Maxillary distraction using a trans-sinusal distractor: technical note


Abstract. In this pilot study, the principle of distraction osteogenesis was used to advance the midface of a boxer dog. A modified high Le Fort I-type osteotomy was performed. Following a latency period of 5 days the maxilla was distracted 14 mm in 14 consecutive days at a rate of 1 mm per day. Ten weeks after the completion of the distraction, multiple biopsies were taken across the distraction gap. Histological observation showed bone deposition in the osteotomy sites. Soft and hard tissue formation resulted in complete healing across the distraction gap. The maxillary sinus was used to accommodate the distraction device. Superimposition of the standardized lateral cephalograms taken at the end of distraction and 14 months after the removal of the distractors showed no sign of relapse in the achieved sagittal advancement of the maxilla. This small, intraoral–trans-sinusal placed distractor has a completely new conceptual design, and may be helpful in distraction of maxilla in children and adults with midfacial hypoplasia.

Key words: distraction osteogenesis; midface; maxillary sinus; cleft lip and palate; bone tissue.

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Introduction

Maxillary distraction osteogenesis can find its indication in severe Angle class III malocclusions, and severe maxillary hypoplasia among some cleft patients and other craniofacial deformities. Attempts were made to treat these malocclusions through the use of maxillary protracting appliances and chin caps, with conflicting opinions about the treatment results. Several external distraction devices, such as the traction mask of Molina & Ortiz-Monasterio and the rigid external distraction system of Polley & Figueroa, permit easy device application and removal, and multidirectional movement. But, the reverse headgear and rigid external distraction apparatus are cumbersome and highly visible. A low profile, intraoral distraction device, used in an experimental study by Weinzweig et al. was successfully used for midface distraction at the Le Fort I level. However, the distraction cylinder protruded through the buccal mucosa and had to be delivered through a skin incision in the nasolabial fold area. In a clinical study by Kessler et al. four patients were treated by high Le Fort I osteotomies and insertion of a subcutaneous distraction device, placed in the malar region. The range of the distraction was limited (7–14 mm) due to the distractor design, and the distraction rods led to injuries at the angle of the mouth and swelling of the lips. Delaire masks had to be used to stabilize the results. An ideal distractor should be easy to apply, easy to activate, and guarantee predictable results. It should not result in any physical or psychosocial complaints, and should allow normal function during the distraction and the retention period.

The aim of this experimental pilot-study is to evaluate the effectiveness of a new maxillary distractor, an intraoral–trans-sinusal placed device.

Material and methods

Animal selection

Clearance of the study protocol was obtained by the Ethical Committee of the Catholic University of Leuven,
Belgium for performing the experimental distraction in a 2-year-old boxer dog. This dog fulfilled the requirements for a good experimental model: a maxillary sinus, deep enough to provide space for placement of the distraction screw, a short splanchnocranium (short snout) and an inherent hypoplastic midface, comparable to the class III malocclusion in humans.

Distractor design

The distractor was made out of three main parts: two plates and a distraction screw. The distraction screw was the axis of a joint formed by the lower plate, which was connected to it and could move around it. All parts of the device were made out of a titanium alloy (Ti-6Al-4V). The device was fabricated by Titamed® Belgium. The upper plate was fixed cranial to the osteotomy line with two screws (Fig. 1). Only two screws per plate were used to see whether the minimal fixation of the plates would be sufficient to withstand the forces applied during the distraction process. The distractor was fixed on the lateral aspect of the nasal wall and the distraction screw, which was almost perpendicular to the frontal plane, entered the maxillary sinus through the anterior wall of the sinus. The other end of the distraction screw (activation head) found its way through the soft tissue covering the anterior wall of the maxillary sinus, and was hidden behind the upper lip. The activation head (AH) was hexagonal, with a matching screwdriver. A 360 degrees counter clockwise rotation of the AH gave a displacement of 0.5 mm.

Animal experiment

The boxer dog was put under general anaesthesia. A modified Le Fort I type osteotomy was then performed, and the distraction devices were placed bilaterally (day one).

After a latency period of 5 days the distraction started at a ratio of 1 mm per day during 14 consecutive days (distraction phase). Activation was performed under light sedation, using Thalamonal® and Pentothal®. The distractors were removed under general anaesthesia after another 10 weeks (retention phase). During the same session multiple bone biopsies were taken at the site of distraction.

A standardized lateral cephalogram was taken on day 1, day 5 (start of distraction), day 12, day 19 (end of distraction), day 33, day 47, day 61, day 75 (end of retention), and 14 months after removal of the distractors. A cephalostat was used to ensure the standardization of the lateral cephalometric radiographs. A fixed distance of 74 cm between the source (90 kV and 60 ms) and the middle of the skull was maintained. All cephalograms were taken under light sedation.

Surgical technique

A 2-year-old boxer dog was premedicated with IV injection of 0.5 ml Thalamonal® (fentanyl, 0.05 mg/ml + droperidol 2.5 mg/ml; Janssen Pharmaceuticals, Beerse, Belgium) and 0.5 ml atropine (atropine sulphate 0.5 mg/ml). Five hundred mg Augmentin® (SK Beecham) IV was given preoperatively. A daily maintenance dose of Augmentin was given during latency and distraction period. The dog was placed on the operating table in a supine position with his head in slight extension. The animal was inducted with IV injection of 30 mg/kg Narcovet® (sodium pentobarbital 60 mg/ml; APharmon, Arnhem, Nederland). An orotracheal tube was placed and anaesthesia maintained with Ethrane® (enflurane 15 mg/ml; Abott, Amstelveen, Nederland). A throat pack...
was placed, and the oral mucosa and dentition were rinsed with chlorhexidine digluconate 1% in water. First, the crowns of the lower canines were lowered to the gingival level, and were treated endodontically in order to minimize the chance of interference during the maxillary protrusion.

Local anaesthesia Xylocaine® (1% in 1/100 000 epinephrine) was injected submucosally.

A Le Fort I type incision was made with electrocautery. Care was taken not to damage the infraorbital nerve. The incision was then carried down to the bone.

Next, a subperiosteal dissection was carried out to expose the midface structures. In order to free the posterior maxillary wall from the skull base the orbital floor had to be osteotomized, because this part forms the orbital floor in dogs. Therefore a subperiosteal tunnel was made from the most medial point of the inferior rim (medial to the infraorbital nerve) over the orbital floor towards the corner made by the horizontal and the perpendicular lamina of the palatinal bone. The posterior maxilla was separated from the rest of the skull via a transpalatinal approach in contrast to the human anatomy where the posterior maxilla can easily be separated via an upper buccal sulcus incision. A modified high Le Fort I type osteotomy was then performed. The cut started from the osseous corner made by the horizontal and perpendicular lamina of the palatinal bone (as described above), continued over the orbital floor and ended 4-mm posterior to the infraorbital rim. Then an osteotomy cut was made starting midway from the zygomaticoalveolar crest to a point midway between the infraorbital rim and the superior border of the infraorbital foramen. This osteotomy line was continued parallel to the hard palate through the lateral nasal wall, approximately 1 cm cranial to the nasal floor.

A small hole with a diameter of approximately 4-mm was made in the anterior wall of the maxillary sinus on the right side, through which the distraction screw would enter the sinus. This opening was located at the most medial point of the anterior wall of the maxillary sinus and was part of the anterior osteotomy line (Fig. 2). The maxilla was slightly mobilized making sure there was no interference between the maxilla and the rest of cranium. At this stage the distractor was fixed to the lateral nasal wall (Figs 3 and 4). The lower plate moves in the same direction as the distraction vector and therefore is fixed to the lateral nasal wall at the lower border of the osteotomy line. Each plate was fixed to the underlying bone with two screws. The same procedure was
performed at the contra-lateral side. The distractors were activated for 4-mm to make sure there were no interferences, and then reversed.

The distractor on the right side was opened for a few mm (before fixation of the lower plate) in order to be distinguished on radiographs. An osteosynthesis screw (diameter 1.5 mm, length 5 mm) was placed in the midline on the frontal bone, as a landmark for the cephalometric analysis. Two small class-5 amalgam fillings were placed on the upper molars on the left side, as additional landmarks for cephalometric analysis.

The distraction head was too short to be exposed into the oral cavity (right behind the upper lip). Therefore a hard silicon tube approximately 2 cm in length and with a diameter that matched the head of the distraction screw was pulled over it and fixed with Ethilon 2/0 to the surrounding periosteum, thus allowing for activation of the distractors. The intraoral incision was sutured with Ethilon 2/0 (Fig. 5). Postoperative diet consisted of soft food.

**Removal of the distractors**

The animal was put under general anaesthesia following the same protocol as described above. A small incision was made at the level of the distractor. A subperiosteal dissection was performed at the level of the distracted area. Subsequently, the distractors were removed very easily. Multiple bone biopsies were taken at the distraction site.

**Histological evaluation**

At the time of distractor removal biopsies were taken and immediately fixated in a solution of one part formaldehyde (Merck, Darmstadt, Germany), neutralized with 50 g CaCO3/1, and two parts 80% ethanol. The samples were dehydrated in graded alcohols and embedded in methylmethacrylate. Nondecalcified serial sections were prepared in a sawing microtome (Leitz 1600, Wetzlar, Germany) and ground and polished to a thickness of approximately 30 to 50 μm (Minimet®, Buehler Inc., Lake Bluff, IL, USA). Finally, the sections were stained with a combination of Stevenel’s blue and Von Gieson’s picrofuchsine for light microscopical evaluation.

**Results**

Insertion of the trans-sinusal maxillary distractor was easy. The monocortical screw fixation gave sufficient stability and the distraction devices were well tolerated by the animal. No signs of infection were observed. The animal tolerated the soft diet very well.

Although the expected linear increase of the cephalometric points was supposed to be 14 mm, an average increase of 8.7 mm was found. The superimposition showed a downward tipping of the maxilla for the first five days of the distraction period. A standard lateral cephalogram was taken 14 months after removal of the distractors. The superimposition of this cephalogram with the one taken at the end of the retention period showed no sign of relapse (Figs 7–10).

Histological examination showed an almost completely filled distraction gap with newly formed bone with a typical woven structure that could clearly be distinguished from the bone at the

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*Fig. 5. White arrows show hard silicon tubes approximately 2 cm in length and with a diameter that matched the head of the distraction screw. The distractors were activated intraorally through the silicone tube.*

*Fig. 6. The difference between the new and old bone is clear. In the newly formed bone islands of active remodelling with osteoclasts and osteoblasts are visible.*
Two types of ossification were observed. Most of the new bone was formed by appositional bone growth. Within some areas, where the gap was not yet completely filled, the newly formed bone was covered with a layer of osteoid tissue and a row of active osteoblasts.

In other areas endochondral bone formation was observed; here the bone formation was preceded by cartilage formation.

Islands of active remodelling could be observed in the newly formed bone, with osteoclasts lying in resorption lacunae and at the other side active osteoblasts (Fig. 6).

**Discussion**

Distraction osteogenesis is of particular interest in patients with midfacial hypoplasia as they lack both bone and soft tissue. The subcutaneous, intraoral devices present several advantages over external distraction devices currently used, which are cumbersome, highly visible, and potentially not well tolerated by patients. The intraoral devices have certain disadvantages. At present, they are all unidirectional. This implicates a perfect preoperative vector planning. The removal of the devices must be performed under general anaesthesia, and can be difficult. This is due to the fact that the current devices are still too bulky, and are placed under the periosteum. The activation rods are either in continuous contact with lips, causing pain and irritation, or have to be delivered through the skin in the nasolabial region.

In this study the distraction screw was placed inside the maxillary sinus rather than in the subperiosteal area. The volume of the sinus cavity provides enough room for positioning of the distraction screw, which determines the vector of distraction. In this way a bulky and movable part of the device is accommodated in an empty cavity, and does not interfere with the surrounding soft tissue and periosteum.

Although the linear increase of the cephalometric points was expected to be 14 mm, an average of only 8.7 mm was found. This could be explained biomechanically by the influence of several factors i.e. distractor design, distractor placement, and the possible movement of the screws in the fixation plates. Secondly, the superimposition of the lateral cephalograms shows a clockwise tipping of the maxilla during the first 5 days of the distraction period, which can contribute to the difference between the expected and the effective gain in sagittal displacement of the maxilla. Apparently the fixation of the distractor plates, each with only two screws did not provide sufficient stability of the device to withstand the forces applied during the initial distraction process.

Histologically two types of ossification were observed in the distraction gap. Endochondral bone formation, which was preceded by cartilage formation, was observed in some areas. This can be due to instability of the bone segments and the distraction rate, but it does not influence the final result.

Islands of active remodelling could be observed in the newly formed bone tissue, with osteoclasts lying in resorption lacunae and at the other side active osteoblasts (Fig. 6). These observations are in accordance with other studies.

Because of a potential communication between the oral cavity and the maxillary sinus a strict protocol with antibiotics was maintained during the distraction period. Brønemark et al. showed that the insertion of implants where sinus or even nasal cavity penetration could not be avoided, was justified, as titanium screws penetrating the
bone of sinus or nasal cavity did not cause undesirable side effects\textsuperscript{1}.

In this study no clinical or radiological sign of infection or fistula formation were found. This distraction device provided skeletal anchorage and relapse was not seen up to 14 months post-distraction (Figs 7–10).

The potential advantages of this distractor are as follows. The distractor is easy to place and is positioned intraorally. The distraction screw goes backward into the sinus rather than forward into the lip, which would implicate the transcutaneous delivery of the distraction barrels in the nasolabial folds bilaterally\textsuperscript{17}. It can serve as a retention device and be left in place as long as necessary. This is in contrast with distraction performed using extra-oral devices or a facial mask with elastic forces. Other studies report on dental anchorage for the fixation of the distraction device\textsuperscript{2,10,13,14,16}, but this resulted often in a significant dento-alveolar displacement.

Distraction can be achieved in horizontal, vertical, and sagittal planes, simply by changing the inclination of the distraction screw. Correction of the midline can be done by distracting one side more than the other.

The clinical prototype was designed by N. Nadjmi in cooperation with Martin MedizinTechnik, Tuttlingen, Germany, and has successfully been applied in a clinical study for the treatment of 10 patients with moderate to severe midfacial hypoplasia\textsuperscript{11}. A detailed report is in progress.

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