JOURNAL OF PLASTIC SURGERY AND HAND SURGERY
2023, VOL. 57, NOS. 1–6, 488–493
https://doi.org/10.1080/2000656X.2022.2164294

ARTICLE

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Long-term patient-reported outcomes after anterior distraction osteogenesis of the maxilla in patients with cleft

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ABSTRACT

Maxillary growth inhibition in patients with cleft lip and palate (CLP) is an undesired effect that may occur in the teens despite proper primary care. Dental malocclusion and distortion of facial appearance can be treated with external distraction osteogenesis (DO) of the maxilla. This entails a Le Fort I osteotomy, fastening a semi-circular distractor to the skull, distraction for three weeks, and fixation for three months before removal of the device.

The aim of this descriptive long-term follow-up study was to evaluate DO of the maxilla from the patient-reported long-term perspective.

Fourteen patients underwent a long-term follow-up including a questionnaire regarding their experience of DO. Sex, CLP diagnosis, age at DO and follow-up, and time required for active distraction and fixation were noted. Furthermore, documentation on rhinoplasty, lip plasty and velopharyngeal plasty after DO was registered. Objective results were assessed by a positive dental overjet in the front.

Ten patients considered the distractor an everyday constraint, but all thought the procedure was worthwhile and would recommend it to others. Thirteen patients experienced improved bite and chewing, whereas one considered function unchanged. All were satisfied with their dental alignment. Three patients underwent a velopharyngeal plasty after DO. Moreover, six rhinoplasties and two lip plasties were performed.

Despite a long and challenging treatment, teenagers and young adults with CLP and maxillary hypoplasia tolerate DO of the maxilla very well. Secondary measures to improve speech and appearance are often indicated.

ARTICLE HISTORY
Received 5 September 2022
Revised 22 November 2022
Accepted 28 December 2022

KEYWORDS
External distraction; RED; anterior maxillary distraction; patient reported outcome; rigid external distractor; DO; cleft

Introduction

Either conventional orthognathic surgery (CO) or distraction osteogenesis (DO) is used for the advancement of the maxilla in cases of maxillary hypoplasia, typically in patients with cleft lip and palate (CLP) and cleft palate (CP). These surgical interventions are often performed in the late teens to allow fully developed bone growth, thus achieving a lasting result [1]. Both methods are based on a Le Fort I osteotomy, which makes the teeth bearing part of the lower maxilla freely movable in the forward direction. CO is the traditionally used method. In CO the lower maxilla is moved forward in one step by means of autologous bone transplantation and rigid fixation [2]. The technique has its limitations. Firstly, just a short advancement is achievable, around 5 mm on average, which constitutes a limitation in the treatment of severe forms of maxillary hypoplasia. Second, the technique is linked to a high relapse risk [3]. DO, on the other hand, is a mechanical bone lengthening procedure that generates new bone by gradual distraction [4]. The method was used for the first time on the human cranium in 1992 [5,6]. DO encompasses the Le Fort I osteotomy supplemented with the application of a rigid external distractor (RED). The device is semi-circular and surrounds the head like a halo. It is fastened to the temporal bones on either side as shown in Figure 1. The loosened lower maxilla is connected to the device via a dental appliance, wires, and a vertical bar. By adjusting the device step by step, 0.5–1.0 mm a day, dragging the loosened lower maxilla forwards, more bone regeneration can be achieved compared with CO. Immediately postoperatively a latency phase up to a week is allowed during which callus is formed around the osteotomies enabling bone regeneration. The distraction itself, referred to as the active phase, begins once callus has formed and can last up to 15 days or more depending on the severity of the maxillary hypoplasia. The fixation phase begins once the desired advancement is achieved to allow the regenerated bone to become consolidated. This process normally takes about three months and then the DO device can be removed [2,3,7]. Considering the long procedure and restrictions involved, DO certainly has an impact on daily life and presumably the quality of life of the patients during the treatment period [3].

In recent years, internal distractors for the maxilla have been developed and have proved useful [8,9]. The basic principle is the same, but the expanding unit is placed intraorally. Distraction is then achieved with a turning arm.

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Figure 1. Image of the rigid external distractor (RED) device. Printed by kind permission of KLS Martin.

Forward distraction of the maxillary complex including the palate may increase the distance between the soft palate and the posterior pharyngeal wall. Consequently, hypernasality may occur postoperatively indicating the need for a velopharyngeal plasty as a complementary measure [3]. Furthermore, the new position of the maxilla may alter the configuration of the nose and lip and secondary measures directed at these domains may also be indicated.

The international scientific literature on DO is rich regarding the surgical procedure itself but relatively sparse regarding patient-reported outcomes from a long-term perspective. A literature search regarding previous reports on patients with CLP and DO for maxillary hypoplasia and their subjective experience of the procedure was therefore performed using the PubMed database. PubMed was searched on 20th of September 2021 with 'Craniofacial Abnormalities'[Mesh] AND (('Patient Outcome Assessment'[Mesh]) OR 'Patient Satisfaction'[Mesh])) AND 'Bone Lengthening'[Mesh]. The literature search resulted in 21 articles. After careful scrutinize two articles remained encompassing patients' experience with distraction. One article was a comparison with internal and external distraction [9]. The other one more precisely targeted our research questions with the RED appliance [10]. This article was included in a previous systemic review on suitable questionnaires for patients undergoing oral and maxillofacial surgery [11].

The aim of the present study was to evaluate DO of the maxilla from the patients' perspective. Consequently, results of the study can add valuable knowledge on this topic and can thereby act as a guideline for future preoperative information to patients with CLP suffering marked maxillary hypoplasia.

Materials and methods

Subjects

The motivation for this descriptive long-term follow-up study arose in 2017 when the CLP treatment team experienced a weakness in their capacity to give adequate preoperative information to patients who were being considered for DO. At that time, a few patients had been operated with DO since the start in 2004. Due to the uniqueness of the procedure, the responsible senior oral- and maxillofacial surgeon (BS) had entered short notes on those patients who had been treated so far. From these notes, combined with a pilot screening of indicated medical records, it was possible to identify 16 individuals who possibly would be available for a long-term follow-up. They were all invited by ordinary mail to attend the outpatient unit of the Department for Oral- and Maxillofacial Surgery for a follow-up including clinical investigation. This involved obtaining dental casts, lateral cephalograms, speech recording, photography, and answering a questionnaire. Fourteen patients accepted the invitation and were accordingly investigated. Two patients declined participation because they resided a long distance away. Analysis of the various objective findings is ongoing and results regarding dental occlusion in terms of positive overjet are set. The present study analyses the patients' subjective reports.

Demographic data

A review of the subjects' medical records was done to collect clinical information relevant to the DO procedure. Sex, CLP diagnosis, age at DO, length of active distraction, length of fixation phase and time to follow-up was noted. Furthermore, complications were noted as well as whether a velopharyngeal plasty, rhinoplasty and/or lip plasty was carried out after DO.

Dental casts

In this study, overjet is used as a main indicator of whether the treatment goals were achieved or not. Measurements were performed by using a digital sliding caliper (Digital 6, 8M007906, Mauser-Messzeug GmbH, Oberndorf/Neckar, Germany). One senior orthodontist (APW) conducted the measurements twice, one month apart, to allow analysis of intra-rater agreement. Another senior orthodontist (IS) also conducted the measurements to allow analysis of inter-rater agreement.

Questionnaire

A validated questionnaire that would be useful for the purpose of highlighting the subjective experience of the DO procedure was not at hand when the study was initiated. A custom-made questionnaire was therefore constructed primarily based on the team's experience of a previous study on the challenge to undergo a two-step lip-nose reconstruction with an Abbé-flap [12]. The custom-made questionnaire had 13 questions in total. Ten questions had pre-set response options. For three of them, the alternatives were 'yes' or 'no'. Six questions had four graded response options related to the impact of the treatment. One question related to speech had three answer alternatives: better, worse, or unchanged. Another three questions allowed the subjects to express their view of the treatment in free text. For the purpose of reporting our results to the English-speaking readership, the questionnaire was translated from Swedish to English and then back-translated into Swedish. The back-translated Swedish version was then compared to the original version and a few adjustments were accordingly made. Based on this widely accepted linguistic validation method the questionnaire is shown in Figure 2.

Statistics

The results are given as medians and ranges and described with descriptive statistics. The sex distribution of the subjects who had either unilateral or bilateral CLP on one hand, and isolated CP on the other, was studied in relation to the general distribution of CLP and CP among boys and girls using the chi-square test.

Long-term follow up of patients born with cleft lip and palate who underwent maxillary advancement by distraction osteogenesis.

Questionnaire (Check the alternatives that apply the best)

1	How did you experience wearing the device on your head?		
	a	No problem	2
	b	Ok	5
	c	Tough	7
	d	Terrible	0
2	Was the device a constraint in social interaction?		
	a	Yes	10
	b	No	4
3	Did you experience difficulties with chewing and/or biting before undergoing the treatment?		
	a	Yes	8
	b	No	6
4	How do you experience the change of your bite regarding the chewing and biting ability?		
	a	Much better	9
	b	Slightly better	4
	c	Unchanged	1
	d	Worse	0
5	How do you experience the change of your frontal teeth?		
	a	Much better	13*
	b	Slightly better	0*
	c	Unchanged	0*
	d	Worse	0*
6	Are you experiencing pain from your jaw or chewing muscles?		
	a	Never	11
	b	Occasionally	2
	c	Once per month	1
	d	Once per week	0
7	Did you have the same struggles before undergoing the treatment?		
	a	Yes	0
	b	No	14
8	Was the result of the treatment worth all the steps and struggles?		
	a	Yes, definitely	13
	b	Yes, to a certain degree	1
	c	Hardly at all	0
	d	Absolutely not	0
9	Would you recommend this kind of treatment to people in the same situation as you?		
	a	Yes, definitely	13
	b	Yes, but with some hesitation	1
	c	Hardly at all	0
	d	Absolutely not	0
10	Did you experience any change in your speech after the treatment compared to before?		
	a	Yes, for the better	6
	b	Yes, for the worse	2
	c	No, unchanged	6
11	What was the main reason you chose to undergo the treatment?		
12	Did you understand what it roughly meant and was the information about the treatment's magnitude sufficient?		
13	If the device was a constraint in social interaction (yes in question 2) feel free to describe in which way.		

Figure 2. Shows the questionnaire used in the present study. The results of the questions with pre-set response options (#1–10) are added and shown in the column to the right. *Indicates missing data from one patient.

The Swedish National Quality Register for Cleft lip and palate was used as a reference [13]. Intra- and interrater reliability of the positive overjet measurements at follow-up was tested with Intraclass Correlation Coefficient (ICC).

Ethical consideration

The research project was approved by the Regional Ethical Review Board in Lund, Sweden (Dnr: 2017/690). The patients received written information by ordinary mail about the project including the purpose of the study, handling of sensitive personal data, the follow-up visit as well as possible risks for participation.

Results

Demographic data

Eight females and six males participated in the study. Ten subjects had unilateral CLP, three bilateral CLP and one isolated CP. Chi-square analysis showed no significant difference in sex distribution of the patients compared with the general distribution of CLP and CP in boys and girls ($p = 0.85$). Age at DO was 20 years (15.7–25.3) and at follow-up 27.8 (22–34.9). Time to follow-up after surgery was 7.6 years (2.5–13.6). Length of active distraction was 16.5 days (11–47) and length of fixation phase was 76 days (31–115). Total treatment time wearing the RED device was 93 days (50–131). Velopharyngeal plasty was carried out in three patients after DO. Six patients underwent rhinoplasty, and another two patients underwent lip plasty after DO. The demographic data of the patients are shown in Table 1.

Dental casts

Results regarding overjet from the first measurement are shown in Table 1. The median positive overjet was +2.4 mm (0–4.1). Intra-rater reproducibility was excellent with an ICC of 0.98. Inter-rater agreement was also excellent with an ICC of 0.97.

Questionnaire

Answers to question #1–10 are specified in Figure 2. Seven patients thought it was tough to wear the RED device (question #1), whereas seven patients responded that it was either okay or reported no problems at all. Ten patients considered the device to be a constraint in social interactions (question #2) and nine of them explained why in question #13 (Figure 3). Six patients thought it was challenging to be in public places because the device could attract people's attention and two patients said that the device made it hard to engage in specific activities. One patient mentioned both of these points. Regarding the question on chewing function prior to DO (question #3), eight patients had difficulties whereas six patients had no difficulties. The chewing function after DO (question #4) improved in 13 patients whereas it was unchanged in one. Thirteen patients answered question #5 and all thought that their frontal teeth looked much better after DO. Three patients experienced pain from the jaw and chewing muscles to some degree after DO (question #6) whereas no patient had pain from the jaw and chewing muscles prior to DO (question #7). (Figure 2)

All patients thought the procedure was worthwhile (question #8); 13 patients answered with 'Yes, definitely' and one with 'Yes, to a certain degree'. All patients would recommend the procedure to other patients with a similar condition (question #9); 13 patients answered 'Yes, definitely' and one 'Yes, but with some hesitation'. Speech after DO (question #10) was perceived as worse in two patients whereas it was perceived unchanged, or even improved, in the rest. (Figure 2)

Thirteen patients answered question #11 and 12 of them explained that the main reason for undergoing DO was a blend

Table 1. The subjects' demographic data.

Pat nr	Sex	CLP diagnosis	Age at operation (years)	DO active (days)	DO fixation (days)	Age at follow-up (years)	Time at follow-up (years)	Age at velopharyngeal plasty (years)	Age at rhinoplasty (years)	Age at lip plasty (years)	Positive overjet at follow-up (mm)
1	F	Q374	24.3	15	35	27.3	3.0	7.9 13.7 27.3	–	–	1.6
2	F	Q375	16.3	19	73	27.8	11.5	–	–	–	0.0
3	M	Q375	23.1	16	78	31.3	8.2	–	24.8	–	2.7
4	M	Q375	21.0	21	94	29.0	8	–	22.0	–	3.8
5	M	Q374	20.1	22	57	32.9	12.8	–	–	23.8	3.2
6	F	Q375	15.7	15	70	27.8	12.1	–	20.2	–	2.5
7	M	Q375	19.5	47	31	23.5	4.0	20.3	–	–	0.7
8	M	Q375	19.4	13	93	26.5	7.1	7.6	–	20.8	3.4
9	M	Q375	19.8	22	83	24.9	5.1	22.9	25.8	–	2.4
10	F	Q374	21.3	40	78	34.9	13.6	–	–	–	4.1
11	F	Q355	25.3	11	87	29.0	3.7	13.8	–	–	1.1
12	F	Q375	20.0	16	74	24.5	4.5	7.8	21.8	–	1.8
13	F	Q375	21.4	17	71	33.8	12.4	6.7	21.9	–	2.3
14	F	Q375	19.5	16	115	22.0	2.5	–	20.7	–	2.2

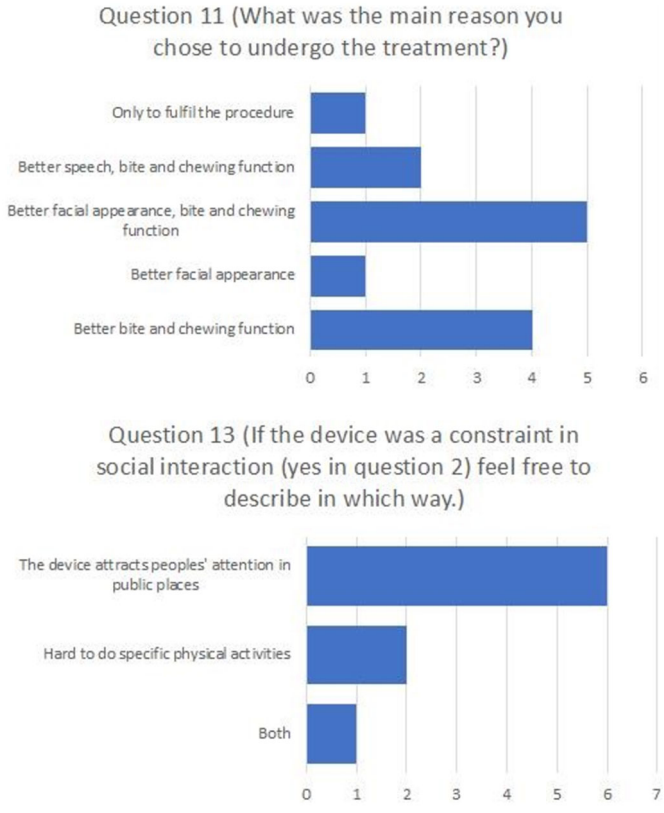

Figure 3. Answers to question #11 ($n = 13$). Answers to question #13 ($n = 9$).

of functional problems related to bite, chewing and speech, and aesthetical shortcomings (Figure 3). One patient simply wanted to fulfil the procedure as a part of the treatment protocol from birth to adulthood. Thirteen patients answered question #12 and all said that they were satisfied with the information regarding the procedure they received prior to surgery.

Discussion

DO is demanding and not all patients may be comfortable with the procedure. There were no data available on whether there had been patients who were recommended DO by the cleft team but declined treatment. Hence, the study includes patients with a confident attitude towards undergoing treatment with DO. This attitude may have coloured their experience of the treatment in a favourable way. Sixteen patients were recruited consecutively to surgery by the senior oral- and maxillofacial surgeon and initiator of the study. Consequently, the risk of selection bias is limited. Fourteen of them participated in the study, and those two who declined to participate did so due to long travelling distance. In summary, the sample seems to be representative for patients with CLP/CP willing to undergo DO.

A predominance of girls was seen among the subjects, although the difference was not statistically significant compared with data from the national quality register. It may still be an indicator that girls care a little more about their functional and/or aesthetical preferences, which were the main reasons for undergoing DO. This reasoning is supported by a recent study which showed that women with CLP do receive more secondary surgery than men [14]. Furthermore, eight of the 14 patients underwent either rhinoplasty or lip plasty to further improve the aesthetic outcome of the DO. The secondary measures were undertaken after DO for two possible reasons. First, an indication for either rhinoplasty or lip plasty already existed before DO but it was postponed until after DO to ensure that no further change in nose and lip configuration would occur. The medical records indicated that this was the case in five instances of rhinoplasty. Second, the new position of the maxilla after DO altered facial aesthetics raising a wish for complementary surgical measures of the nose or lip aimed at approaching normality as close as possible. The medical records indicated that this probably was the case in the other three patients.

A previous systemic review reported no significant difference in speech between patients treated with DO or CO [3]. In the present study, three patients underwent velopharyngeal plasty after DO, indicating a disadvantage of the procedure, i.e. that it causes hypernasality requiring complementary speech improving surgery. Two patients (#7 and #9) described a worsening of their speech after DO, and both underwent velopharyngeal plasty accordingly. Also, patient #1 underwent velopharyngeal plasty after DO and the operation was actually performed in close connection to the follow-up. She reported a better speech after DO but obviously she misinterpreted the question. The effect on the velopharyngeal function by DO was not registered as a part of the routine. Patients who complained of hypernasality were investigated by a speech and language pathologist before complementary speech improving surgery was commenced.

Positive overjet at follow-up was used as a rough and simple measure to study a possible association between this objective outcome and the patients' subjective experience. Only two observers conducted the measurements which can be considered a limitation. However, for the purpose of the study focusing on patient related outcomes, two observers should be adequate enough. A clear association was found in the meaning that all patients had a positive objective outcome, and they were generally very satisfied with the DO procedure. Two patients (#2 and #7) had an overjet of less than 1 mm, but they were also pleased. Overjet may change over time but we found no correlation between overjet measures and follow-up time (Table 1). Further studies on the skeletal relations and the dental occlusion are ongoing and these will include other skeletal and dental variables using cephalometric measurements and orthodontic indices.

No widely accepted questionnaire was available targeting patients undergoing DO when the study was initiated. FACE-Q [15] is a patient-reported outcome instrument that could possibly have been used, but a validated Swedish version was not at hand. Consequently, a questionnaire was constructed with questions that were judged relevant to the target group. All participants completed the questionnaire. Only in one case was missing data noted in the set of different response options. Patient #10, who had a large overjet of +4.1 mm, did not answer the question regarding frontal teeth position after DO.

Modern primary cleft care is in most cases effective and later DO is therefore seldom indicated. The limited number of patients operated with DO reflects the wide range in follow-up time (2.5–13.6 years). A long delay between treatment and follow-up may carry a risk that predominantly positive memories are recalled when answering the questionnaire. Although some negative memories may have vanished, the results clearly indicate that DO is tolerated well by most patients and we found no correlation between subjective experience and follow-up time.

Active phase and fixation phase varied among the patients and thereby also the total length of the treatment. Subjective experience of DO seems not to be correlated with the time required to carry through the treatment since all patients were satisfied with DO and thought the procedure was worthwhile. Thirteen patients said they would definitively recommend the procedure to other patients with similar conditions. This recommendation was also given by the patient who only achieved a 0 mm overjet (patient #2). One patient (#14) stood out with a fixation phase of 115 days. She was slightly more indecisive than the others and thought the procedure was worthwhile but only to a certain degree. Furthermore, she said she would recommend the procedure to other patients with a similar condition but only with some hesitation. Consequently, the prolonged fixation phase may have played a role in her particular experience of the procedure. The rest of the patients had a fixation phase that did not exceed 94 days, which is compatible with the expected treatment interval.

The literature search regarding previous studies on patient-reported outcomes of the RED device experience resulted in two relevant original articles. One study reported on nine CLP patients' satisfaction with the RED device [10]. The authors used a self-made questionnaire based on in-depth interviews with three of the patients. Seven patients experienced negative attention in civic situations and difficulties in everyday activities during treatment. One patient reported having poorer speech due to velopharyngeal insufficiency after DO. Seven of nine patients were satisfied with their overall aesthetic outcomes. Eight patients were satisfied with the overall results and said they would undergo the same treatment again. The study has great similarities with our present one in terms of design and outcomes. Patients are generally happy with the RED procedure but both studies also show that the RED device causes difficulties in specific everyday activities and attracts people's attention. Furthermore, both studies report on speech impairment after treatment. The previous study neither mentions anything about the patients' satisfaction with their noses and lips after treatment, nor does it say anything about rhinoplasty and lip plasty after DO.

The other study used FACE-Q to compare intraoral and RED devices in DO [9]. The study included 64 patients divided equally into 32 treated with an intraoral device and 32 with a RED device. The patients had a variety of different diagnoses but the majority, 19 in each group, had had clefts. Aesthetic outcomes included assessment of the nose and upper lip. Functional outcomes included airway/breathing, ocular/vision, occlusion/eating, and speech/articulation. All patients were satisfied with their noses and lips and no significant differences were seen either in aesthetic or functional outcomes between the groups. There was no information provided regarding surgical procedures of the lip and nose. Patients treated with internal DO, however, had significantly higher quality of life scores and they were more satisfied with their decision to commit to treatment, indicating that it is less cumbersome for a patient to wear an internal distractor than an external one. Anyhow, external distraction of the maxilla provides better three-dimensional control and is preferred whenever it can be tolerated [16]. This is the reason why the RED device is preferred in most cases in whom DO is considered. Our study patients tolerated the procedure well and they would also recommend it to others with similar conditions.

Conclusion

Despite a long and challenging treatment, teenagers and young adults with CLP and maxillary hypoplasia tolerate DO of the maxilla very well. Secondary measures to improve speech and appearance are often indicated.

Acknowledgements

We thank Bo Sunzel, DDS, associate professor, Ingemar Swanholm, DDS, and Mia Stiernman MD, PhD for their various contributions to the present study.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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