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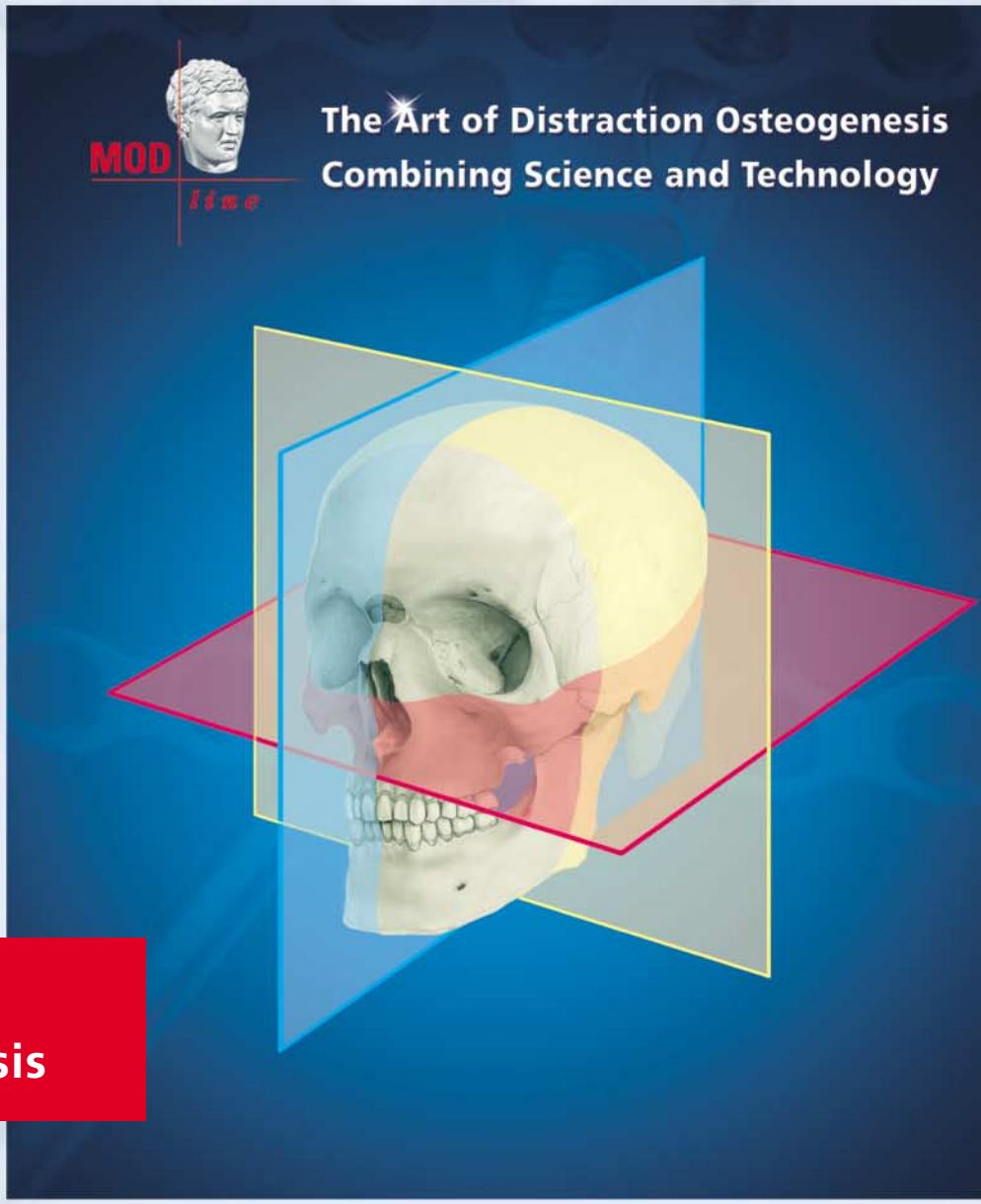
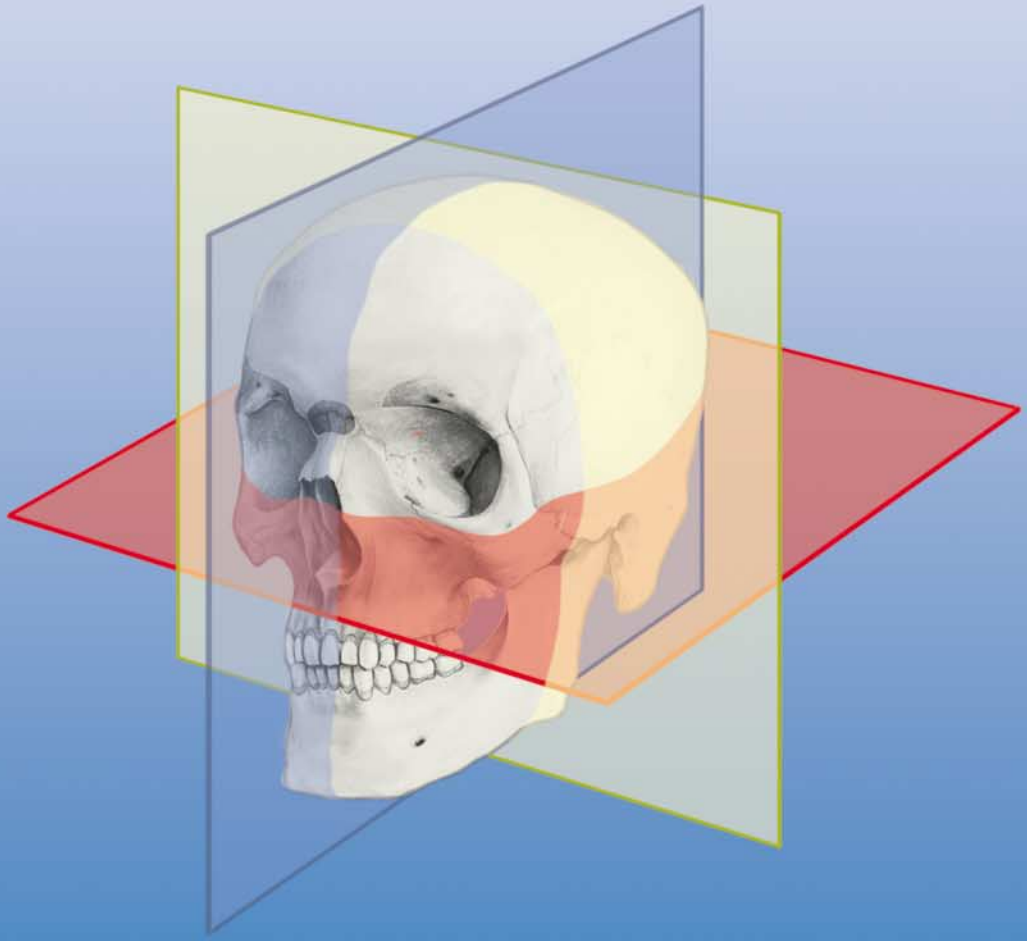


Distraction Osteogenesis

Antwerp Trans-Sinusoidal Maxillary Distractor (TS-MD)

MOD line

The Art of Distraction Osteogenesis
Combining Science and Technology



Developed in cooperation with

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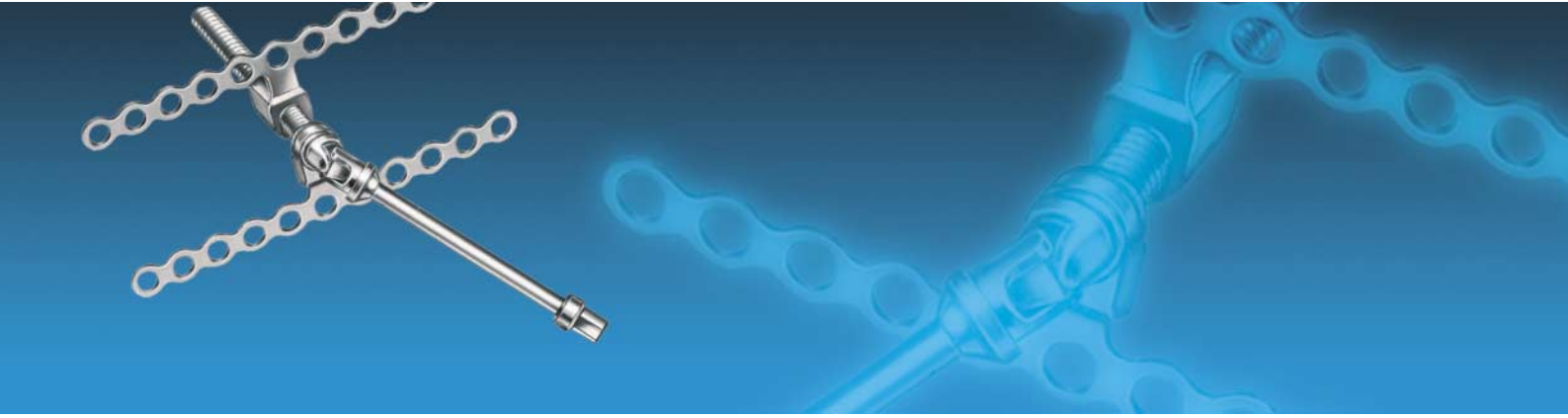


Introduction

Maxillary distraction osteogenesis finds its indication in severe-angle class III malocclusions, and severe maxillary hypoplasia among some cleft patients and other craniofacial deformities. This patient group shows a pronounced maxillary hypoplasia already at a young age. Distraction osteogenesis at a young age (6-8 years) may play an important role in the psychosocial development of a child with severe craniofacial deformities.

According to the literature, the human sinus is deep enough even at the age of 6 to 8 years to provide room for the distraction screw, and this is not significantly different in cleft patients. The anatomy of the maxillary sinus causes no limitation in the choice of the vector of distraction, which is indicated by the position of the distraction screw.

In the clinical trial performed by Dr. Nadjmi, no sign of sinusitis, fistula formation or any other major undesirable side effects was observed during the whole treatment period.

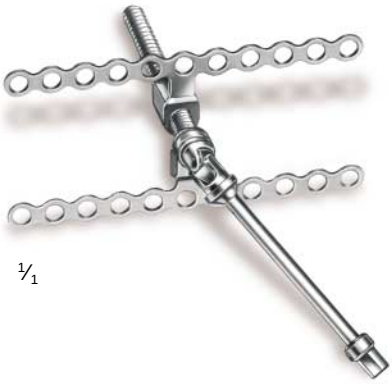
An ideal distractor should be easy to apply, easy to activate, and should guarantee predictable results. It should not result in any physical or psychosocial complaints, and should allow normal function during the distraction and the retention period. The introduction of intra-oral and miniaturized devices has substantially improved the clinical application.
The **T**rans-**S**inusoidal **M**axillary **D**istractor **(TS-MD)** can be used in children from 6 to 8 years and also in adults, regardless of the cause of midfacial hypoplasia.

Indications

- Treatment of moderate to severe maxillary and midfacial deficiency in cleft lip & palate patients.
- Treatment of patients with class III dentofacial malocclusion at a much younger age (from 6 to 8 years).
- **Treatment** of maxillary hypoplasia with **anterior open bite.**
- Correction of maxillary retrusion prior to the orthodontic treatment in class III malocclusion cases.

Contraindications

- In patients where the maxillary sinus is too small for the placement of the distraction screw.
- In cases where there is insufficient bone volume or quality for a secure planning of the distraction.
- A general contraindication is a severely diseased system: immune deficiency – irradiated patients – severe diabetes.



1/1

51-540-20 max. distraction length 20 mm
51-540-25 max. distraction length 25 mm
51-540-30 max. distraction length 30 mm

Advantages

- **Stable** distraction device to be used in children as well as adults.
- Maxillary advancement might be accompanied by clockwise rotation of the maxilla, which is desirable in the **correction of an anterior open bite.**
- **Submerged** intraoral application.
- **Easy** to place and to remove.
- Ability to produce **predictable** results by using the recommended software and transfer technique (see preoperative planning).
- May be a **valuable alternative** for patients with developmental class III malocclusion, who otherwise would be treated by conventional orthognathic surgery and autogenous bone grafting techniques.
- Treatment of **shifted maxillary dental midline** while advancing the maxilla.
- **No** post-distraction **retention device** necessary.
- No physical or psychological complaints during the entire treatment procedure.
- Allows **normal function** during the distraction and retention periods.

Special notes

The rigid activators must enter the oral cavity through a separate stab incision cranial to the LeFort I incision. The intake of soft food is mandatory during the distraction procedure and 6 weeks following the completion of the distraction.

Preoperative planning

Computer planning

In order to define the distraction vector, 3D image-based preoperative planning is highly recommended. From CT images (Fig. 1 indicates the area that needs to be scanned), input data for the planning environment can be generated by specialized software providers.

Fig. 1: The spiral CT scan (no gantry tilt, 1-time scanning, 1mm reconstruction slice thickness, head positioning: axial slices are parallel with the occlusal plane) must cover the region indicated by the rectangular area.

Within the planning environment, a LeFort I osteotomy is simulated. The distraction vector is virtually positioned on the maxilla, and the distraction is simulated. The bone movements are measured with respect to the Frankfurter plane and the mid-sagittal plane.

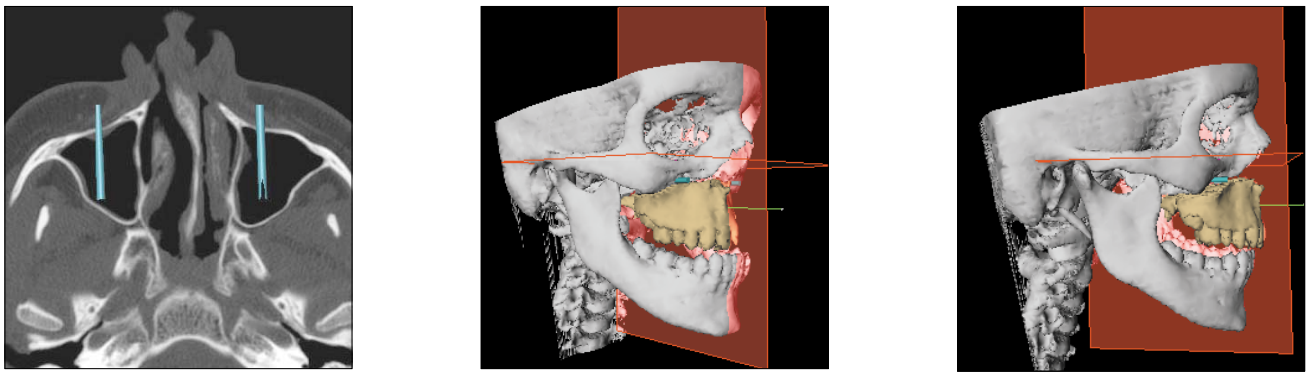


Fig. 2 a: Blue cylinders indicate the distraction screws inside the sinuses.

Fig. 2 b: Pre-distraction: reference planes in red, osteotomized maxilla in brown

Fig. 2 c: Post-distraction

From this planning, a stereolithographic model comprising the maxillary region is fabricated. It contains a tube in the maxillary sinus into which the distraction screw fits, and shows the distraction vector.

Note: 3D planning images provided by courtesy of MEDICIM N. V., Belgium

Fabrication of the positioning template by dental technician

In order to transfer the planned vector to the patient as accurately as possible, the upper plate needs to be positioned with the help of a template.
The distractor is placed on the STL model (Fig. 3a).
The upper plate is fixed by at least two bone screws. Then the lower plate is removed together with the distraction screw (Fig. 3b).

Fig. 3 a: STL model with TS-MD

Fig. 3 b: STL model with upper plate, frontal view

The STL model, with the upper plate fixed on it, is sent to the dental lab. The dental technician makes a plaster model of the STL model. A methyl-methacryllate template is then made on the plaster model (Fig. 3c).
This template helps to position the upper plate on the maxilla intraoperatively, which in turn determines the vector of distraction (Fig. 3d).

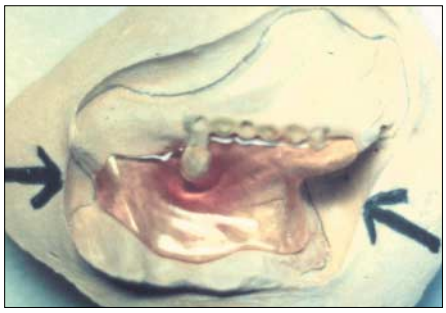


Fig. 3 c: The template made from the plaster model of the STL model

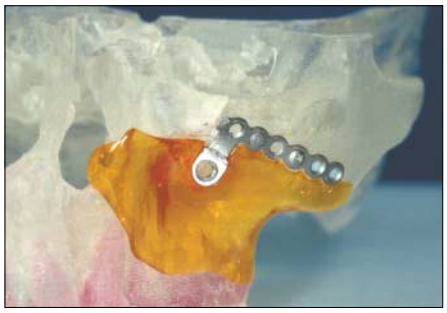


Fig. 3 d: STL model with upper plate and template

In figure 3e, the solid red line indicates the tube inside the maxillary sinus. The dotted line indicates the position of the distraction screw inside the tube.

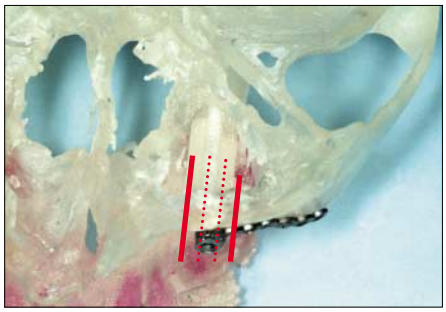


Fig. 3 e: STL-model with upper plate, top view (demonstration of the tubes inside the sinus)

Intraoperative approach

Preparation of the maxilla for a high LeFort I type osteotomy.

Placement of the maxillary template for the exact positioning of the upper plate of the TS-MD. Creation of an entry hole for the distraction screw on the anterior maxillary wall using a round burr (Fig. 1).

Placement and fixation of the pre-bent upper plate (Fig. 2). In case of a high LeFort I type osteotomy it is placed medially (Fig. 3), and in case of a classic LeFort I type osteotomy it can be placed laterally (Fig. 4).

Placement of the lower plate and the distraction screw, but no fixation yet.

Marking of the desired osteotomy line.

Removal of the lower plate and the distraction screw.

Performing the desired osteotomy. Separation of the pterygoid process from the tuberosity. Separating the nasal septum from the maxilla.
Mobilization of the maxilla without complete downfracturing.

Placement of the lower plate together with the distraction screw. Counterclockwise rotation of the distraction screw until it is completely inside the sinus. Fixation of the prebent lower plate.

Activation of the distractor bilaterally for about 5 to 6 mm to check if there is any interference. Then return to zero position.

A stab incision cranial to the LeFort I incision at the desirable place (usually cranial to the root of the canines). The activation arm is then brought to the oral cavity through this incision.

Intraoral wound closure.

Application with illustrations

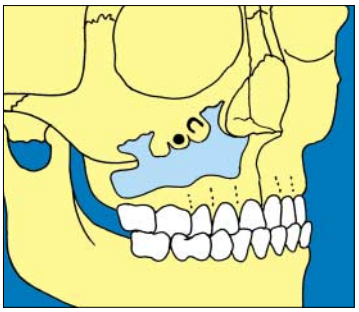


Fig. 1: Application of the template on the anterior maxillary wall and creation of the entry hole for the distraction screw, using a round burr.

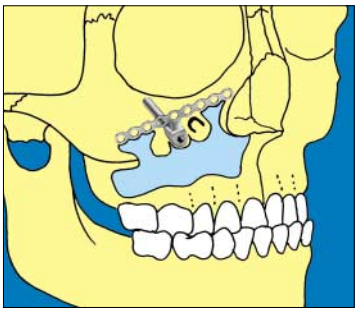


Fig. 2: Application of the template on the anterior maxillary wall, placement and fixation of the upper plate.

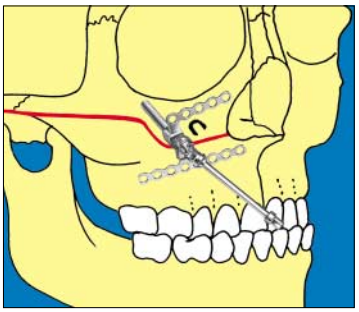


Fig. 3: High LeFort I osteotomy, placement of the lower part of TS-MD and fixation of the lower plate.

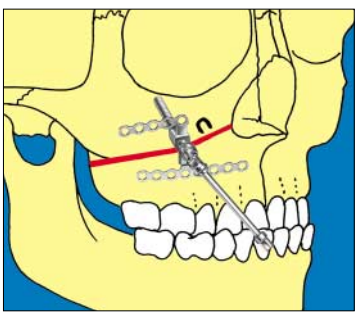


Fig. 4: Classic LeFort I osteotomy, placement of the lower part of TS-MD and fixation of the lower plate.

Distractor removal

The intraoral part of the activation head is cut with a plate cutter (ref. no. 25-420-16) at the completion of the distraction period.
The distractors can be left in place as long as possible, because they do not interfere with normal function and social activities.
The removal of the upper plate after the retention period is not mandatory. The lower plate of the TS-MD, together with the activator screw, can be removed in the clinic under local anesthesia and IV sedation.

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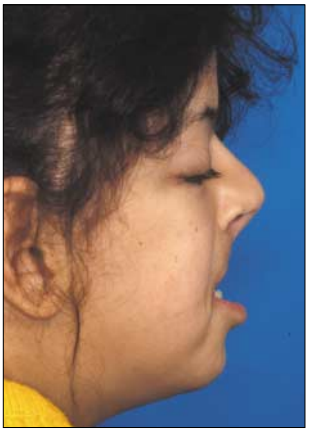
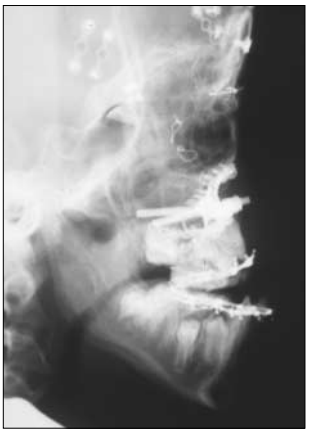
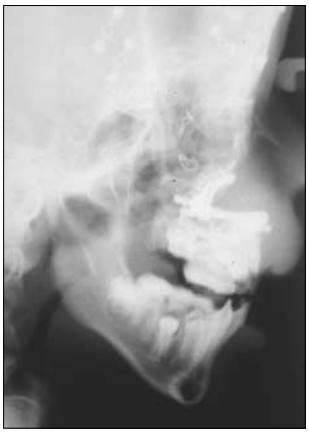
Helena

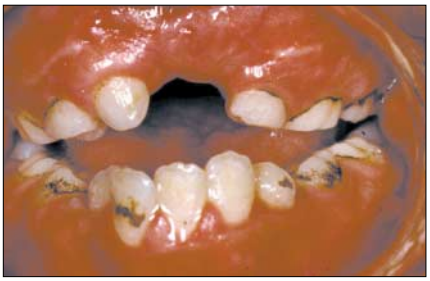
An eight-year-old girl with a fronto-naso-orbital dysplasia and **bilateral cleft lip and palate** is presented. The patient had undergone multiple craniofacial procedures and had lost her premaxilla. There was a **severe mid-facial hypoplasia and an anterior open bite.** A high LeFort I osteotomy was performed.

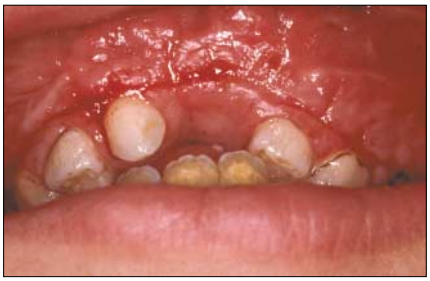
Bilateral TS-MDs were placed after computer aided planning.
On the fifth post-operative day, distraction was initiated at the rate of 1 millimeter per day.
A **clockwise rotation** of the maxilla during the advancement helped to **close the open bite.**
A total advancement of 14.5 mm on the left side and 13.5 mm on the right side was achieved. After 6 months of retention, the distractors were removed under general anaesthesia in the day clinic.
Clinical slides show correction of mid-facial deficiency. The lateral cephalograms and the intraoral photographs demonstrate the **closure of the open bite** and optimum bimaxillary relationship.
The software planning and the vector of distraction are demonstrated in the lower photographs.

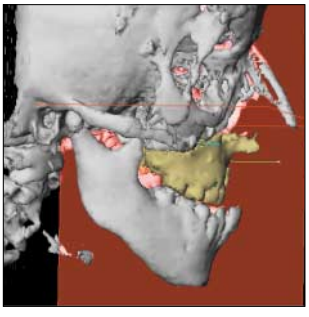


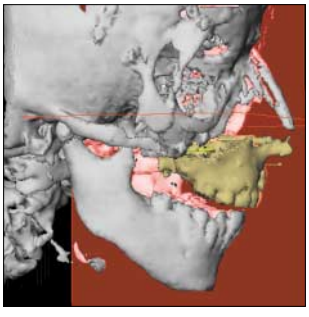










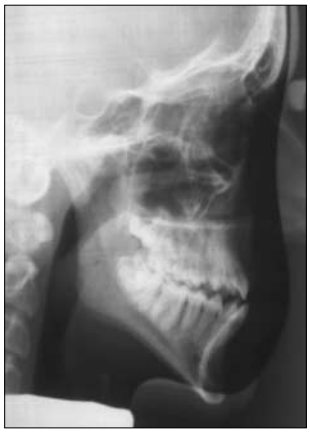


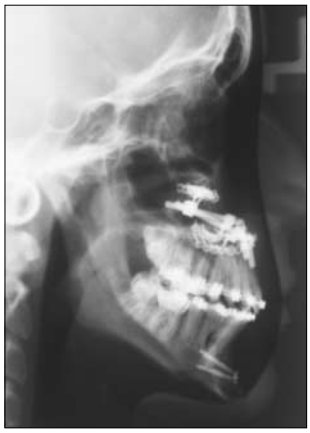
Note: 3D planning images provided by courtesy of MEDICIM N. V., Belgium

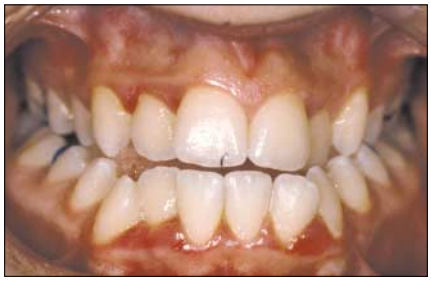
Chaima

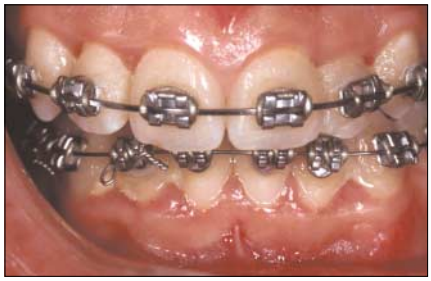
A thirteen-year-old girl with a **class III malocclusion** and an **anterior open bite** is presented. There was also a **shifted maxillary midline.**

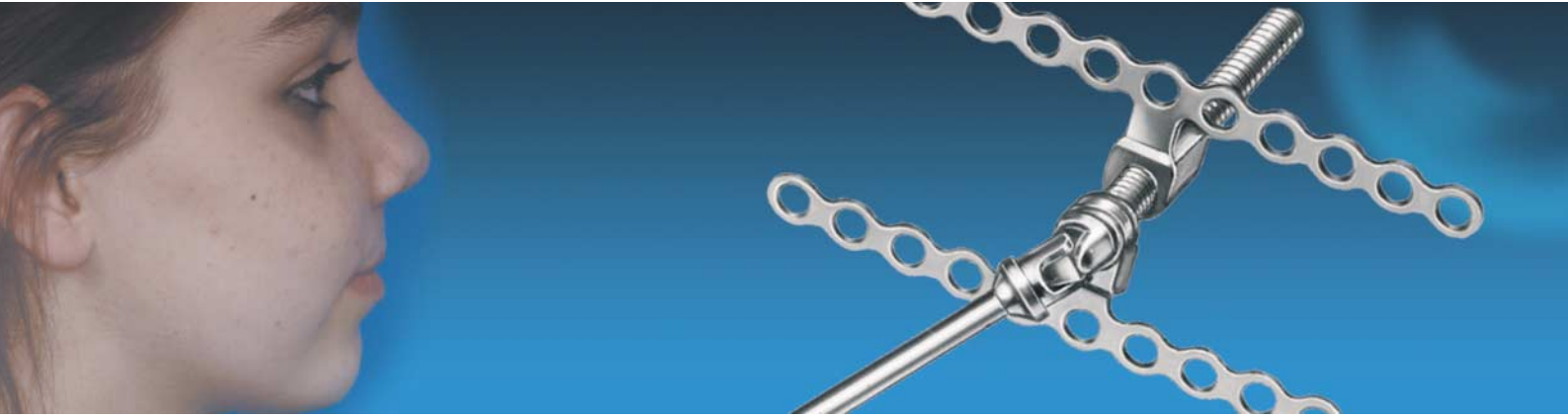
A high LeFort I osteotomy including the lower 2/3 of the zygomatic body was performed.
Bilateral TS-MDs were placed after software planning. The vectors of distraction were parallel, but oriented to the right in order to correct the maxillary midline shift. A genioplasty was performed at the same time.
On the fifth post-operative day, distraction was initiated at the rate of 1 millimeter per day. The activation arms were cut under small amount of local anaesthesia. The TS-MDs were activated for 14 mm on the left side and 13 mm on the right side. This resulted in 8.5 mm advancement, 8 mm vertical extrusion at the level of the central incisors, and a shift of 5 mm of the maxillary midline to the right. After 5 months of retention, the distractors were removed under general anaesthesia in the day clinic.
Clinical slides show correction of mid-facial deficiency as well as inter-arch asymmetry. The lateral cephalograms demonstrate the **closure of the open bite** and optimum bimaxillary relationship.







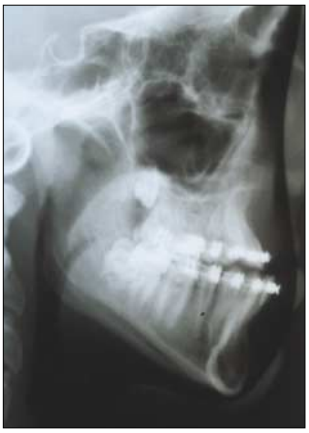


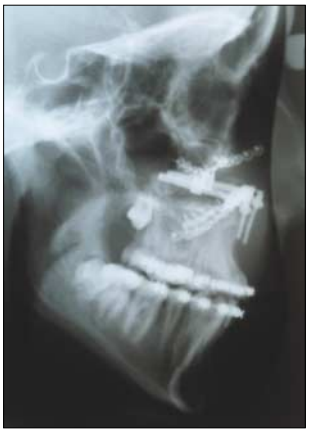


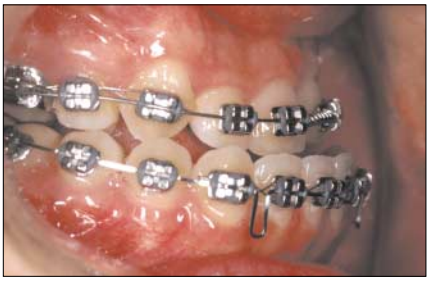
Klaartje

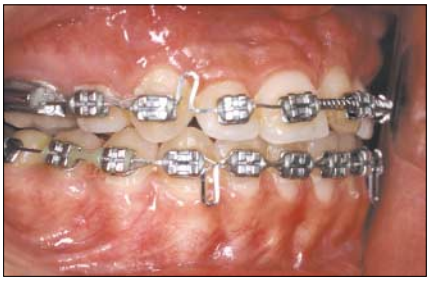
A sixteen-year-old girl with a repaired left **unilateral cleft lip and palate and moderate maxillary deficiency** was treated with TS-MD. A high LeFort I osteotomy was performed.

On the fifth post-operative day, distraction was initiated at the rate of 1 millimeter per day. The distraction was performed by the patient herself.
A total advancement of 8 mm and a vertical extrusion of 1 mm were achieved.
After 4 months of retention, the distractors were removed under general anaesthesia in the day clinic. The photographs demonstrate correction of the sagittal and the vertical relationships and harmonization of the face.
A class I dental occlusion was achieved. The lateral cephalograms demonstrate optimum bimaxillary relationship.



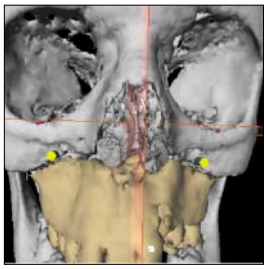


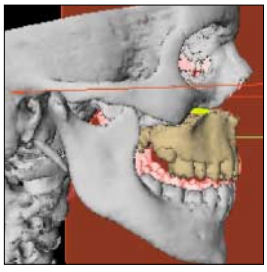


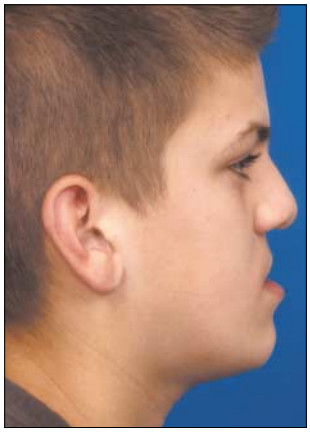


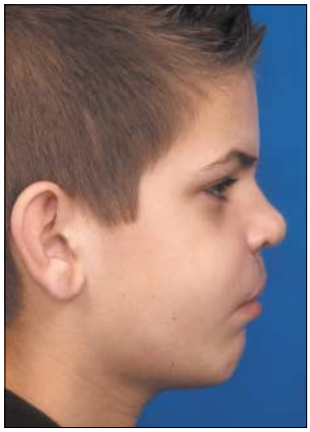
Stefaan

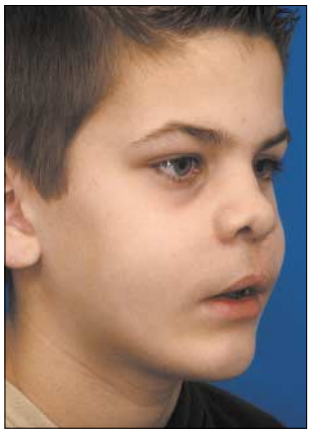
A fourteen-year-old boy with a repaired left **unilateral cleft lip and palate and severe maxillary deficiency with anterior open bite** was treated with TS-MD. A high LeFort I osteotomy was performed.
The yellow cylinder on the computer images indicates the vector of distraction and shows therefore the exact position of the distraction screw. A sagittal view of the distraction simulation is also presented.
On the fifth post-operative day, distraction was initiated at the rate of 1 millimeter per day. The distraction was performed by the patient himself.
The sagittal and vertical relationships were corrected. The anterior open bite was corrected by clockwise rotation of the maxilla.
Clinical photographs demonstrate a class I dental relationship and the harmonization of the face. After 17 mm of activation, a total advancement of 10 mm and a vertical extrusion of 6 mm at the level of the central incisors were achieved.
The distractors were removed after 5 months under general anaesthesia in the day clinic.
The relationship between the distraction screw and the infraorbital foramen and the sagittal simulation of the distraction are demonstrated in the lower photographs.

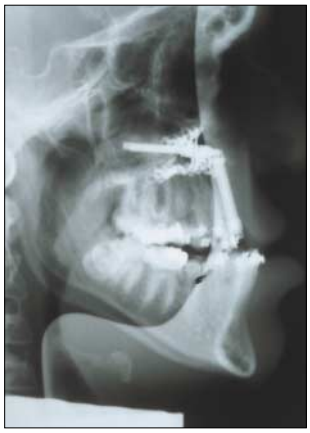


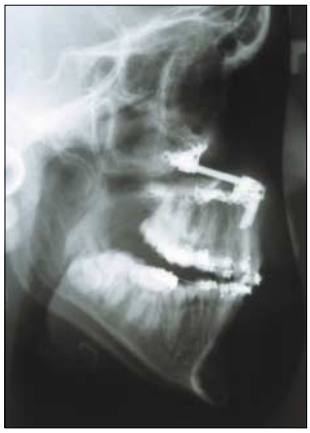


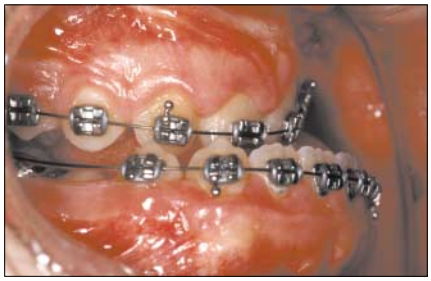


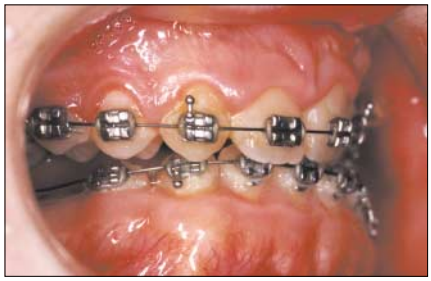












Note: 3D planning images provided by courtesy of MEDICIM N. V., Belgium

Ordering Details:

The Antwerp Trans-Sinusoidal Maxillary Distractor (TS-MD)

1/1

51-540-20	Distraction length 20 mm
51-540-25	Distraction length 25 mm
51-540-30	Distraction length 30 mm

Recommended Instruments:

25-430-16	Centre Drive® screwdriver 1.5 mm
25-483-97	Blade for handle 25-402-99
25-402-99	Handle, only
25-486-13	Modelling pliers (two are recommended)
25-441-16	Plate holding forceps
25-435-15	Plate holding forceps Lindorf
51-500-90	Patient screwdriver
25-451-07	Twist drills 1.1 x 50 x 7 mm, cylindrical attachment (5 each)
25-451-07-91	Twist drills 1.1 x 50 x 7 mm, cylindrical attachment (1 each)

alternative:

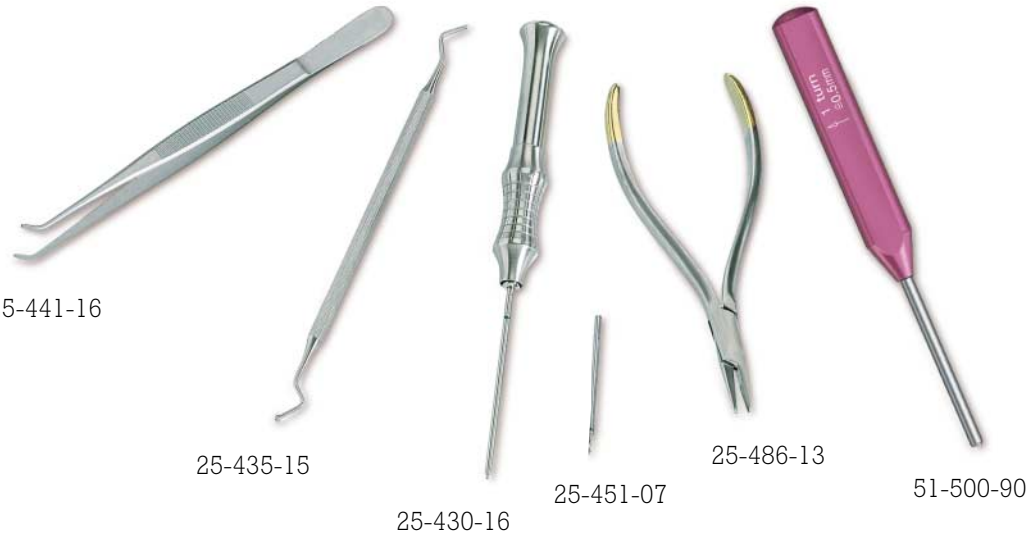
25-452-07	Twist drills 1.1 x 50 x 7 mm, Stryker attachment (5 each)
25-452-07-91	Twist drills 1.1 x 50 x 7 mm, Stryker attachment (1 each)

Recommended micro screws:

25-665-03	Centre Drive® screws 1.5 x 3.5 mm (5 each)
25-665-05	Centre Drive® screws 1.5 x 5 mm (5 each)
25-665-06	Centre Drive® screws 1.5 x 6 mm (5 each)
25-665-07	Centre Drive® screws 1.5 x 7 mm (5 each)
25-666-05	Centre Drive® emergency screws 1.8 x 5 mm (5 each)

25-675-03*	Cross Drive screws 1.5 x 3.5 mm (5 each)
25-675-05*	Cross Drive screws 1.5 x 5 mm (5 each)
25-675-06*	Cross Drive screws 1.5 x 6 mm (5 each)
25-675-07*	Cross Drive screws 1.5 x 7 mm (5 each)
25-676-05*	Cross Drive emergency screws 1.8 x 5 mm (5 each)

* If you are using Cross Drive screws, please order the handle 25-402-99 and the blade 25-483-97 seperately.



25-441-16

25-435-15

25-430-16

25-451-07

25-486-13

51-500-90

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