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Clinical Paper
Distraction Osteogenesis

Patient satisfaction related to rigid external distraction osteogenesis

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Bas vanEggermontJ. Jansma, M. W. J. Bierman, B. Stegenga: Patient satisfaction related to rigid external distraction osteogenesis. Int. J. Oral Maxillofac. Surg. 2007; 36: 896–899.

Abstract. The aim of this study was to evaluate satisfaction with treatment among cleft lip and palate patients who underwent maxillary advancement using a rigid external distraction (RED) device. Nine patients (four boys, five girls), mean age 17.7 years (SD 4.0), were included in the study. Outcome measures included satisfaction with facial appearance and function (sensitivity/pain, discomfort during daily functioning, daily activities, speech, eating and/or drinking, expression of affection) before, during and after treatment with the RED device assessed by a self-administered questionnaire. Before treatment, the majority of patients were not satisfied with their facial appearance. Some received negative remarks about their appearance and experienced minor functional problems. Dissatisfaction with appearance, negative remarks and functional problems increased significantly during active treatment, and the majority of patients experienced pain or sensitivity. After treatment all patients but one were satisfied with their appearance and level of function. Overall patient satisfaction after treatment with a RED device is high, but the active treatment period, during which the frame is worn, significantly compromises function and may be painful. For most patients, satisfaction with the final result and appearance outweighs the negative factors they reported.

Key words: cleft lip and palate; maxillary distraction osteogenesis; patient satisfaction.

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Maxillary hypoplasia is a common developmental problem in cleft lip and palate patients. Known causes include congenital reduction in midfacial growth[2] and surgical interventions aimed at cleft closure[8,18]. Traditionally, maxillary hypoplasia is treated by means of a Le Fort 1 osteotomy. Long-term results of this treatment in cleft lip and palate patients show an increased tendency to relapse after maxillary advancement, especially in cases with severe maxillary deficiency and extensive scarring of the palatal and pharyngeal tissues[1,11,3,17,6].

In 1997, distraction osteogenesis was first described as an alternative treatment option[15]. Ever since, numerous advantages of this approach over the conventional Le Fort 1 osteotomy have been reported[4,13,14,16]. The most important is that skeletal maturity no longer seems a prerequisite for surgery. This means that facial aesthetics and function can be improved in young adolescents, thereby helping to prevent negative psychosocial development[7,22]. The distraction method described by Polley & Figueroa[15] utilizes a rigid external distraction (RED) device fixed to the skull in combination with an intraoral splint. Beside the advantages this device is likely to have drawbacks. Wearing an extraoral frame for several months may interfere with the patient's social life

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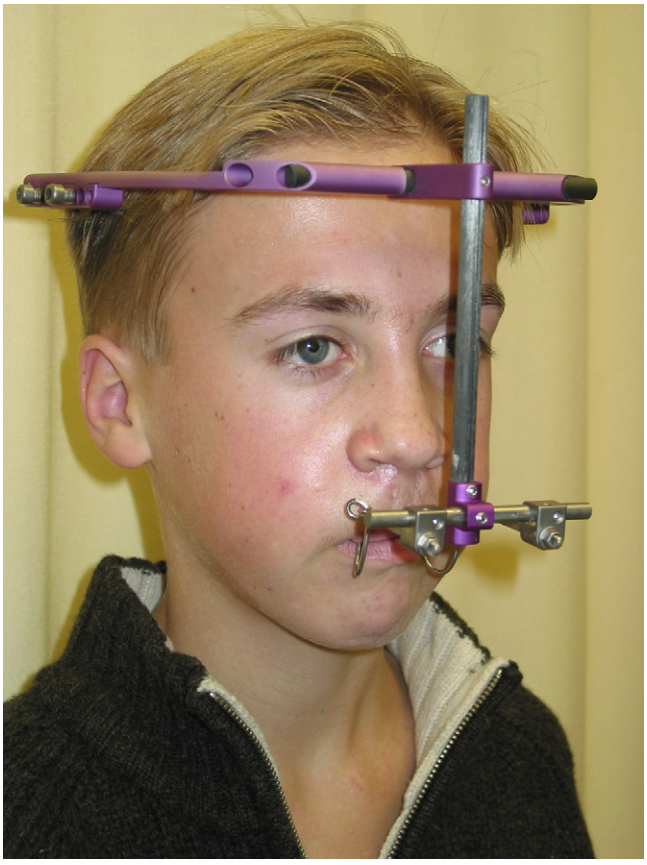

Fig. 1. Patient wearing a RED device.

and daily activities (Fig. 1). The aim of the present study was to evaluate the impact of treatment with the RED device particularly from the patient's perspective.

Materials and methods

Patients

Patients with complete unilateral or bilateral cleft lip and palate treated at the University Medical Center Groningen, The Netherlands, were eligible to participate in the present study. They all received surgical treatment for maxillary hypoplasia by means of distraction osteogenesis with a RED device (KLS Martin, Tuttlingen, Germany).

Distraction procedure

All patients underwent pre-surgical orthodontic treatment with fixed appliances. A palatal arch (1.1 mm) attached to the upper molar bands was inserted in direct contact with the palatal surface of the teeth. The headgear was modified to fit in direct contact with the outer surface of the brackets. The outer arms of the headgear were bent forward in the horizontal plane for about 10 mm before being bent upward to permit swelling of the soft tissues following surgery. A Le Fort 1 osteotomy, including complete pterygomaxillary and septal disjunction, was performed under general anaesthesia. After reaching adequate mobilization of the maxilla by down-fracture, the RED device was fixed to the skull with four pins. During surgery the inner bow of the modified headgear was fixed to the dentition and the palatal arch with wire ligatures of 0.4 mm. The outer arms were fixed to the vertical bar of the RED device with two stainless-steel wires of 0.5 mm. After a latency period of 6–7 days active distraction was started. Distraction was performed at a rate/rhythm of two times 0.5 mm/day. The distraction period ended when sufficient horizontal and vertical movement was reached. After active distraction there was a consolidation period during which the RED frame remained in place without being activated. The external distraction device was then removed after injecting local anaesthetic around the skull pin sites.

Questionnaire

A preliminary in-depth interview with three cleft patients treated with a RED device was performed to gain insight into patients' experiences related to treatment with the RED device. Using the interview as guidance, a questionnaire was developed in which patients were requested to rate their satisfaction with facial appearance and function (sensitivity/pain, discomfort during daily functioning, daily activities, speech, eating and/or drinking, expression of affection) before, during and after treatment with the RED device on a four-point scale. Additionally, patients were asked to answer several specific questions related to the presence of the RED device, pain and/or sensitivity caused by the RED device, impediment of personal hygiene, satisfaction with treatment and treatment length. The potential study population consisted of nine consecutively treated cleft palate patients who underwent maxillary advancement by RED distraction. A questionnaire was sent to all patients, 6–28 months postoperatively.

Results

Patients

All nine patients, four boys and five girls, mean age 17.7 years (SD 4.0), filled out the questionnaire. Four had unilateral and five had bilateral cleft lip and palate. The questionnaire was sent to all patients, a mean of 18.7 months (SD 8.4) after the surgical procedure. All patients filled out the questionnaire, six within 2 weeks and three after being reminded.

Distraction

The active distraction period lasted 20 days on average (SD 7.7 days) in which a mean forward movement of 10.8 mm (SD 2.9) was achieved. An average consolidation period of 45.1 days (SD 9.5) was sustained during which the RED frame remained in place to support osteogenesis. Due to complications, in three cases the distractor had to be removed prior to the end of the consolidation period. It was replaced by a Delaire facemask to make up the rest of the consolidation time, which was 6–8 weeks, and allow further osteogenesis. The mean total treatment time with the distractor in place was 72 days (SD 11.4). During this period the patients attended the clinic 10.4 times on average (SD 3.8).

Satisfaction with facial appearance

Before treatment, the majority of patients (six) were dissatisfied with their facial appearance. Three patients reported frequent remarks about their appearance, mostly negative in nature.

During treatment, the number of patients dissatisfied about their facial appearance increased to seven. The number of patients who received remarks about facial appearance increased from three to eight. These remarks were negative in nature (being pointed at, stared at and teased, shock reactions) and mostly expressed by strangers.

After treatment, most patients (seven) were satisfied with their facial appearance, and all patients but one (eight) reported receiving positive remarks about their facial appearance (having an improved facial appearance, being more handsome). Positive remarks were mostly made by friends and family.

Functional problems

Before treatment, one patient experienced functional problems with respect to daily activities caused by deafness, one patient had problems during eating and drinking due to fistulae, another one experienced problems speaking due to stuttering, and one patient was limited in affective expression. During active treatment, seven out of nine patients experienced problems in daily activities, namely sports, getting dressed, sleeping and social activities. Also, seven patients indicated experiencing speech problems due to the presence of the RED frame. Seven patients reported difficulties with chewing and indicated mainly having to take a liquid-to-soft diet. Finally, seven patients reported having been limited in their affective expression during the treatment period.

After RED frame removal, the patients did not encounter any problems during daily functioning, activities, and eating and drinking. One patient reported encountering problems caused by unclear speech related to velopharyngeal incompetence.

Specific problems related to the presence of the RED device

All patients but one reported to experience pain or sensitivity during active distraction and consolidation at the insertion site of the skull pins. Five of the patients experienced pain as a consequence of removal of the RED device. More than half of the patients (five) indicated that the RED device significantly impeded their personal hygiene (tooth brushing and hair washing). Two patients scored the RED treatment as worse than they had expected. The same patients were dissatisfied with the length of the period during which the RED frame was worn. Eight out of nine patients were satisfied with the final treatment outcome, and five out of nine stated that they would undergo the treatment again with their acquired knowledge.

Discussion

Maxillary distraction in cleft lip and palate patients is a relatively new technique to advance the maxilla. It is mostly performed with an externally placed distractor using a frame attached to the cranium for stabilization (halo frame). The most popular distractor for this purpose is the RED frame[15,5]. Several studies have been performed to evaluate the technical outcome and morbidity of treatment with a RED device[7,22,9,10,19,23], but there appear to have been none published that evaluate the patient's personal experiences of this treatment.

In the present study, all nine patients with cleft lip and palate that were treated with a RED frame responded to the request to fill out a questionnaire. Eight out of nine were satisfied with the final treatment outcome after the distraction procedure, but the period during which the RED frame was worn significantly compromised their daily activities, speech, eating and drinking, personal hygiene and expression of affection. Most patients received negative attention related to the presence of the distractor frame. Additionally, most patients reported pain and sensitivity mainly at the insertion site of the skull pins. Despite this, five of the nine patients stated that they would undergo the same treatment again. For most of the patients, their satisfaction with the final result and appearance outweighed the negative factors reported.

Distraction osteogenesis by means of a RED frame introduces a new range of problems into cranio-facial surgery. Besides the RED device being conspicuous and adversely affecting social life and daily activities, as shown in this study, complications caused by the distractor itself may occur. Device failure has been observed[5], but most complications are seen in relation to the external frame fixed to the skull. Minor complications such as skin irritation, sensitivity and pain surrounding the skull pins have been reported[5] and are supported by the present findings, but also more severe complications such as meningitis resulting from intracranial pin migration may occur[21]. Additionally, dental compensation may be introduced when the traction force is delivered through a tooth-borne intraoral splint consequently reducing the amount of skeletal correction[20].

Up until now, no evidence is available as to whether the maxilla will continue to grow after distraction osteogenesis[5]. No postoperative growth was observed after maxillary distraction in a sample of eight patients[23] (two patients with Apert syndrome and six cleft patients) with a mean age of 13.7 years (range 8.1–18.7) using both intraoral and extraoral distractors.

Although it is assumed that, because of the gradual movement of the maxilla and simultaneous histiogenesis, relapse rates after maxillary distraction osteogenesis are lower than after conventional Le Fort 1 osteotomy, there are no long-term data to substantiate this[23,20]. Therefore, it seems rational to warn patients undergoing distraction before skeletal maturity is reached that there is a risk that they may develop a recurrent class III occlusion and have to undergo further distraction osteogenesis or conventional osteotomies once skeletal maturity has been achieved. With the improvement of facial appearance during young adolescence and the correction of the cleft stigmata, the psychosocial impact of early advancement with distraction osteogenesis may still outweigh this risk. The greater the antero-posterior discrepancy, the greater this advantage may be.

Given its potential impact on a patient, RED distraction may not always be the treatment of choice. In selected cases maxillary advancement may be achieved using internal distractors[5]. The use of internally placed distractors is now limited, especially with respect to vector control (open bite closure, midline correction), since they are unidirectional[4]. Intraoral devices can be applied in cases where distances up to 10–15 mm are sufficient for correction of the growth deficit[12].

When the amount of maxillary advancement needed is limited, and the surgical conditions are adequate, in adults a Le Fort 1 osteotomy still remains the first choice treatment. In growing patients it is not common to perform a Le Fort 1 osteotomy but, compared to distraction osteogenesis using a RED frame, it would have the advantage that patients are not afterwards compelled to experience a long period of social compromise and increased vulnerability.

This study comprised only nine patients, but provides insight into the problems patients encounter during maxillary distraction with an external device. A proper randomized trial that compares the results of conventional Le Fort 1 osteotomy and distraction osteogenesis (with both externally and internally placed distractors) in cleft lip and palate patients would be worthwhile. Apart from the surgical aspects, long-term stability and relapse, complications and impact on speech and facial aesthetics, patient satisfaction with treatment, and impact of treatment on social functioning need to be further evaluated.

Prospective administration of the questionnaire (prior to treatment, during treatment and after a standard post-treatment period) would have given more reliable information and would probably have strengthened the outcomes of the present study. Since the longer the lapse between the end of treatment and administration of the questionnaire the less accurately the patients recall details of the experience, negative associations might be stronger than presented in this study.

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