ORIGINAL ARTICLE

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Management of the severe cleft and syndromic midface hypoplasia

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Structured Abstract

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Distraction Osteogenesis (DO) has become a treatment alternative to treat severe craniofacial skeletal dysplasias. A rigid external distraction (RED) device has been successfully used to advance the maxilla as well as the maxillary, orbital and forehead complex (monobloc) in children as young as two years, adolescents and adults. This approach has provided predictable and stable results. It can be applied by itself or as an adjunct to traditional orthognathic and craniofacial surgical procedures. The technical aspects, including planning, surgical and orthodontic procedures, required to properly apply the technique are presented. For this severe group of patients the technique has been found to be simpler and safer than traditional surgical methods. Maxillary and midfacial advancement through distraction has been found to be extremely stable in the patients in whom the technique was used. The reasons for stability are discussed as well as the observed morphologic changes in the facial soft tissues, velopharyngeal mechanism and airway. However, challenges remain to be solved to improve all distraction techniques and the need for collaboration between researchers and clinicians is emphasized to maximize the benefits of this already promising and rewarding approach.

Key words: Distraction osteogenesis, cleft, syndromic, hypoplasia, maxilla, midface, Le Fort I, monobloc, advanement, rigid external distraction

The conventional treatment of dento-facial deformities includes both orthodontic treatment and orthognathic surgery. The key surgical procedures required for the correction of these conditions include the LeFort I osteotomy, sagittal split mandibular ramus osteotomies, and on occasion a genioplasty utilizing rigid fixation techniques. With this approach, successful and predictable correction of these patients is usually obtained. Some of these classic orthognathic surgical techniques can be nicely applied to patients with cleft-related secondary deformities, especially those presenting with maxillary hypoplasia (Figs 1 and 2). However, the use of these classical orthognathic surgery techniques in patients with severe conditions, either related to clefts or syndromic deformities, may fall short of expectations as this particular group of patients includes additional challenges. It is a well-known fact

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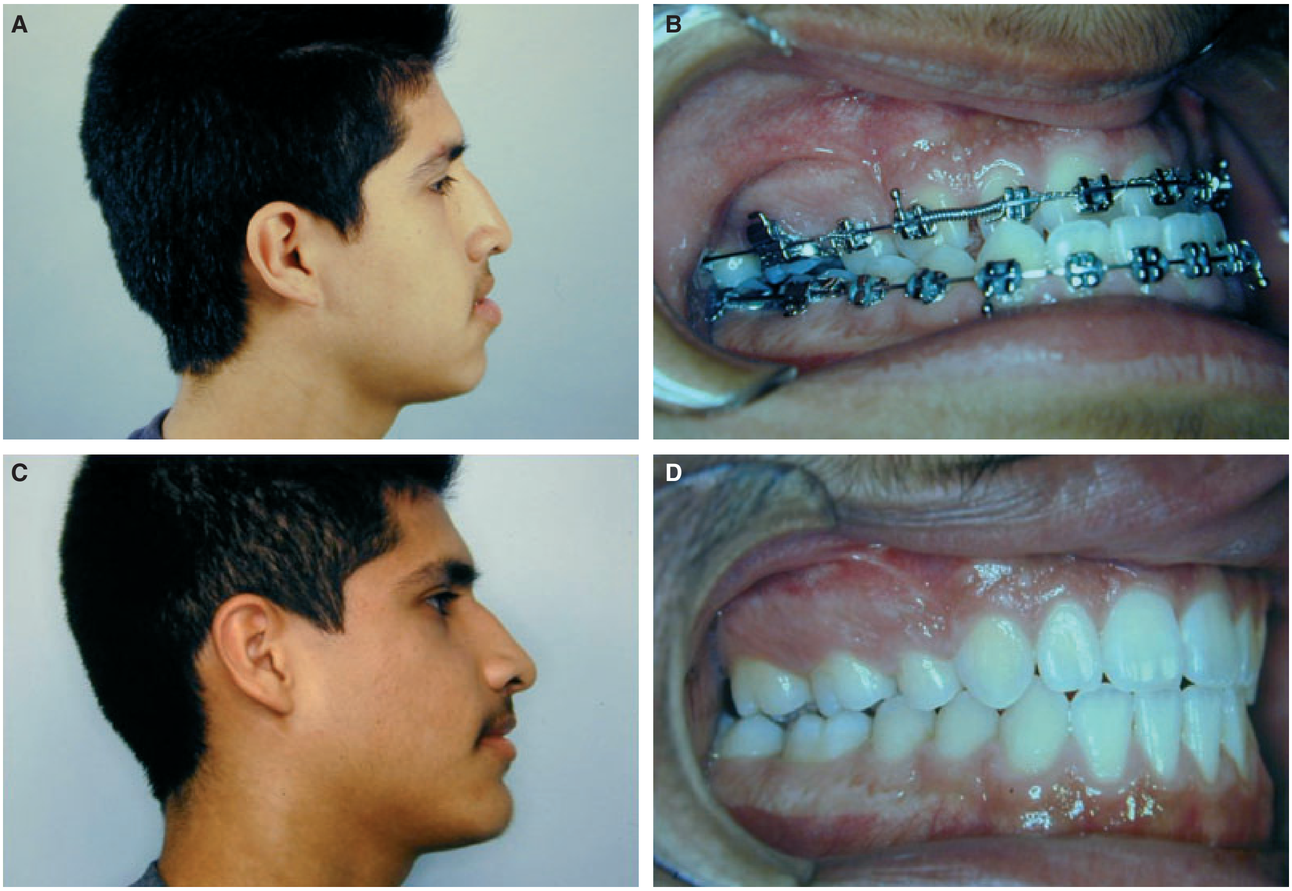


Fig. 1. Patient with maxillary hypoplasia, anterior cross bite, Class III skeletal and dental relations. (A, B) Note facial and dental improvement after maxillary Le Fort I advancement with conventional orthognathic surgery. (C, D).

that patients undergoing orthognathic surgery in which multiple segments are required for the correction of the deformity represent a higher risk for the patient [1]. These complications may include instability of segments, loss of teeth or a segment including multiple teeth as well as bone secondary to vascular compromise. It has recently been reported that the risks for complications after LeFort I maxillary surgery are about 4% in non-cleft patients. However, the risk for complications in patients with oro-facial clefts and other deformities increases to about 25% [2]. It is also known that maxillary advancement in a cleft patient is not stable and the tendency for long-term relapse is quite high compared with that in non-cleft patients [3–6].

Based on the above, it appears that undertaking conventional orthognathic surgical procedures in this challenging group of patients needs to be done with the utmost care and preferably alternative treatments should be explored. In 1992, McCarthy *et al.* [7] introduced the use of distraction osteogenesis in the craniofacial skeleton. Since then, the technique has been applied to all of the bones of the craniofacial skeleton. At this time, the use of distraction osteogenesis has been selected as an alternative to treat patients with previously unsuccessful conventional orthognathic surgery procedures. It is now the treatment of choice for patients with syndromic conditions such as Crouzon and Apert's syndrome [8–12], hemifacial microsomia [7, 13–15], mandibular-facial dystosis, etc. In addition, the technique has successfully been applied to patients with severe maxillary hypoplasia secondary to oro-facial clefts [16–21]. It has now been applied in infants presenting with obstructed airway problems [22–24]. It has also been applied in cases that had larger bone defects as a result of tumor resection or trauma [25]. More recently, the technique has been applied to speed up orthodontic tooth movement [26, 27] and also to reconstruct deficient alveolar bone in the vertical and

Fig. 2. Facial and intra-oral photographs and cephalometric radiograph of a patient with a repaired unilateral cleft lip and palate with residual dental gap and maxillary hypoplasia. (A, B, C) After surgery with conventional 2-piece Le Fort I maxillary surgery, rigid skeletal fixation with simultaneous bone grafting and after final dental rehabilitation. Note improvement on facial balance, closure of dental gap and excellent occlusion. (D, E, F).

transverse dimensions and also to increase the circumference of the maxillary and mandibular dental arches [28, 29] (Figs 3 and 4).

Molina and Oriz Monasterio [30] were the first to suggest maxillary advancement utilizing distraction osteogenesis by means of applying traction with an

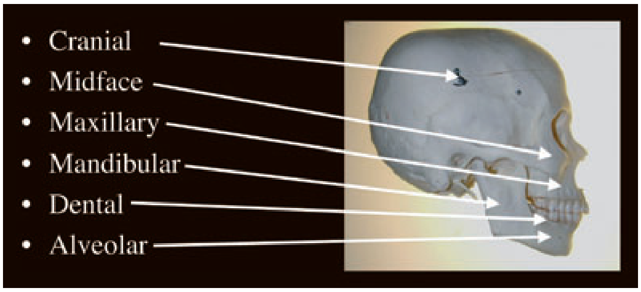


Fig. 3. Distraction osteogenesis has been applied to all the bones of the craniofacial skeleton.

Fig. 5. Intra-oral splint with removable external traction hooks utilized during maxillary advancement with the use of a rigid external distraction (RED) device. The splint is usually cemented to bands on the first permanent molars prior to surgery in the clinical setting. (A) After surgery, the removable traction hooks are secured into the rectangular tubes (B) and used to apply traction to the maxilla using the dentition as anchorage.

orthopedic face mask and elastics. Although this approach appeared promising, the results were disappointing. Our group then developed the use of an external cranially fixed halo as a point of anchorage to advance the maxilla that was connected through the dentition by an intraoral splint to the halo device. The use of this technique has provided impressive results in situations that otherwise would have been difficult to manage. In addition, the technique has demonstrated to be relatively simple, predictable and has shown long-term stability [16, 17, 20, 31].

The protocol for maxillary distraction utilizing a rigid external distraction device includes pre-surgical orthodontic alignment of the dentition and the fabrication of an intraoral splint. The splint is secured to the dentition and also to the anterior maxillary bone with orthodontic anchorage screws. The splint has two square tubes just medial to the oral commissures that are used to secure the rectangular hooks that will be utilized to connect the intraoral splint to distraction screws mounted on to the halo system [32]. After the intraoral splint is fitted in the clinical setting, the patient is ready to undergo surgery (Fig. 5). The surgeon further secures the intraoral splint by placing

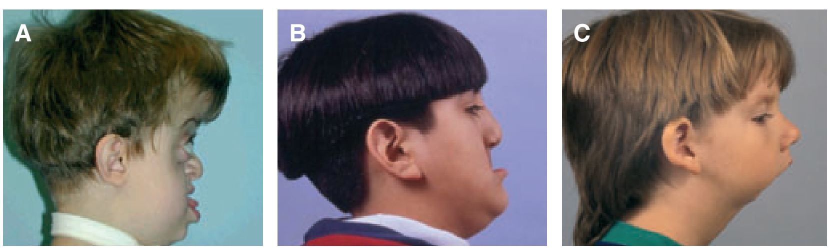


Fig. 4. Patients with severe syndromic craniofacial, cleft and mandibular deformities present a challenge to traditional surgical approaches. Distraction osteogenesis provides an alternative to patients with these difficult problems.

Fig. 7. Modified high Le Fort I osteotomy including the base of the malar bone as well as the inferior aspect of the lateral nasal wall. (A, *Modified from *Polley, J.W. and A.A. Figueroa, Maxillary distraction osteogenesis with rigid external distraction. Atlas Oral Maxillofac Surg Clin North Am, 1999. 7(1): p. 15–28.)* Unilateral cleft lip and palate patient with secondary maxillary hypoplasia before (B), during (C) and after (D) maxillary advancement after a modified high Le Fort I ostoetomy and advancement with rigid external distraction (RED)device. Note correction of upper lip retrusion, paranasal and infraorbital deficiency.

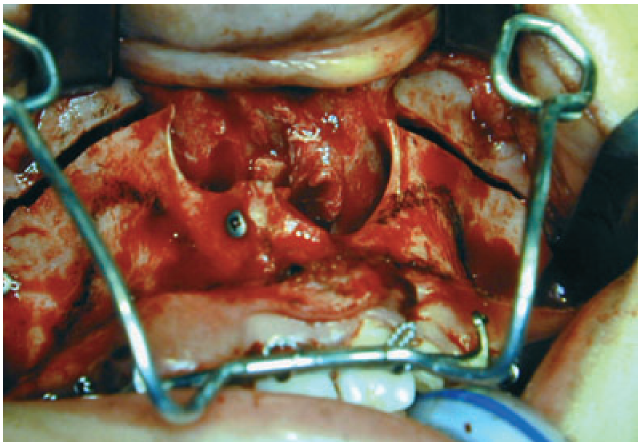
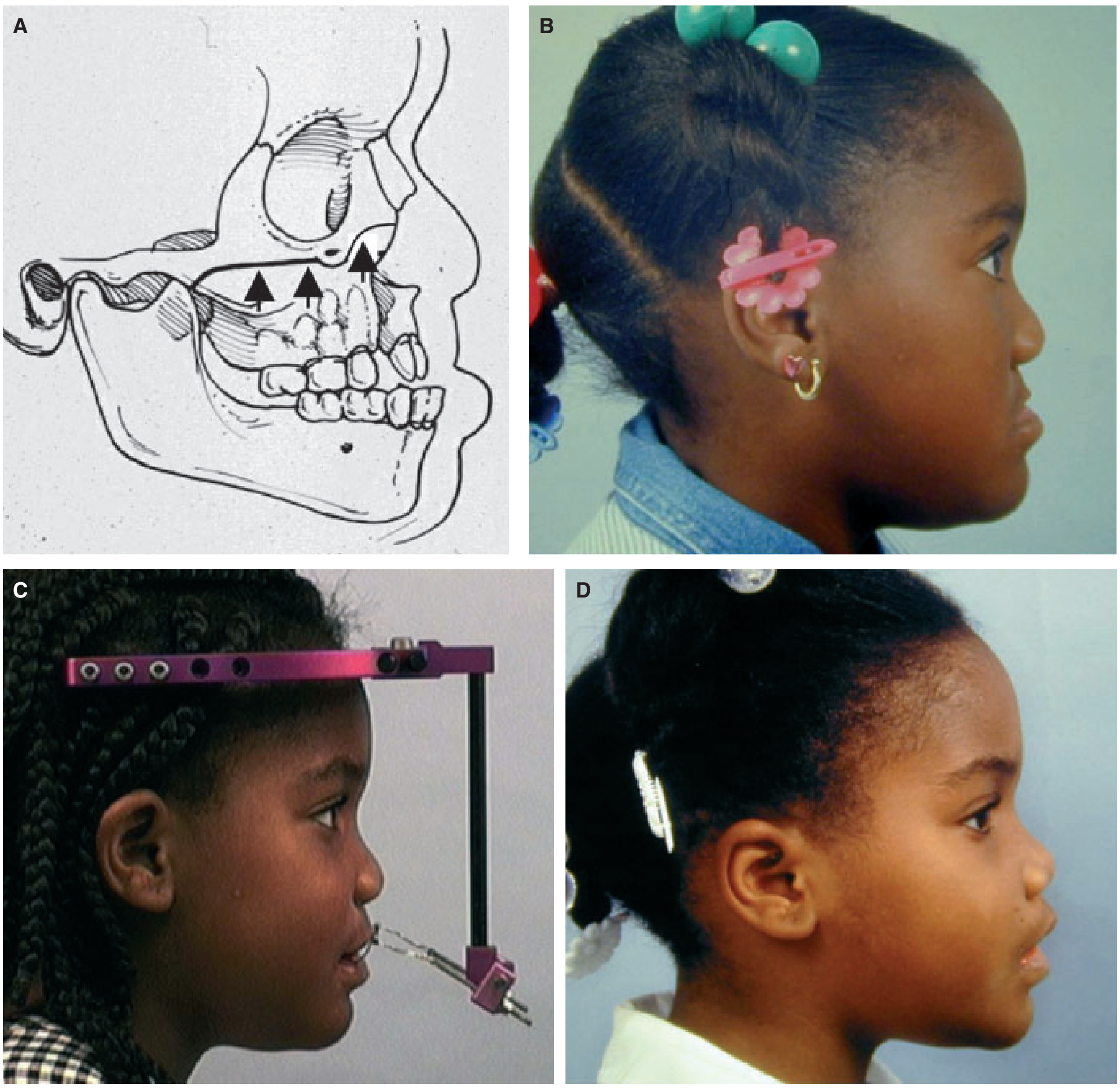


Fig. 6. A complete high Le-Fort I osteotomy with septal and pterygomaxillary disjunction is completed. Note proximity of the osteotomy to the infraorbital nerves.

two orthodontic bone anchorage screws between the root apices of the maxillary lateral incisor and canine bilaterally and suspends it with surgical wire. Afterwards, a complete LeFort I osteotomy with pterygo maxillary disjunction is completed (Fig. 6). The maxilla is not down fractured, as is usually done during conventional orthognathic surgery, but the surgeon must assure that the maxillary bone is completely loose. The surgeon can position the height of the osteotomy to include the base of the malar bones and also the lateral aspect of the nasal bones. In this way, the paranasal and infraorbital regions can be significantly improved (Fig. 7). After closure of the incision, the halo is secured to the cranium utilizing specialized safety cranial pins. The surgeon must be careful to position these pins on the thickest part of the tem-



poral-parietal bones, usually about 3–6 cm above the earlobe. The halo is usually positioned parallel to or slightly above the Frankfort plane. The vertical anterior bar utilized to secure the distraction screws is placed parallel to the facial plane and 3- to 5-cm anterior to it. The distraction system is not assembled until 3–7 days after surgery. In this way, the anesthesiologist does not have any interference with masking and ventilation of the patient in the postoperative period.

Patients are on a liquid diet 24 h after surgery and a progressive soft diet afterwards. After the desired latency period is completed, the distraction device is assembled in the clinical setting without discomfort to the patient. Surgical wire is utilized to connect the traction hooks to the distraction screws mounted on the halo. The rate of distraction is usually between 1 and 2 mm/day, depending on the severity of the condition. Most patients are corrected in a period of about 2 weeks and afterwards they enter the phase of consolidation that is usually 4–8 weeks, depending on the clinical stability of the maxilla. On occasion some patients demonstrate resistance to advancement toward the end of the distraction period and in these situations a second bar with distraction screws is mounted on the vertical bar of the distractor and two additional distraction screws are mounted and directly connected to the intraoral splint with surgical wires. This provides a four-point traction system that is significantly stronger and overcomes any soft tissue resistance (Fig. 8).

Once it is determined that the maxilla is consolidated, the halo and the distraction system are removed in the clinical setting. Usually, in teenage and adult patients, there is no need for local anesthesia to remove the cranial pins. In young children who might be apprehensive, it is advisable to remove the halo in the operating room under light sedation.

Once the halo is removed, the traction hooks attached to the intraoral splint are also removed, and an orthopedic face mask is utilized at night, to promote additional retention. The face mask is used with elastics exerting a total force of about 400–500 g. The face mask is used for 6–8 weeks or until the clinician notes that the maxilla is stable in its new position. At this point, the intraoral splint can be removed and orthodontic treatment can be continued to finalize the occlusion of the patient.

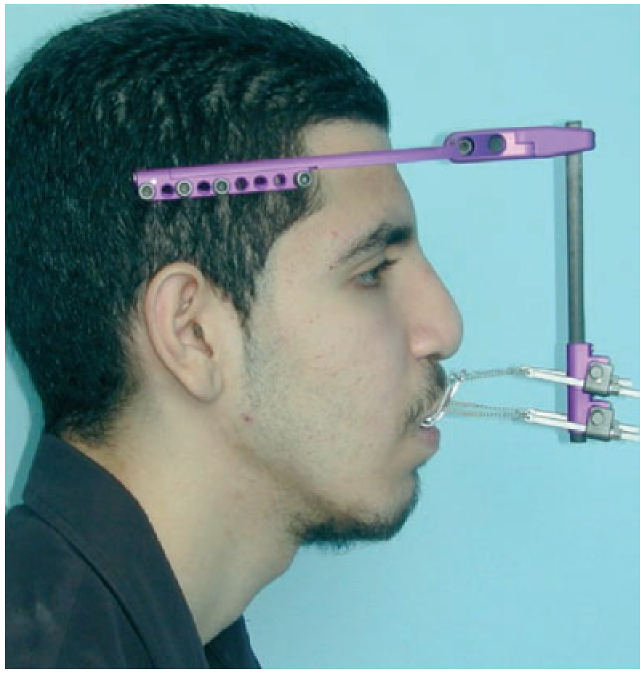


Fig. 8. Patient undergoing maxillary advancement with a rigid external distraction (RED) device. Note use upper and lower traction points and in this way overcome any soft tissue resistance to the maxillary advancement.

In patients needing extreme maxillary advancement, clinicians might note mobility of the maxillary bone even after 3 months of halo and face mask consolidation. If the motion of the maxilla is uncomfortable for the patient, the surgeon may elect to place rigid fixation plates to further secure the maxillary bone. It is of interest to note that in patients with delayed consolidation of the maxilla, the motion of the bone is usually in the vertical and transverse planes and there is minimal or no tendency for anterior/posterior movement.

The following figures illustrate a cleft patient in which the rigid external distraction system has been utilized to correct a cleft-related maxillary hypoplasia (Fig. 9).

In cases with severe craniofacial syndromes in which there is significant frontal, orbital and maxillary deficiency, the rigid external distraction system has also proven extremely effective to safely and predictably improve the severe midface deficiency. Rather than advancing the whole midface and frontal bone (monobloc advancement)[33] in an acute fashion, the segment is advanced gradually. The main disadvantages of the acute advancement include cerebral spinal fluid leakage, creation of an intra-cranial

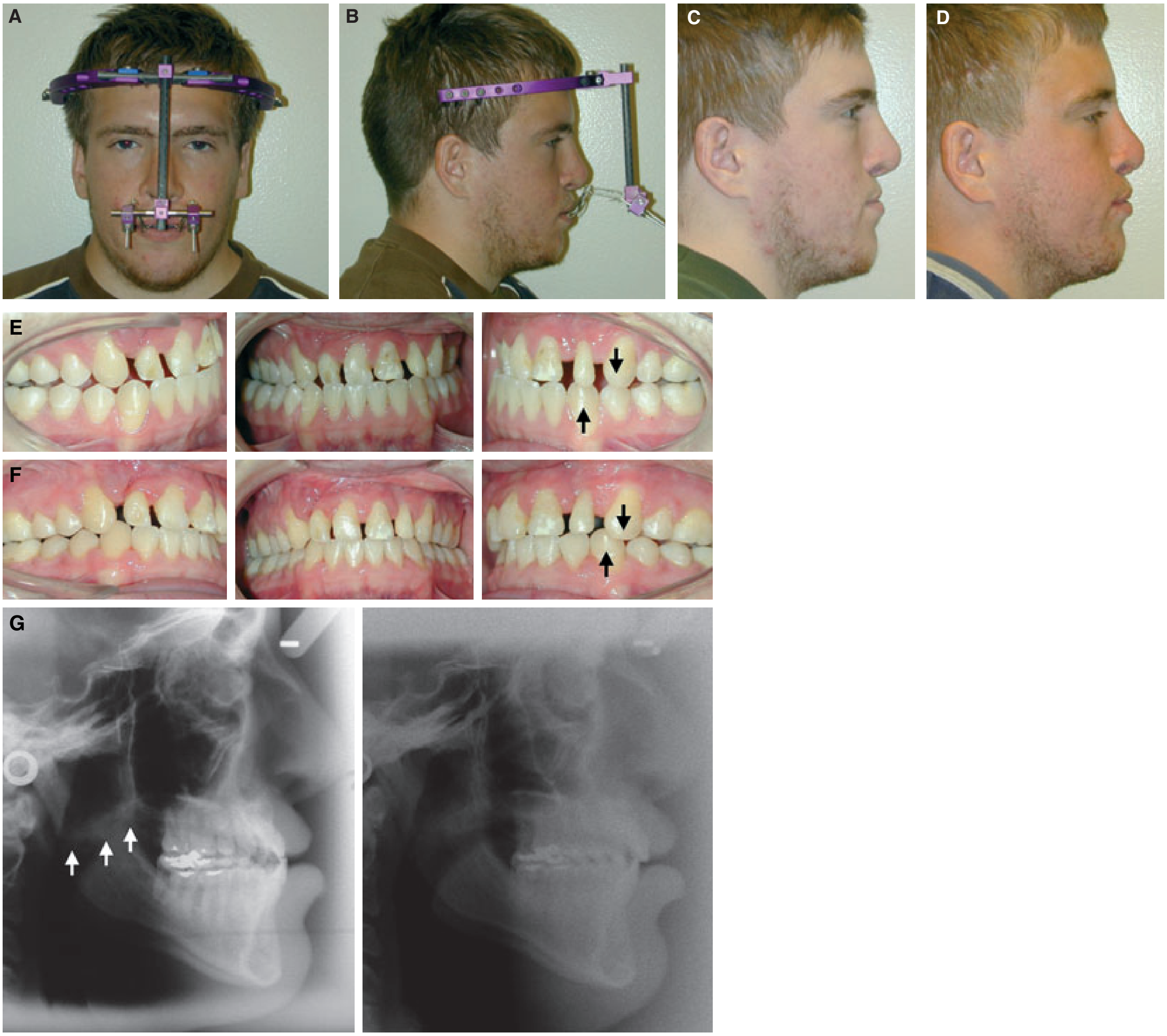


Fig. 9. Patient with repaired unilateral cleft lip and palate, secondary maxillary hypoplasia with left asymmetry and Class III skeletal and dental relations who underwent correction with a rigid external distraction (RED) device (A, B). Facial photographs before (C), and after (D) maxillary advancement. Note improved facial balance and convexity. Intra-oral views before (E) and after (F) distraction. Arrows illustrate antero-posterior correction. Note correction of midlines and post-treatment ideal occlusal relations. Anterior dental spacing due to dental structural abnormalities will eventually be corrected with esthetic dental restorations. Cephalometric radiographs before (G-left) treatment. Note presence of pharyngeal flap (arrows) and maxillary hypoplasia with anterior dental cross bite. After surgery (G-right) skeletal convexity was restored and the anterior cross bite corrected. Note bone formation posterior and superior to last maxillary molar and stretching of the pharyngeal flap.

dead space vulnerable to infection, need for extensive bone grafting and bone fixation; the procedure is clinically demanding, the advancement can be limited due to soft tissue restrictions, there is a need for blood transfusions and the long-term stability of this procedure has been questionable. The advantages of gradual advancement of the monobloc segment with a rigid external distraction system utilizing the principles of distraction osteogenesis include a predictable and stable midface advancement, reduction of complications especially infection, reduction of intra and post-operative morbidity, simpler procedure, no need for bone grafts nor rigid fixation, operative time and morbidity significantly decrease, reduction in the number of cases requiring blood transfusion.

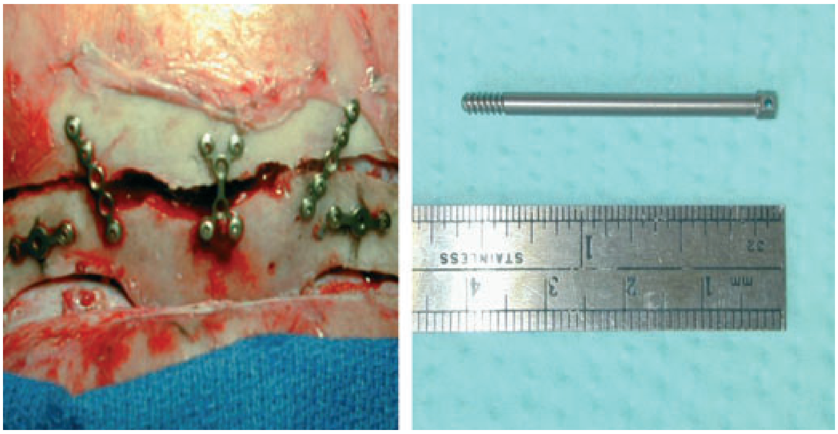


Fig. 10. After completing the monobloc osteotomies and rigidly fixing the frontal bone flap, three holed plates are placed over each supraorbital rim. (left) The lateral holes are used to fixate the plate to the bone, the central one is threaded and it is used to insert a percutaneous pin that will be used as upper anchorage during the monobloc advancement, (right).

The technique for midface advancement at the monobloc level follows similar steps to that of maxillary advancement in cleft patients. The first step is to have the orthodontist prepare an intraoral splint similar in design to that used in cleft patients [32]. At the time of surgery, the splint is further secured to the maxillary bone with bone anchorage screws. At surgery, the classical monobloc osteotomy is performed and the surgeon must assure complete mobilization of the skeletal segment. After fixating the frontal bone flap to the supraorbital rim with rigid fixation plates and screws, the surgeon places two additional plates above the supraorbital rim. These specialized plates contain three perforations. The two lateral ones for fixation to the supraorbital bone with screws and the central perforation have a thread for future placement of the superior traction pin screw that will come through the skin at the level of the eyebrow (Fig. 10). After this supraorbital traction pin is secured through the skin, the coronal incision is closed and the surgeon places the rigid external distraction halo. In cases with craniofacial syndromes that might have had previous surgery, the surgeon must be careful with the placement of the fixation cranial pins, as many of these patients do have cranial defects from the condition itself or from previous operations. It is important that the halo is properly anchored to solid bone. The anterior part of the halo is positioned about 2–3 cm ahead of the forehead and the halo is placed either parallel to the Frankfort plane or with a slightly upward inclination and 3–6 cm above the ear. After surgery, the patient returns to the clinical setting in 5–7 days to have the distraction device assembled with two points of distraction; a superior at the suprorbital level through the traction pins and a lower one at the dental level by means of the traction hooks connected to the intraoral device (Fig. 11). The distraction protocol is similar to that in cleft patients with a 1- to 2-mm advancement per day until correction of the skeletal deformity is achieved. Subsequent to this, the halo is left in place during the consolidation period between 6 and 12 weeks. In

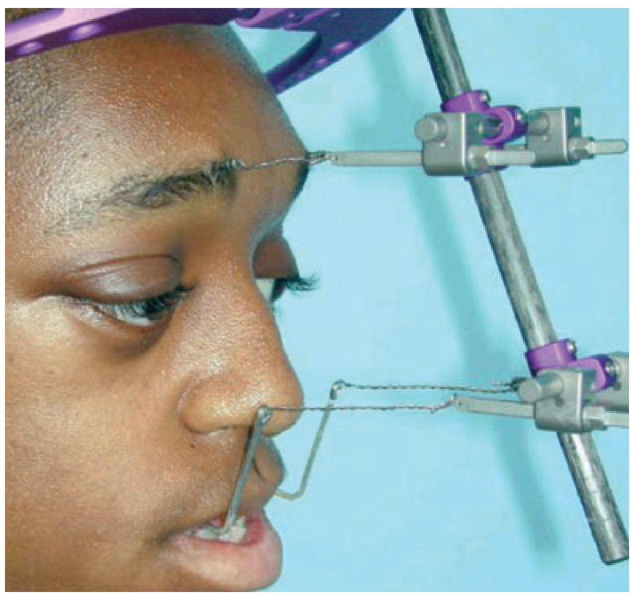


Fig. 11. Patient undergoing monobloc advancement with a rigid external distraction (RED) device. Note four traction points, two in the forehead and two at the oral level. Note pins through both eyebrows, as well as traction hooks attached to intra-oral device and all connected with wires to the distraction system.

cases undergoing monobloc advancement, it is not possible to utilize a face mask for retention; therefore, it is recommended that the consolidation period be longer than in cleft patients or until the clinician assures stability of the skeletal segment by radiographic and clinical examination.

This procedure has proven to be simpler than traditional methods, predictable and stable. The following

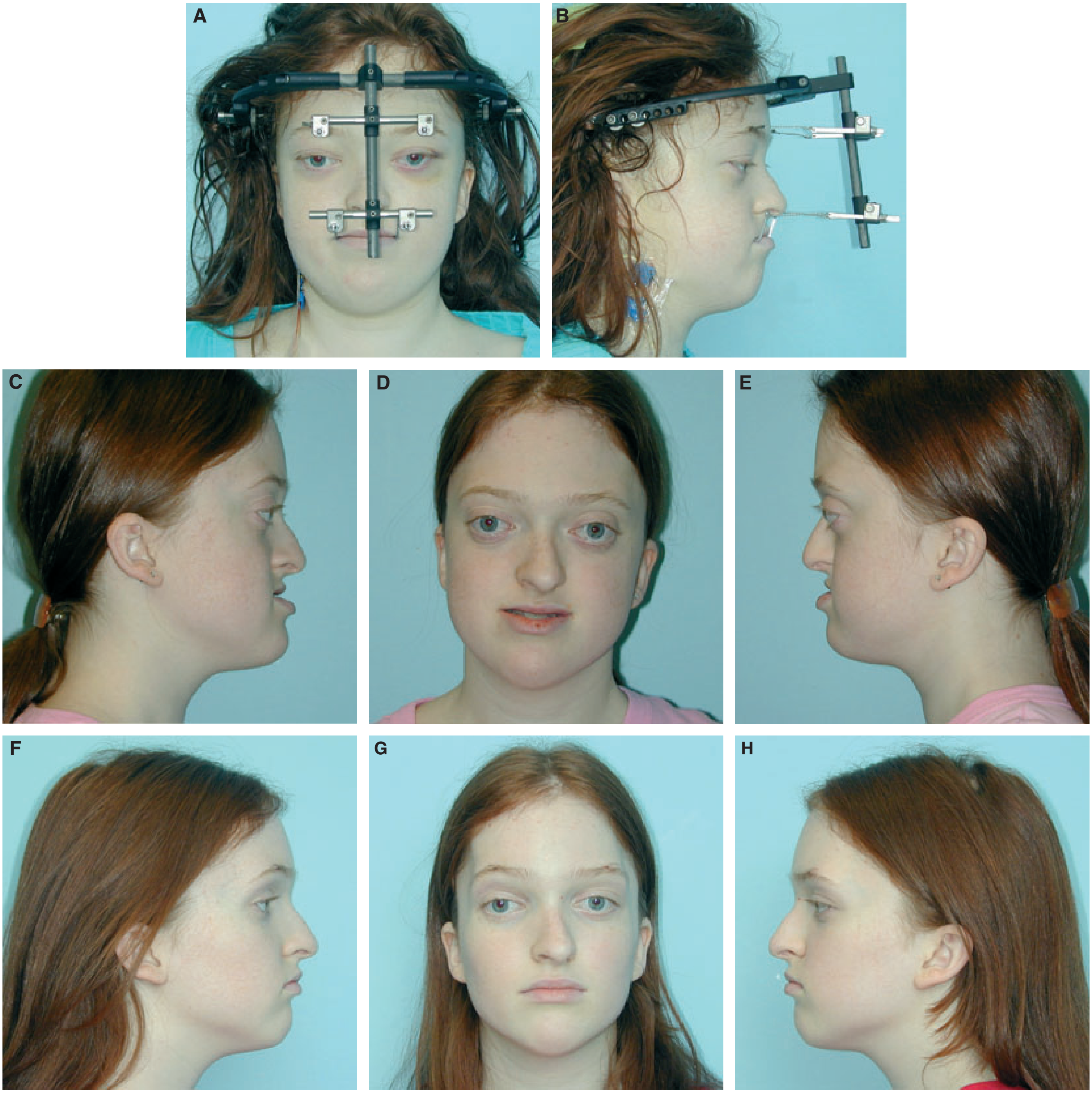


Fig. 12. Patient with Crouzon syndrome undergoing monobloc advancement with a rigid external distraction (RED) device. Note four traction points for maximal control of the large osseous segment. (A, B) Pre (C, D, E,) and post-surgery (F, G, H) facial photographs. Note severe exorbitism and midface deficiency and dramatic correction after treatment. Intra-oral photographs before (I) treatment. Note Anterior and posterior cross bites with Class III relations. After surgery (J) the cross bites have been corrected and the occlusion normalized. Pre- treatment (K-left) cephalometric radiograph reveals orbital, midface and maxillary deficiency with anterior cross bite. After surgery (K-right) the orbital and maxillary correction is evident and the anterior cross bite has been corrected. Note bone and space created for eruption of maxillary third molars.

Fig. 12. *Continued.*

case report illustrates the technique which was utilized to correct a syndromic craniofacial deformity (Fig. 12).

The long-term stability after maxillary advancement in cleft patients and midface advancement in patients with syndromic conditions has been excellent ([17, 34]). The reason why the technique is stable in both cleft and syndromic patients is that a significant amount of bone is formed in the pterygo-maxillary area (Fig. 13). This area has been known to be key concerning stability after maxillary and midface advancements. The bone found in this area through histologic and radiographic examination has been found to be dense lamellar bone [17, 35]. The creation of new bone in the posterior maxillary region not only provides stability, but also provides additional space for dental eruption (Fig. 13).

As we have become experienced with the technique, it has been applied to other conditions in which it was thought that conventional orthognathic surgery might not be sufficiently stable to provide the desired outcome. In addition, in severe patients, we have utilized the technique in combination with conventional orthognathic surgery. In some instances, because of directional movement limitations of the distraction technique, it becomes necessary to finalize the case with conventional orthognathic surgery. The benefit of combining the two techniques resides in the fact that the distraction component of the intervention attains most of the correction and with the conventional orthognathic technique, the surgeon refines the position of the bones and the occlusion, usually with a minor safe, predictable and stable skeletal movement.

It is the opinion of the authors that at this time several challenges remain to be solved for patients requiring distraction for the correction of maxillary and midface hypoplasia. Some of these challenges are technical while others are related to the patient's response to treatment. On the technical side, we have issues concerning surgical technique that pertain mainly to case selection, such as use of distraction alone or in combination with conventional orthog-

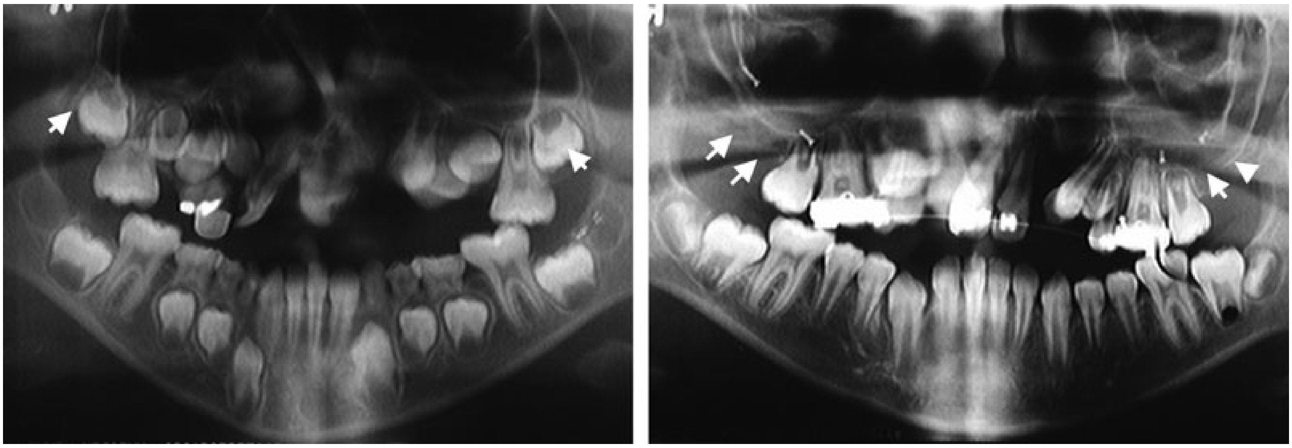


Fig. 13. Panoramic radiographs obtained before (13-left) and 2 years after (13- right) maxillary advancement with a rigid external distraction (RED) system. Note creation of space and new bone posterior to the last maxillary molars (double arrows). Also observe continued eruption and root development of the maxillary second molars.

nathic surgical techniques. The other includes hardware, for example, how does the clinician decide on using a rigid external distraction system like the one presented in this chapter. In which situations can we use an internal distraction system? Internal systems are more appealing because they are concealed, but they do have significant limitations concerning surgical placement, adjustment and degree of advancement. New devices are in development at our unit to assist the surgeon in the use of a versatile internal system for less severe cases [36]. Other issues that still remain a challenge include the length of the consolidation period, which has been noted to be age specific; younger patients have a shorter consolidation period. However, if the bone is significantly advanced, it has been observed that the time required for consolidation can be extremely long and impractical. For this reason, the close cooperation between clinicians and researchers to decrease this very important stage in the distraction process is critical. Recent advancements in the use or delivery of bone morphogenetic proteins, growth factors and the use of ultrasound appear to be addressing this concern [37–39].

Although evaluated by some clinicians, more needs to be known concerning the soft tissue responses to the gradual movement of bone with its attached soft tissues. Some of these changes appear to be more favorable utilizing distraction techniques, such as an improved lip and nose response after maxillary advancement with distraction when compared with conventional orthognathic surgery [18, 40]. In addition, the response of the velopharyangeal tissues appears to be more favorable in the gradual advancement than in the acute advancement [41, 42].

Finally, little is known of what the emotional and psychological response of the patients to this gradual advancement compared with the acute change. How much do the distraction devices interfere in the psycho-social well being of the patient [43] and what is the impact of patient participation in the improvement of their condition in their psycho-social well being and development when dealing with a challenging facial difference?

Conclusion

Distraction osteogenesis has now been applied to all the bones of the craniofacial skeleton with remarkable success (Fig. 4). The technique of rigid external distraction for maxillary and midface advancement in cleft and craniofacial syndromic patients has proven to be safer, simpler and more predictable and stable than conventional approaches. The clinical knowledge available at this time indicates that distraction is an alternative approach to the management of conditions that in the past were a challenge for traditional surgical techniques. The use of distraction techniques does not preclude the combined use of traditional surgical techniques with the new distraction approach. Although the benefits of distraction are well recognized, challenges remain to further improve the incorporation of the technique for the clinical management of cleft and syndromic patients. These include the development of new hardware, surgical designs and technique, reduction of the consolidation period through cytokines, and the understanding of soft tissue response to gradual distraction as well as the psycho-social aspects of the technique on the overall well being of the patients.

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