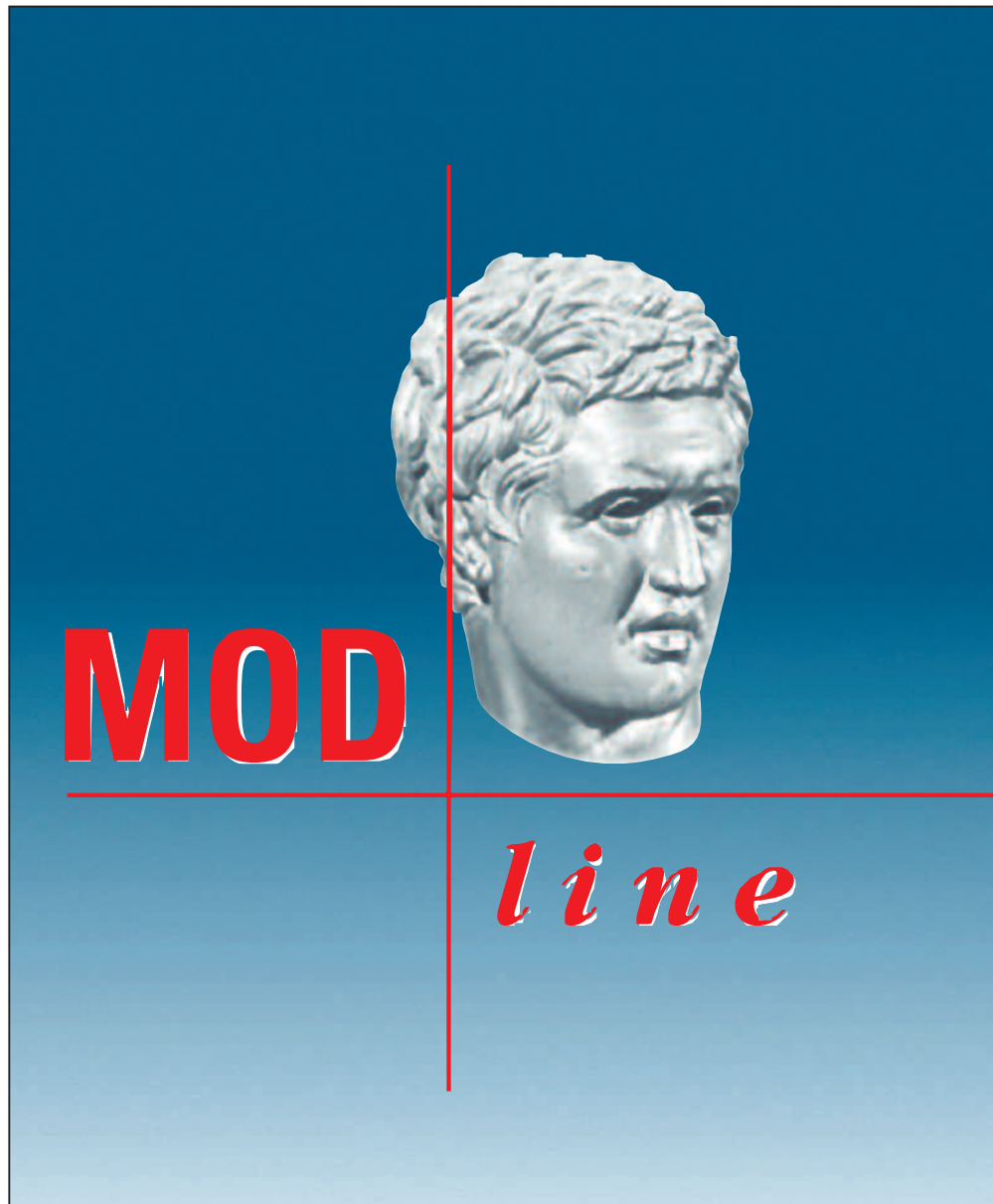


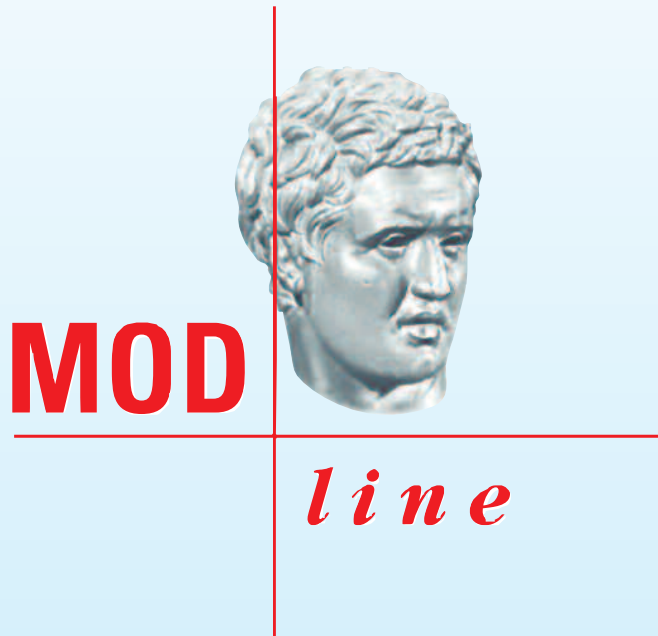
**Distraction**

**Osteogenesis**



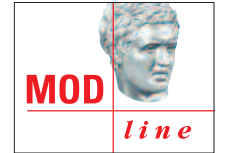
Molina Osteo Distraction Systems

# The Art of Distraction Osteogenesis Combining Science and Technology



Developed in cooperation with

Fernando Molina M. D.  
Mexico City,  
Mexico



## Introduction

Distraction Osteogenesis is one of the most innovative concepts in craniomaxillofacial surgery today.

This surgical technique represents a period of “Inductive Surgery” or the regeneration of the missing anatomic part that represents the modern concept of Reconstructive Surgery.

The clinical experience of the last 10 years shows that osteodistraction may have benefits over traditional techniques for both, the patient and the surgeon.

Osteodistraction simplifies and minimizes the surgical procedures with reduction of hospital stays. It is highly effective with significant lower morbidity.

It eliminates the need of bone grafts and permanent rigid fixation methods. All of these properties produce a safe and predictable surgical procedure and eliminate bone relapse. Osteodistraction is a less invasive surgical procedure than standard bone graft techniques.

Only an extended corticotomy that preserves the vascularity and nerve function is required. The pins placement is needed to achieve the correct vector of distraction, producing new bone formation that closely resembles the normal growth of the bone structure of the face.

Most beneficial however is the expansion of overlaying soft tissues simultaneously with the formation of the new bone; the soft tissue expansion results in a more natural appearance and greater stability.

An up-to-date range of uni- and bi-directional mandibular devices as well as a distraction device for the orbital-malar region are now available serving most of the indications.

Fernando Molina M. D.

## Intraoperative approach

The procedure is done under general anaesthesia. A 3 - 5 cm incision is made in the oral mucosa along the lateral mandibular vestibule.

Using the panorex view of the mandible, to locate the position of the toothbuds, the site for the insertion of the pins is decided.

The exact position of the corticotomy is decided.

The corticotomy and the position of the pins will determine the vector of the distraction according to the grade of mandibular hypoplasia.

The periosteum is elevated to expose the gonial angle and the neighboring area of the ascending ramus and the mandibular body.

A corticotomy is made on the lateral mandible and the cancellous bone is exposed.

The corticotomy is extended inferiorly around the lower border of the mandible where the bone is thick and then extended to the retromolar triangle.

The mandibular vessels and nerves are not exposed, the 5 - 6 lingual cortical plate and the cancellous layer remains intact.

The pins are inserted percutaneously manually or using a running handdrill so avoiding thermal injury to the bone.

The pins are placed parallel to each other to facilitate their fixation to the distractor.

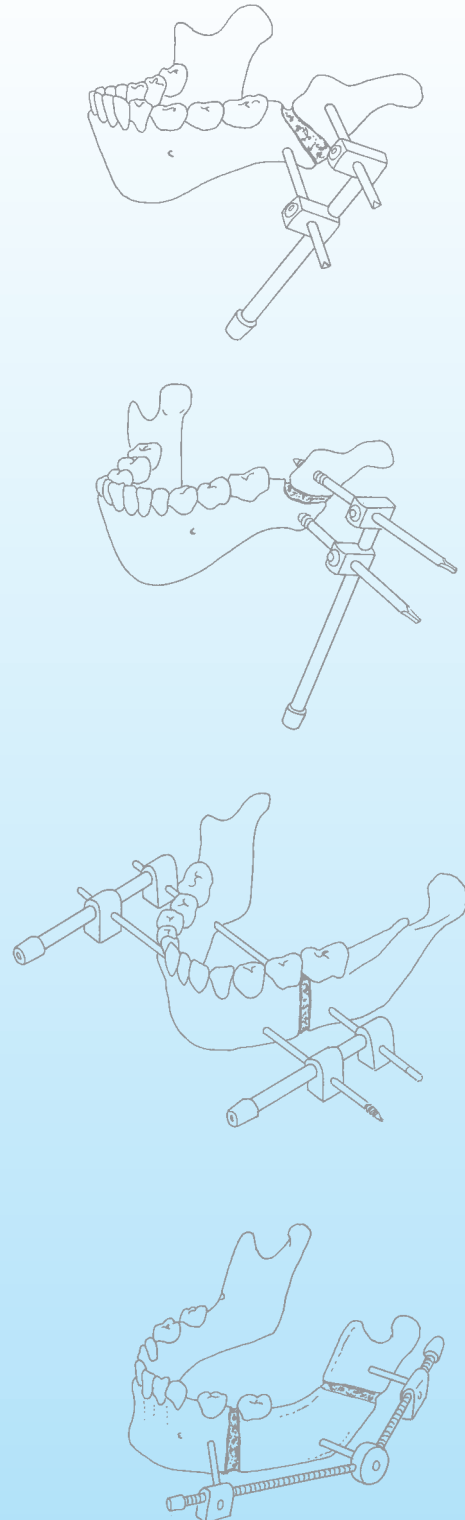
The mucosa is closed and the distraction device is applied to the pins.

The distraction is started on the fifth post-operative day at a rate of 1 mm per day.

The distraction is completed according to the treatment planning (in general 3 - 4 weeks). The device is left in place for 6 - 8 additional weeks to complete the consolidation period.

In patients with micrognathia two corticotomies are performed, one vertical in the mandibular body and the other one horizontal in the ascending ramus.

Three pins are used to allow the bi-directional devices to achieve independent and precise elongation of each segment.



**Distraction Osteogenesis**  
Mandibular Distraction in Hemifacial Microsomia

Schematic drawings of the  
Distraction Technique

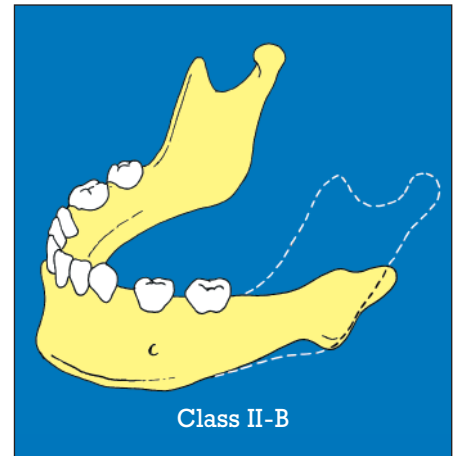
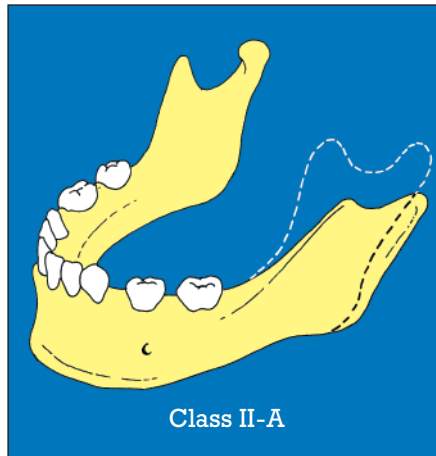
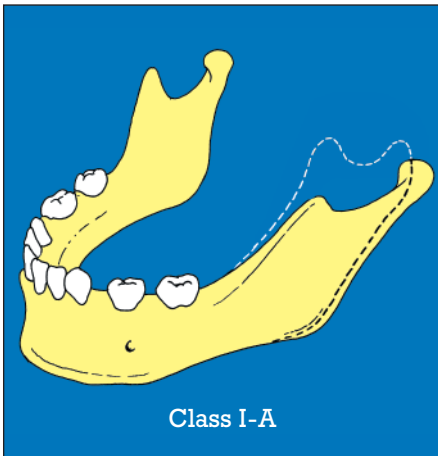


Fig. 1a: Mandibular deformity observed in hemifacial microsomia of varying severity. The dotted lines indicate the amount of missing bone.

Fig. 1b:

Fig. 1c:

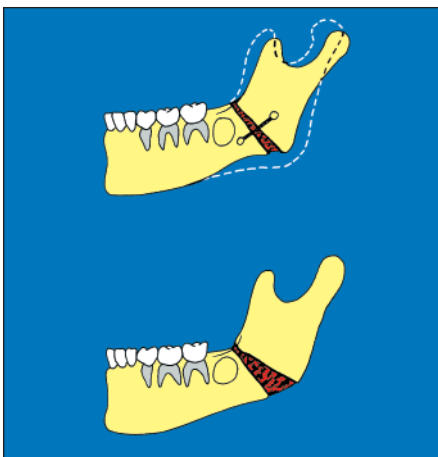


Fig. 2a: Location of the corticotomy and vector of the distraction forces in Class I hemifacial microsomia.

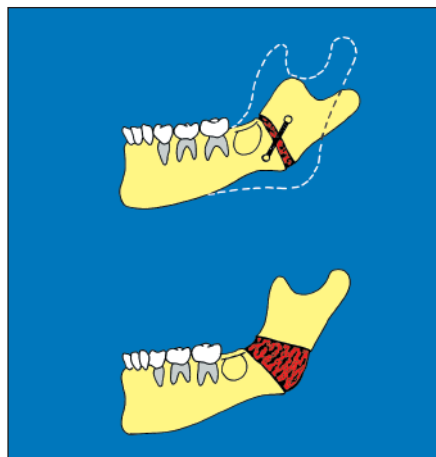


Fig. 2b: Location of the corticotomy and vector of the distraction force in Class IIA hemifacial microsomia.

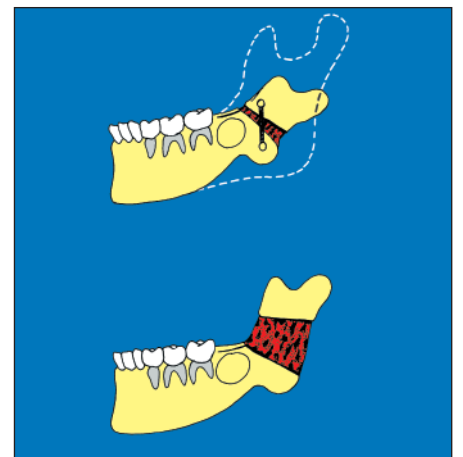
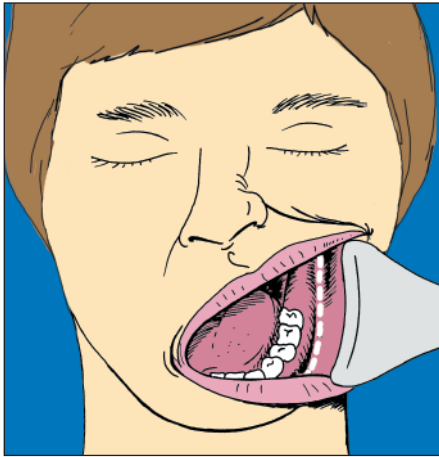


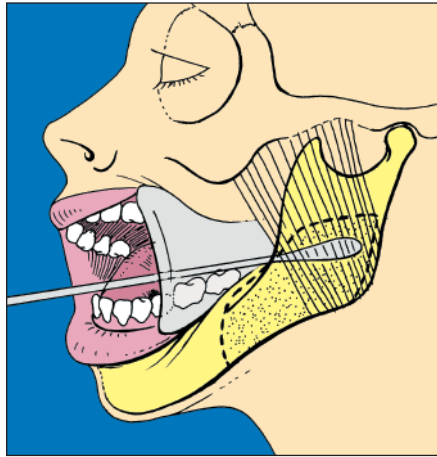
Fig. 2c: Location of the corticotomy and vector of the distraction force in Class IIB hemifacial microsomia.

**Distraction Osteogenesis**  
**Mandibular Distraction in Hemifacial Microsomia**

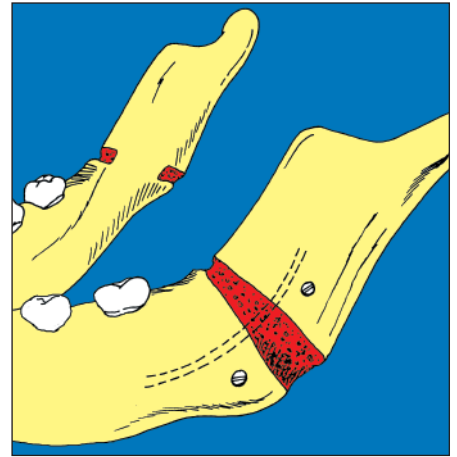
Schematic drawings of the  
Distraction Technique



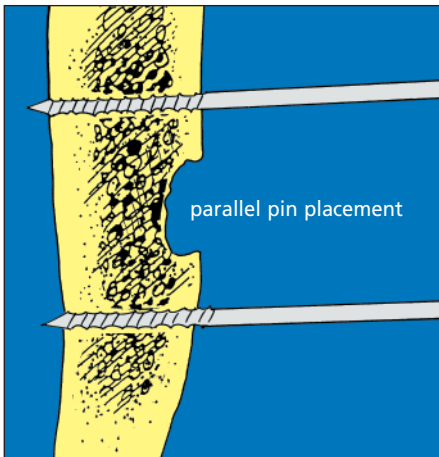
*Fig. 3:*  
An incision is made on the mandibular buccal vestibule.



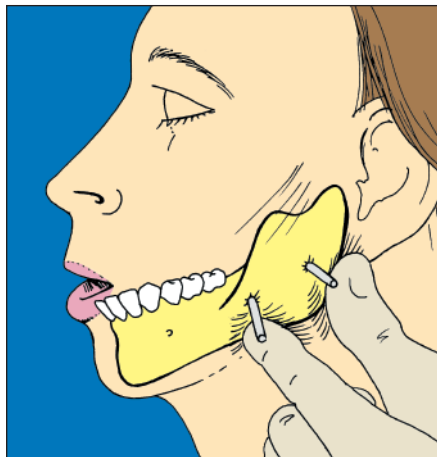
*Fig. 4:*  
Extent of the periosteal undermining on the lateral aspect of the mandible.



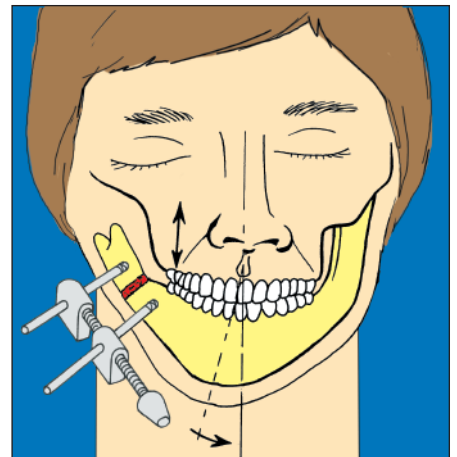
*Fig. 5:*  
Diagram showing the direction of the corticomy extending obliquely from the free edge of the mandibular angle. The corticotomy extends around the free posterior edge where the bone is thicker. Notice the site for introduction of the intrasosseous pins.



*Fig. 6:*  
The pins must penetrate the whole thickness of the bone. The external cortical layer is eliminated at the corticotomy site. The cancellous and internal cortical layers remain intact.



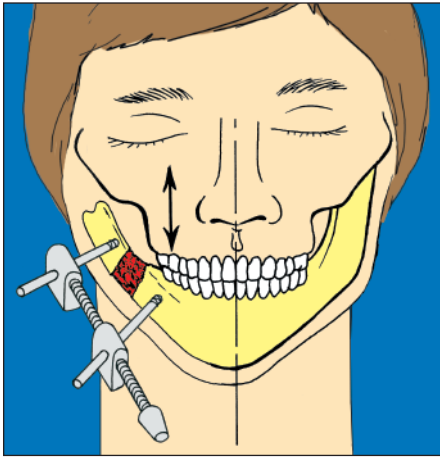
*Fig. 7:*  
The cheek skin is pinched between the fingers before the introduction of the pins to minimize the scarring produced by the distraction pins.



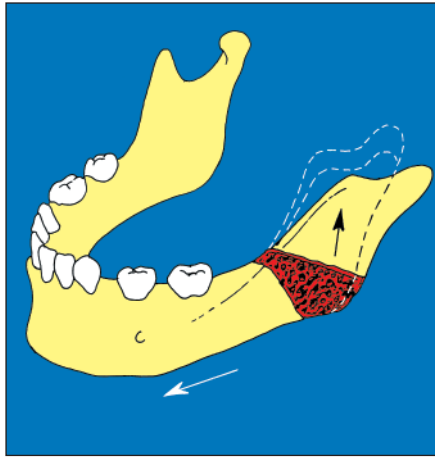
*Fig. 8:*  
Diagram showing the parallel position of the intrasosseous pins and the corticotomy immediate after surgery. The short vertical dimension of the maxilla is shown in the vertical line.

**Distraction Osteogenesis**  
Mandibular Distraction in Hemifacial Microsomia

Schematic drawings of the  
Distraction Technique

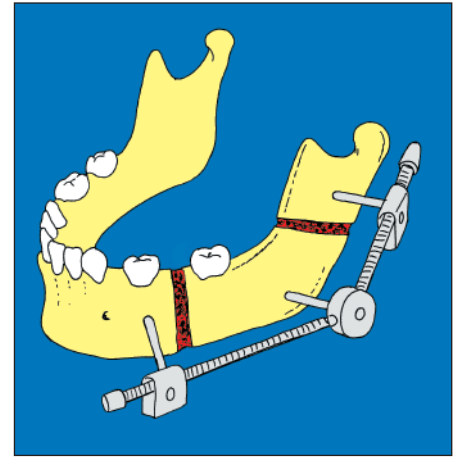


*Fig. 9:*  
After elongation, the intraosseous pins that were originally parallel become divergent, and the corticotomized section of the mandible is enlarged. Increased vertical dimension of the maxilla occurs very rapidly.



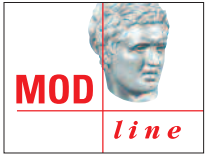
*Fig. 10:*  
When the distraction is completed, a zone of low bone density in the external cortex is observed.

*It is narrow at the free border and wide at the posterior margin because the elongation follows the curve of mandibular growth.*



*Fig. 11:*  
When vertical and horizontal distraction is necessary, two corticotomies are performed, one in front and another above the angle.

*Three pins are used. The central one at the angle serves as a pivot for the two independent vertical and horizontal distraction devices.*



## Orbital Malar Distraction

### Introduction

The use of the Orbital Malar Distractor (51-605-25) is demonstrated on the following pages 9 to 10.

The device has been designed to create new bone by osteogenic distraction in the malar zygoma, the orbit, the maxilla, the frontal and the temporal bones.

A wide variety of anomalies may be treated using this Orbital Malar Distractor, for example: Crouzon and Apert Syndromes, simple and complex craniosynostosis, plagiocephalies, Treacher Collins syndromes and certain major facial clefts.

The device allows different vectors to move the osteotomized bones. From a simple mono-directional (forward) advancement of the complete mid-face, more complex combined advancements and rotation movements of the mid-face.

In order to achieve a gradual, accurate and safe bone advancement, the surgeon has to decide on the correct placement of the devices, supported by the pivots (51-605-01/02/03), acting as a guide to the centre of rotation of the device.

It is also recommended to define the size and the number of the devices necessary for each case.

- a single device is used in a plagiocephaly case.
- two devices are indicated to advance the complete mid-face including the orbits.
- four devices have to be used to produce a monobloc-advancement, two for advancing the frontal bone and another two devices in a lower position to produce the controlled advancement of the mid-face.

### Surgical Technique

In all of the cases, surgical access is by a coronal incision. A subperiosteal dissection is performed over the frontal, orbit, zygoma and the anterior surface of the maxilla. It is recommended to preserve the temporalis muscle insertion and to perform a limited dissection to access the lateral orbital wall.

The osteotomy must be a complete one, not just a corticotomy, including separation of the pterygo-maxillary fissure. Different osteotomies are used according to the deformity to be treated. In the group of patients for complete mid-face advancement, the osteotomy is a subcranial LeFort III.

The device must be placed behind the orbital-malar area. To insert the device the pivot fig. 51-605-04 is attached to

the distractor and pushed into the temporalis muscle. This provides a gliding hole and reaches the posterior aspect of the zygoma. The pivot is then removed.

For the fixation of the device three different pivots (51-605-01/02/03) are available. These pivots are selected to get the best adaptation to the orbital malar complex and can be placed either on the lateral orbital wall or in the retro-malar region.

The final position of the distractor is determined and the device is fixed to the parietal bone with 4 Centre-Drive® 1,5 mm micro-screws, length 5 or 7 mm (25-074-05/07).

The device is completely submerged with the only visible part at the coronal incision where the activation takes place.

Before closure it is mandatory to check if the device can be activated and advanced freely (to a maximum of 10 mm), then go back to the zero position.

After a latency period of five days, the activation of the device is done at a rate of 1 mm per day, if possible by two incremental steps of 0.5 mm each.

Two turns of the activator (51-600-90) corresponds to 1 mm distraction length. The maximum distraction length is 25 mm.

*In Treacher-Collin cases* the osteotomy is different, as it is limited to the maxillo-malar-zygoma area. In the vast majority of these patients, a previous parietal bone graft has been performed some years earlier and the osteotomy must include the bone graft as well.

To achieve a lateral advancement-rotation movement of the osteotomized segment, a cuff of 3 to 4 mm of bone is preserved at the orbital frontal region for the pivot. The pivot can be placed either in the lateral aspect of the malar bone or in the retro-malar region.

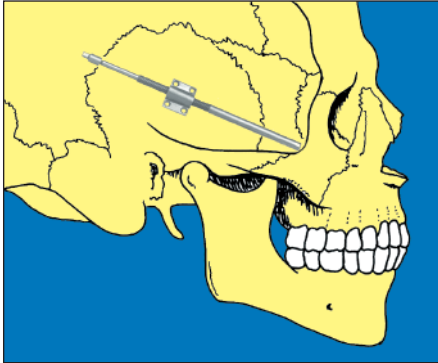
For a *monobloc* advancement, the osteotomy which includes the frontal bone must follow the lateral orbital wall and reach the pterygo-maxillary junction. In this technique, the supra orbital bar is avoided. The osteotomy has to be complete at the zygomatic arch as well as at the orbital roof floor and medial wall. In these cases the surgeon must imagine two different distraction vectors to advance simultaneously the frontal bone and mid-face. In most of the frontal bone cases a horizontal vector is necessary and is achieved using two devices placed horizontally.

To advance the *mid-face*, one oblique vector is indicated and is achieved using two additional devices placed obliquely. The four devices are fixed to the neighbouring parietal bone.

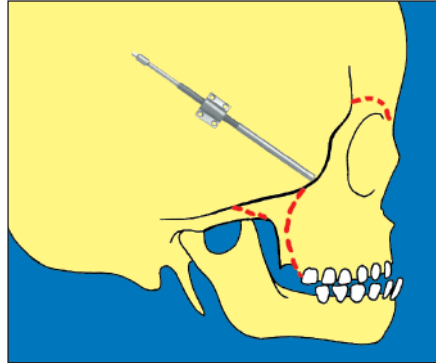


**Distraction Osteogenesis  
Orbital Malar Distraction**

**Schematic drawings of the  
Distraction Technique**

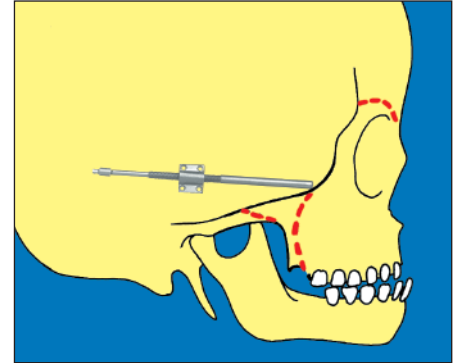


*Fig. 1:  
The application of the Molina Orbital Malar  
Distraction Device*



*Fig. 2:  
Figure showing a boy with Crouzon disease  
showing exorbitism, severe maxillo-malar  
hypoplasia, occlusion in Class III and the classi-  
cal facial concavity.*

*The dotted line shows the osteotomies, notice  
that the pterigo-maxillary junction shows a com-  
plete osteotomy that goes up to the orbital floor  
and the lateral wall of the orbit.*

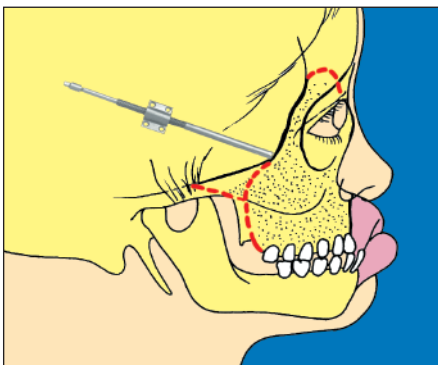


*Fig. 3:  
According with the cephalometric tracings in  
many cases the horizontal vector is the one to  
be used in the patients, as is shown in the figure,  
the vector is almost parallel to the occlusal  
plane.*

*With this mechanical force we produce new  
bone formation around the lateral wall and the  
orbital floor, at the pterigo-maxillary junction,  
at the zygomatic arch and the nasal bones.*

*The distraction process takes three weeks, then  
the patient goes into the consolidation period  
(six to eight weeks) and then the devices are  
removed.*

*The use of this horizontal vector can produce an  
anterior open bite, for this reason, orthodontic  
care is mandatory in this group of patients.*

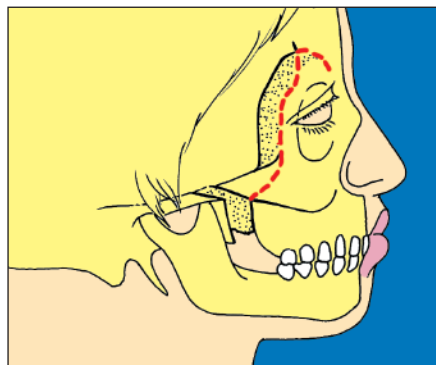


*Fig. 4:  
This figure shows an oblique vector of distraction.*

*This vector modality is indicated in moderate  
and severe cases of Midface Distraction,  
Crouzon Disease, Apert Syndromes and many  
other complex Craniosynostosis are excellent  
indications of this technique.*

*The oblique vector of distraction resembles  
closely the maxillary growth going downward  
and forward.*

*The use of this vector induces the development  
of a posterior open bite and for this reason  
orthodontic care is required.*

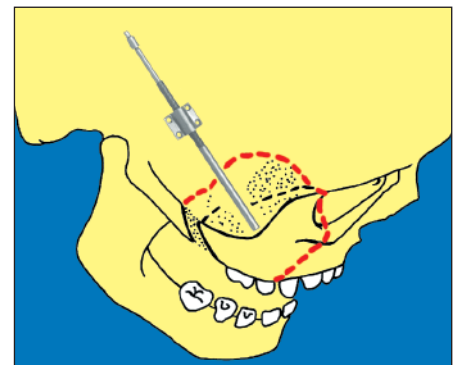


*Fig. 5:  
This figure represents a patient with Crouzon  
disease after the Distraction process.*

*The dotted area shows the new bone formation.  
Because of the movements of advanced rotation  
of the midface, new bone formation is produced  
in different amounts around the osteotomies.*

*The large amount of new bone formation is  
located behind the malar bone and the pterigo-  
maxillary junction.*

*This new bone formation will produce stability  
as a long term result. The new position of the  
orbit, the malar and the maxilla corrects the  
exorbitism, the midface retrusion and the  
malocclusion. In the growing patients over  
correction in Class II malar relationship is  
always mandatory.*



*Fig. 6:  
In Treacher-Collins patients, the osteotomy only  
includes the malar, the zygoma and lateral floor  
of the orbit.  
The semi-oblique position of the device pro-  
duces new bone formation.*

*This new bone formation will produce a new  
dimension in the bi-zygomatic distance and  
corrects the position of the soft tissue as well  
as the insertion of the lateral cantal ligament.*

## The Molina Baby Mandibular Distractor

This uni-directional distractor is designed for babies and infants.

- The device can be used for either the right or the left side of the mandible.
- Pins of 2 x 40 mm are used for bi-cortical positioning.
- Pins of 2 x 120 mm are used for penetration of both sides of the mandible (transfixed pins) to increase stability and to prevent pins from donning out.
- The distraction length is max. 28 mm.
- Two turns of 360° correspond to 1 mm distraction length.
- The Baby-Mandibular Distractor and pins are manufactured of Titanium in implant quality.
- Colour coding system: gold coloured.



1/4

51-600-28 Distraction length 28 mm



51-606-40 Pins 2 x 40 mm, 2 each



51-606-12 Pins 2 x 120 mm, 1 each



1/2

51-600-85 Screwdriver for pins



1/2

51-600-90 Activator and Fixation Screwdriver

## Indications

Corrections of airway problems in infants with Pierre Robin's Syndrome and other micronathias.

## Distraction Osteogenesis

### Uni-directional Mandibular Distraction

## The Molina Mandibular Distractors

These uni-directional distractors are designed for children and adults.

- The devices can be used for both the right and the left side of the mandible.
- The distraction length of the children-size is max. 43 mm.
- The distraction length of the adult-size is max. 53 mm.
- For children the pins of 2.7 mm are recommended.
- For adults the pins of 3.2 mm are used.
- Two turns of 360° correspond to 1 mm distraction length.
- The Mandibular Distractors and screws are manufactured of Titanium in implant quality.
- Colour coding system: Children size is blue coloured and adult size is natural grey.

## Indications

Used in treatment of uni-lateral mandibular hypoplasias

- Hemifacial microsomia Class I, II-A and II-B
- Facial asymmetry
- Mandibular asymmetries
- Some micrognathias



1/1

51-600-43 Distraction length 43 mm, for children



51-608-60 Pins 2.7 x 60 mm, 2 each



1/1

51-600-53 Distraction length 53 mm, for adults



51-610-60 Pins 3.2 x 60 mm, 2 each



1/2

51-600-85 Screwdriver for pins



1/2

51-600-90 Activator and Fixation Screwdriver

## The Molina Mandibular Distractors Bi-directional

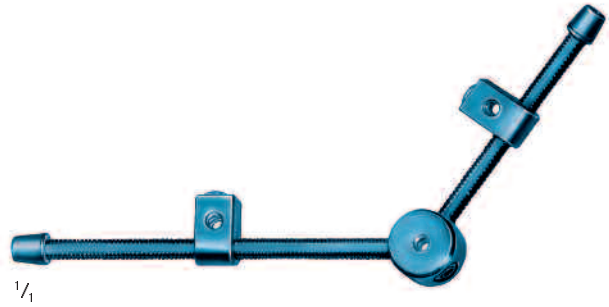
These bi-directional distractors are designed for children and adults, allowing four independent vectors for simultaneous lengthening of the ascending ramus and mandibular body.

If one segment is completed before the other segment has reached the desired distraction length, it is possible to continue the distraction procedure independently while the other segment is in the consolidation phase.

- The distraction length of the children-size is horizontally max. 56 mm and vertically 40 mm.
- The distraction length of the adult-size is horizontally max. 76 mm and vertically 40 mm.
- For children the pins of 2.7 mm are recommended.
- For adults the pins of 3.2 mm are used.
- Two turns of 360° correspond to 1 mm distraction length.
- The distractors and pins are manufactured of Titanium in implant quality.
- Colour coding system: Children size is blue coloured and adult size is natural grey.

## Indications

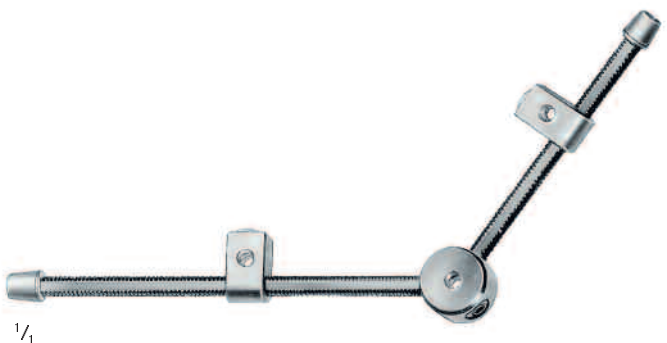
- Micrognathias of any etiology, Treacher-Collins, Nager's and Pierre Robins Syndromes.
- Bi-lateral microsomia



51-601-56 Distraction length 56 x 40 mm, left, for children  
51-602-56 Distraction length 56 x 40 mm, right, for children



51-608-60 Pins 2.7 x 60 mm, 2 each



51-601-76 Distraction length 76 x 40 mm, left, for adults  
51-602-76 Distraction length 76 x 40 mm, right, for adults



51-610-60 Pins 3.2 x 60 mm, 2 each



51-600-85 Screwdriver for pins



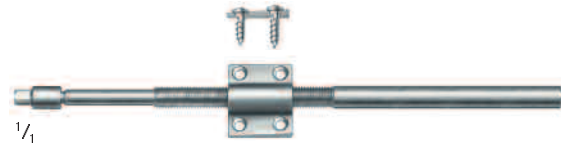
51-600-90 Activator and Fixation Screwdriver

**Distraction Osteogenesis**  
Orbital Malar Distraction

## The Molina Orbital Malar Distractor

The uni-directional distractor is designed for infants and children.

- The device can be used for both the right and the left side of the skull.
- Allowing various vectors of distraction depending on the placement.
- An advancement of up to 25 mm of the orbital malar bone is possible.
- The shaft moves in relation to the plate.
- The anterior point of the distractor has several pivots ensuring the positioning behind the malar, the lateral orbital wall or the frontal bone.
- The remaining external component of the device, emerging behind the ears, allows the activation.
- Two turns of 360° correspond to 1 mm distraction length.
- Manufactured in Titanium implant quality.



51-605-25 Distraction length 25 mm



51-605-01 Pivot fig. 1 (one each)



51-605-02 Pivot fig. 2 (one each)



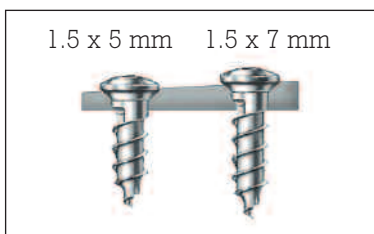
51-605-03 Pivot fig. 3 (one each)



51-605-04 Pivot fig. 4 (one each)

## Indications

- Orbital, malar, maxillae advancements or monoblock advancements in Crouzons, Aperts, other craniosynostosis and plagiocephaly.



Positioning of the Centre Drive® Microscrews on the fixation plate



51-600-90 Activator and Fixation Screwdriver

### Recommended Centre Drive® Micro Screws:

- 25-074-05 Centre Drive® screws 5 x 1.5 mm (10 each)
- 25-074-07 Centre Drive® screws 7 x 1.5 mm (10 each)
- 25-430-16 Centre Drive® screwdriver 1.5 mm
- 25-451-07 Drill bits 1.1 x 50 x 7 mm, cylindrical (5 each) alternative

## Ordering Details:

### Molina Uni-directional Mandibular Distractors

**51-600-28 Mandibular Distractor, baby-device distraction length 28 mm, 1 each**

51-606-40 Pins 2 x 40 mm, 2 each

51-606-12 Pins 2 x 120 mm, 1 each

51-600-01 Spare screws for fixation part, 2 each optional:

51-606-50 Pins 2 x 50 mm, 2 each

51-606-60 Pins 2 x 60 mm, 2 each

51-606-14 Pins 2 x 140 mm, 1 each

**51-600-43 Mandibular Distractor, for children distraction length 43 mm, 1 each**

51-608-60 Pins 2.7 x 60 mm, 2 each

51-600-01 Spare screws for fixation part, 2 each

**51-600-53 Mandibular Distractor, for adults distraction length 53 mm, 1 each**

51-610-60 Pins 3.2 x 60 mm, 2 each

51-600-01 Spare screws for fixation part, 2 each

51-600-85 Screwdriver, for pins, 1 each

51-600-90 Activator and Fixation Screwdriver, 1 each



### Molina Bi-directional Mandibular Distractors

**51-601-56 Mandibular Distractor, small distraction length 56 x 40 mm, left, 1 each**

**51-602-56 Mandibular Distractor, small distraction length 56 x 40 mm, right, 1 each**

51-608-60 Pins 2.7 x 60 mm, 2 each

51-600-01 Spare screws for fixation part, 2 each

**51-601-76 Mandibular Distractor, large distraction length 76 x 40 mm, left, 1 each**

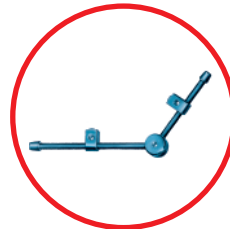
**51-602-76 Mandibular Distractor, large distraction length 76 x 40 mm, right, 1 each**

51-610-60 Pins 3.2 x 60 mm, 2 each

51-600-01 Spare screws for fixation part, 2 each

51-600-85 Screwdriver, for pins, 1 each

51-600-90 Activator and Fixation Screwdriver, 1 each



### Molina Uni-directional Orbital Malar Distractor

**51-605-25 Orbital Malar Distractor, distraction length 25 mm, 1 each**

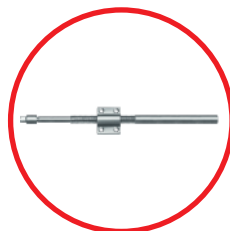
51-605-01 Pivot fig. 1, 1 each

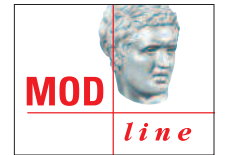
51-605-02 Pivot fig. 2, 1 each

51-605-03 Pivot fig. 3, 1 each

51-605-04 Pivot fig. 4, 1 each

51-600-90 Activator and Fixation Screwdriver, 1 each





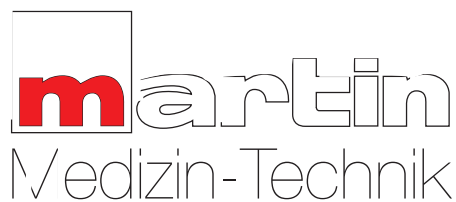
**Distraction Osteogenesis**  
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