KLS martin GROUP

Transversal Distraction Overview

Sophisticated Transversal Distractors in CMF Surgery

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Oral and maxillo-facial surgery is our passion! Its further development, together with our customers, is our ambition. Every day we work on developing innovative products and services which meet the highest demands on quality, and which contribute to the wellbeing of the patient.

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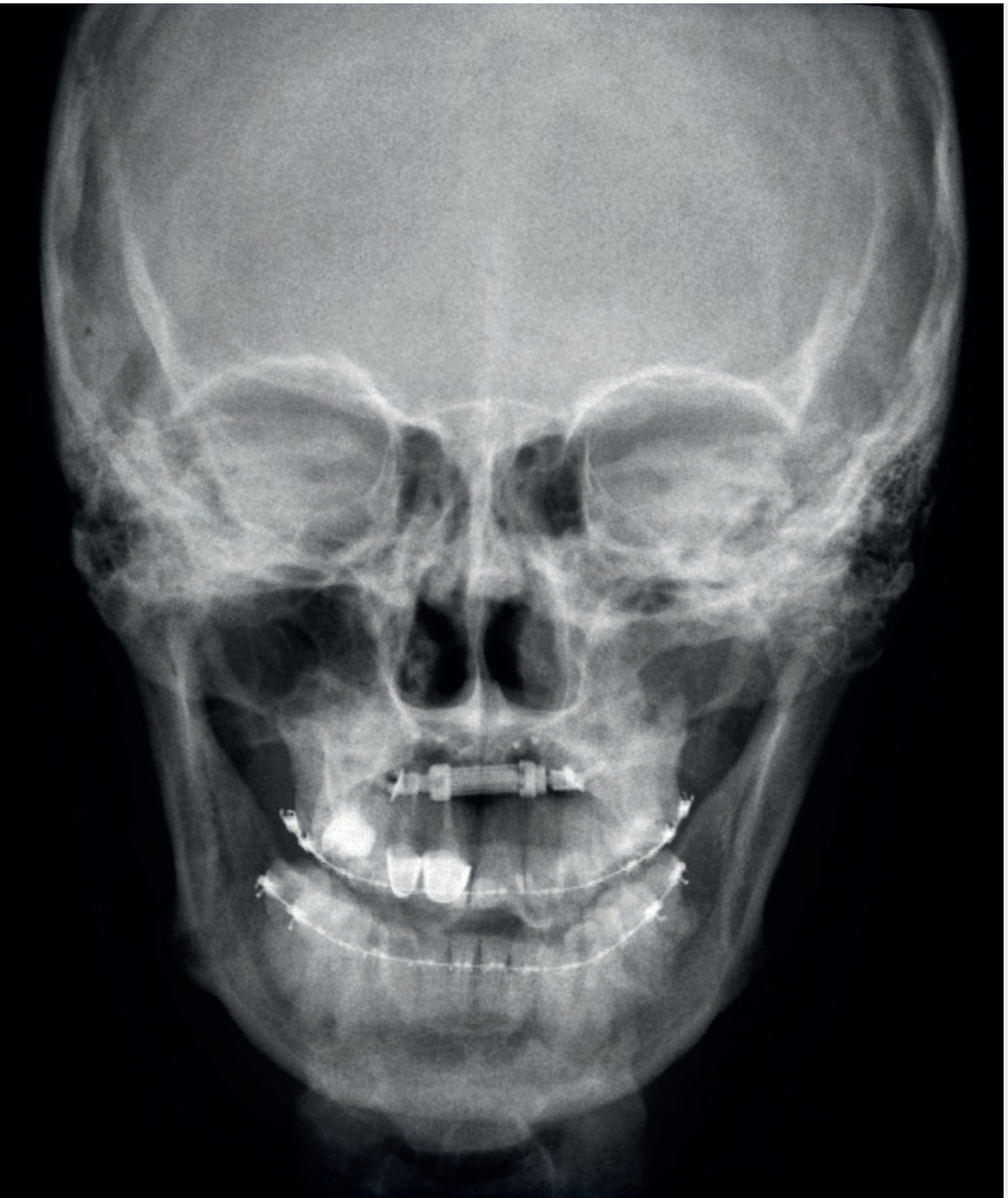
Transversal Distraction Overview

Sophisticated Transversal Distractors in CMF Surgery

Transversal discrepancies are among the most frequent cranio-facial disorders in cranio-maxillofacial surgery. Bone-borne devices offer clear advantages in comparison to tooth-borne solutions, as they allow simultaneous treatment of the orthodontic team leading to a significant reduction of the overall treatment time.

KLS Martin has done pioneering work in transversal distraction osteogenesis. With the RPE transversal distractor, the Rotterdam car jack distractor, the Bologna and the Rotterdam mandibular distractors the company offers four important bone-borne strategies which make sure the surgeon has the complete choice of bone-borne solutions for a reliable skeletal base for adequate positioning of teeth. In this brochure we bring all four product solutions together in order to sum up the complete scope of options.



Clinical photos by courtesy of Dr. Hamid-Reza Sarajian, Rotes Kreuz Krankenhaus, Kassel, Germany

Rapid Palatal Expander
Bone-borne distractor for transverse maxillary hypoplasia (RPE)

Rapid Palatal Expander (RPE)

Transverse maxillary hypoplasia in adolescents and adults is frequently seen in non-syndromal and syndromal patients including cleft palate patients. The hypoplasia may lead to arch length discrepancy and crowding, buccal corridors and posterior cross-bites. Uni- and bilateral transverse hypoplasia can be corrected by means of a surgically assisted rapid palatal expansion (SARPE). The treatment is a cooperation of orthodontic and surgical procedures and provides dental arch space for lining up the maxillary teeth.

The procedure also causes a substantial enlargement of the maxillary apical base and of the palatal vault and may therefore provide space for the tongue for improved swallowing and thus preventing relapse. In addition, a distinct subjective improvement in nasal airway associated with enlargement of the nasal valve towards normal values is seen with an increase of nasal volume in all compartments. It improves arch length and may reduce the need for premolar extraction as a measure to align the teeth. Widening the maxilla might reduce the unaesthetic buccal corridors, as seen in smiling.

Traditionally, transverse maxillary hypoplasia in adults is corrected with corticotomies and tooth-borne expanders. Tooth-borne distractors have some disadvantages as dental movements occur: periodontal problems, buccal root resorption, cortical fenestration, segmental tipping and tipping of the anchorage teeth.

In contrast, bone-borne distractors are positioned at a higher level in the palatal vault, consequently maxillary expansion is predominantly skeletal and forces are directed at the desired level. In addition, the forces are on the bone and no tooth tipping, fenestration, etc. are to be expected.

The KLS Martin Rapid Palatal Expander is an elegantly designed bone-borne distractor which is very versatile in both placement and activation.

Advantages

- Bone-borne distractor
- Forces are directly applied to the bone
- No tooth tipping and extrusion
- No orthodontic relapse expected after the expansion
- Shortened treatment time due to the opportunity for early orthodontic teeth alignment
- No periodontal ligament compression, buccal root resorption, and fenestration are to be expected
- Easily placed and activated
- Easy removal
- Available as a sterile product

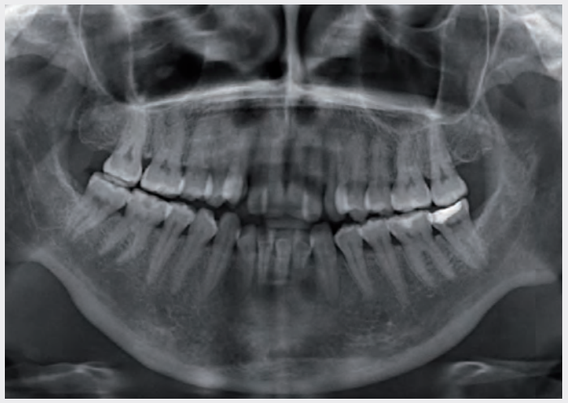
Indications

- Transverse uni- or bilateral maxillary hypoplasia in syndromal and non-syndromal patients
- Anterior dental crowdings and buccal corridors

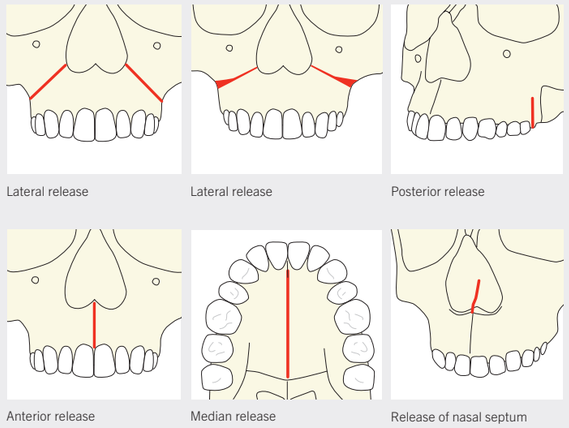
Contraindications

- General or local health issues as immune deficiency, titanium allergy, irradiated maxilla, palatal defects
- Psycho-social inability to comply, suspected lack of patients collaboration
- Shallow palatal vault, might result in loosening

Schematic procedure step by step



Preoperative X-ray*



1. Intraoperative approach
Osteotomies of the lateral, anterior and median bony supports of the maxilla. In case of posterior (parallel) expansion pterygo-maxillary disjunction (posterior release) might additionally be performed. Release of nasal septum is discussed controversially among physicians.

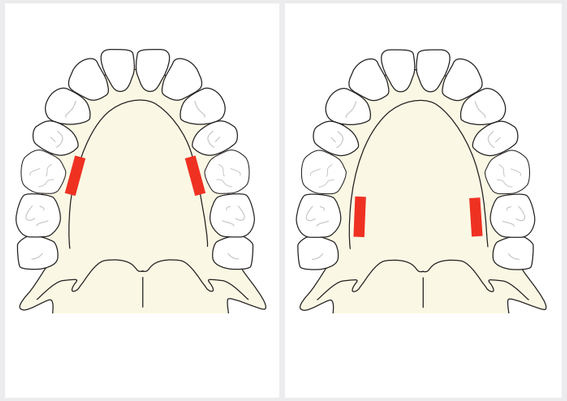
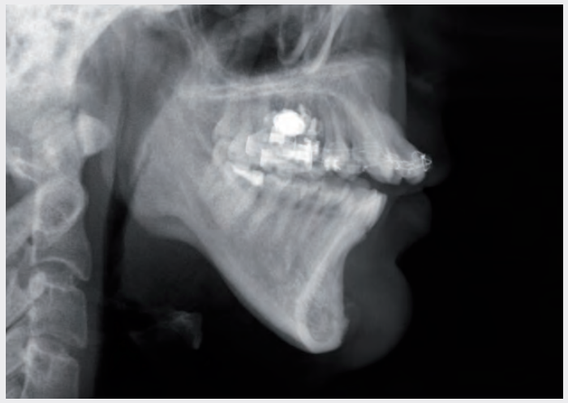


Fig. 1

Fig. 2

2. First placement
The KLS Martin Rapid Palatal Expander (RPE) is positioned with the abutment plates on the mucosa over the roots of the second premolar (in case of anterior (3:2) expansion, Fig. 1) and first molars (in case of posterior expansion, Fig. 2). The activation rod is in the midline and must not interfere with the lower teeth in occlusion.



3. First activation*
The distractor is slightly activated. Thus the print of the plates is clearly visible on the mucosa. Now the palatal mucosa on the anterior and occlusal side directly around the abutment plates is incised. The distractor is deactivated and removed.

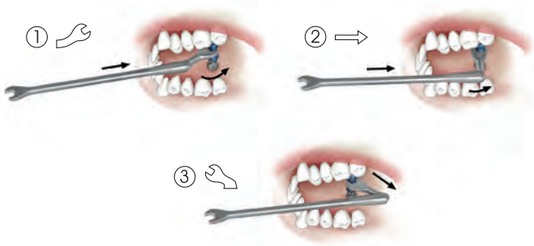
4. Final placement
The area of palatal mucosa removed is slightly smaller than the abutment. Local haemostasis is performed. The RPE Distractor is placed again with the plates now on the bone. The distractor is slightly activated so the spikes penetrate the bone stabilizing the distractor. Make sure that the distractor is adequately placed with osteosynthesis holes of the abutment plates placed towards anterior.

5. Fixation of the distractor
Finally, the distractor is secured with the two additionally supplied drill-free screws in the holes of the distractor plates.

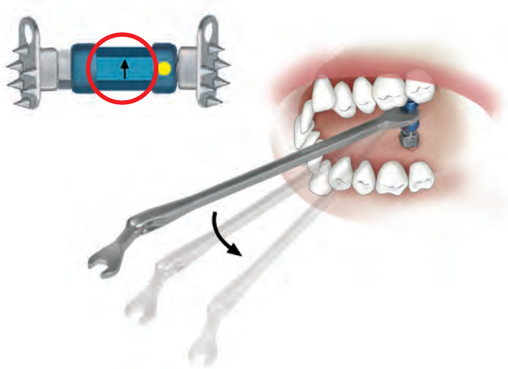
* Clinical photos by courtesy of Dr. Hamid-Reza Sarajian, Rotes Kreuz Krankenhaus, Kassel, Germany

* Clinical photos by courtesy of Dr. Hamid-Reza Sarajian, Rotes Kreuz Krankenhaus, Kassel, Germany

Schematic procedure step by step



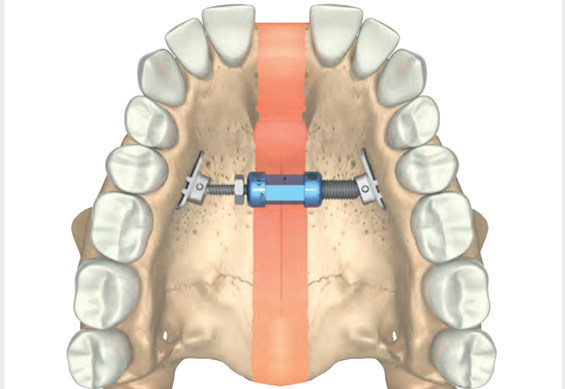
Activation is carried out with the flexible working end
(item No. 51-565-95-07)

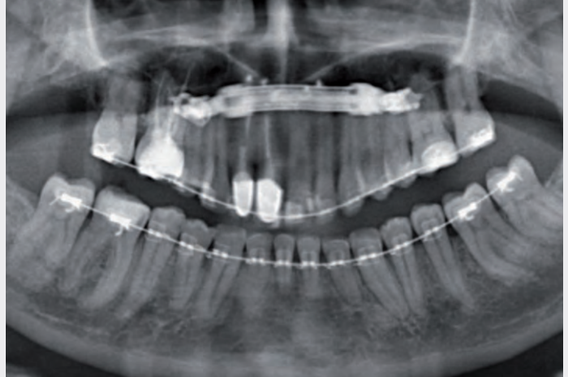


6. Latency period
Activation can begin 5 – 7 days after device placement based on the surgeon's treatment plan.

7. Distraction period
The distractor is easily activated with the patient activating wrench (item No. 51-565-90-07 or item No. 51-565-95-07). A rotation through 120° to the next color coding corresponds to a distraction travel of 0.33 mm. A rotation through 120° (– 240°) per day is recommended which corresponds to a distraction travel of 0.33 (– 0.66) mm per day**. The exact activation can easily be identified thanks to the differently colored dots on the distraction corpus.

8. Tighten the locking nut
To avoid undesired movements of the distractor body during latency period, it is necessary to tighten the locking nut with the rigid working end of the patient activating wrench (item No. 51-565-95-07).





9. Consolidation period*
A 3 – 4 months consolidation period is recommended. Orthodontic tooth movements can already be performed early in the consolidation period.

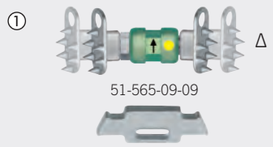
Treatment protocol:**

- General anaesthesia, antibiotic prophylaxis.
- Corticotomies at lateral wall of the maxillary sinus and median alveolus and bony palate, simultaneous placements of fitted RPE (maximal size given by anatomy).
- Start oral hygiene protocol, with antiseptic mouth rinse, prolonged antibiotics if indicated.
- Latency period: 5 – 7 days, start distraction and patient instruction.
- Daily distraction 0.33 mm until desired width, use closure wheel.
- Consolidation period: 4 months.
- Removal of distractor under local anaesthesia.

* Clinical photos by courtesy of Dr. Hamid-Reza Sarajian, Rotes Kreuz Krankenhaus, Kassel, Germany

** The distraction varies according to surgeon's wishes, orthodontic protocols or patient's needs. The protocol can be altered during the period of active distraction.

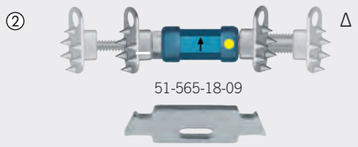
Ordering details



① Δ

51-565-09-09

Measuring template 51-564-09-09



② Δ

51-565-18-09

Measuring template 51-564-18-09

③ Δ

51-565-27-09

Measuring template 51-564-27-09

④ Δ

51-565-36-09

1:1 scale

Measuring template 51-564-36-09

Δ max. extension

2 maxDrive® Drill-Free screws*/**
2.0 x 7 mm

51-565-90-07*/**

Additionally available:
Flexible activating wrench 51-565-95-07

* Distractor including activating wrench 51-565-90-07 and 2 maxDrive® Drill-Free screws 2.0 x 7 mm
** Sterile packed distractor, including activation wrench 51-565-90-07 and 2 maxDrive® Drill-Free screws 2.0 x 7 mm

① 9 mm distraction length
② 18 mm distraction length
③ 27 mm distraction length
④ 36 mm distraction length

Icon explanations

- Ti Titanium
- St Steel
- Sic Silicone
- 1 unit(s) Packing unit
- STERILE R Implants in sterile packaging

Rapid Palatal Expander (RPE)

Distractors (1 unit(s))	Item Number	STERILE R
① 9 mm distraction length	51-565-09-09*	51-565-09-71 **
② 18 mm distraction length	51-565-18-09*	51-565-18-71 **
③ 27 mm distraction length	51-565-27-09*	51-565-27-71 **
④ 36 mm distraction length	51-565-36-09*	51-565-36-71 **

Δ tips		Δ plates	
closed	open	closed	open
19.0 mm	28.0 mm	15.5 mm	24.5 mm
23.5 mm	41.5 mm	20.0 mm	38.0 mm
28.0 mm	55.0 mm	24.5 mm	51.5 mm
32.5 mm	68.5 mm	29.0 mm	65.0 mm

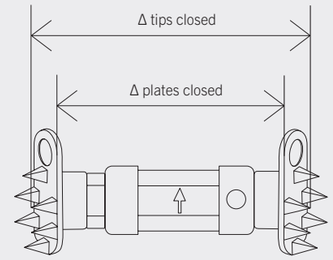
Recommended distraction length
1-2 color codes = 0.33-0.66 mm/day (one complete turn = 1.0 mm)

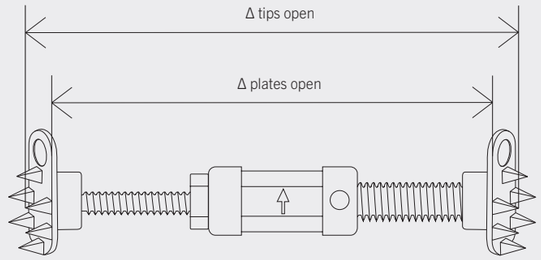
Measuring templates (Ti, 1 unit(s))	
Size I	51-564-09-09
Size II	51-564-18-09
Size III	51-564-27-09
Size IV	51-564-36-09

Recommended screws (Ti)
maxDrive® Drill-Free: 2.0 x 7 mm

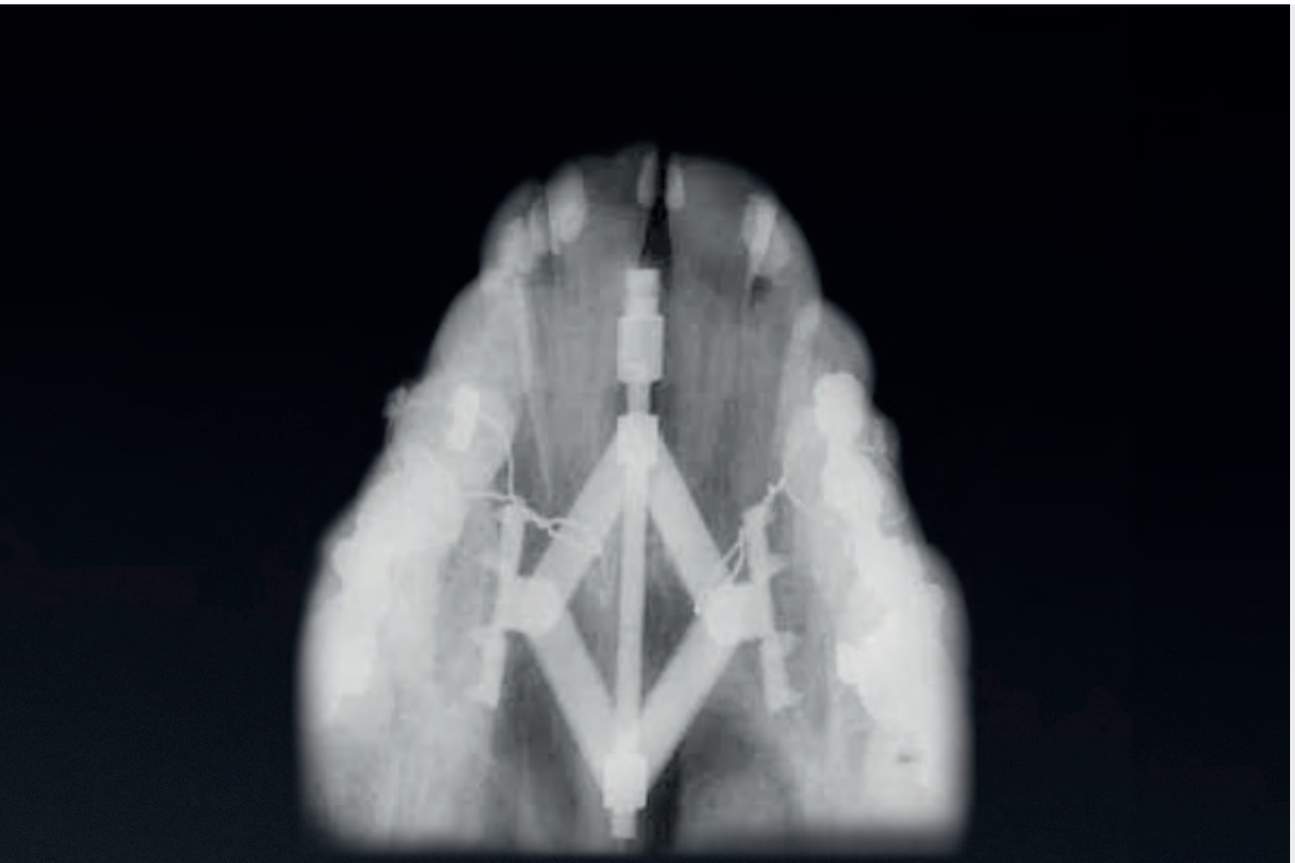
Patient screwdriver (St, 1 unit(s))	
Activating wrench	51-565-90-07
Flexible activating wrench	51-565-95-07

Screwdrivers and blades for 2.0/2.3 mm maxDrive® screws (St, 1 unit(s))	
Screwdriver	25-407-03-04 (Sic)
Screwdriver flattened, for storage in Level One modules	25-407-04-04 (Sic)
Blade for screwdrivers 25-407-03-04 and 25-407-04-04	25-486-97-07
Blade for KLS Martin angled screwdriver	50-917-20-07





* Distractor including activating wrench 51-565-90-07 and 2 maxDrive® Drill-Free screws 2.0 x 7 mm
** Sterile packed distractor, including activation wrench 51-565-90-07 and 2 maxDrive® Drill-Free screws 2.0 x 7 mm



Introduction

Transverse maxillary deficiency in adolescents and adults is frequently seen in syndromatic as well as non-syndromatic patients including cleft patients. The transverse hypoplasia can be corrected by means of a surgically assisted rapid maxillary expansion.

The treatment is an association of orthodontics and surgical procedures and provides dental arch space for lining up the teeth. The procedure also causes a substantial enlargement of the maxillary apical base and of the palatal vault, providing space for the tongue for correct swallowing and thus preventing relapse. In addition, a distinct subjective improvement in nasal breathing associated with enlargement of the nasal valve towards normal values is seen with an increase of nasal volume in all compartments.

Traditionally, the distractors for expansion are tooth-borne devices, i.e. hyrax appliances, which might have some serious disadvantages:

1. periodontal problems like buccal root resorption and cortical fenestration
2. segmental tipping and anchorage-tooth tipping
3. dental caries in syndromatic patients with poor oral hygiene

In contrast, with bone-borne distractors applied at a higher level in the palatal vault, most of the maxillary expansion is orthopaedic and at a more mechanically desired level.

In addition, the forces are directly applied to the bone and no tooth tipping and other unwelcome side effects are to be expected.

All clinical pictures by courtesy of E.B. Wolvius/K.G.H. van der Wal, Erasmus University Medical Centre, NL-Rotterdam

Rotterdam Palatal Distractor for surgically assisted rapid maxillary expansion

Developed in cooperation with

K.G.H. van der Wal, D.D.S., M.D. Ph.D.
E.B. Wolvius, D.D.S., M.D. Ph.D.
Dept. of Oral & Maxillofacial Surgery
and Craniofacial Centre,
Erasmus University Medical Centre Rotterdam,
The Netherlands

Indications

- Extreme transverse maxillary deficiency in syndromatic and non-syndromatic patients
- Anterior crowding and buccal corridors

Relative contraindications

- Class II deep bite; the distractor or the small activation rod on the palate may interfere with the teeth of the mandible. This can be overcome by placing the Rotterdam Palatal Distractor more distally or by wearing an occlusal splint during the distraction and consolidation period.

Absolute contraindications

- Extreme low palate; in case of an extreme low palate, the pins of the abutment plates will loose fixation and the distractor will not be stable.
- A general contraindication is an immune deficiency and irradiation.

Benefits

- Easily placed and activated
- No dental anchorage
- No screw fixation with possible damage to the (pre-)molar roots
- Easily blocked with a stainless steel wire
- Allows simultaneous orthodontic treatment with fixed appliances
- Easily removed with local anaesthesia

Special notes

- For primary stabilization, the Rotterdam Palatal Distractor has to be slightly activated.
- One should realize that due to the mechanical principle of a car jack, equal activation during the distraction period will result in a progressively decreasing distraction length. Therefore, in the course of the distraction, the rhythm of activation changes (see page 5).
- Patients with the Rotterdam Palatal Distractor have to keep up oral hygiene; regular visit to the oral hygienist is recommended.

Intraoperative procedure

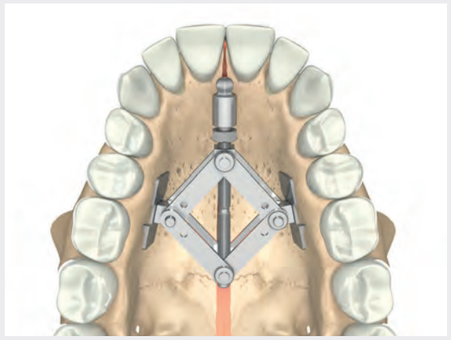


Fig. 1: Rotterdam Palatal Distractor, start position

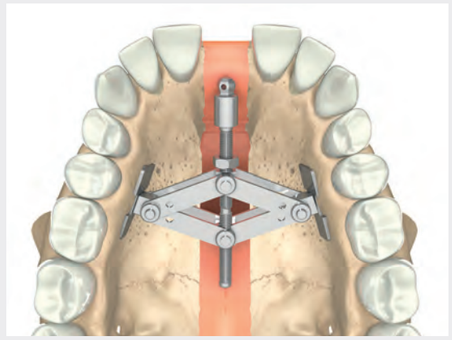


Fig. 2: During distraction period

Intraoperative approach

Standard corticotomies of the anterior, lateral and median bony supports of the maxilla are performed. The palatal gingiva of the premolars is infiltrated with local anaesthesia including a vasoconstrictor.

Firstly, the Rotterdam Palatal Distractor is positioned temporarily with the abutment plates on the mucosa over the roots of the first or second premolars. The activation rod is in the midline and must not interfere with the lower teeth in occlusion. The distractor is slightly activated. Thus the print of the plates is clearly visible on the mucosa. Now the palatal mucosa on the anterior and occlusal side directly around the abutment plates is incised. The distractor is deactivated and removed.

The palatal mucosa slightly smaller than the abutment plate is removed. Local haemostasis is performed. The Rotterdam Palatal Distractor is placed again with the plates now on the bone. The distractor is slightly activated so the pins penetrate the bone stabilizing the distractor and, as a consequence, the vector.

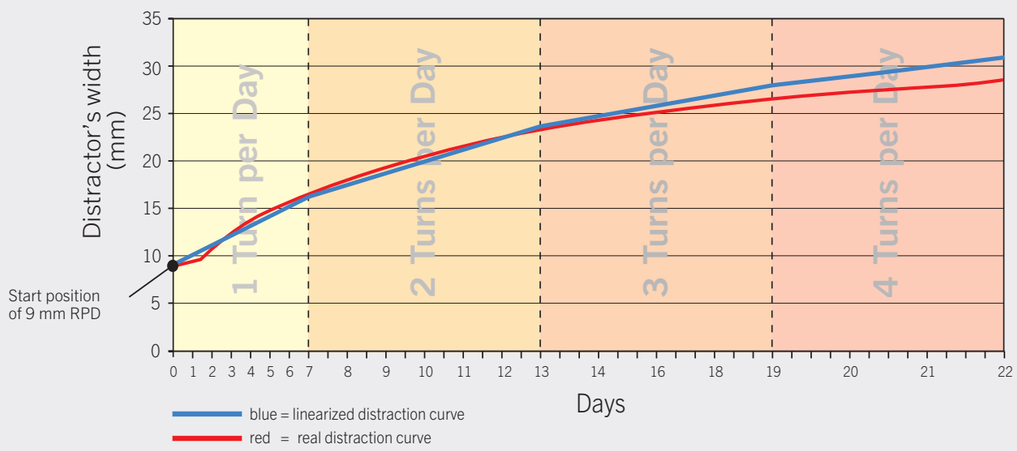
Note:

Do not intend to place the distractor epimucosally (on the mucosa), as its sharp spikes might irritate the palatal mucosa and may cause pain and discomfort for the patient.

The number of turns is counted in order to know where to start in the distraction protocol. Finally, the distractor is secured with stainless steel wires around the premolars on both sides.

Distraction diagram

showing the width of a 9 mm Rotterdam Palatal Distractor in relation to active distraction time



Distraction protocol

Due to the mechanical principle (trigonometric function) of a car jack, equal activation will result in a progressively decreasing distraction length (see figure). Activation with 0.6 turn (0.6 x 360° = 216°) at the start of the distraction will result in a distraction length of 1 mm. After 5 mm of distraction, 1.3 turns (1.3 x 360° = 468°) are necessary to achieve the same distraction length of 1 mm. In the graphic, the changing length during the distraction period is demonstrated. As a result a distraction of exactly 1 mm per day is not feasible. To come close to the 1 mm and to achieve optimal patient's comfort, different distraction rhythms have been selected:

1st interval:
Closed distractor until 7 complete turns: 1 turn per day

2nd interval:
From 7 turns (distractor is opened for approx. 7 mm) until 13 complete turns: 2 turns per day

3rd interval:
From 13 turns (distractor is opened for approx. 14 mm) until 19 complete turns: 3 turns per day

4th interval:
From 19 turns (distractor is opened for approx. 17 mm) until maximal distraction length: 4 turns per day

It is very important to note the opening length (amount of turns) of the distractor during the placement in order to know where to start in the scheme respectively in which interval.

- Latency period: 7 days.
- Distraction is performed according to the different intervals by using the patient screwdriver (item No. 51-500-91-07).
- Consolidation period after distraction: 3 months.
- Orthodontic treatment can already be started or continued during the consolidation period.

Clinical examples

Case 1 – Non-syndromatic patient
Non-syndromatic patient with mandibular retrognathia and transversemaxillary hypoplasia

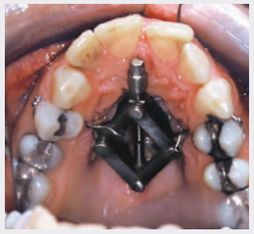


Fig. 1: Submucosal application of the distractor.

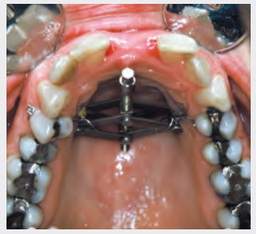


Fig. 2: At the end of distraction the maxilla has been widened.

Case 2 – Non-syndromatic patient
Non-syndromatic patient with mandibular prognathia, open bite and narrow-tapered arch form

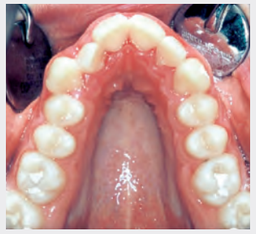


Fig. 1: Narrow-tapered arch form with anterior crowding.

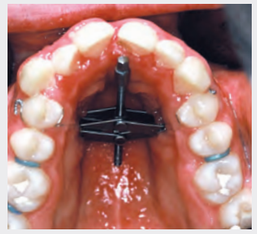


Fig. 2: The maxilla has been widened and already the central incisors have migrated mesially without orthodontics.

Case 3 – Non-syndromatic patient
Non-syndromatic patient with mandibular retrognathia and transverse maxillary hypoplasia

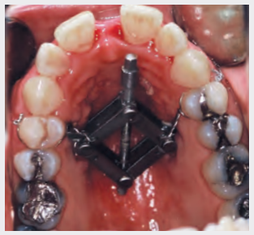


Fig. 1: The distractor is slightly out of the midline but without any clinical consequences.

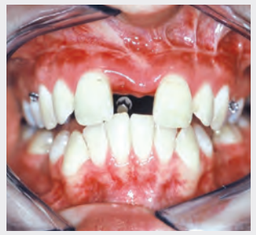


Fig. 2: The maxilla has been widened; a clear central diastema appears which can be closed orthodontically.

Case 4 – Syndromatic patient
Syndromatic patient with Treacher Collins including transverse maxillary hypoplasia

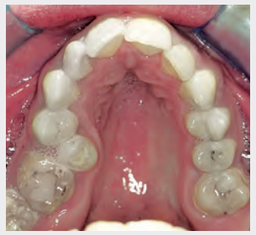


Fig. 1: Narrow-tapered arch form with high palate and anterior crowding.

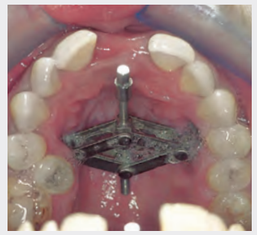


Fig. 2: Clinical situation directly after end of distraction period.

Removal of the distractor
At the end of the consolidation period, the distractor can be removed in an outpatient clinic. The palatal mucosa surrounding the distractor is infiltrated with local anaesthesia including a vasoconstrictor. The stainless steel wires are removed, the distractor is deactivated and removed (picture 1). The healing of the mucosa is normally complete within a week (picture 2).

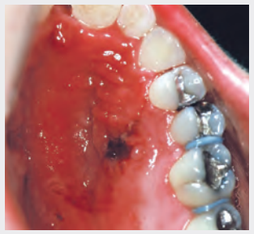


Fig. 1: Directly after removal of the distractor.

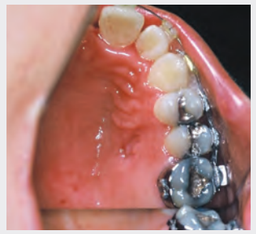


Fig. 2: Complete healing of the mucosa after one week.

All clinical pictures thanks to E.B. Wolvius/K.G.H. van der Wal, Erasmus University Medical Centre, NL-Rotterdam

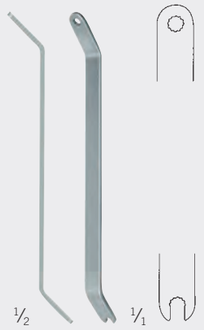
Ordering details

1/1

51-555-09-09
Rotterdam Palatal Distractor for patients with congenital deformities: for extreme narrow maxillas particular in syndromatic patients. Especially in these cases, there is no space for a conventional hyrax appliance or bone-borne type distractors that have to be fixated with screws.
Closed: 9 mm (distance from plate to plate)
Maximal open: 28 mm

1/1

51-555-13-09
Rotterdam Palatal Distractor for patients with regular tranverse maxillary hypoplasia:
Closed: 13 mm (distance from plate to plate)
Maximal open: 32 mm



1/2 1/1

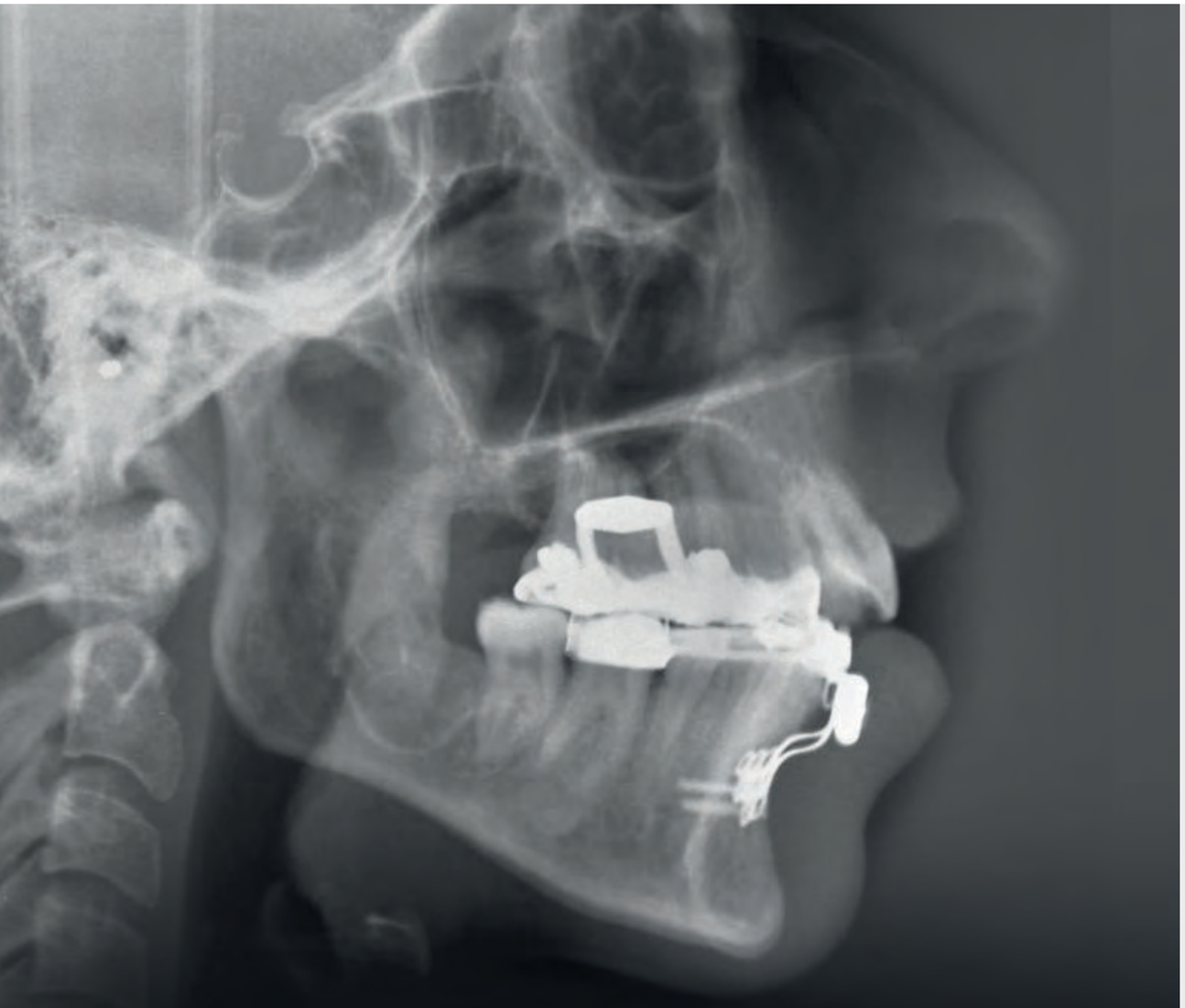
51-555-90-07
10 cm/3 7/8“
Patient screwdriver hockey stick-like

1/2

51-500-91-07
16 cm/6 2/8“
Patient screwdriver straight

Design of the distractor

The Rotterdam Palatal Distractor is a bone-borne distractor which can easily be placed and activated. It has the design of a car jack and is totally made of titanium grade II. By activating the distractor, the 2 mm long pins of the two abutment plates will penetrate the bone and the device is stabilized automatically. No screws are necessary to fixate the distractor to the bone. At the end of the distraction period, the distractor is easily blocked with a stainless steel wire.



Introduction

Transverse mandibular hypoplasia (TMH) with crowding of the anterior teeth and a V-shape of the mandible is frequently seen in patients with Class I and II malocclusions and Class III patients requiring decompensation before orthognathic surgery. Traditionally, teeth slicing and teeth extractions with compensating orthodontics, functional appliances or orthopaedic devices have been the first choice of treatment, but have resulted in instability, compromised periodontium and compromised facial aesthetics.

The surgical technique of widening the symphyseal area of the mandible is based upon gradual distraction following vertical interdental symphyseal osteotomy and has proven to be successful. However, the distraction devices used so far are rather bulky with great discomfort for the patients, including mucosal irritations, hyperplasia and pain.

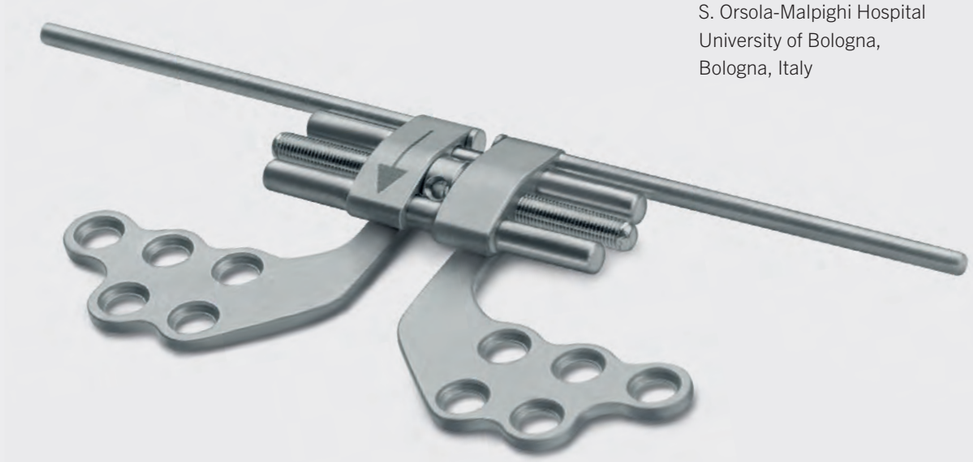
The Bologna Midline Distractor (BMD) is a slim and relatively strong alternative.

All clinical pictures thanks to E.B. Wolvius/K.G.H. van der Wal, Erasmus University Medical Centre, NL-Rotterdam

The Bologna Midline Distractor (BMD)

Developed in cooperation with

Dr. Alberto Bianchi, MD; DMD
Oral and Maxillofacial Surgery Unit,
S. Orsola-Malpighi Hospital
University of Bologna,
Bologna, Italy



The Bologna Midline Distractor

The Bologna Midline Distractor (BMD) follows the principles of the Rotterdam Midline Distractor (RMD) but offers the combination of bone-borne and tooth-borne anchorage.Therefore a maximum reliability of force transmittance can be guaranteed. The L-shaped mesh offers flexible fixation options, giving in this way the possibility to avoid damaging of the dental roots.
The distractor is made of titanium alloy (Ti-6AL-4V) and the plates are made of titanium grade II.
The bar for the dental fixation is made of stainless steel to enable a stable fixation with the dental anchoring. The connection to the teeth will be made by the orthodontic team in correspondence to the patient's individual dentition. The distractor is robustly designed which is a prerequisite for an ideal parallel widening. The activation mechanism remains completely extra mucosal. Once the inferior plates have been removed, the upper tooth-bone average can be left in situ as an orthodontic retainer.

The Bologna Distractor (BMD) avoids any inter-canine/premolar relapse, which has been referred with other types of symphyseal distractors, and allows a parallel bone and dental arch widening.

Advantages

- Easily placed and activated
- Parallel widening due to robust device applying a very slim and comfortable distractor
- No mucosal irritation with discomfort and pain
- Allows simultaneous orthodontic treatment with fixed appliances
- Can be removed easily under local anaesthesia

Indications

- (Extreme) transverse mandibular hypoplasia in non-syndromal and syndromal patients
- Anterior dental crowding
- V-shape of the mandible

Relative contraindication

- Class II/1 and II/2 deep bite; the deep bite may interfere with the position of the Midline Distractor. This can be overcome by placing the BMD more apically or by wearing an occlusal splint during the distraction and consolidation period.

Intraoperative procedure

Fig. 1: Incision

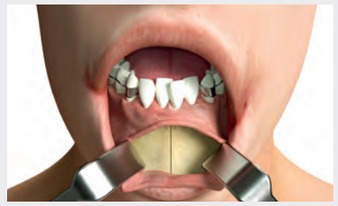


Fig. 2: Marking of the osteotomy line

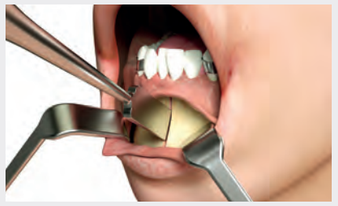


Fig. 3: Spreading the mandible using an osteotome or Smith Spreader 38-846-20-07

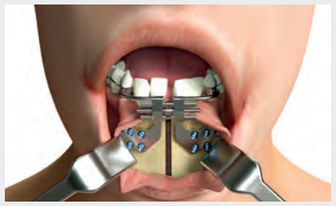


Fig. 4: Distractor is fixed to the bony aspect and the dentation of the mandible

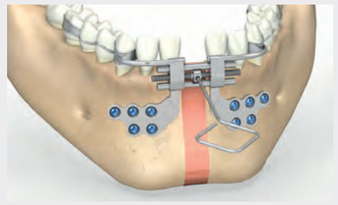


Fig. 5: Intraoperative functional testing

Fig. 6: Soft tissue closure and begin of the latency period

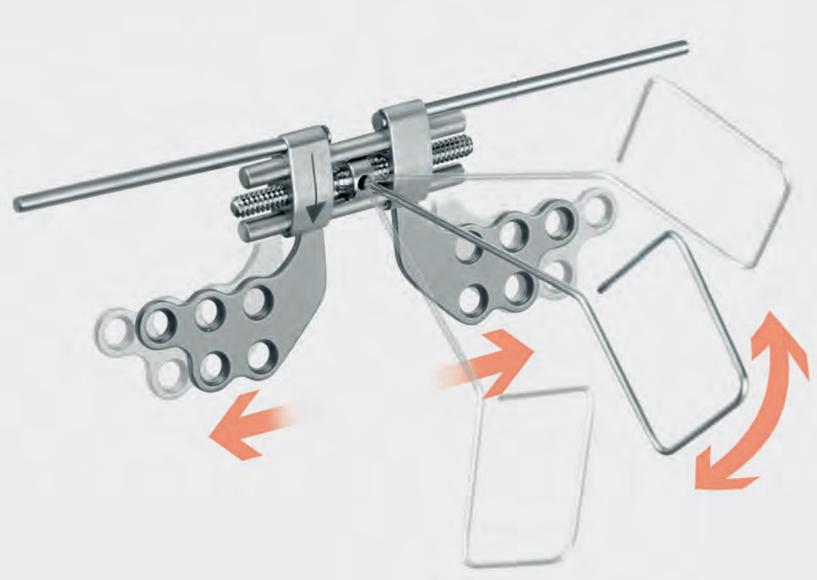
Intraoperative procedure

The surgery is performed under general anaesthesia with preferable naso-endotracheal intubation. Via a standard incision in the labial vestibulum easy access is gained to the bony structures of the dental roots in the symphyseal area. The inferior plates of the distractor are bent and adjusted to the form of the mandible. The superior teeth anchoring arms are bent, inserted and fixed with steel wires in the slots of the dental bands, which have been previously applied by the othodontist. The BMD is fixed with six monocortical screws, placed in the best holes in the plates to avoid the dental roots. The line of the ideal interdental symphyseal osteotomy is marked and the lower part is osteotomized with a saw. A possible interference of the distractor with the upper incisors is checked. The distractor is removed and the osteotomy is completed with a chisel. Now the distractor is refixed in a final manner. To check undisturbed distraction the distractor is slightly activated and then deactivated again. The mucosa is primarily closed. Complete healing of the mucosa without irritation during distraction can be observed.

Oral hygiene

The design of the Bologna Midline Distractor is based on a hyrax appliance and therefore food remnants are not likely to stick in the device. Patients must be instructed to routinely clean the device at least twice per day thoroughly. Visit of an oral hygienist is recommended on a regular base.

Distraction protocol



Latency phase:

Once the Bologna Midline Distractor has been implanted, a latency period of approx. 5-7 days (depending on the patient) must be observed before starting the distraction process.

Distraction phase:

Active distraction is performed with a patient activating wire (ref. No. 51-509-90-07, see page 7). The distractor features an arrow to indicate moving direction.

One complete movement with the activating wire (90°) equals 0.25 mm. The recommended distraction length per day is 0.5 mm (two movements) to 1.0 mm (four movements) based on the general patient considerations.

Consolidation phase:

The consolidation phase lasts approx. 8-12 weeks. In order not to jeopardize the distraction result, the distractor must be left in situ until complete osseous consolidation has been achieved. Orthodontic treatment can already be started during this phase.

Removal of the distractor:

At the end of the consolidation period the distractor can be removed in an outpatient clinic. The mucosa surrounding the distractor is infiltrated with local anaesthesia including a vasoconstrictor. A mucosal flap is raised and the screws including the distractor are removed. The mucosa is primarily closed. The healing of the mucosa is normally restored within one week.

Clinical examples

Case 1

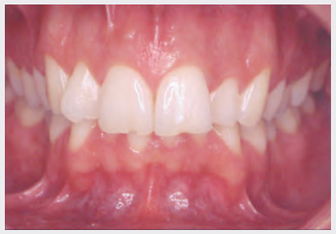


Fig. 1: Pre-OP

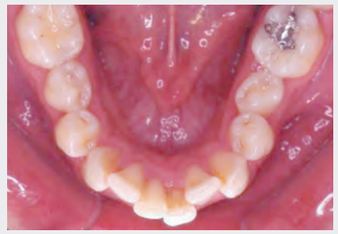


Fig. 2: Pre-OP

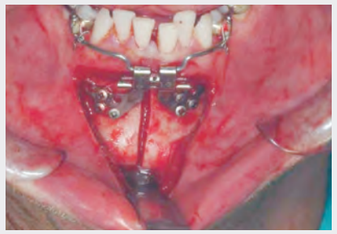


Fig. 3: Complete osteotomy and fixation with monocortical screws

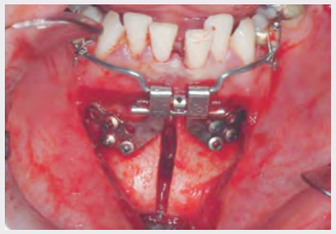


Fig. 4: Intraoperative activation

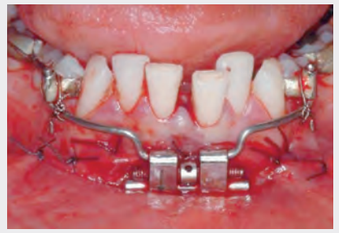


Fig. 5: During active distraction

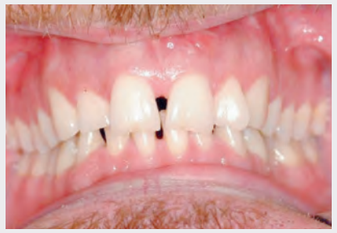


Fig. 6: After orthodontic treatment

Case 2

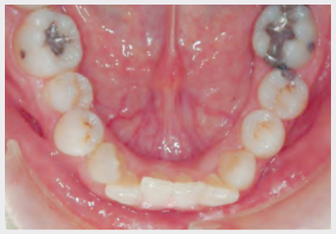


Fig. 1: Pre-OP

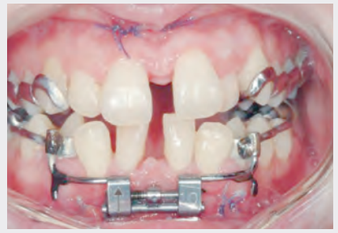


Fig. 2: End of distraction

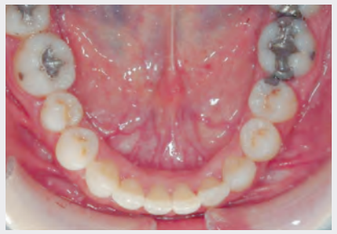


Fig. 3: After orthodontic treatment

Case 3

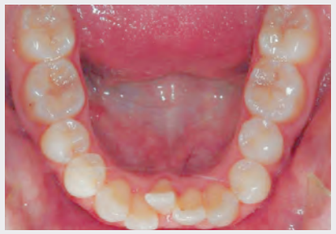


Fig. 1: Pre-OP

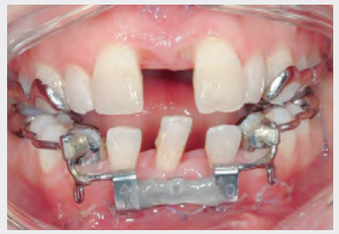


Fig. 2: End of distraction

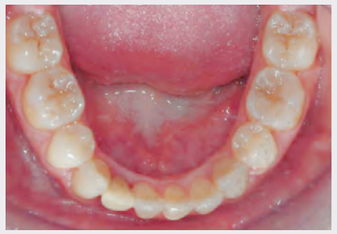
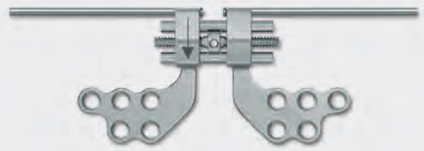


Fig. 3: After orthodontic treatment

Clinical pictures thanks to A. Bianchi, S. Orsola-Malpighi Hospital, I-Bologna

Ordering details



Bologna Midline Distractor

Activating wire

Ordering details

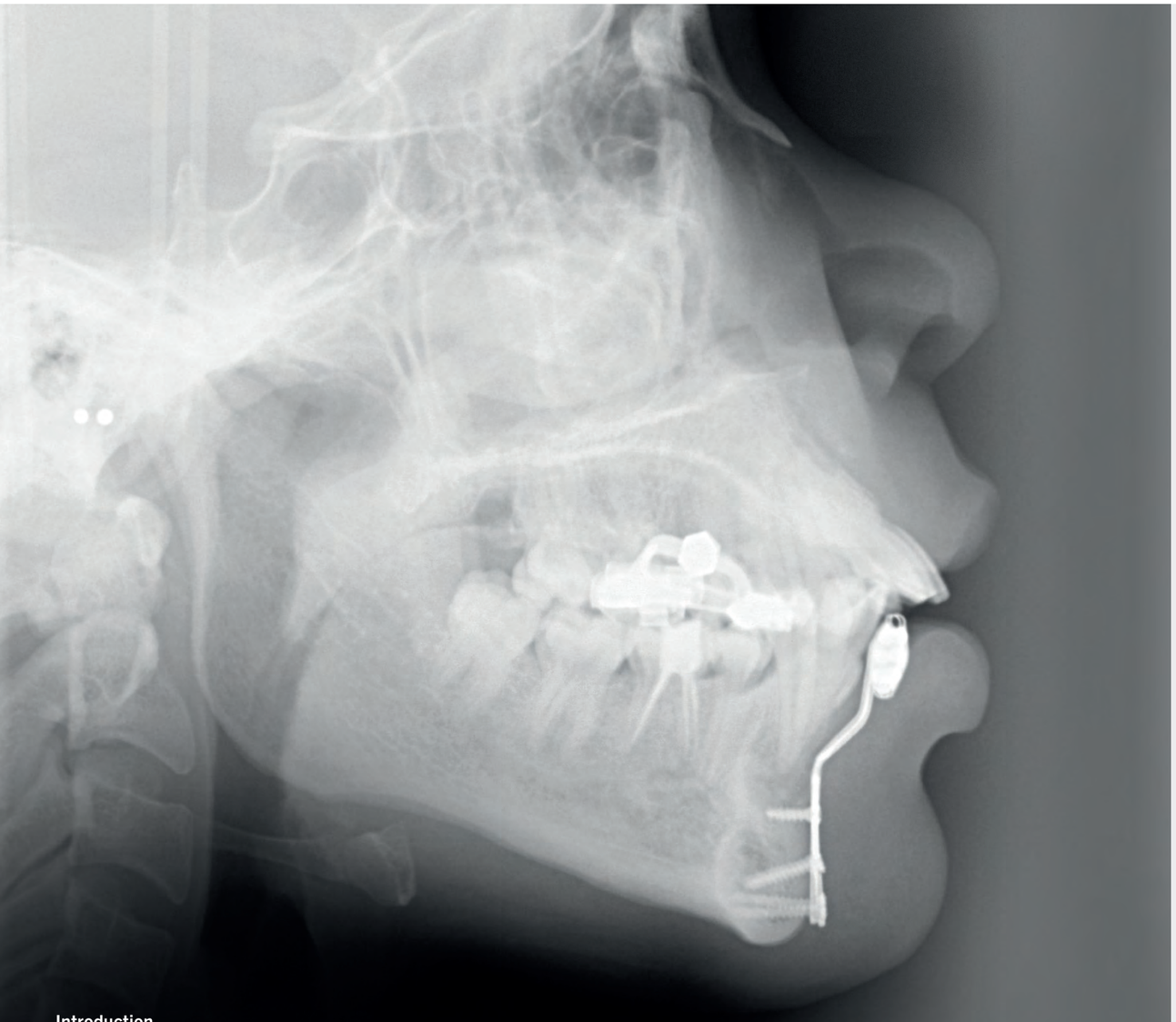
Distractors	
51-508-15-09	Bologna Midline Distractor, 15 mm (incl. activating wire)

Recommended screws (Centre Drive® or maxDrive®)	
25-872-05-09	maxDrive® mini screws 2.0 x 5 mm
25-872-07-09	maxDrive® mini screws 2.0 x 7 mm
25-662-05-09	Centre Drive® mini screws 2.0 x 5 mm
25-662-07-09	Centre Drive® mini screws 2.0 x 7 mm

Recommended instruments	
25-407-04-04	Screwdriver handle
25-486-97-07	maxDrive® screwdriver blade 2.0 mm
25-540-98-07	Centre Drive® screwdriver blade 2.0 mm
25-449-05-91	Twist drill 1.5 x 50 mm, 5 mm stop
25-449-07-91	Twist drill 1.5 x 50 mm, 7 mm stop
25-516-13-07	Modelling plier (2 recommended)
25-441-18-07	Plate holding forceps
25-435-20-07	Lindorf plate holding instrument

Optional instruments	
51-509-90-07	Patient activating wire (spare part)
38-846-20-07	Smith spreader
48-160-12-07	Osteotome

Storage	
55-962-08-04	Insert module, purple, w/o lid and inserts
55-963-17-04	Lid for distraction module
55-962-18-04	Storage module, purple, w/o lid and inserts
55-963-09-04	Lid storage module
55-964-24-04	Insert empty, 2 sections
55-964-17-04	Insert universal



Introduction

Transverse mandibular hypoplasia (TMH) with crowding of the anterior teeth and a V-shape of the mandible is frequently seen in patients with Class I and II malocclusions and Class III patients requiring decompensation before orthognathic surgery. Traditionally, teeth slicing and teeth extractions with compensating orthodontics, functional appliances or orthopaedic devices have been the first choice of treatment, but have resulted in instability, compromised periodontium and compromised facial aesthetics.

The surgical technique of widening the symphyseal area of the mandible is based upon gradual distraction following vertical interdental symphyseal osteotomy and has proven to be successful. However, the distraction devices used so far are rather bulky with great discomfort for the patients, including mucosal irritations, hyperplasia and pain.

A small, slim and relatively strong distractor has been developed, the Rotterdam Midline Distractor (RMD).

The Rotterdam Midline Distractor (RMD)

Developed in cooperation with

Prof. Dr. K.G.H. van der Wal, Dr. E.B. Wolvius
Dept. of Oral & Maxillofacial Surgery and
Special Dental Care, Craniofacial Centre Rotterdam,
Erasmus Medical Centre Rotterdam,
The Netherlands

Rotterdam Midline Distractor

The Rotterdam Midline Distractor (RMD) is a totally bone-borne distractor and is very easily placed and activated. It has the design of a simple hyrax appliance with two four-hole mini plates attached. Its flat design will guarantee a maximum patient comfort. As the distractor is totally bone-borne early orthodontic teeth alignment can take place. The activation unit is made of titanium alloy (Ti-6AL-4V) and the plates are made of titanium grade II. The distractor is robustly designed which is a prerequisite for an ideal parallel widening. The activation mechanism remains completely extramucosal.

The Rotterdam Midline Distractor (RMD) is available in one size, 15 mm. Limited vertical height can be compensated by simply shortening the attached mini plates caudally.

Advantages

- Easily placed and activated
- Parallel widening due to robust device applying a very slim and comfortable distractor
- No mucosal irritation with discomfort and pain
- Allows simultaneous orthodontic treatment with fixed appliances
- Can be removed easily under local anaesthesia

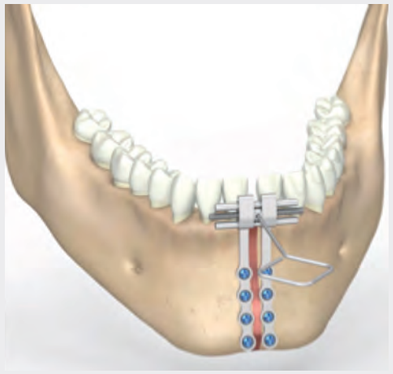
Indications

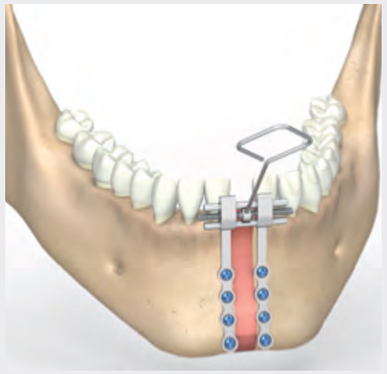
- (Extreme) transverse mandibular hypoplasia in non-syndromal and syndromal patients
- Anterior dental crowding
- V-shape of the mandible

Relative contraindication

- Class II/1 and II/2 deep bite; the deep bite may interfere with the position of the Midline Distractor. This can be overcome by placing the RMD more apically or by wearing an occlusal splint during the distraction and consolidation period.

Intraoperative procedure
Device activation





Intraoperative procedure

The operation is performed under general anaesthesia, preferably with naso-endotracheal intubation. Via standard incision in the labial vestibulum easy access is gained to the bony structures of the symphyseal area. The line of the ideal interdental symphyseal osteotomy is marked and the lower part is already osteotomized. The plates of the distractor are bent and adjusted to the form of the mandible. The RMD is fixed with six screws of which at least four are bicortical. Possible interference of the distractor with the upper incisors is checked. The distractor is removed and the osteotomy is completed.

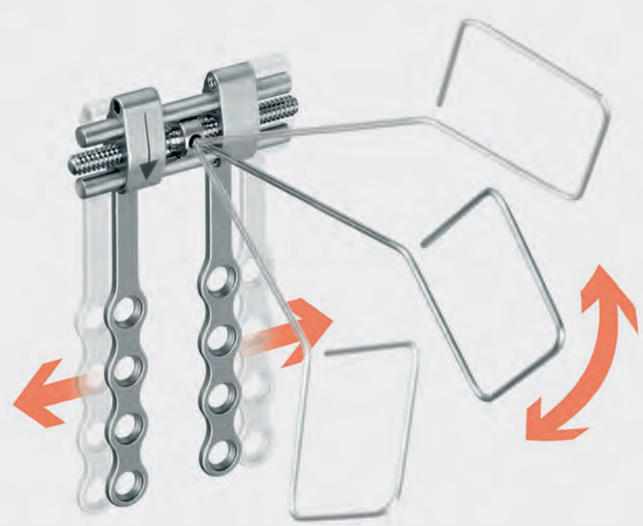
Now the distractor is refixed in final manner.
The correct functionality of the distractor needs to be checked intraoperatively by activating the device 2-3 mm. After checking the device it is returned to start position. The mucosa is primarily closed.

For more details, please see the equivalent animations on page 21.

Oral hygiene

The design of the Rotterdam Midline Distractor (RMD) is based on a hyrax appliance and therefore food remnants are not likely to stick in the device. Patients must be instructed to routinely clean the device at least twice per day thoroughly. Visit of an oral hygienist is recommended on a regular base.

Distraction protocol



Latency phase

Once the Rotterdam Midline Distractor has been implanted, a latency period of approx. 5-7 days (depending on the patient) must be observed before starting the distraction process.

Distraction phase

Active distraction is performed with a patient activating wire (ref. No. 51-509-90-07, see page 7). The distractor features an arrow to indicate moving direction.

One complete movement with the activating wire (90°) equals 0.25 mm. The recommended distraction length per day is 0.5 mm (two movements) to 1.0 mm (four movements) based on the general patient considerations.

Consolidation phase

The consolidation phase lasts approx. 8-12 weeks. In order not to jeopardize the distraction result, the distractor must be left in situ until complete osseous consolidation has been achieved. Orthodontic treatment can already be started during this phase.

Removal of the distractor

At the end of the consolidation period the distractor can be removed in an outpatient clinic. The mucosa surrounding the distractor is infiltrated with local anaesthesia including a vasoconstrictor. A mucosal flap is raised and the screws including the distractor are removed. The mucosa is primarily closed.
The healing of the mucosa is normally restored within one week.

Clinical examples

Case 1

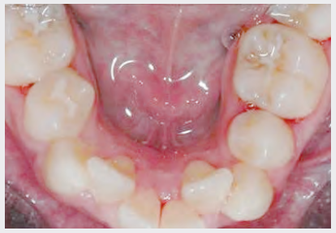


Fig. 1: Pre-OP

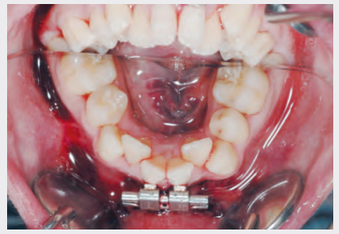


Fig. 2: During distraction period

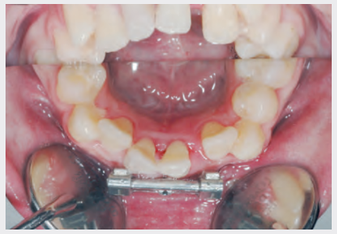


Fig. 3: Post-OP

Case 2

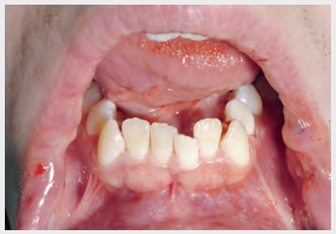


Fig. 1: Pre-OP

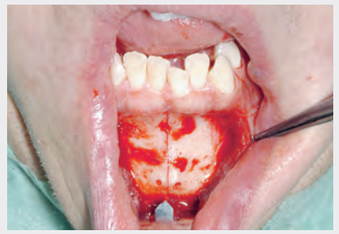


Fig. 2: Vertical osteotomy

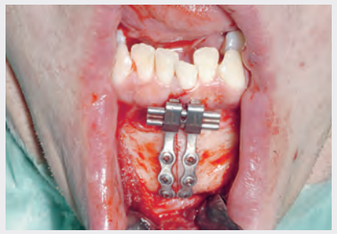


Fig. 3: Refixation of the distractor

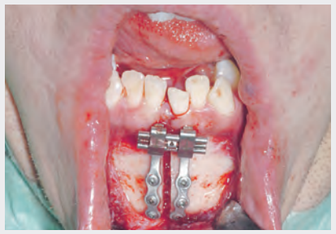


Fig. 4: Test of the distraction procedure intraoperatively

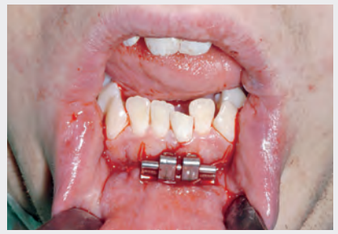


Fig. 5: Start of distraction after latency period

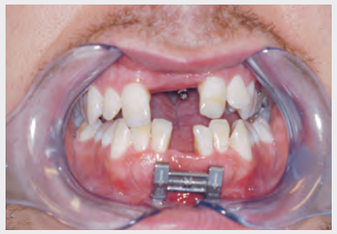


Fig. 6: Post-OP

Clinical pictures thanks to E.B. Wolvius / K.G.H. van der Wal, Erasmus University Medical Centre, NL-Rotterdam

Ordering details and literature

Rotterdam Midline Distractor

Activating wire

Ordering details

Distractors	
51-509-15-09	Rotterdam Midline Distractor, 15 mm (incl. activating wire)

Recommended screws (Centre Drive® or maxDrive®)	
Standard	2.0 x 4 mm to 2.0 x 11 mm
Emergency	2.3 x 5, 7, 9 mm
Drill-Free	2.0 x 5, 7 mm

Recommended instruments	
25-407-04-04	Screwdriver handle, silicone, flat
25-540-98-07	Centre Drive® screwdriver blade 2.0 mm
25-486-97-07	maxDrive® screwdriver blade 2.0 mm
25-449-05-91	Twist drill 1.5 x 50 mm, 5 mm stop
25-449-07-91	Twist drill 1.5 x 50 mm, 7 mm stop
25-449-09-91	Twist drill 1.5 x 50 mm, 9 mm stop
25-449-11-91	Twist drill 1.5 x 50 mm, 11 mm stop
25-516-13-07	Modelling plier (2 recommended)
25-441-18-07	Plate holding forceps
25-435-20-07	Lindorf plate holding instrument
51-509-90-07	Activating wire (optional)

Storage	
55-962-08-04	Distraction module, purple, w/o lid and inserts
55-963-17-04	Lid for distraction module
55-962-18-04	Storage module, purple, w/o lid and inserts
55-963-09-04	Lid for storage module
55-964-17-04	Insert universal
55-964-24-04	Insert empty, 2 sections

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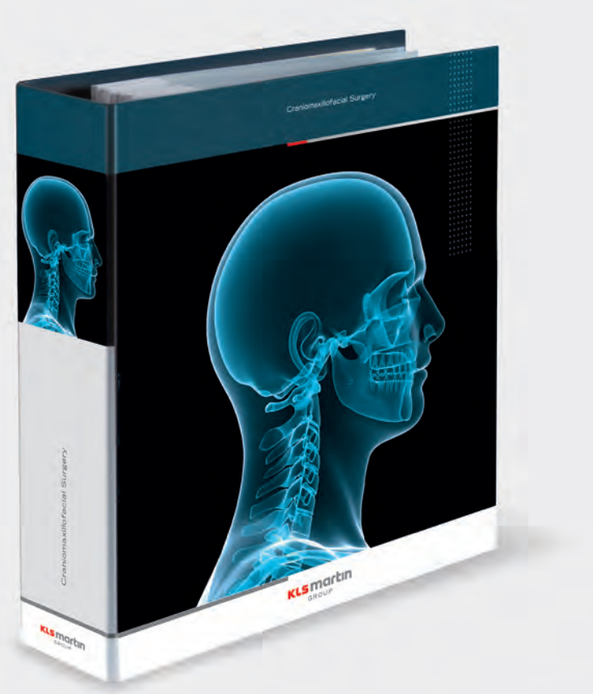

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KLS Martin Group

KLS Martin Australia Pty Ltd.
Sydney · Australia
Tel. +61 2 9439 5316
australia@klsmartin.com

KLS Martin do Brasil Ltda.
São Paulo · Brazil
Tel. +55 11 3554 2299
brazil@klsmartin.com

KLS Martin Medical (Shanghai) International Trading Co., Ltd
Shanghai · China
Tel. +86 21 5820 6251
info@klsmartin.com

KLS Martin India Pvt Ltd.
Chennai · India
Tel. +91 44 66 442 300
india@klsmartin.com

KLS Martin Italia S.r.l.
Milan · Italy
Tel. +39 039 605 67 31
info@klsmartin.com

KLS Martin Japan K.K.
Tokyo · Japan
Tel. +81 3 3814 1431
info@klsmartin.com

KLS Martin SE Asia Sdn. Bhd.
Penang · Malaysia
Tel. +604 261 7060
malaysia@klsmartin.com

KLS Martin de México, S.A. de C.V.
Mexico City · Mexico
Tel. +52 55 7572 0944
mexico@klsmartin.com

KLS Martin Nederland B.V.
Huizen · Netherlands
Tel. +31 35 523 45 38
infonl@klsmartin.com

KLS Martin SE & Co. KG
Moscow · Russia
Tel. +7 499 792 76 19
russia@klsmartin.com

KLS Martin Taiwan Ltd.
Taipei · Taiwan
Tel. +886 2 2325 3169
taiwan@klsmartin.com

KLS Martin SE & Co. KG
Dubai · United Arab Emirates
Tel. +971 4 454 16 55
middleeast@klsmartin.com

KLS Martin UK Ltd.
Reading · United Kingdom
Tel. +44 118 467 1500
info.uk@klsmartin.com

KLS Martin LP
Jacksonville · Florida, USA
Tel. +1 904 641 77 46
usa@klsmartin.com

KLS Martin SE Asia Sdn. Bhd.
Hanoi · Vietnam
Tel. +49 7461 706-0
info@klsmartin.com

KLS Martin SE & Co. KG
A company of the KLS Martin Group
KLS Martin Platz 1 · 78532 Tuttlingen · Germany
PO Box 60 · 78501 Tuttlingen · Germany
Tel. +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com · www.klsmartin.com

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