

**THE HISTOLOGY AND LONG TERM STABILITY OF ANTERIOR
MAXILLARY DISTRACTION OSTEOGENESIS IN HYPO-PLASTIC
MAXILLAE IN OPERATED
CLEFT LIPPED & PALATE PATIENTS.**

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INTRODUCTION

INTRODUCTION

Cleft lip and cleft palate are congenital malformations resulting in non-fusion of lip and palate during development *in utero*. These clefts of the lip and palate are some of the more commonly occurring malformations observed in 1:800 live births. Apart from the obviously detrimental cosmetic effects, these malformations contribute to feeding difficulties right from birth, persistent recurring ear infections, speech difficulties, dental problems and psychological challenges.

The management of these patients requires a team of specialists (Pediatricians, Oral & Maxillofacial Surgeons, Plastic surgeons, Pedodontist, Orthodontist, Otolaryngologist, Speech and Language therapists, Anesthetists and Psychologists) with a treatment plan from birth to adulthood directed towards ensuring the child's ability to eat, drink, speak, hear and a normal facial appearance.

Surgical corrections are undertaken between 10 weeks to 3 months of age for cleft lip and between 6 and 18 months of age for cleft palate.

Surgery on the upper lip, alveolus and maxillae seems to lead to an interference with growth of the mid face. Skeletal maxillary growth is known to be affected due to such surgery and leads to hypo plastic maxillae. This produces a concave facial profile leading to poor facial esthetics. The hypo-plastic maxillae also frequently lead to dental crowding due to tooth size arch length discrepancy.

During early dentition period or during the mixed dentition period, the skeletal hypoplasia can be corrected by maxillary osteotomies or by maxillary distraction. Osteotomies are done after completion of facial growth. Surgery usually performed is Le-Fort 1 osteotomy with anterior advancements and sometimes also with inferior repositioning to gain facial height. The surgical advancement especially if involving significant magnitude of movement can lead to surgical relapse, instability and

worsening of velo-pharyngeal dysfunction (VPD), especially in patients with a pre existing borderline VPD. This can also worsen the individual's speech.

Distraction of the maxillae and palatine bones by means of internal or external distractions at the level of the Le-fort -1 became popular due to limitations of surgery. The advantages claimed include stability and the possibilities of operating even during the growth period.

External distractors were often cumbersome and had poor patient compliance. Internal distractors were less obtrusive, but still had significant morbidity and still require surgery for their removal.

Long term results with complete maxillary distractions were however, not very promising with significant long term relapse being reported.

Segmental distractions of the maxillae seems to be the answer. This procedure entails Anterior Maxillary Osteotomy followed by gradual distraction. These distractors were either bone borne or teeth borne. Tooth borne distractors produce significant amount of maxillary distraction and increase the alveolar volume in the distraction site which can be used for orthodontic de-crowding or for dental implant placement. This also helps keep the distraction segment is stable. The morbidity for the patient is far lesser than for full jaw distraction. The present study is to observe and report:

- 1) Long term stability of Anterior Maxillary Distraction which is done with tooth borne device.
- 2) Study the histology of the distracted soft tissue.
- 3) Study if speech is affected by the procedure.

AIMS AND OBJECTIVES

AIMS AND OBJECTIVES

Since skeletal maxillary hypoplasia is common in operated cleft lip and palate patients and there is no uniformly recommended procedure for a stable surgical correction, the anterior maxillary distraction procedure was done with the following aims and objectives.

- 1) To study the stability of this procedure by :-
 - i) Pre and post operative radiographic records;
 - ii) Pre and Post Operative Photographs
- 2) To study the histology of soft tissues in the distraction zone.
- 3) To do a pilot assessment of speech before and after distraction surgery.

SCOPE AND PLAN OF WORK

SCOPE AND PLAN OF WORK

When we started anterior maxillary distraction for cleft lip and palate patient, there was no long term data available in the literature regarding the stability of this procedure. Hence, we decided to do the study and observe our results over several months and then analyze the results.

Surgeries were performed by the author and his team of assistant surgeons under general anesthesia. Patients were from Ragas Dental College and Hospital and from Rajan Dental Institute.

The analysis of the skeletal and dental land marks were done by orthodontist independently.

Speech was assisted pre-operative and 3 months post operative by a qualified speech pathologist.

Histology of the distracted cleft maxillary tissue, both soft and hard tissue, was analyzed under H & E sections. This was done by Oral and Maxillo-facial pathologists. The possibility of distracting fibrous scar tissue of the palate and alveolus was assessed.

MATERIAL AND METHODS

MATERIALS AND METHODS:

All the patients were from Rajan Dental Institute, Mylapore, Chennai and Ragas Dental College, Chennai. All the patients or their parents were explained the surgical procedure and informed consent was obtained from them.

A. The study was carried out in three parts:

i. **To study the stability of anterior maxillary distraction in hypoplastic cleft maxilla**

8 patients in a mixed dentition period and adult dentition period were operated on to correct the hypoplastic cleft maxilla. There were six males and two females. Few patients had pre-surgical fixed orthodontics (straight wire) and others had post surgical fixed Orthodontics. The purpose of pre-surgical orthodontics was to obtain sufficient space between the roots of the teeth in the intended osteotomy site. Post-surgical orthodontics was done to align and level the arch using the distracted bone also as part of the alveolar arch.

Pre-surgical records such as radiographs and study model and photographs were obtained and stored. Post-surgical records were obtained six months and one year after completion of distraction. These were then assessed by two orthodontists independently to ascertain the extent of distraction and the skeletal and dental stability of the anterior segment of the maxilla following the procedure.

ii. **To assess the effect of the segmental distraction procedure on the patients' pre-operative speech:-**

Speech can be affected in many individuals with surgically repaired cleft lip and palate. Very little is known about the effect of segmental distraction surgery on speech and velo-pharyngeal defect in cleft individuals. Pre-surgical speech assessment was done in 3 patients and analyzed by speech pathologists. Speech was again evaluated using identical methods three months after completion of distraction and removal of the hyrax appliance. Speech assessment was again done by speech pathologists and compared to the pre-surgical evaluation.

iii. **Histology of distracted tissue :-**

Distraction of scar tissue has not been described before. It was decided to biopsy the distracted soft tissue in the surgical site. This was done as part of the procedure to dentally rehabilitate the edentulous distracted maxilla by using implants. The soft tissue was taken out as a punch biopsy which was prepared to take an implant fixture was also taken out as a core sample and assessed under H & E stain. This was to determine the nature of tissue formation in a scar area which was distracted.

B. Pre-operative preparation

Separators were placed between the 1st molars and 2nd premolars, 2-3 days before surgery. The next day patient was recalled for molar banding and banding of 1 or 2 teeth anterior to the distraction site. Upper impression with Rubber base material was taken with molar bands and they were transferred to the impression and cast was poured and the AMD appliance was fabricated.

C. Surgical method:

- All the surgical procedures were done under general anesthesia with naso-tracheal intubation.

- After surgically preparing and draping the patient, a throat pack was placed.
- The distraction appliance was tried on to check for accuracy of fit.
- 2% lignocaine with 1:200000 adrenaline was infiltrated along the buccal vestibule of the anterior maxilla and palate.
- A horizontal circum vestibular incision was made in the unattached alveolar mucosa about 5 mms apical to the teeth apices extending from the first maxillary molar region to the opposite side first maxillary molar region to expose the anterior surface of the maxilla and the piriform aperture.
- Mucoperiosteal flap was raised with a Howarth's periosteal elevator or molts no 9. The nasal mucoperiosteum was elevated of the bony floor and walls with care being taken to detach the septal mucoperichondrium from its attachments to the maxillary crest and anterior nasal spine.
- Crevicular incisions was placed in the maxillary premolars and molar areas bilaterally, this was done on both labial and palatal aspects and a mucoperiosteal flap was elevated along with interdental papilla and tunneled to expose the interdental bone at the osteotomy site.
- A horizontal osteotomy beginning at the piriform fossa 5mms above the maxillary anterior teeth extending till the planned distraction site was done and vertical interdental osteotomy cut extended caudal from the horizontal osteotomy.
- The interdental osteotomy was performed on both the labial and palatal surfaces and extended to meet the horizontal limb in the anterior maxilla. The position of the interdental osteotomy was determined by

the root inclination of the teeth in the vicinity of the osteotomy and the number of teeth in the proximal and distal aspect of the osteotomy which will be used for anchorage of the tooth borne appliance. The interdental osteotomies which was performed using a 701 drill was completed with a thin spatula osteotome.

- The interdental osteotomy was connected to the horizontal limb completing the desired osteotomy.
- The same osteotomy procedure was done in the opposite side.
- The septal attachments to the maxillary crest was removed with a guarded septal chisel.
- The lateral nasal wall was osteotomised with a guarded lateral nasal chisel.
- Care was taken to ensure that the osteotomy was completed on the palatal alveolar and the palatal vault which may prevent complete mobilization and the segment from distracting forward. A finger was placed in the palatal vault while the osteotomy is being done with a osteotome to give us a tactile feedback on the depth and direction of the osteotome. This ensured the completion of the osteotomy without injuring the greater palatine artery pedicle for the viability of the osteotomised segment. The same osteotomy procedure was done on the opposite side.
- The anterior maxilla was down fractured with finger pressure and ensured that the segment was completely mobilized and free to finger pressure. The wound was closed with 3-0 vicryl.

- The AMD appliance was fixed in the upper arch and a band pusher was used to achieve anatomically snug fit. The distractor was trial activated to confirm the completion of osteotomy and demonstrate the movement. The device was removed, cleaned and dried. The upper arch was isolated with gauze pack and dental air syringe. The AMD appliance was cemented with zinc phosphate cement due to the better tolerance to moisture.
- A single suture placed at the interdental site to ensure good approximation of the interdental papilla. The patient was given IV antibiotics and analgesics on the first post-operative day and was continued on oral antibiotics for a period of five days.

D. **Post-Operative procedures**

Orthopantomograph and Lateral cephalometric x-ray were taken on 1st post-operative day. The latency period was for five days and activation was started on sixth post-operative day and was continued till the desired result was achieved.

During the activation period the AMD appliance was activated at a rate of 1mm and rhythm of 2 (twice daily). The AMD appliance was sealed with light cure composite at the end of the activation period. A consolidation period of six months was maintained

OBSERVATIONS

I. Skeletal and Dental Changes of Anterior Maxillary

Distraction

Maxillary Retrognathism which is measured as SNA angle was determined pre and post operatively. All the patients had improvement of SNA which showed that the maxillae had moved anteriorly. The range varied from a maximum of 9° to a minimum of 2°.

The skeletal class 3 pattern improved (ANB angle) for all patients and this varied from a maximum of 10° in one patient to a minimum of 2°. All other patients had values close to 7°.

The anterior movement of the anterior nasal spine (HP-ANS) was seen to occur in all patients. This again ranged from a maximum of 7 mms to a minimum of 2 mms. The posterior movement of the posterior nasal spine was also observed. This could be explained by either the loss of anchorage in the posterior teeth or by the presence of severe scarring of the palatal tissues due to previous surgery. This movement ranged from the maximum of 3 mms in 3 patients, 2mms in 3 patients and 1 mm in 2 patients.

The upper central incisors showed proclination following distraction of the anterior segment. This varied from 6° to 17°. Most of these patients did not have prior fixed orthodontics. In severe proclination, the appliance also dislodged in the final stages of distraction.

The maxillary incisors showed superior movement ranging from 2 to 4 mms.

The maxillary molars also moved superiorly but the movement was lesser ranging from 1 mm upto the maximum of 3 mms.

The naso-labial soft tissue angle decreased in all patients. The variation is from 5° to a maximum of 19°. The decrease in naso- labial angle was accompanied by increased fullness in the lower paranasal areas imparting projection in the under developed cleft maxillae.

The upper lip length increased in all patients. This was probably due to the thinning of the lip with the anterior movement of the upper anterior teeth and alveolus. This ranged from 1 mm to a maximum of 3 mms.

Superior movement of point A: This closely follows movement of the anterior nasal spine. In six of these patients. the movement of point A superiorly matched that of anterior nasal spine. For two patients there was a discrepancy of 1 mm.

Lower facial height: This was measured from the anterior nasal spine of the menton. This increased in all patients with one patient showing the increase of 10 mms. Most of the increase in facial height ranged between 4mms & 7 mms.

II) Histological changes :-

Post distraction, most of the patients were started on fixed orthodontics to align the crowded maxillary teeth. Some patient who had had previous extraction were left with an edentulous space. We planned to rehabilitate such patients with dental implants and a fixed prosthesis as a two stage procedure. The first stage involved preparation of the Titanium Implant fixture site. During this period the overlying soft tissues was removed with a

tissue punch for a flapless technique of implant placement. This tissue was sent for histology examination.

This area represented the area of new tissue regeneration caused by the activation of the distraction appliance. This area corresponded to the area of the osteotomy cuts and hence the bone regenerate or soft tissue regenerate in this region had to be necessarily only tissue developed by distraction.

The soft tissue histology section showed strands of stratified squamous surface epithelium in association with dense fibrous connective tissue exhibiting capillaries and fibroblasts. Few chronic inflammatory cells were also seen.

Some of these patients had heavily scarred palates due to prior surgery. In spite of heavy scarring, the palatal soft tissue and gingival tissue showed significant distraction.

III. Speech in relation to Anterior Maxillary Distraction :-

Velo-Pharyngeal dysfunction and speech defects are recognized in operated cleft lip and palate patients.

The pre and post surgery speech of 03 patients who had undergone anterior maxillary distraction were collected. The recording protocol adopted was uniform for all the subjects. All the speech samples were recorded by a speech language pathologist in a sound treated room using a voice recorder. The participants were instructed to perform the speech tasks including repetition of words, sentences, number counting (from 1-10) and 60-70, in English) and general conversation. The sentence repetition task included repetition of ten phonetically loaded sentences in Tamil language.

The speech samples collected were perceptually rated independently by three speech language pathologists for articulation, resonance, speech understandability and speech acceptability. All the listeners had a minimum of three years experience in the assessment of speech in individuals with cleft lip and palate. The ratings were carried out based on the universal parameters for reporting speech outcomes in individuals with cleft palate. The listeners were blindfolded regarding details of the subjects to eliminate factors biasing the analysis. All the speech samples were randomized before presenting to the listeners. The speech samples were presented to all the 3 listeners at the same point of time.

The analysis of speech samples rated by 3 listeners was compared. It was observed that in all the three patients there was no difference in the rating of any parameter of speech pre and post surgery. The small sample size of the subjects in this study makes it difficult to draw any conclusions in reporting the outcomes of this particular procedure.

No deterioration of speech in any patient.

INFERENCE

DISCUSSION

Superior movement of anterior nasal spine of the patients had a vector in a forward and cephalic direction thereby increasing the existing open bite or reducing the existing overbite. This movement varies between 5 mm and 2 mm. The reason for this could be the rigidity of the hyrax appliance. Since the anterior maxilla is completely sectioned from all its bony attachments and also from the cartilaginous nasal septum, there was no counter acting or restricting force for the vertical movement of the anterior segment.

1) **Skeletal and Dental changes in anterior maxillary distraction using Hyrax appliance** .:-

Skeletal hypoplasia especially in the antero posterior plane is common in cleft lip and palate patients who have had surgery earlier. This hypoplasia can be corrected by one of the following techniques.

- a) Maxillary Osteotomy and advancement surgery.
- b) Maxillary distraction (Full jaw with Le Fort Osteotomy and using external or internal distractors.
- c) Anterior segmental distraction (Osteotomy in one or two stages and then using extra oral or intra oral distractors).

Most of the distraction was done by bone borne distractors. The use of a hyrax appliance as a tooth borne distractor has only been described recently but not much data has been reported. Our patients have all had anterior maxillary osteotomies followed by a latency period and distraction using the hyrax tooth borne distraction device. The anterior maxillary segment including anterior floor of the nose and the teeth in the anterior segment were all moved over several mms anteriorly by distraction. The anterior maxillary skeletal base moved forward with anterior

nasal spine with point A moving forward as much as 7 mms. There was anchorage loss with certain amount of posterior movement of the posterior nasal spine and also the first molars. The effective increase in the palatal length was as high as 9 mms in one patient with an average increase of 6.5mm length. The skeletal movement was accompanied by forward positioning of the upper lip and also increased fullness of the para-nasal area. The reduction of naso-labial angle further enhanced facial aesthetics. This movement has been stable for more than 6 months follow-up in all the patients. Distraction of palatal soft tissue and alveolar soft tissue and buccal mucosal soft tissue were all documented.

Good volume of bone regenerate was noticed in the entire alveolar region with a slight concave pattern) near the maxillary sinus floor region (reminiscent of the hour glass appearance of bone regenerate).

Tooth borne distraction has several advantages compared to bone anchored distractors. Those include:

- a) Ease of application
- b) Less morbidity such as cheek & lip ulcers seen with bone anchored appliances.
- c) Removal of appliance at the end of consolidation period is very simple and can be done without anesthesia
- d) Economical
- e) Less chances of infection since there are no fixation screws.

The procedure however does have a few disadvantages such as follows:

- a) Vector control unidirectional only
- b) Need for more diligent oral hygiene maintenance
- c) Activation at home being difficult

The ease of anchoring the appliance and the ease of adaptation to the appliance by the patient especially during the consolidation phase is significant.

Stability of the procedure is also a great advantage. Distraction in cleft lip and palate has always had a certain degree of surgical relapse within the first 1 year. This relapse can be as high as 50% of the movement achieved. Maximum relapse happens within the first six months of surgery. In Thongdee's study, total relapse of surgical movement was 31% in the horizontal plane and 52% in vertical plane as well as 30% in rotational.

In our series of patients relapse has been shown to be minimal. The follow-up period has ranged from 12 months to 36 months. The stability of the procedure is hence a great advantage in this technique.

The bone regenerate in the alveolar region is used to either decrowd the maxillary teeth with fixed orthodontics or used to anchor Titanium implants to support a fixed dental prosthesis. The consolidation period is atleast 3 months during which bone maturation occurs.

The paranasal fullness is contributed by the advancement of the piriform rim.

The procedure is not without **complications**. These include:

- i) Root Damage
- ii) Anterior Open Bite
- iii) Bur breakage
- iv) Appliance Fracture
- v) Appliance dislodgement

Histology of Distracted tissue:

Distraction is a well-known phenomenon to expand bone. Invariably, soft tissue, vascular channels and nerves also can be distracted without loss of

integrity and function. This distraction histogenesis can also extend to scar tissue as evidenced by distraction of the palatal scar tissue in these patients. Histology in the distraction site revealed connective tissue interspersed with fibroblast and new vascular channels. The bone quality was normal and in one instance could also take the load of an osseointegrated dental implant with a ceramic crown. The gingival epithelium also showed evidence of new tissue formation with histology similar to that of a normal gingiva.

3. Speech before and after anterior maxillary distraction:

Speech can be affected and Velo-pharyngeal deficiency is commonly seen in operated cleft lip and palate patients. When such patients have border line VPD, the possibility of them getting worse with a full maxillary i.e. Le Fort 1 maxillary distraction (which essentially mobilizes the maxilla anteriorly) is very high. When distraction is done as a segmental procedure we have shown that there is no deterioration in speech.

Furthermore, loss of anchorage moves the posterior nasal spine and the posterior maxillary teeth further towards the oro-pharynx. One patient was assessed as having speech improvement. This is an important advantage of anterior maxillary distraction. However, the entire VPD has not been studied and could be the basis of future work.

4. Stability of Skeletal Movement :

Increase in the palatal length ANS to PNS was monitored from the completion of consolidation period for a further minimum period of 6 months. The relapse varied between 0.5 to 1 mm absolute value with the % relapse

varying from 10% to 25%. Literature shows that most of the skeletal relapse happens in the first six months period.⁵⁵ The anterior movement of the nasal spine again relapsed between 1 & 3 mms, the percentage change being between 21 & 33%. This shows that there is a certain degree of skeletal relapse and we need to build in some over correction in such distraction techniques. The posterior movement of the posterior nasal spine showed an average 30% relapse. (Range from 0% to 66%).

The superior movement of the anterior nasal spine showed a correction relapse between 25% and 50%. The other important change which is the superior movement of point A relapsed again between 25% and 50%. This can however, be controlled by some form of callus moulding technique one week after completion of distraction. The proclination of upper incisor reduced between 23% and 44%. This can also be altered to a more stable position by use of post distraction orthodontics. The soft tissue stability in terms of nasolabial angle also showed change in the immediate post consolidation period. The decrease in nasolabial angle relapsed about 30%, 6 months after consolidation. The detailed values of the relapse and the percentages are in the table given. (Appendix III).

The upper lip length showed a mild increase between 1 mm & 3.5 mms. This however, relapsed between 0 to 33%.

Stability of the segment which has been distracted adds to a long term success of the procedure in the form of function of aesthetics.

SUMMARY AND CONCLUSION

Summary & Conclusion

This innovative technique of distraction of a scarred operated cleft lip and palate by means of segmental distraction has shown to be more stable than the classical methods of Le-Forte 1 distraction.

The technique has no deleterious effects on speech when analyzed by speech language pathologists. This is a significant factor while considering surgical options in patients with pre-existing speech disorder or VPD.

Histology shows that there is a real increase in soft tissue mass and that distraction is possible even in scar tissue.

The distracted regenerate bone was of adequate volume and quality to be able to have orthodontic realignment or support an osseo-integrated implant.

The complications seen were minor and easily rectifiable.

Patient adaptation and acceptance was good. However, patient's attenders have to be alert enough to activate the appliance correctly and note any complication early enough.