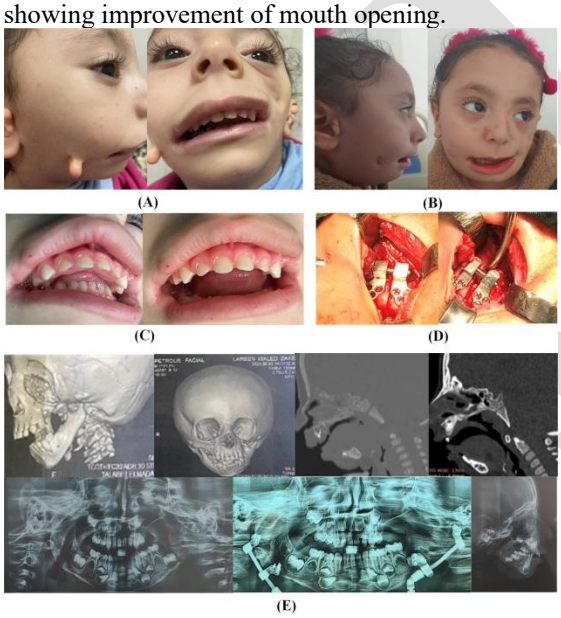


Figure (5): (A) Extraoral photographs show facial asymmetry with missing left mallar bone, skin tags as well as auxiliary auricles and mandibular hypoplasia-related obvious convex profile. (B) Final images displaying scars from the procedure and bettering the facial profile, increase in mandibular size and a small correction of facial asymmetry (C) intraoral photographs show improvement of maxillary mandibular relationship and salivary drooling. (D) The procedure involves submandibular incisions and bilateral mandibular body osteotomies with semibuierd distractors. (E) Images before and after demonstrate improved airway patency via the oropharynx., (OPG) x-ray before and after treatment show amount of bone gained after completion of distraction & lateral view showing improvement of size of the mandible.

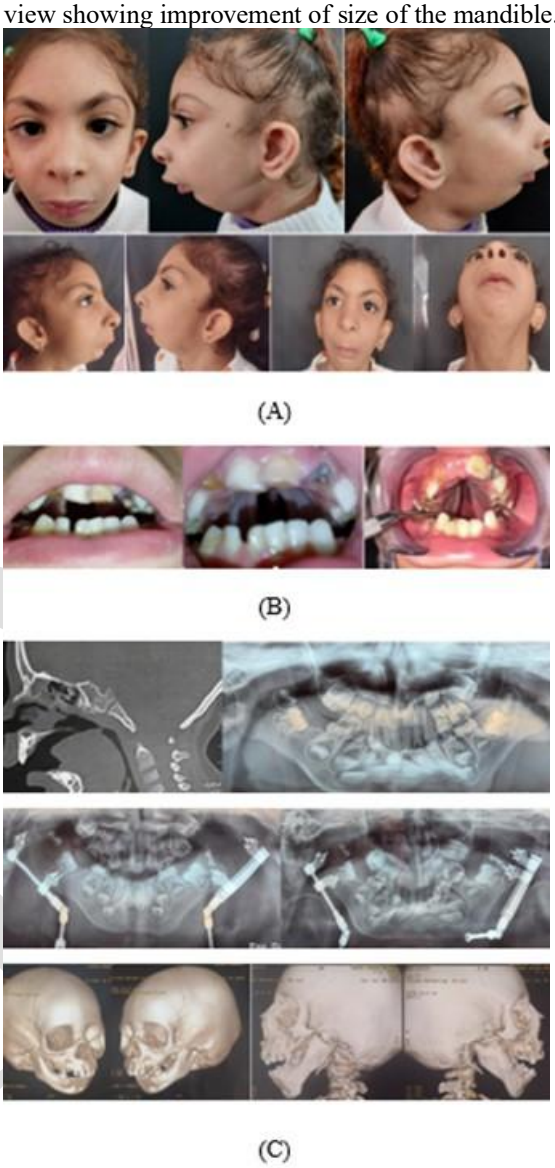


Figure (6): (A) Extraoral views show marked retracted mandible with microcephally and convex facial profile then marked improvement of mandibular shape and increase of mouth opening. (B) Intraoral photographs showing anterior open bite and multiple carious teeth with bad oral hygien and complete posterior cleft palate then improvement of mouth opening .(C) Radiograghs : Lateral view show posteior narrowing of oronasopharynx with marked retracted mandible and OPG show mixed dintition with prominent antigonial angel compared to Immediate post operative OPG and Finally after distraction completed 3 monthes after complete distraction for conselidation and before distraction removal and lateral view showing marked elongation achived.

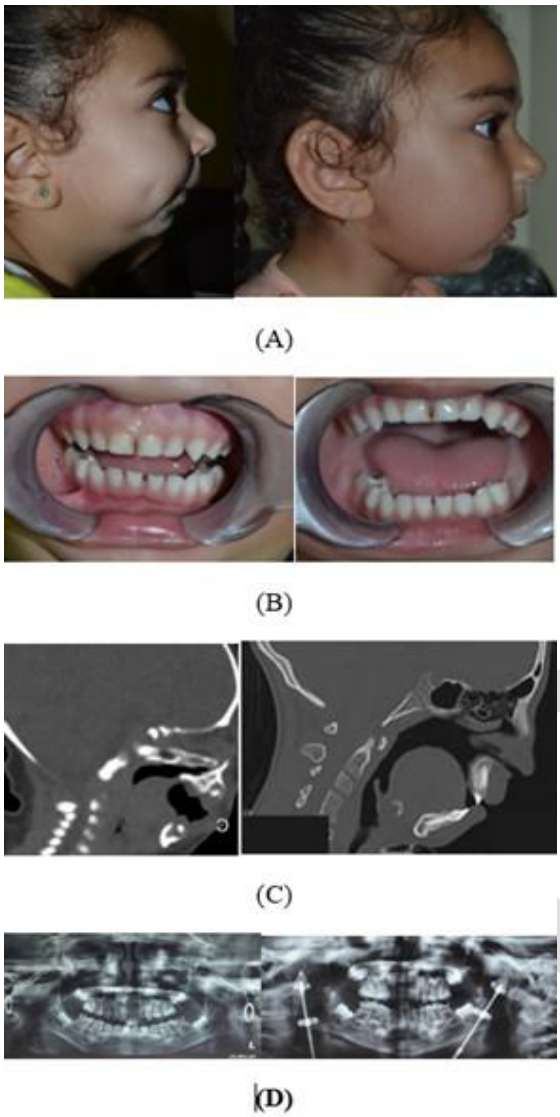


Figure (7): Comparison between preoperative and postoperative changes achieved by surgery (A) lateral profile. (B) Improvement of mouth opening. (C) Airway improvement. (D) Amount of mandibular elongation.

DISCUSSION

Mandibular hypoplasia is a condition that can produce severe airway obstruction to the affected person. When occurring in neonates and childhood it will interfere with breathing and facial development and will lead to face and jaws deformity with inability to perform adequate function and even will distort the patient's social relationships. (26)

The abnormal anatomical component of micrognathia with a retrognathic chin restricts the airspaces compromising the airflow. Such restricted airflow leads to myriads of health consequences, some with disastrous consequences including hypoxia, hypercapnia, pulmonary heart disease, and pulmonary hypertension in the long term. Till the last decade of the 20th Century, the "gold standard" of treatment for obstructive sleep apnea was tracheostomy. This invasive procedure was associated with high morbidity such as tracheomalacia, chronic bronchitis, laryngeal stenosis, and risk of death due to mucus plugs or extrusion/dislocation of the cannula. (27,28)

Long-term dependence on tracheostomy has its limitations leading to diminished quality of life. The other alternative procedures included nasal reconstruction, uvulopalatopharyngoplasty, advancement genioplasty, bilateral sagittal split ramus osteotomy with advancement genioplasty, and inferior mandibular osteotomy with hyoid myotomy. In most severe cases, maxilla-mandibular advancement (MMA) with advancement genioplasty was indicated. All these procedures are extensively invasive and have their own anatomical and physiological complications, especially in a growing child. (29) Since 20th century, Distraction osteogenesis has been emerging as an alternate treatment modality for patient suffering from obstructive sleep apnea.

Distraction osteogenesis offers several advantages over the other conventional techniques by eliminating the need for bone grafting and involving less surgical dissection because the lengthening is the result of natural bone healing in a gap created by a simple osteotomy. The incremental skeletal movement permits accommodation of the soft tissues as well as promotes its growth. The procedure also could help to lengthen or widen the bone by a determined vector in a controlled fashion. A larger dimension of skeletal movement was realized with minimum risks, complications, and morbidity. The associated soft tissue structures such as muscles, blood vessels, and nerves are also newly formed along with the neo-osteogenesis. This accounts to the increased better soft tissue adaptation, a factor that was not achieved by conventional techniques.

Although less surgical dissection is necessary for distraction osteogenesis, the procedure is highly technique sensitive, especially in achieving the proper alignment of the distraction devices as well as vector control. (30) The presence of TMJ ankylosis complicated the obstructive sleep apnea scenario. We could not decipher whether the micrognathia and genial retrusion are the cause or the effect of the TMJ ankylosis. The net result was that TMJ ankylosis and mandibular retrusion restricted the airspace. Correction of the TMJ ankylosis at the age of 3 years was not preferred as there were other local issues retracted mandible. Correction of TMJ ankylosis in children is a matter of debate. While some suggest deferring the surgery till oral functional movements are achieved, some are in favor of early intervention. (31) In the present case, it was decided to defer the surgery till the growth of midface stabilizes. To correct the severe obstructive sleep apnea that the child suffered from, we had no other better option to perform than the

distraction osteogenesis of the mandible. In a growing child, mandibular elongation by progressive distraction is gradual and thus better tolerated by our patient, both functionally and morphologically. The procedure was less time consuming, and placement of the distractors causes no particular problem apart from the care required in achieving the proper vectors of distraction. The development of miniaturized intraoral distractors and reduction in their cost should result in more widespread use of the procedure. (32)

There are recent reports such as that by Hu et al. (33) that has performed such a procedure on adults and achieved success while there are very few reports of the same in children as old as 7 years. (34) In the present cases, the procedure was successfully performed in 3-5 years old patients. Procedurally, to facilitate administration of anesthesia and sustain the space till sufficient airspace was created, the tracheostomy was performed. During the procedure and in immediate postoperative situation, the child had no issues with this approach. (35) The desired airspace expansion was achieved. Recently internal resorbable devices have been proposed that can be left in place as they resorb during a 6-8 month period, avoiding a second surgical procedure. (36) This procedure improves comfort and reduces the risk of infection during consolidation.

CONCLUSION

Distraction osteogenesis 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.

Bilateral mandibular distraction osteogenesis is a relatively safe and effective mean of treating airway obstruction and feeding difficulty in infants with congenital mandibular hypoplasia. The effects of this procedure, which carries a relatively low morbidity, persist through early childhood in most patients.

Distraction osteogenesis has improved the management of severe upper airway obstruction caused by pediatric mandibular micrognathia. By gradually lengthening the mandible, this procedure improves airway patency, alleviates respiratory distress, and enhances facial aesthetics. As advancements in surgical techniques and technology continue, distraction insertion is simple, complications are rare and no need for bone grafts. The disadvantage of this procedure the two-step surgery, the need of guardian's cooperation and patient discomfort from the distractor device. So, the numerous advantages broadening of the indicational spectrum can be anticipated.

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