DISTRACTION OSTEOGENESIS VERSUS CONVENTIONAL ORTHOGNATHIC SURGERY FOR CLEFT LIP AND PALATE MANAGEMENT: A CRITICAL REVIEW

Rais Ahmed\textsuperscript{1}, Satinder Pal Singh\textsuperscript{2}, Vinay Kumar\textsuperscript{3}
\textsuperscript{1}.Post Graduate, Department of Orthodontics, PGIMER, Chandigarh
\textsuperscript{2,3}.Professor, Department of Orthodontics, PGIMER, Chandigarh

ABSTRACT:
In this study the literature dealing with various aspects of two different surgical treatment modalities i.e. distraction osteogenesis and conventional orthognathic surgery were reviewed. The keywords used were distraction osteogenesis; conventional orthognathic surgery; cleft lip and palate; velopharyngeal insufficiency; speech; stability; relapse; complications; quality of life. Apart from these other literature was hand searched. This search revealed a total of 112 articles which included 17 reviews of literature, 4 systematic reviews, 5 randomized controlled trials (RCTs) and 2 meta-analyses. All the literature included in this review was thoroughly reviewed. This review revealed that maxillary distraction in moderate or severe cases of maxillary retrusion offer long-term stability of hard and soft tissues as compared to conventional orthognathic surgery. Cleft lip–cleft palate patients, with severe maxillary deficiency who underwent distraction, had less relapse than those who underwent conventional Le Fort I osteotomy. For mild to moderate cases none of the two procedures i.e. distraction osteogenesis and conventional orthognathic surgery were found to be superior to each other. This literature review has tried to answer a few critical questions regarding all the pros and cons of these two procedures and their future outcomes.

Keywords: distraction osteogenesis; conventional orthognathic surgery; cleft lip and palate; velopharyngeal insufficiency; speech; stability; relapse; complications; quality of life

INTRODUCTION:
When there is disproportionate growth of maxilla, mandible or other midfacial skeletal structures then nature tries to align the dento-alveolar structures so as to be in harmony with the altered skeletal bases. They are then said to be in compensation. So to correct the skeletal disharmony, dental decompensation is done by multibracketed fixed orthodontic therapy and then surgical intervention is planned. Two broad surgical options available in literature are- conventional orthognathic surgery and distraction osteogenesis to correct the skeletal dysplasia in all the three planes of space in both maxilla and mandible.

DO is defined as the creation of neoformed bone and adjacent soft tissue after the gradual and controlled displacement of a bone fragment obtained by surgical osteotomy. Some tissues besides bone have been observed to form under tension stress,
including mucosa, skin, muscle, tendon, cartilage, blood vessels, and peripheral nerves \cite{1,2}. Orthognathic Surgery is the art and science of diagnosis, treatment planning and execution of treatment by combining orthodontics and oral and maxillo-facial surgery to correct the musculo-skeletal, dento-osseous and soft tissue deformity of the jaws and associated structures.

In literature, various treatment options available to implement on any case are based upon Ackerman-Proffit system of Classification of malocclusion \cite{3,4}. Too severe malocclusion which cannot be treated by orthodontics alone becomes an indication for either orthodontic tooth movement combined with growth modification or skeletal anchorage assisted orthodontic tooth movement. but if the growth is complete then finally surgical movement of jaw bases is required to correct the severe skeletal dysplasia. One drawback of this envelop of discrepancy is that the soft tissue limitations are not considered. In this 21st century the paradigm has shifted from occlusion to facial aesthetics as the prime concern. So soft tissues need to be considered as a major factor in the decision for orthodontic or surgical-orthodontic treatment planning\cite{5,6}. There have been dramatic improvements in patient profile by conventional orthognathic surgery for the past 30 years \cite{7}. By conventional orthognathic surgery, occlusion and esthetics are improved instantly but questions arise as to whether it will be stable in long term and whether the soft tissue drape adapts easily to newly arranged bony structures etc. Single stage orthognathic surgery was the conventional plan earlier but with the development of distraction osteogenesis in 1990s an alternative approach to correct the skeletal mismatch came into existence \cite{8}.

This article aims to provide an insight into the comprehensive review for conventional orthognathic surgery and distraction osteogenesis for the management of skeletal dysplasia. Major issues viz. long term stability, potential complications, adverse side effects, impact on quality of life, advantages and disadvantages and patients satisfaction have been reviewed critically for both the treatment modalities.

This critical review for the management of cleft lip and palate concentrates on studies that report various aspects of two broad surgical treatment modalities i.e. distraction osteogenesis and conventional orthognathic surgery, for the correction of severe skeletal dysplasia. In this regard, apart from other literature work, 17 reviews of literature, 3 systematic reviews, 5 randomized controlled trials (RCTs) and 2 meta-analyses have been thoroughly reviewed and a collective piece of knowledge is presented here.

The present review of literature will try to cover all aspects of this debate between conventional orthognathic surgery and distraction osteogenesis,
while trying to answer a few critical questions as follows:

**WHICH TREATMENT MODALITY HAS MORE STABLE RESULTS?**

The term "stability" covers a broader spectrum than the term "relapse" as former means deviation from the intended position while later means only a return towards the original position [9]. Relapse is simply a postoperative movement either toward the preoperative position or farther away from it. Mean relapse for a particular study and procedure may be 0, but there may still be significant relapse in both directions for individual patients such that the overall mean relapse of 0 may be non-significant. A meta-analysis of all the literature using rigid internal fixation (RIF) correctly represents the actual amount of relapse. Relapse is usually three dimensional with vertical, horizontal and sagittal components that may occur concurrently [10].

So even if the mean relapse is zero, significant instability i.e. movement may be present [9,10]. Relapse following conventional orthognathic surgery is more as compared to distraction osteogenesis [11]. A review by Austin et al. (2015) reported a weak evidence that there was improved horizontal stability for internal maxillary distraction [12].

Literature has reported a relapse rate of 5-80%, in patients with cleft palate having severe maxillary hypoplasia, when treated with conventional Le-Fort I osteotomy [13,14,15,16]. Rachmiel et al. (1995) found a 7% relapse after one year in a sheep after 40 mm maxillary distraction [17]. Based on all available literature, Swennen et al. (2002) and Rachmiel A (2007) separately conducted an extensive review of literature and concluded that distraction osteogenesis is a better option in cases with great tendency of relapse, like cleft cases [18,19]. Mature lamellar bone is generated in the distraction site between the 2 bony segments which is responsible for reduced relapse rate. Formation of mature lamellar bone is seen histologically after distraction osteogenesis [20,21]. Bone graft is not needed in distraction osteogenesis, thus reducing local infection and resorption. Simultaneous regeneration of new bone occurs at the distal side and in the pterygoid region thus preventing relapse. Several long term follow up studies of maxillary distraction cases have shown stable results [22,23,24,25].

Figueroa et al. (2004) in a prospective 3 year follow up study of 17 patient with cleft maxillary hypoplasia who were treated with maxillary distraction by Rigid External Distraction (RED) concluded that maxilla was stable in sagittal plane [23]. Harada et al. (2005) concluded that in cleft lip and palate patients the growth of mandible should be restricted to reduce the resultant overall relapse after maxillary distraction [24] Randomized control trial
was conducted by Ow et al. (2010) on lateral cephalogram with the aim to compare the skeletal stability of bilateral sagittal split osteotomy and mandibular distraction osteogenesis and concluded that there was no statistically significant difference between the two. Although mandibular distraction osteogenesis group reported less relapse at 1 yr follow up in case of 6-10 mm advancement range [26].

Saltaji et al. (2012) conducted a systematic review of 10 studies comparing the stability of maxillary distraction osteogenesis with conventional orthognathic surgery and concluded that maxillary advancement by conventional LF-I osteotomy in cleft lip and palate patient show a moderate relapse in horizontal and a high relapse in vertical plan [27].

Chua et al. (2010) did a serial cephalometric study to access the stability of distraction osteogenesis and conventional orthognathic surgery in cleft lip and palate patients requiring maxillary advancement of 4 to 10 mm and concluded that distraction osteogenesis is more stable in forward and downward position [11].

Conventional orthognathic surgery has been popular for more than 25 years, although relapse has been a big problem for both orthodontists and maxillofacial surgeons. Post surgical orthodontics takes care of this relapse most of the time given that the relapse is not severe [9]. Study conducted in University of North Carolina (UNC) showed 20% cases, who underwent maxillary advancement by conventional orthognathic surgery, had relapse movement of 2-4 mm during the 1st post operative year. After long term follow-up of 1-5 years, only 10% of the total cases showed mild relapse of Point-A [28].

Patient compliance with the distraction device is a risk factor responsible for relapse in distraction osteogenesis which is not seen in bilateral sagittal split osteotomy [9].

In larger maxillary advancements, relapse can be prevented by placing a bone graft between the separated segments [29]. Stability is least reliable in cases of mandibular setback, inferior positioning of maxilla, increasing transverse width of maxilla [30].

Bays et al. (2003) carried out a meta-analysis on studies that report complications with the weight of randomized clinical trials or cohort studies. They reported that with 12 month follow-up in maxillary advancement cases by conventional osteotomy, a relapse ranging from a 34% relapse to 9% forward continuous movement with mean relapse of 8% in posterior direction was present. They also reported condylar resorption as a source of relapse [10].

Transoral vertical ramus osteotomy (TOVRO) with and without fixation and bilateral sagittal split osteotomy with rigid fixation have been used for
mandibular setback. Studies indicate that the two procedures manifest relapse in opposite directions. TOVRO has been shown to have a relapse range of 5% to 12%, with a mean relapse of 9% with a continued posterior movement at a mean follow-up of 10 months \[^{10,31}\]. Bilateral sagittal split osteotomy setback has been shown to have a relapse range of 10% to 62%, with a mean relapse of 22% in the anterior direction at a mean follow-up of 28 months \[^{10,32,33,34}\].

Serafin et al. (2007) reviewed a wide range of literature and concluded that it was very difficult to judge the stability of mandibular advancement after conventional orthognathic surgery. The reasons are many like fixation problems, slippage of the osteotomy site, errors in condylar positioning, condylar sag, fossa-condylar remodelling and resorption, orthodontic movement and growth \[^{9}\].

Vertical Ramus Osteotomy (VRO) for setback is favored by some over bilateral sagittal split osteotomy because of lower incidence of neurosensory disturbance\[^{9}\]. Bays et al. (2003), through there meta-analysis on mandibular setback by VRO, had reported a mean relapse of 9% whereas Lai et al. (2007) found less than 1% relapse in the mean amount of mandibular setback done by VRO \[^{10,35}\]. Literature is scant on stability after orthognathic surgery because only in severe cases and syndromic cases require osteotomy at Le-Fort III level which is a rare condition \[^{9,36,37}\].

Distraction osteogenesis produces more stability than conventional orthognathic surgery for maxillary advancement in cleft lip and palate cases \[^{9}\]. Cheung et al. (2006) had conducted randomized controlled trial on 29 cleft lip and palate cases by randomly allocating them to either distraction osteogenesis or conventional orthognathic surgery group of treatment modality. They showed statistically significant level of vertical relapse at A point in conventional orthognathic surgery group \[^{38}\]. Similarly, Figueroa et al. (2004) did a long term cephalometric study in 17 patients to review the relapse tendency of maxillary advancement by distraction osteogenesis. They reported that 2 years post distraction, a 10.2° increase achieved in the SNA angle after distraction, was decreased by 2.4° (23.5%). Also the 9.5-mm postoperative increase in the length of the maxilla measured to the A' point increased significantly by 1.9 mm (20%). They found no change in length of the maxilla measured to the anterior nasal spine point. There was significant increase in vertical position of the anterior maxilla by 2.6 mm (50% of the initial 5.2-mm increase seen after surgery) \[^{23}\].

Baumann et al. (2003), after a retrospective longitudinal study of 15 patients for 2 years, reported that there was an additional advancement of point A of an average of 0.7 mm in 11 patients but a relapse of 0.9 mm in
rest of 4 patients. They also reported a relapse of 0.8 mm in mandible after an average setback of 3.9 mm during the same period. Vertical elongation at point A resulted in relapse in both groups and impaction of the maxilla led to further impaction as well [39]. Figueroa et al. (2004) and Baumann et al. (2003) together concluded that distraction osteogenesis was highly stable as compared to conventional orthognathic surgery [23,39].

In case of mandibular distraction, results are much more stable in adult patients as compared to children because of the inherent uncertainty of growth status of later. There remains a dilemma as to what skeletal relationship and dental occlusion would be achieved in the end [9,40]. Based on their study, Louis et al. (1993) have concluded that the relapse rate of orthognathic surgery becomes higher as the amount of maxillary advancement increases [41,42].

Major limiting factor for the amount of maxillary advancement in such patients is the palatal and pharyngeal scarring [9]. Maximum of maxillary advancement that can be achieved by conventional orthognathic surgery techniques is about 10 mm in repaired cleft lip and palate patients [32,41]. While some others suggest that due to scar contracture, the maximum advancement by conventional orthognathic surgery in patients with cleft lip and palate is only 5 mm [32,43]. Several studies [44,45,46] have reported that overcorrection during distraction osteogenesis is needed, especially for the growing children. Gursoy et al. (2010) performed maxillary distraction in 13 prepubertal children having cleft lip and palate along with mid-face deficiency and they overcorrected ANB to 13° and overjet to 13.7 mm with significantly decreased overbite. After 5 year follow-up their overjet decreased and overbite normalized so as to remain in Class I relationship [44]. Similarly, Krimmel et al. (2005) retrospectively conducted a study of 17 patients who had undergone maxillary distraction osteogenesis. Based on cephalometric measurements at follow-up period of 1 to 5 years, they concluded that growth of cranio-facial skeleton must be considered when distraction osteogenesis is chosen for the advancement of the maxilla in adolescents [45]. Baek et al. (2007) after comparing the treatment outcome and relapse between maxillary advancement surgery with Le Fort I osteotomy and maxillary distraction osteogenesis in patients with cleft lip and palate with maxillary hypoplasia, concluded that there were no significant differences in the amounts of relapse between the two groups despite the fact that amounts of forward movements of A point, upper incisor and upper lip were greater in the distraction group.
Singh et al. (2012) evaluated the long term stability of skeletal changes following maxillary distraction in adult cleft lip and palate patients with maxillary hypoplasia and concluded that maxilla showed a relapse of 30% 6 month post distraction [22]. Almost similar results were earlier reported by Cho and Kyung (2006) who suggested that an overcorrection of 20% to 30% was needed to minimize relapse [47]. Some researchers could not reach any conclusion regarding any difference in surgical relapse [48].

WHICH TREATMENT MODALITY HAS MORE COMPLICATIONS FOLLOWING SURGICAL INTERVENTION?

Sriram et al. (2014) evaluated change in the magnitude of posterior airway space (PAS), after the mandibular setback and distraction osteogenesis of maxilla/mandible and concluded that the surgical procedures have significant effect on airway and resultant effects were more in case of mandibular movements as compared to maxillary movements [49].

Lanigan et al. (1991) reported that among the rare complication of orthognathic surgery are false aneurysms and arteriovenous fistulas which most commonly involves internal maxillary artery. Most commonly used method to treat these two methods is embolization [50]. Traditional ischemic complications associated with conventional orthognathic surgery are not present in distraction osteogenesis cases but some oral mucosal infections might occur [48].

Many studies support the view that most of conventional orthognathic surgery are safe [51,52,53,54]. Chow et al. (2007) reviewed 1294 patients undergoing conventional orthognathic surgery and reported no serious or rare event [52]. Panula et al. (2001) reviewed 665 patients who underwent conventional orthognathic surgery and only one serious complication i.e. intra-operative bleeding was reported [53]. Ayub et al. (2001) studied 821 patients undergoing conventional orthognathic surgery and out of that only 12 cases had early post operative complications which required surgical intervention [55].

Neurologic complication is well established following conventional orthognathic surgery and the effect on Inferior Alveolar Nerve is common after mandibular surgeries [10,56,57]. Seventh cranial nerve palsy was reported in 9 out of 1747 patients who underwent bilateral sagittal split osteotomy and about 95% of the osteotomies were setback thus pointing towards the more risk associated with setback rather than advancement [58]. Other studies also reported the same findings [58,59]. Choi et al. (2010) reported facial nerve palsy in 6 out of 3105 patients who were operated with bilateral sagittal split osteotomy [60]. Their review concluded that recovery is affected in most cases. Other neurologic complications reported
were Frey’s syndrome [61], bilateral hypoaesthesia in dermatome of mylohyoid nerve [62], traumatic neuroma of inferior alveolar nerve [63] and stroke [64] etc.

Ophthalmic complications may occur viz. lack of tears [65], damage to greater petrosal or vidian nerve, nasolacrimal duct damage and palsy of abducent [66] or oculomotor nerve. Blindness after LF1 osteotomy is also reported [67].

Baker et al.(1991) reported brain abscess case who had undergone LF-I osteotomy [68]. A meta analysis by Bays et al.(2003) concluded that Infection can occur following either a perioperative or a combined perioperative and postoperative antibiotic course with an overall reported incidence being between 0% and 18%. While rates of infection between 0% and 53% have been reported without antibiotics [10]. An indirect complication of conventional orthognathic surgery is iliac abscess which occurs after iliac graft is harvested [69].

Till date literature lacks the evidence that supports the occurrence of osteonecrosis of maxilla following orthognathic surgery [51]. Lanigan and West (1990) have reported two cases in which post operative aseptic necrosis of mandible occurred [70]. Dislocation of condyle is also reported [71]. Condylar resorption to varying degrees is reported in literature as an uncommon but established complication following conventional orthognathic surgery. Borstlap et al.(2004) reported a 4% resorption of condyle following bilateral sagittal split osteotomy and stabilization with two minipates. They further said that low age patients (≤ 14 years) were at risk for the occurrence of condylar alterations including resorption. Pain and TMJ sounds in the first few months postoperatively are highly suspicious risk factors for condylar changes to occur in the next months [72]. Scheerlinck et al.(1994) studied 103 mandibular retrusion patients for skeletal stability, TMJ function and inferior alveolar nerve function who underwent bilateral sagittal split osteotomy. They reported no appreciable relapse at B-point in 93 out of 103 patients and rest of the 8 patients had relapsed due to condylar resorption. Of the total, 68% of the patients with preoperative TMJ-dysfunction symptoms reported improvement or resolution of their symptoms while 16% of them experienced worsening of their TMJ symptoms [73].

Bhaskaran et al.(2010) reported a case of cerebrospinal fluid leakage from the floor of the left middle cranial fossa at the site of attachment of the pterygoid plates on the third post operative day following 4 mm anterior and 5 mm posterior maxillary impaction. The CSF leak ceased after 16 days by neurosurgical intervention with lumbar drain [74]. Other complications like lateral nasal mucosa perforation by fixation screws
leading to post operative nasal congestion and pain \[75\], formation of oroantral and oronasal fistula \[76\] and dislodgment of bracket into airway etc. have been reported in literature \[77\]. Damage to neurovascular structures through the forces transmitted during pterygo-maxillary disjunction by using osteotome, or during maxillary down fracture has also been reported \[81\].

WHICH SURGICAL MODALITY HAS MORE POTENTIAL SIDE AFFECT: DISTRACTION OSTEOGENESIS OR CONVENTIONAL ORTHOGNATHIC SURGERY?

Steel et al. (2012) reviewed the then available literature and claimed that conventional orthognathic surgery was safe, yet risk existed \[81\]. One of the relatively frequently related side effects of conventional orthognathic surgery is dental malocclusion \[78\]. Other adverse effects like post-operative edema and mild pain for a few weeks are unavoidable signs and symptoms associated with either distraction osteogenesis or conventional orthognathic surgery.

DOES DISTRACTION OSTEOGENESIS HAVE A PROFOUNDER IMPACT ON IMPROVING QUALITY OF LIFE AT THE EARLIEST?

In the early phases, distraction osteogenesis reduces the social self esteem and confidence of patients. But in the long run it results in better life satisfaction as compared to conventional orthognathic surgery \[79\]. Conventional LF-I osteotomy can be done only when growth completes but this is not the limitation with distraction osteogenesis thus leading to early improvement of psychosocial stigma of the patients \[19,48\].

Usually conventional orthognathic surgery leads to dramatic improvement in self esteem of patient but it has been reported to sometimes have a detrimental impact like conversion disorder and depression, especially when inter-maxillary fixation (IMF) is used \[80,81,82\]. “Four-day blues” is a well recognized and common phenomenon associated with conventional orthognathic surgery post-operatively \[83\]. Satisfaction With Life Score (SWLS) was significantly greater in distraction osteogenesis group in comparison to conventional orthognathic surgery. Distraction osteogenesis treatment initially lowers the psychosocial confidence of patients, but in the long run, it produces more satisfaction as compared with conventional orthognathic surgery. This can be attributed to the better stability of the distraction osteogenesis treatment as well as the self-perceived contribution of the patients to the success of their treatment \[79\].

Retrospective pilot study by Andersen et al.(2012) aimed to evaluate and compare the patient satisfaction following maxillary distraction osteogenesis and conventional orthognathic surgery in 25 cleft lip and palate patients. They found that at follow-up both groups of patients were
satisfied with functional parameters and aesthetics. Those who underwent distraction osteogenesis were less satisfied due to increased duration of treatment [84].

DISTRACTION OSTEOGENESIS OR CONVENTIONAL ORTHOGNATHIC SURGERY: WHICH HAS BETTER ESTHETIC OUTCOME?

Jena et al. (2011) reported a significant improvement in soft tissue profile, total soft tissue profile and nasolabial angle after immediate, 6-months and 2-years follow-up of maxillary distraction. According to them, forward movement of the nasal tip and nasal base were increased significantly and the length and thickness of the upper lip was improved after various time intervals of maxillary distraction osteogenesis. They further reported that 75% of the changes had remained stable at the end of 2-years of follow-up [85].

A randomized control trial by Chua and Cheung (2012) reported some aesthetic differences between distraction osteogenesis and conventional orthognathic surgery [86]. Distraction osteogenesis produces hard and soft tissue ratios that are more consistent and the amount of changes produced are more with distraction osteogenesis [86]. Also since the nose is severely retroclined in most of the cleft lip and palate patients [87,88] hence distraction osteogenesis is more favorable for this aspect of deformity as there is better improvement as compared to maxillary advancement by osteotomy because nasal movement in distraction osteogenesis cases occur at the rate of 1:2 while it occurs in the ratio of 1:389 in Le Fort I osteotomy cases. Thus the soft tissue profile is better improved in terms of improved nasolabial angle and more prominent upper lip [25,90].

DISTRACTION OSTEOGENESIS OR CONVENTIONAL ORTHOGNATHIC SURGERY: WHICH HAS BETTER IMPACT ON SPEECH?

Some studies agree that there is a potential of velo-pharyngeal incompetence following maxillary advancement but no difference in rate of occurrence with respect to distraction osteogenesis and conventional orthognathic surgery could be found [12,91]. Distraction osteogenesis has no extra advantage over conventional orthognathic surgery in preventing velopharyngeal incompetence and speech disturbance in cases of cleft maxillary advancement[91]. Some researchers could not reach any conclusion regarding any difference in velopharyngeal function and speech between the two procedures [48].

Ko et al. (1999) evaluated the static velopharyngeal anatomic changes on lateral cephalograms in patients who underwent maxillary advancement through distraction osteogenesis with a rigid external distraction device and correlated the changes with clinical speech data. Speech evaluation was
performed preoperatively, immediate post-distraction and then at 6-month intervals and included assessment of air pressure flow, hypernasality and articulation. For an average amount of 8.9 mm maxillary forward advancement, 14% of patients (3 of 21) showed deterioration in hypernasality while 57% of patients (12 of 21) showed improvement in articulation. The cephalometric analysis demonstrated an increase in nasopharyngeal depth by 8.5 mm (1:1 ratio with bony movement) and velar angle by 14.1°. Hypernasality deteriorated especially in patients without a preexisting pharyngeal flap (PF). Thus, they concluded that increase in nasopharyngeal depth might compromise VP closure. The increase in velar angle was considered to be part of the compensation in the VP mechanism. There was no adverse effect of a preexisting PF on maxillary distraction but it did prevent postoperative hypernasality [92].

Guyette et al.(2001) performed a descriptive, post hoc clinical report comparing the performance of patients before and after maxillary distraction to describe changes in articulation and velopharyngeal function following maxillary distraction osteogenesis. After evaluating 18 patients for 1 year they found that 16.7% exhibited a significant increase in hypernasality whereas 75% of patients with preoperative hyponasality experienced improved nasal resonance. They concluded that "In a predominately cleft palate population, the risk for velopharyngeal insufficiency following maxillary distraction is similar to the risk observed in Le Fort I maxillary advancement" [93]. While others advocate that maxillary advancement by conventional orthognathic surgery leads to quick correction of dental articulation but at the same time it compromises velopharyngeal closure due to increase in nasopharyngeal distance [94,95,96]. Such a complication has not been reported with distraction osteogenesis [97]. Kumar et al.(2006) concluded that the cleft lip–cleft palate patients, with severe maxillary deficiency, who underwent distraction, had 48% less relapse than those who underwent conventional Le Fort I osteotomy [98].

Chanchareonsook et al.(2006) critically reviewed 39 published articles regarding the effect of cranio-maxillofacial osteotomies and distraction osteogenesis on speech and velopharyngeal status. It consisted of a sample of 747 cases of cleft and non-cleft patients. They reported much variation in results like many studies found that surgery had no impact on speech and velopharyngeal status while some reported worsening only in patients with preexisting velopharyngeal impairment or those with borderline velopharyngeal function before surgery. They finally concluded that the difference in outcome between distraction and conventional osteotomy was not clear and randomized controlled trials with
adequate number of subjects and follow-up duration were needed \[99\]. Chanchareonsook et al. (2007) further conducted a study, on 22 patients with repaired cleft palate, to compare speech outcome and velopharyngeal status of subjects. Ten of them underwent conventional Le Fort I osteotomy and the rest 12 underwent Le Fort I distraction. They reported no statistical difference in any of the outcome measures \[100\].

WHICH MODALITY IS PREFERRED WITH REGARDS TO TREATMENT DURATION AND CORRECT TREATMENT TIMING?

It is generally observed that the use of distraction osteogenesis to advance the retruded maxilla is more expensive and time consuming than conventional orthognathic surgery \[7\]. Although relapse in LF-I osteotomy is not significant but growth status must be assessed carefully. Growth of anterior maxilla is hindered by LF-I osteotomy but vertical maxillary growth continues \[9,101\]. Distraction can be done at any stage of life: with growth spurt and after cessation of growth. While conventional orthognathic surgery should be done only after cessation of growth to avoid any future complications.

WHICH MODALITY IS BETTER?

Distraction osteogenesis allows progressive adaptation of surrounding soft tissues and palatal scar tissue. Process of neuro-muscular adaptation following conventional orthognathic surgery is acute while it is slow in distraction osteogenesis \[102\]. A meta analysis done by Cheung and Chua (2006) to provide the evidence based choice between distraction osteogenesis and conventional orthognathic surgery in the treatment of a particular type of craniofacial and dentofacial deformity revealed that distraction osteogenesis was more preferred in younger cleft lip and palate cases. In such cases concurrent mandibular osteotomy was less frequently required \[48\].

Maxillary hypoplasia is a common occurrence in cleft lip and palate patients and the usual plan is maxillary advancement \[9\]. Many studies have reported the limitations of distraction osteogenesis \[103,104\]. Precious et al. (2007) have concluded that distraction osteogenesis is simply the lengthening and remodeling of bone by surgical fracture and stepwise separation. Surrounding tissues are simultaneously and unavoidably stretched called as distraction histogenesis. They further said that conventional orthognathic surgery is a more accurate and predictable method as it is associated with accurate method of diagnosis \[7\]. But Figueroa et al. (2004), in contrast, said that the technique of distraction osteogenesis is relatively simple, has minimal morbidity and high predictability \[23\]. Van Strijen et al. (2004) said that distraction osteogenesis in high angle...
cases is unsafe and unpredictable while in low angle cases it is safe and predictable \cite{105}. Maxillary hypoplasia in unilateral cleft lip and palate cases is usually treated by LF-I osteotomy to regain the facial balance and occlusion. But mobilization of maxilla through osteotomy in such cases is different from non-cleft patients due to inherent scarring of tissues because of previous operations \cite{106,107}. Various computer simulation programs like Dolphin Imaging are available which can show the treatment outcome beforehand. Stability of bone which are moved can be assessed. Also vertical maxillary excess case and any maxillo-mandibular setback cases can be done by conventional orthognathic surgery only because there is no applicability of distraction osteogenesis in such cases \cite{7}.

Conventional orthognathic surgery is not just concerned with osteotomy as is distraction osteogenesis. Conventional orthognathic surgery is a combination of one or more of the below given procedures which allow different modification and rearrangement of bone, cartilage, teeth, muscle, mucosa, gingiva and skin \cite{7}. Most of the facial bones are membranous in nature and we also know that muscles are formed first in the course of development of human body. Hence the muscle gives shape to the bones working as the functional matrix. A good example of which is cleft cases, where after surgical correction of soft tissue of cleft, bone growth follows \cite{7}. Both in adult and pediatric patients, muscular surgeries combined with conventional orthognathic surgery produces muscle symmetry and enhances the bone symmetry. Such combination is not reported with distraction osteogenesis \cite{7}. Another advantage of conventional orthognathic surgery in unilateral cleft lip and palate cases is that when a LF-1 osteotomy with muscle (lip) surgery is done then, access is provided to all structures that must be repaired\cite{7}. Conventional orthognathic surgery is safe and predictable. Overall complication rate is only 1.5% with respect to infection, bleeding, central nervous system complication, fixation problems and ocular and ophthalmologic complications \cite{7}. Kramer et al.(2004) found Le fort I to be safe after he studied 1000 patients. He reported complications in 64 patients (6.4%) only. Out of those affected 26 (2.6%) had deviated nasal septum and non-union of the osteotomy gap, 11 (1.1%) patients suffered extensive bleeding, infections such as abscesses or maxillary sinusitis occurred in 11 (1.1%) patients, ischemic complications affected 10 (1.0%) patients and 5 (0.5%) patients experienced an insufficient fixation of the osteosynthesis material \cite{108}.

Distraction forces vary with the technique and type of osteotomy done. Also the effect of force of distraction on the midface in young patients is
unknown. This effect could be due to some “remote distraction”, differential response from various parts of face [7]. It has been reported that if the maxilla is completely osteotomized then less force will be needed during distraction osteogenesis [109,110].

Additional surgical procedures can be done along with conventional orthognathic surgery but not with distraction osteogenesis. This is especially important in cleft cases where primary gingiva-perioplasty or secondary alveolar bone graft is usually required [7]. Non-compliance in distraction osteogenesis cases is a reason for their relapse, not seen in bilateral sagittal split osteotomy [111,112].

CONCLUSION:

Generally, distraction osteogenesis has no extra advantage over conventional orthognathic surgery in prevention of velo-pharyngeal insufficiency and speech disturbance in moderate cleft maxillary advancement cases. But sufficient evidence exists that maxillary distraction in moderate or severe cases of maxillary retrusion offer long-term stability of hard and soft tissues as compared to conventional orthognathic surgery.

Significant maxillary advancement by distraction osteogenesis results in significant increases in posterior airway space. Distraction osteogenesis promotes correction of bone and soft tissues simultaneously. According to Precious (2005) “distraction osteogenesis and conventional orthognathic surgery are not mutually exclusive”. A point that favors distraction is not necessarily an argument against orthognathic surgery. Both these treatment strategies are unique in themselves. we cannot replace distraction osteogenesis with conventional orthognathic surgery and vice versa. Both these modalities of treatment are independent of each other.

Vertical maxillary excess cases and any maxillo-mandibular setback cases can be done by conventional orthognathic surgery only because there is no applicability of distraction osteogenesis in such cases. Distraction osteogenesis remains a powerful tool amongst the armamentarium of cleft lip and palate management team for the correction of mid-face retrusion. Both these treatment modalities can result in substantial improvement in various measures of facial esthetics.

The litmus test for these treatment strategies is the extent to which either can restore the normal development of one's pathological pattern of facial growth, yet this issue largely remains unsolved.
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