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Assessment of Maxillary Distraction Forces in Cleft Lip and Palate Patients

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1. Introduction

Distraction osteogenesis is a process that depends on biomechanics, where the application of progressive traction forces leads to bone lengthening by gradual new bone formation. (Illizarov, 1989a, 1989b) Consequently, stretching of surrounding soft tissues occurs at different tissue depths, allowing correction of severe skeletal dysplasias in short periods of time. However, biomechanical data from the craniofacial distraction osteogenesis process is limited and the mechanical and biological nature of the traction forces involved is not fully understood (Gardner et al., 1997).

Assessment of distraction forces within the structure being distracted may provide current information about the mechanical response and therefore conditions in the distracted structure, including, premature consolidation, device failure, or the existence of incomplete osteotomies (Aarnes et al., 1994, Younger et al., 1994). This assessment may further lead to improved understanding of the nature and biology of distraction, and help determine optimum rates and rhythms (Samchukov, 1998).

Studies have been published on forces during distraction of the tibia and femur using instrumented external fixators in conjunction with micrometers or goniometers (Evans et al., 1988, Richardson et al., 1994, Aronson et al., 1994). Similar studies have been performed in animals (Gardner, 1998). However, the results obtained by these authors are extremely controversial. The great variability of distraction devices, complexity of methodology employed, site of distraction force application, and anatomical structure seem to dictate great influence.

In the craniofacial area, only few studies have examined the distraction forces required to lengthen the mandible during distraction, even though measurements were performed indirectly through the measurement of torque necessary to perform the activation of the distractor (Robinson et al., 2001, Burstain et al. 2008).

Recently, the authors have developed a simple mechanism to measure and adjust maxillary distraction forces during maxillary advancement (Suzuki & Suzuki, 2010). The mechanism was developed in order to allow direct assessment of distraction forces.

Therefore, the purpose of the present study is to monitor the distraction forces applied through maxillary distraction osteogenesis in cleft lip and palate patients with this simple mechanism.

2.1 Materials and methods

This clinical study was carried out on patients who underwent maxillary distraction osteogenesis through the use of the rigid external distraction (RED) device combined with a Twin-Track distractor in an attempt to optimize the distraction process and improve patient comfort during maxillary advancement. A simple mechanism to monitor the tension force on the traction wire was designed to obtain data, analyzing the behavior applied through maxillary distraction osteogenesis by means of a force gauge.

Twenty patients with a variety of dento-alveolar clefts and one non-cleft (asymmetric) patients that were selected for treatment by maxillary distraction osteogenesis were asked to take part in the study. Criteria for selection were based on the presence of a severe maxillary hypoplasia. There were 10 unilateral cleft lip and/or palate (UCLP) patients, 8 bilateral cleft lip and palate (BCLP) patients, and 2 non-cleft patients (Table 1). Maxillary advancement was performed at the mean age of 21.8 years (subjects ranged from 15.2 to 24.8 years of age). In none of these patients had alveolar bone grafting been previously performed.

Case	Cleft Type	Age	Distraction Protocol			Maximum Force (N)
			Latency (days)	Activation (days)	Advancement (mm)	
1	UCLP	15.6	5	10	16.0	35.6
2	UCLP	17.2	6	11	16.5	36.2
3	UCLP	22.6	5	9	14.6	35.0
4	UCLP	18.8	5	11	16.5	41.5
5	UCLP	19.2	5	10	15.6	42.0
6	UCLP	23.5	4	12	17.3	45.0
7	UCLP	18.6	4	13	21.2	46.0
8	UCLP	22.3	6	11	19.5	42.0
9	UCLP	26.0	6	10	18.6	40.0
10	UCLP	21.2	4	9	20.0	43.0
11	BCLP	23.4	5	11	13.0	29.0
12	BCLP	24.3	5	10	12.5	26.0
13	BCLP	21.6	5	9	12.6	24.3
14	BCLP	22.3	4	12	12.0	21.3
15	BCLP	24.2	4	14	11.3	24.0
16	BCLP	22.2	4	14	16.0	28.6
17	BCLP	25.3	4	16	15.0	27.0
18	BCLP	19.6	6	12	13.0	21.2
19	Non-Cleft	22.3	6	14	18.0	45.8
20	Non-Cleft	25.6	6	15	15.0	39.5
	Mean	21.8	5.0	11.7	15.7	34.7
	SD	2.8	0.8	2.1	2.8	8.7

Table 1. Patient characteristics and distraction protocol

All patients underwent a thorough history and clinical examination as well as complete dental and orthodontic examination. Clinical photographs, dental casts, lateral and postero-anterior cephalograms, panoramic radiographs, and three-dimensional computed tomography were taken preoperatively. Further lateral cephalograms were obtained after the latency period, during the distraction period, after completion of the active period of distraction, and at the completion of the consolidation period. The amount of distraction osteogenesis, the progression of osteogenesis and remodeling, and any relapse were evaluated on the radiographs.

2.1.1 Simple mechanism to measure distraction forces

A simple mechanism to measure and adjust the maxillary distraction forces was specially designed and assembled to the RED device in order to allow direct measurement of tension force during maxillary distraction osteogenesis (Figure 1). The mechanism was developed based on principles used in the US space programme and described by Iacomini in 1998. Iacomini proposed a simple mechanism to anchor and adjust tension force on cables in order to suspend a structure for thermal isolation. Unlike turnbuckles and other conventional cable-tensioning mechanisms, this mechanism facilitates direct measurement of the tension in the cable. Structural modification of Iacomini's method was performed in order to allow clinical assessment of the traction forces applied during the maxillary distraction osteogenesis. The near end of the cable was threaded through the mechanism and tied off in a loop at the crimp stopper. The tension was measured directly by simply pulling on the cable with an attached force gauge and reading the measurement when the stopper was unseated.

Mechanism to Measure and Adjust Distraction Forces

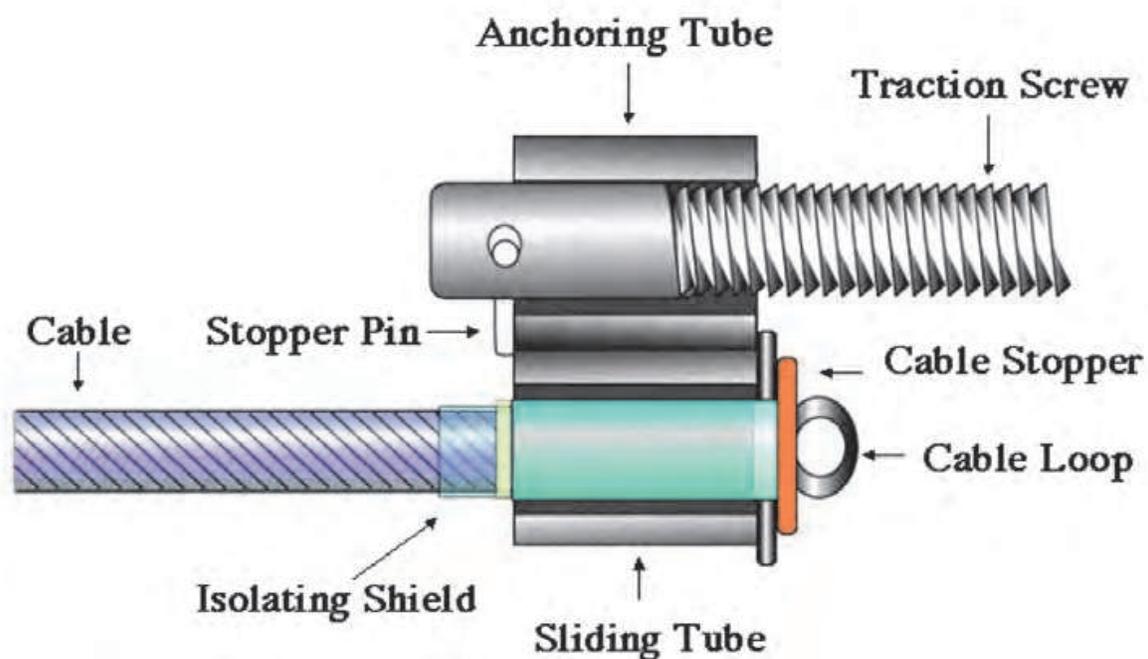


Fig. 1. Simple mechanism to measure and adjust distraction forces

2.1.2 Distraction protocol

2.1.2.1 Measurement

Maxillary distraction osteogenesis was performed after a complete Le Fort I osteotomy, under general anesthesia with orotracheal intubation, using an external distraction device (RED system, Martin L. P., Jacksonville, FL, USA) in combination with a Twin-track (Suzuki et al., 2006) and removable intraoral splint (Suzuki et al., 2006) for anchorage of distraction

forces (Figure 2). A latency period of 4 to 6 days was preserved before initiating the distraction.

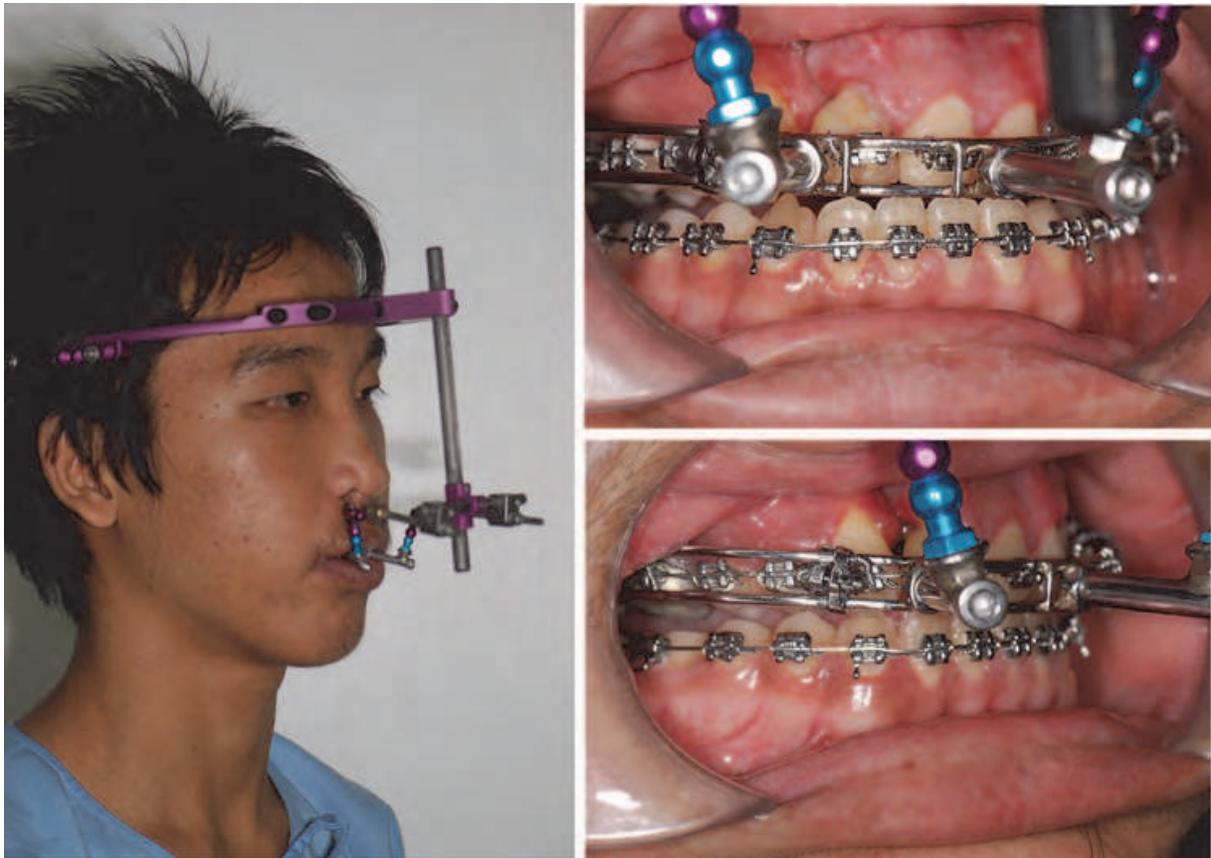


Fig. 2. RED system in combination with a Twin-Track distraction device.

The simple mechanism was connected bilaterally to the traction screws of a RED system in order to permit the assessment of distraction forces (Figure 3). In all cases, the maxilla was advanced parallel to the functional occlusal plane. The traction micro-cables replaced the conventional surgical wires in order to optimize the transference of traction forces to the maxillary bone, thereby avoiding the distortion that was observed in the traction wires.

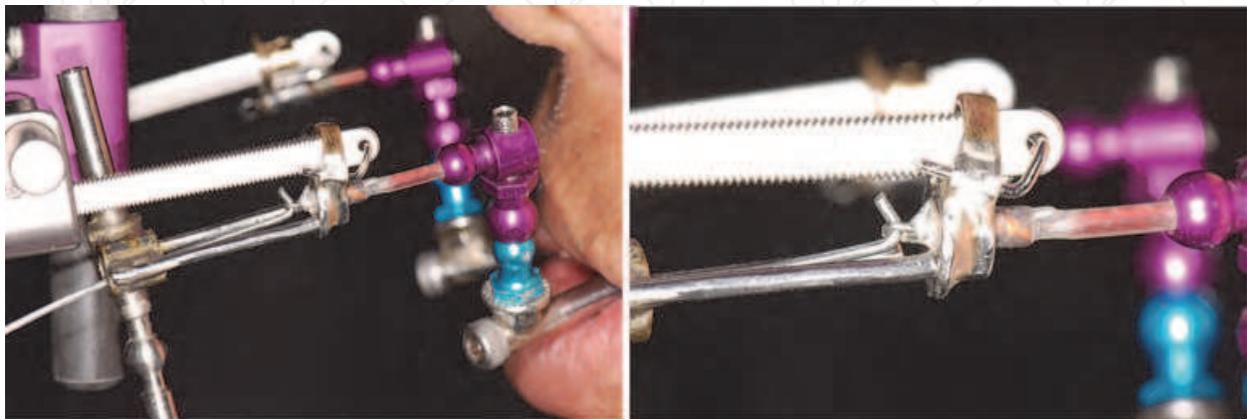


Fig. 3. The simple mechanism is connected bilaterally to the traction screws of a RED system in order to permit distraction force measurement.

Distraction force can be measured directly by simply pulling on the cable loop. An electronic light sensor was developed to identify the minimum distance necessary to unseat the stopper. Distraction force equals the measurement force that is just sufficient to unseat the stopper (Figure 4).



Fig. 4. A light sensor was developed to identify the minimum distance necessary to unseat the stopper

Distraction was performed at the rate of 1.0 mm/day in two increments, preserving a 12-hour interval between activations. Measurements were carried out before and after activation using a digital force gauge (Shimpo FGS-50S, Nidec-Shimpo America Corporation) during the distraction and consolidation periods. The amount of force being applied was monitored every day before the distraction was carried out. The duration of the maxillary distraction period was determined clinically and cephalometrically by the severity of the midface retrusion and anterior dental cross-bite. All patients remained in the hospital during the distraction period. Activation and distraction force measurements were performed by the same orthodontist (EYS). The patients were followed-up daily to assess progression of distraction until the proper overjet, overbite, and relatively stable occlusion were achieved. The device was maintained for three weeks for rigid retention after activation was completed. After this period, the patient was returned to the clinic for removal of the cranial portion of the RED device with a small amount of local anesthetic at the scalp pin sites. An additional 4 to 6 weeks of retention using facial mask elastics at night-time only was utilized.

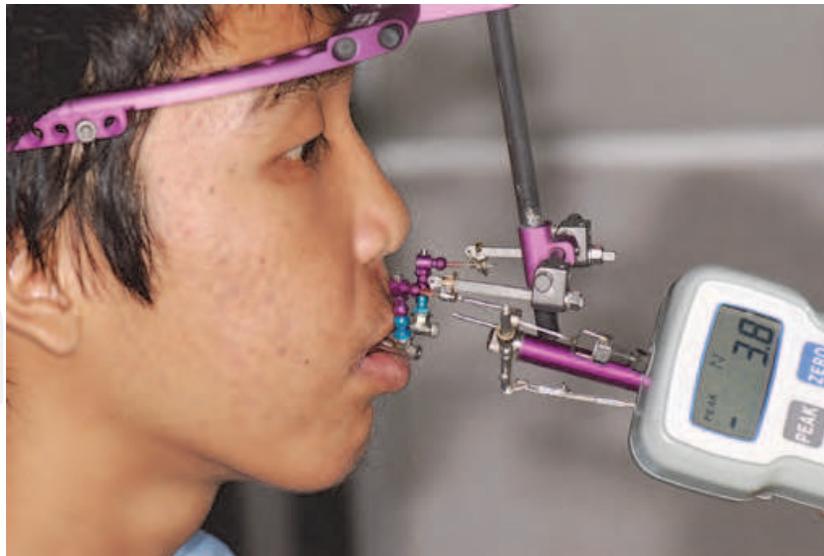


Fig. 5. Direct assessment of distraction forces in a patient. There were no complications, such as pain, discomfort, or procedural delays in measuring and adjusting the distraction forces.

3. Results

Distraction forces were monitored from the fourth to the sixth day following surgery. The typical patterns of the force registered immediately before and after distraction are shown in Figures 6 to 9. Forces recorded before and after each lengthening showed a progressive increase of distraction forces. Each distraction step resulted in an immediate increase in load followed by gradual but incomplete relaxation. As advancement progressed, distraction forces increased; on the other hand, the amount of maxillary movement decreased. Figures 6 to 9.

After distraction was discontinued the force decayed slowly and progressively. The amount of movement observed was inversely proportional to the increase of forces. Pain and discomfort were reported with high forces. In all patients, the intended amount of distraction was achieved. Figures 10 to 12.

The average maximum force applied throughout the distraction period was 34.7N (range 21.2 to 46.0N) with increments after activation averaging 6.7N (range 3.4 to 11.7 N). A significant correlation (0.738) was observed between the maximum forces and the amount of maxillary advancement.

In the UCLP patients, differential pattern of forces between the lateral segments were clearly observed. Distraction forces on the larger segment were approximately 70% higher than on the lesser segment. The typical pattern of the force registered immediately before and after distraction in a UCLP patient is illustrated in the Figure 6.

The forces measured in both larger and lesser segments showed a cycle of instantaneous load increase after each distraction followed by a varying degree of stress relaxation. In both segments, the amount of movement observed was inversely proportional to the increase of forces.

The differential pattern of forces between segments (larger and lesser) was not observed in the BCLP patients. Figure 7 shows the typical pattern of the force registered immediately before and after distraction in a BCLP patient. As in UCLP patient, the forces measured in both segments showed a cycle of instantaneous load increase after each distraction followed by a varying degree of stress relaxation. In both segments, the amount of movement observed was inversely proportional to the increase of forces.

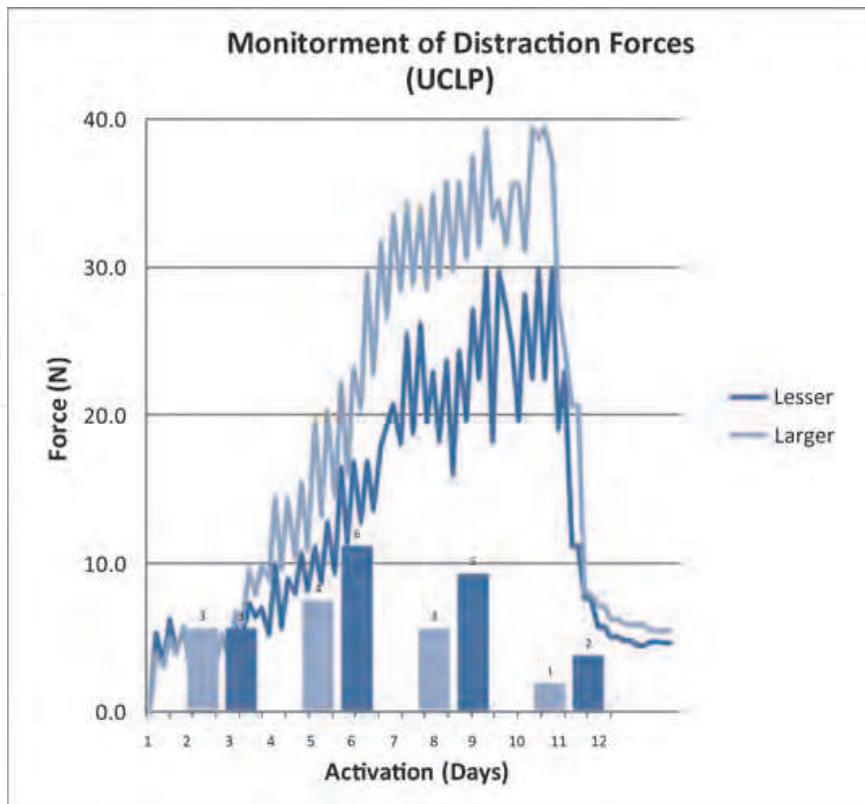


Fig. 6. Typical pattern of distraction forces observed in UCLP patients. As advancement progressed, distraction forces increased; on the other hand, the amount of maxillary movement decreased.

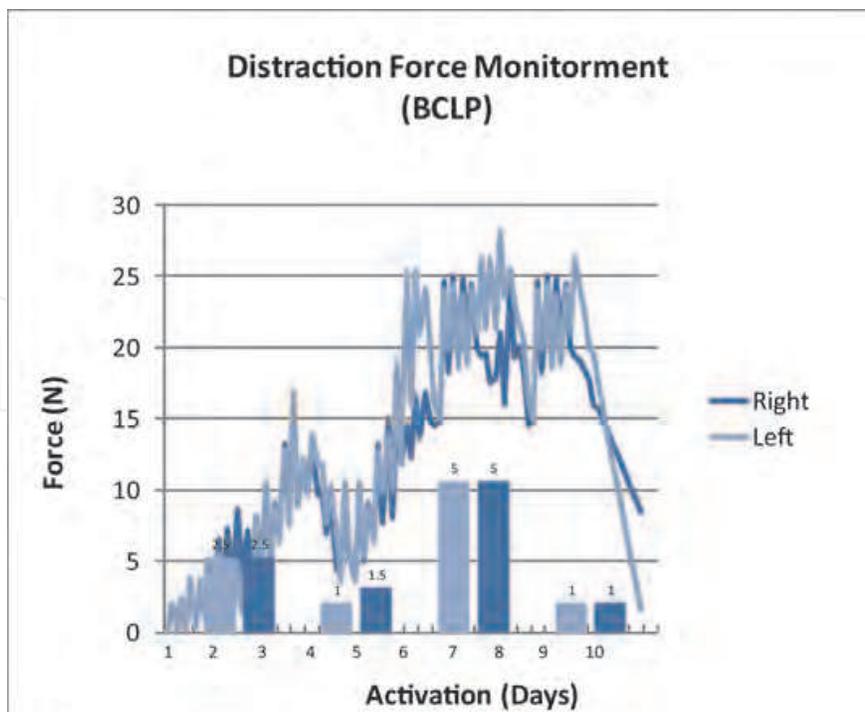


Fig. 7. Typical pattern of distraction forces observed in BCLP patients. Similar pattern of forces are observed in the right and left segments.

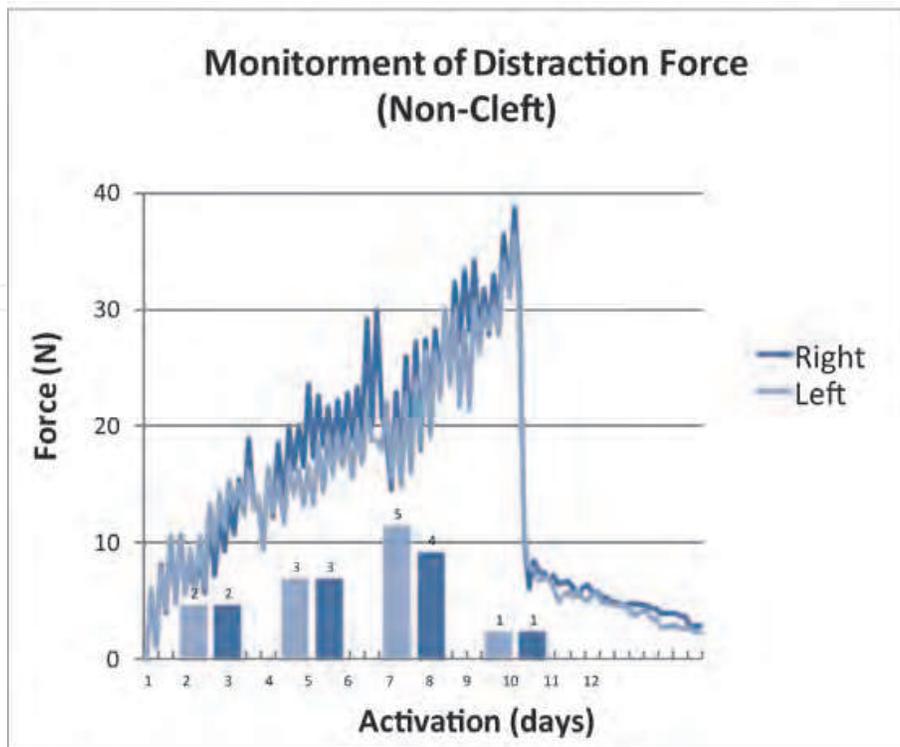


Fig. 8. Typical pattern of distraction forces observed in non-cleft patients. Similar pattern of forces are observed in the right and left segments.

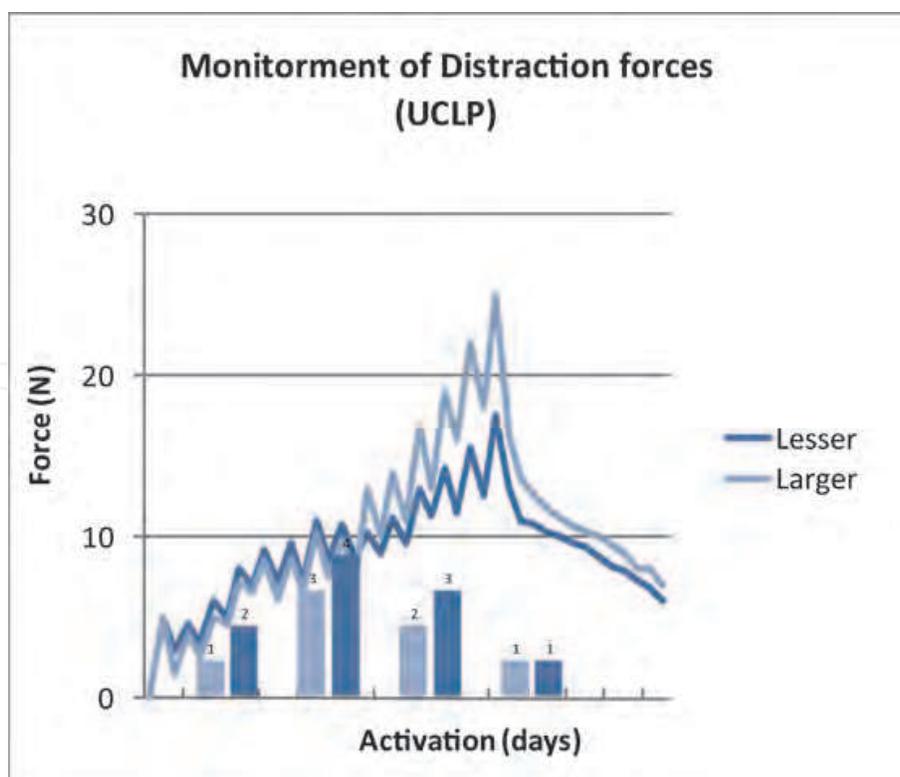


Fig. 9. Pattern of distraction forces observed in a young UCLP patient. Large amount of advancement was obtained in a short period of time.

No differential pattern of forces was observed in the non-cleft patients. Figure 8 shows the typical pattern of the force registered immediately before and after distraction in a non-cleft patient. The pattern of forces was similar to the BCLP patients.

Relatively short distraction period was necessary to complete the maxillary advancement in a young UCLP patient (Figure 9). Monitoring of distraction forces also demonstrated that the amount of force necessary to advance the maxilla in young patients is smaller than those applied in adult patients.

The most interesting aspect is the analysis of how forces varied during the course of maxillary distraction osteogenesis. We can thus see from the graphs how the force increases each day, rising dramatically after distraction, and then slowly falling until it reaches a value slightly greater than the final force on the previous days.

Monitoring of distraction forces was relatively easy and no time-consuming. There were no complications, such as pain, discomfort, or procedural delays in measuring and adjusting the distraction forces.

The mechanism remained intact in all patients through the active and retention phases. Distraction forces increased progressively with distraction.

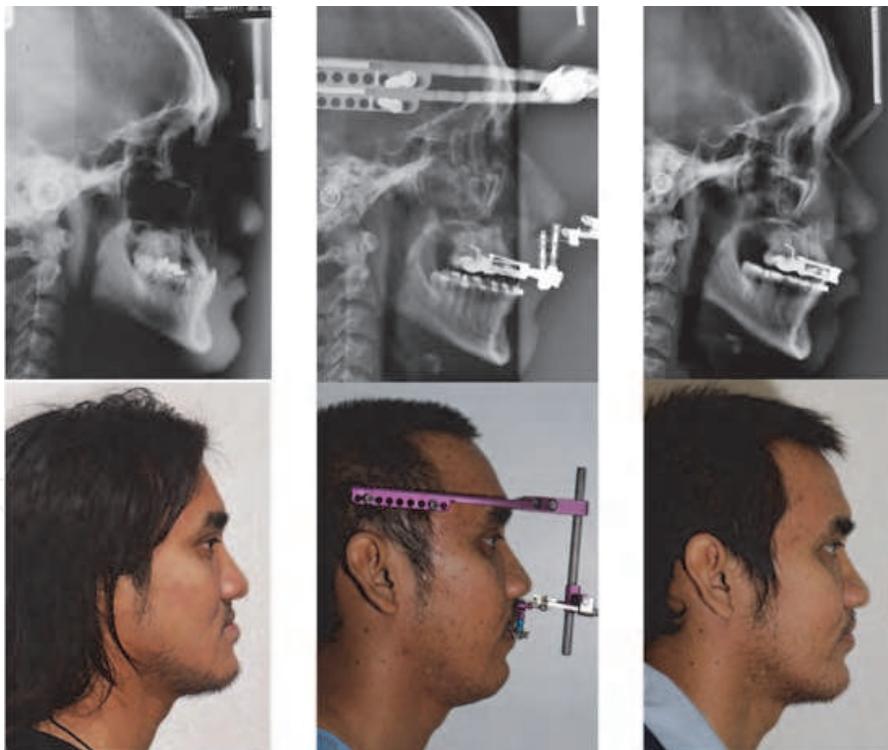
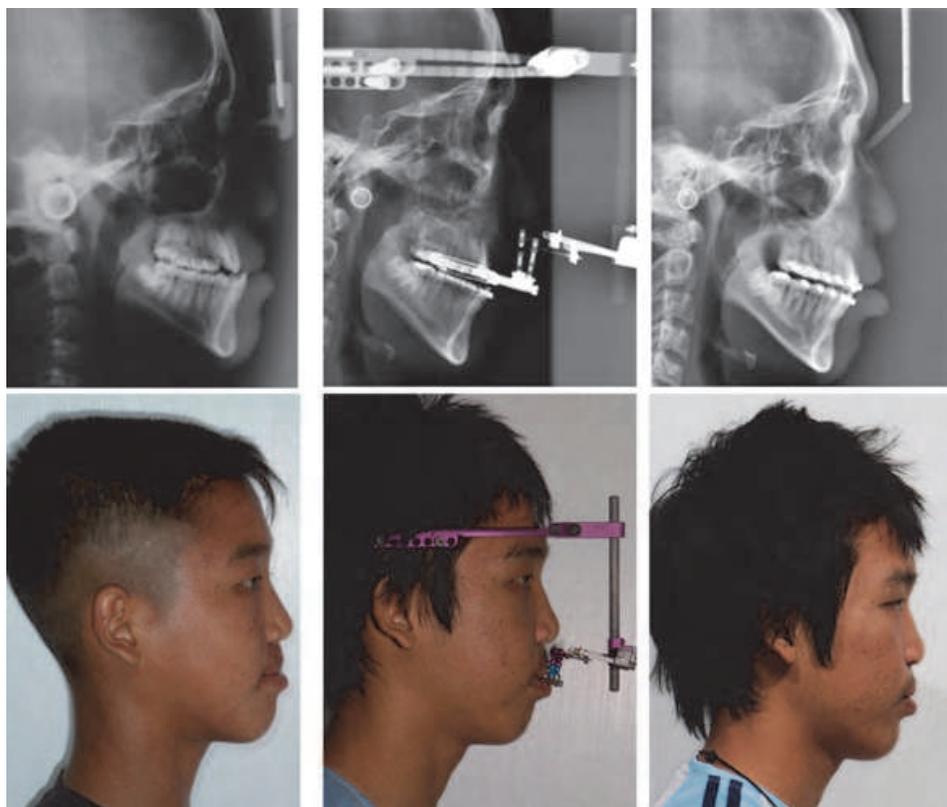


Fig. 10. Pre-surgical, distraction and post-distraction pictures. Significant improvement of the face and profile can be obtained with distraction osteogenesis.

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Fig. 11. Pre-surgical, distraction and post-distraction pictures. Significant improvement of the face and profile can be obtained with distraction osteogenesis.

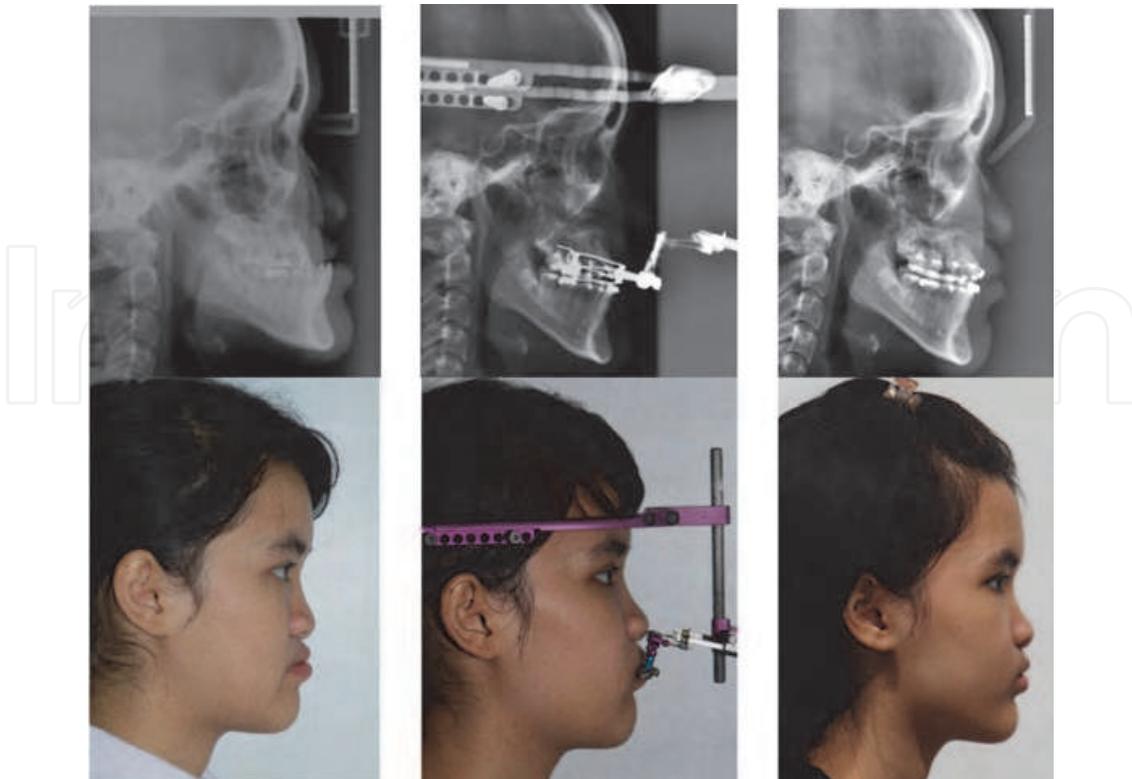


Fig. 12. Pre-surgical, distraction and post-distraction pictures. Large amount of advancement was obtained in a short period of time.

4. Discussion

The present study described the development of a simple method of adjusting and measuring tensile forces during maxillary distraction osteogenesis. Although distraction osteogenesis of the maxilla is well reported in the literature, no study has been published describing the monitoring of distraction forces necessary to advance the maxillary bone either in humans or in animals. It may be explained due to the difficulties encountered to measure the healing process accurately and for the complexity of monitoring techniques available today (Wiltfang *et al.*, 2001).

Several studies have been performed to assess the magnitude of traction forces applied on the distracted structure. However, most of measurements were performed in long bones or on experimental models basis. Moreover, the data obtained by these authors show great disparity. Forces exceeding 1500 N at the time of lyses were measured by Monticelli and Spinelli (1981) in two patients. Kenwright *et al.* (1990) recorded the force of 600 N, and Jones *et al.* (1989) a load of 400 N. Roermund *et al.* (1992) monitored continuously the traction forces during tibial lengthening in a patient and found that 800 N was required for complete lyses. Forriol *et al.*, (1997) measured the force required for distraction osteogenesis of the lamb tibia. The maximum force occurred after activation of force and attained values over 8 Kgf. In the craniofacial area, Wiltfang *et al.* (2001) using a micro hydraulic distractor device on the mandible of pigs observed that forces up to 2500kPa were necessary to move the cylinders` piston and 1200 -1300 kPa necessary for continuous distraction. Robinson *et al.* (2001) measured the mean force of 4.2 N-cm of torque or an equivalent force of 35.6 N to lengthen the human mandible. However, measurements were performed indirectly using

laboratory data and clinical correlation. The great variability of distraction devices, complexity of measurement methodology applied, site of distraction force application, and anatomical structure seems to dictate great influence. All authors agreed that the assessment of distraction forces clinically is an important tool for the clinician to better understand the biomechanical response of the distracted structures and to manage the symptoms.

In the present study, the assessment of maxillary distraction forces was possible using the proposed mechanism. Distraction forces could be measured directly by simply pulling on the cable loop with a force gauge. The mean force observed in this group of patients was 34.7N. However, great variation of the maximum forces was observed in all patients, despite to the amount of maxillary advancement or cleft type suggesting that an individual adjustment of forces is highly desirable. During distraction, force measurement showed a gradual increase in the force needed to activate the device during the initial days. Force peaks were reached immediately after the activation of the distraction device. Twelve hours later the distraction force had fallen substantially and reaches a value slightly greater than the final force on the previous days. As the soft tissue has substantial viscoelastic behavior, these are just a transient peak force, and after distraction the force decrease exponentially (Leong et al., 1979) with an average rate of 2.3 N/h the first 3-5 h (Aarnes et al., 2002).

The main finding of this study was the differential pattern of forces between the lateral segments observed in unilateral cleft lip and palate subjects. Distraction forces measured on the larger segments were approximately 70% higher than on the lesser segment, indicating differential force requirements to advance a cleft maxilla. On the other hand, the amount of advancement on the lesser segment was higher than on the larger segment, suggesting that the increase of distraction forces is inversely proportional to the amount of bone movement. Namely, the increased resistance to the movement causes the increase of forces. The magnitude and the pattern of forces are greatly determined by the biomechanical properties of the tissues to be lengthened. These biomechanical properties may vary between individuals, necessitating an individual adjustment of the distraction rate to prevent excessive traction forces. The explanation of the differential pattern of forces between the lesser and larger segments in unilateral cleft lip and palate patients should therefore be addressed to the cross-sectional area of the callus, modified by the rate, rhythm, and age of the patient rather than to the presence of scarring tissue.

In the present study, assessment of distraction forces did not allow differentiation between contribution from the soft tissue envelope and the regenerate. Previous investigations have suggested the soft tissue (Aarnes et al., 2002; Gardner et al., 1997), the regenerate (Aronson and Harp, 1994) or both (Gardner et al., 1998) to be the source of the tensile force. The force in the rigid external distractor is a result of the resistance in the composite tissue system, and the interpretation of the results depends on which structure provides the major resistance. If the force mainly originates from the regenerate, high forces suggest good bone mineralization and should be preferable. However, with the soft tissue being the major contributor a high tensile force indicates poor adaptation with risk for tissue damage, and lower forces are desired. Further studies are necessary to clarify the effects of distraction osteogenesis on the soft and hard tissues, and the influence of the scar tissue from both a clinical and an experimental point of view.

The process of distraction osteogenesis involves an interaction of mechanical and biological factors that influence each other. The mechanical factors are usually only defined in terms of distraction frequency and velocity, and in terms of rigidity of fixation.

In the present study, mini cables replaced the conventional surgical wires used to deliver the traction forces to the maxillary bone. It will optimize the traction forces applied to the maxillary bone avoid the lack of rigidity often observed on the traction wires that will result in an inadequate transmission of forces to the maxillary bone (Suzuki et al., 2004). Moreover, the ideal 1:1 ratio of bone to device movement will not be accomplished. As a result the recommended bone movement rate of 1mm/day will not be achieved (Block et al., 1995).

Complications arising from excessive forces are often severe and include pain and discomfort for the patient, traction injuries to the nerves and vessels, dental compensation and alteration in the mechanical conditions of the distraction device. To minimize the complications is necessary to optimize the procedure of lengthening biomechanically. The process of biomechanical optimization requires an examination of the constraints and continuous monitoring of forces. The measurement of distraction forces clinically using the innovated mechanism proved to be helpful to better adjust the distraction rate in the maxillary advancement and to reduce the risk of causing excessive tensile forces and associated complications. Moreover, the quantitative measure of bone loading capacity would allow an estimation of individual time requirements for healing, therefore permitting individual adjustments.

In the daily bone lengthening procedure, the greatest forces are produced in a short period of time immediately after lengthening. They could be reduced to decrease pain in the patient and loads on the device by performing lengthening over a greater number of steps or using dynamic equipment able to absorb these forces (Wiltfang *et al.*, 2001).

Aarnes et al. (2002) has shown that in the stepwise lengthening, a total lengthening of 1 mm cause less force accumulation than a 1.75 mm elongation. The present study indicates that this is valid for the maxillary distraction as well. Accordingly, there is a mutual dependency between the force increment and the amount of maxillary advancement. Lower rates seem to reduce the tensile force in the soft tissue during distraction osteogenesis. The reduction is assumed to be due to less tissue injury and increase of muscle growth, and thereby the increased adaptation of ability in the soft tissues.

To date, assessment of distraction forces during maxillary advancement have not been determined, consequently it has not been possible to examine optimum rates and rhythms for maxillary distraction. Knowledge of these forces can be used in the clinical setting to determine the safety margins for the device manufacturing and to give immediate clinical feedback regarding what may be happening in the distraction site, including, premature consolidation, device failure, or incomplete osteotomies. This information can be used to determine if the rate, rhythm, or distance of distraction should be modified.

The maximum mean force of 34.7N needed to distract the maxilla means that in designing a device, greater miniaturization is possible as long as a safety factor is incorporated into the design. At times, it is necessary to readjust the traction angle to permit the three-dimensional control over the maxillary bone (Polley and Figueroa, 1997). Assessments of distraction forces will permit the adjustment of forces delivered to the distraction process at the same levels, avoiding loss of forces. Another advantage of the force assessment is the possibility to adjust individually the amount of force delivered to the maxillary segments in cleft patients, therefore optimizing the distraction procedure and reducing the patient discomfort and symptoms.

5. Conclusion

We have developed a direct method for monitoring the distraction forces during maxillary distraction osteogenesis using a simple mechanism. Direct measurement of maxillary distraction forces provides current information about the mechanical response and, thereby, the condition in the distracted structures. Assessment of the forces within the maxillary bone during distraction osteogenesis may lead to a better understanding of the nature and biology of distraction, and help determine the most appropriate distraction protocol. The optimum distraction forces and a system to permit continuous distraction forces to the maxillary bone are to be determined by future studies.

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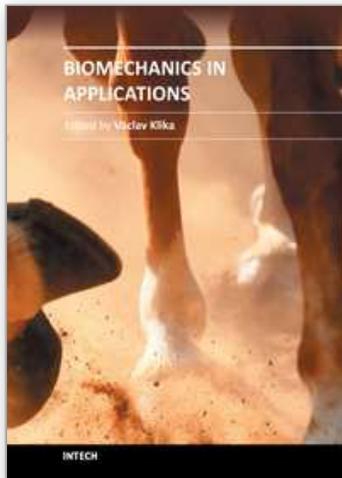
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During last couple of years there has been an increasing recognition that problems arising in biology or related to medicine really need a multidisciplinary approach. For this reason some special branches of both applied theoretical physics and mathematics have recently emerged such as biomechanics, mechanobiology, mathematical biology, biothermodynamics. The Biomechanics in Application is focusing on experimental praxis and clinical findings. The first section is devoted to Injury and clinical biomechanics including overview of the biomechanics of musculoskeletal injury, distraction osteogenesis in mandible, or consequences of drilling. The next section is on Spine biomechanics with biomechanical models for upper limb after spinal cord injury and an animal model looking at changes occurring as a consequence of spinal cord injury. Section Musculoskeletal Biomechanics includes the chapter which is devoted to dynamical stability of lumbo-pelvi-femoral complex which involves analysis of relationship among appropriate anatomical structures in this region. The fourth section is on Human and Animal Biomechanics with contributions from foot biomechanics and chewing rhythms in mammals, or adaptations of bats. The last section, Sport Biomechanics, is discussing various measurement techniques for assessment and analysis of movement and two applications in swimming.

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