Journal of Plastic, Reconstructive & Aesthetic Surgery (2015) 68, 79—86

JPRAS
An International Journal of Surgical Reconstruction
www.JPRASurg.com

# Long-term follow-up of large maxillary advancements with distraction osteogenesis in growing and non-growing cleft lip and palate patients

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Received 5 April 2014; accepted 24 August 2014

**KEYWORDS**
Cleft lip and palate;
Le Fort I osteotomy;
Distraction osteogenesis;
Long-term stability;
Maxillary growth;
Cephalometry

**Summary** *Background:* Maxillary distraction osteogenesis (DO) in cleft lip and palate patients has been described by several authors, but most studies have a relatively short follow-up and do not clearly separate growing patients from non-growing patients.
*Method:* The records of 22 consecutive patients affected by cleft lip and palate, who underwent Le Fort I osteotomy and maxillary distraction with a rigid external distractor (RED), were reviewed. The sample was subdivided into a growing and a non-growing group. All patients had pre-DO cephalometric records, immediately post DO, 12 months post DO and long-term records with a long-term follow-up of >5 years (range 5—13 years). As a control sample for the growing group, cleft children with a negative overjet not subjected to distraction or any protraction treatment during growth were followed up until the completion of growth.
*Results:* The average maxillary advancement in the growing group was 22.2 ± 5.5 mm (range: 15—32 mm); in the non-growing group, it was 17.7 ± 6.6 mm (range: 6—25 mm). Excellent post-surgical stability was recorded in the adult sample. On the other hand, growing children had an average 16% relapse in the first year post DO and an additional 26% relapse in the long-term follow-up.
*Conclusions:* This study seems to point out that early Le Fort I DO allows for the correction of very severe deformities. It is followed by a relatively high amount of true skeletal relapse in

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http://dx.doi.org/10.1016/j.bjps.2014.08.069

children with cleft lip and palate. Prognosis should be discussed in depth with the family and true aesthetic and psychological needs assessed.


Although surgical protocols and results have greatly improved in the past decades,[1] some patients with cleft lip and palate still present extremely severe maxillary hypoplasia. Approximately 25—50% of cleft patients present a class III malocclusion that requires surgical intervention,[2] and, while the majority may be corrected with traditional osteotomies, in some cases, the maxillary advancement required is too large to be safely obtained with a Le Fort I osteotomy and rigid fixation.

Traditional osteotomy failure may often be caused by the presence of multiple scars, which do not allow stretching of the soft tissues. Distraction osteogenesis (DO), on the other hand, allows for gradual lengthening of all structures, whereby the risks are reduced, while advancing hypovascularized structures.[3]

In 1997, Polley and Figueroa[4] introduced a technique of maxillary DO, using a rigid external distraction (RED) device. This method allows gradual maxillary advancement according to Ilizarov's principles,[5] avoiding the need for rigid fixation or bone grafts. Furthermore, it allows progressive correction of the distraction vector.

Relapse in maxillary DO in the long term is reported by various authors to be minimal. Rachmiel et al.[6] reported stable results 2 years after an average maxillary distraction of 21 mm in 12 patients with cleft (aged 11—22 years). In this study, though, growing and non-growing patients were not separated. Similar results were reported by Krimmel et al.[7] on 17 patients aged 12—31 years. The authors reported that after 1 year the maxilla had a stable position in all patients, though there was a further increase of the facial concavity, but again the two age groups were not separated in the study.

Cho et al.[8] suggested that an overcorrection in the maxillary advancement of 20—30% is needed in the growing child (13—19 years), to compensate for potential relapse and growth deficit.

To our knowledge, only few studies in the literature clearly separate growing patients from non-growing patients.[9—11] Furthermore, most studies have a relatively short follow-up, between 2 and 4 years, and report relatively low skeletal advancements.[7,9—15]

The purpose of this retrospective outcome study was to evaluate cephalometrically, in growing and non-growing cleft lip and palate subjects with severe maxillary hypoplasia, changes induced by very large maxillary advancements through RED and long-term post-surgical stability of the maxillary movement.

## Materials and methods

### Patient sample

The records of patients who underwent Le Fort I osteotomy and maxillary distraction, between 1999 and 2008 in two different centres, were reviewed.

Our sample included a total of 22 consecutively treated patients, specifically 11 unilateral cleft lip and palate, four bilateral cleft lip and palate, two lateral facial clefts, one cleft in Robinow syndrome, two clefts in Binder's syndrome and two clefts in median facial syndromes. All patients presented a severe maxillary hypoplasia, negative overjet and class III malocclusion. All patients presented follow-up records longer than 5 years post DO.

Ten growing patients underwent surgery between 7 and 12 years of age (the average age was 10.4 $\pm$ 2.1 years). In growing patients, if the maxillary advancement needed was $<$6—8 mm, an orthopaedic—orthodontic technique (Alt-Ramec) described by Liou in 2005[16,17] was preferred. Therefore, the inclusion criteria for DO in young children were the need for an advancement $>$8 mm and clinically severe psychosocial problems. Otherwise, correction was postponed to a later stage. This clinical selection is the reason for the large advancements obtained in the growing sample, not only for the young age of the sample but also for the small sample size.

Twelve adult patients were operated at a mean age of 24.4 years (range 17—44 years). The selection criteria for DO in the non-growing patients were the need for an advancement $>$10—12 mm or extremely severe scarring.

Although all patients had similar severity in terms of maxillary hypoplasia, some had identified syndromes (32% of the total sample). In order to investigate any possible influencing factor on surgical outcome, the sample was subdivided not only into growing and non-growing individuals but also into syndromic and non-syndromic individuals.

All patients underwent maxillary distraction with a RED device. The device was placed at the time of surgery and the distraction was achieved through mechanical activation of the distraction device, after a latency period of 2—5 days. The mean time of distraction was 34.5 $\pm$ 8.4 days for growing patients and 28.7 $\pm$ 6.8 days for adult patients. The consolidation period was three to four times the length of distraction.

As a *control sample* for the *growing sample*, a group of 12 class III cleft patients not subjected to distraction or any protraction was selected. This group was extrapolated from a large sample of unilateral cleft lip and palate children who had been retrospectively collected for a previous growth study.[18] In order to select a control sample with a comparable class III growth pattern, only the patients from the sample who had needed a Le Fort I osteotomy at the completion of growth were included.

### Surgical protocol

All patients underwent endotracheal intubation. A high-level Le Fort I osteotomy, just below the infraorbital foramen with a lateral extension to the anterior prominence of the zygomatic bone to avoid injuring the unerupted molar