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ORIGINAL RESEARCH

Design of an internal distraction device for maxillary advancement in cleft-lip-palate patients

Diseño de un distractor interno para el avance maxilar en pacientes con labio y paladar hendido

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ABSTRACT

Introduction: Cleft lip and palate (CLP) is the most frequent craniofacial defect. (1:1000 newborns). CLP patients present severe maxillary retrusion that require a surgical procedure to advance their maxilla. Distraction osteogenesis is an effective treatment; however available internal maxillary distraction devices present inconveniences. **Objective:** To design a biocompatible, inexpensive and mechanically efficient prototype of an internal maxillary distraction device. This device should be easy to place and comfortable for the patient. **Method:** Computed tomography (CT) data of an adult CLP patient was obtained. DICOM files were processed and a stereolitographic (STL) model was printed. Computer aided design (CAD) software was used to design the device and to perform a finite element analysis (FEA) to evaluate the mechanical behavior of the appliance. Finally a prototype was manufactured by a computer aided manufacturing (CAM) process and tested on the STL model. **Results:** This prototype complied with our requirements for an efficient internal maxillary distraction device. **Conclusions:** The integration of clinical knowledge with novel technology (CT, STL, CAD, FEA, and CAM) is very useful for the development of medical or dental appliances.

RESUMEN

Introducción: La malformación cráneo-facial más frecuente es el labio y paladar hendido (LPH), 1:1000 recién nacidos vivos. Estos pacientes presentan una severa retrusión de tercio medio facial que requiere de un procedimiento quirúrgico para avanzar el maxilar. La distracción osteogénica es una opción de tratamiento. Sin embargo, los distractores actuales presentan inconvenientes. **Objetivo:** Diseñar un distractor maxilar intraoral, biocompatible, económico y de fácil colocación, que sea mecánicamente eficiente y cómodo para el paciente. **Método:** Se obtuvo una tomografía axial computada (TAC) de un paciente adulto con LPH, los archivos DICOM fueron procesados y a partir de estos datos se hizo un modelo de estereolitografía, en seguida se diseñaron las piezas mediante diseño asistido por computadora (CAD) y se realizó un análisis de elemento finito (FEA) del distractor para evaluar su comportamiento. Por último se realizó un prototipo físico mediante modelado asistido por computadora (CAM), el cual fue probado sobre el modelo de estereolitografía. **Resultados:** Se logró el diseño de un prototipo eficiente, que cumple con los requisitos mecánicos y de operación. **Conclusiones:** La integración de conocimientos clínicos y la aplicación de nuevas tecnologías de imagen clínica, prototipos rápidos, CAD, FEA y CAM son muy útiles para materializar diseños de uso médico.

Key words: Distraction osteogenesis, finite element analysis, cleft lip and palate.
Palabras clave: Distracción ontogénica, análisis de elemento finito, labio y paladar hendido.

INTRODUCTION

Cleft lip and palate (CLP) is a congenital malformation that develops in the first few weeks of intrauterine life and consists in the lack of union of the palatal processes. In Mexico, from all newborn, 2 to 3% have some congenital malformation and from them, 15% have cleft lip and palate, so it is the most common craniofacial anomaly.[1-3]

The presence of cleft lip and palate causes a series of anomalies in the patient's craniofacial growth, due in part to the presence of scars produced as a result of the surgical closure of the lip and palate. These scars cause midfacial growth restriction that affects mainly the upper jaw.[4]

Distraction osteogenesis, (DO) is the process of generating new bone in a gap between two bony segments as a response to the application of gradually applied force through the bone gap.

The technique for elongating bones was described in 1905 by Codivilla, who reported the elongation of

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a femur through the application of distraction axial forces.

Ilizarov in 1950 applied the DO technique to endochondral bone of the upper and lower extremities successfully for more than 35 years.

DO is divided into four stages, which are: osteotomy, latency, distraction and consolidation and is accompanied by the simultaneous expansion of the functional matrix of soft tissue, including blood vessels, nerves, muscles, skin mucosa, fascia, ligaments, cartilage and periosteum, this is called histogenic distraction.[5]

Rachmiel mentions that between 25 and 60% of patients with CLP develop maxillary hypoplasia that does not respond to maxillary orthopedic treatment or orthodontics and therefore requires surgical treatment; cleft lip palate patients have a greater tendency towards relapse after a Le Fort I advancement surgery than non- cleft-palate patients. Relapse is a disadvantage of the traditional method of maxillary advancement and rigid fixation. It occurs especially when the maxillary advancement includes the lowering of one or both segments maxillae. An alternative is distraction osteogenesis (DO) because after the sixth week from a started DO maxillary procedure, bone neoformation can be seen in the area of the pterygoid processes which at the end of the treatment makes the result stable and makes unnecessary the use of bone grafts thus eliminating possible complications in both the donor site as well as in the recipient.

Another significant advantage of maxillary DO is that the soft tissue profile substantially improves thanks to the anterior projection of the nasal tip and the nasolabial angle correction. Regarding the velopharyngeal function, in general, it is not affected in less than 15 mm advancements.[6]

The stability of the internal distractors is a very important point to be taken into consideration since, without it, the formation of a fibrous union or pseudoarthrosis in the site of the distraction can be caused. Cheung conducted a study which assessed by means of tomographic slices the thickness of the bone in 5 different maxillary regions (paranasal, infraorbital, back wall of the maxillary sinus, the alveolar and zygomatic region) to subsequently perform mechanical tests on animal bone specimens about the force required to dislodge a miniplate. The compared screws were 1.5 and 2 mm in diameter, 3 were used for each miniplate and were tested in 2 configurations, triangular and straight.

At the end of the study, it was concluded that the paranasal and zigomatic regions were the best to establish a maxillary anchorage and the 2 mm diameter screws were preferable to the 1.5 mm. Miniplate configuration showed no significant difference.[7]

Today many authors agree that internal distractors are better than external for the patients because they are discrete, however, this type of distractors are difficult to place and their distraction vector cannot be changed as in the external devices. Internal appliances have advantages in terms of aesthetics since they are less noticeable and hinder less during sleep hours. Their main disadvantage is that they restrict oral function when eating and talking, maintaining oral hygiene also becomes more complicated.

Kebler et al. reported in 2001 the use of internal maxillary distractors in four patients with maxillary retrusion. The appliance of choice was the Zurich pediatric ramus distractor which has some extensions for activation that were placed behind the lips causing injuries and discomfort. The obtained results were advancements between 7 and 14 mm without relapse in post-distraction control, the need for excellent hygiene to avoid infections is highlighted, and it was mentioned that the withdrawal of the device is sometimes more complicated than its placement. The authors also refer to the need for orienting the distractors correctly at the time of their placement.[8]

In relation to the problems for distraction vector positioning and adjustment, Yamayi et al. in 2004, designed in Houston an internal maxillary distractor located inside the maxillary sinus, making it easy to achieve parallelism with the axis of distraction, however, a second surgery is necessary for the withdrawal of the appliance. In their study, a 15.5 mm advancement and an absence of relapse are reported.[9]

Van Sickels in 2007 reported the use of an internal distraction design and its placement in 10 patients. Although it was the same design, some distractors were made from titanium and others from stainless steel. This did not seem to have made any difference. Among complications that occurred during treatments the author noted that in one case there was a lack of union of the bony segments, in two other cases, unacceptable occlusal results. Other minor complications were loosening of the device and pain.

Among his conclusions it was also mentioned that the manufacture of stereolitographic models helps reduce operating room time, makes it easier to position the device and helps determine distraction vectors with greater precision. He also mentions that changes in the device design would help make the use of distractors more comfortable.[10]