Maxillary Advancement in Cleft Patients by Means of Transantral Distraction: Development of a New Type of Distraction Device and Pilot Study of Its Clinical Application

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In a single-stage procedure, a maximal advancement of 10 to 12 mm can be achieved in noncleft patients after good mobilization of the separated upper jaw complex. The greater the distance through which the upper jaw is operatively advanced, however, the greater the resulting skeletal relapse.1 The blood vessels supplying the area and the soft tissue attached to them are elastic and together they exert a force pulling the upper jaw back toward its original position and relapse occurs.2–4 It is possible to decrease this tendency to a limited extent by means of plate osteosynthesis and/or interposition of an autologous bone block in the pterygomaxillary fissure.5

In patients with a cleft lip or palate that has previously been operated on, the situation is much less favorable. In this group of patients, the upper jaw is often not only markedly retrodisplaced, but also shows a clear deficit in the vertical dimension. In cleft patients who have already undergone multiple operations, scar tissue adds to the force leading to relapse that is exerted by the soft tissue and blood vessels.3 Scarring also makes intraoperative surgical mobilization considerably more difficult than in noncleft patients and increases the magnitude of relapse.5,6–8 After advancement of the upper jaw through large distances, the extent of relapse is considerable,1,3,9 leading to reoperation in over 10 percent of cases.10 In single-stage maxillary advancement in cleft patients, it is therefore necessary to carry out extensive overcorrection, even at the surgical planning stage. Not only does this make the end result less predictable, it also brings with it the risk of maxillary necrosis because the blood supply of the area in cleft patients can be inhibited as a result of scarring.

Since 1992,11 attempts have been made to solve the problem of the lack of soft tissue and bone availability in the mouth, jaw, and facial area by means of distraction osteogenesis.12 A variety of distraction devices have been used both intraorally and extraorally.11,13–17 The relapse rate seems to be lower with these methods than with the conventional procedure.18,19

However, there are also problems associated with these distraction procedures. They can be summarized as follows. If the distractors are fixed intraorally to the outer surface of the maxilla, which is convex overall, the distance between them and the bone surface is relatively large. This in turn leads to space problems and peri-implant inflammation. Only in very few cases is it possible to attach a pair of distractors parallel and targeted with respect to their angle to the Frankfort horizontal plane.

Extraorally fixed distractors have the disadvantage of relatively poor three-dimensional...
controllability of movement, as well as being uncomfortable for the wearer. For these reasons, our aim was to perform maxillary distraction with prior three-dimensional planning and clinical controllability, but without the disadvantages of extraorally fixed distraction devices or of intraoral devices fixed to the maxillary surface.

**Patients and Methods**

The osteotomy line runs through the cavities of the maxillary sinuses. We decided to make use of the space of these cavities to house the linear spindle drives of our distraction device. The spindle drive is fixed on the vestibular surface of the facial maxillary sinus wall and the drive passes through the mucous membrane into the vestibulum of the upper jaw. The distractors are fixed firmly using variable osteosynthetic plates, which can be adjusted to fit the individual bone situation (Fig. 1). The force is exerted close to the ideal point of mass of the maxilla. This means that the movement can be well controlled without dorsal-caudal sliding of the upper jaw.

*Planning of the Target Position of the Upper Jaw*

Upper jaw advancement is planned step by step using digitalized lateral cephalograms (Table I). After optimizing the position of the lower jaw by means of clockwise rotation, the advancement route for the upper jaw segment is established in both the horizontal and vertical dimensions. The total advancement distance can be determined using the formula $c^2 = a^2 + b^2$. The value $c$ is calculated from the square root of $a^2 + b^2$. The total advancement distance $c$ is equivalent to the required spindle travel of the distractors. The angle of the caudal advancement to the Frankfort horizontal is calculated from the formula $\tan \beta = b/c$. The angle $\beta$ is obtained from $\beta = \tan h \times b/c$ or $\beta = \tan \beta^{-1}$. The angle $\beta$ indicates the angle with the Frankfort horizontal at which the distractors must be fixed to achieve the calculated vertical dimension with the given distraction distance. The operation can additionally be simulated on a three-dimensional model: using a face bow (SAM Corp., Munich, Germany), and with the aid of a flange-connected insertion tool (Fig. 2), the distractors are set to the calculated angle $\beta$. The insertion tool is then used to carry out the procedure in the operating room.

The relation of the osteotomy plane to the Frankfort horizontal is established at the same time as the caudal advancement angle $\beta$. The resulting osteotomy gap is small and can easily be bridged with bone.

**Table I**

<table>
<thead>
<tr>
<th>Event</th>
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</thead>
<tbody>
<tr>
<td>Lower jaw position is optimized according to standard values and aesthetic considerations</td>
</tr>
<tr>
<td>Route of vertical correction of the upper jaw is established on the lateral cephalogram</td>
</tr>
<tr>
<td>Route of horizontal correction of the upper jaw is established on the lateral cephalogram</td>
</tr>
<tr>
<td>Angle with the Frankfort horizontal plane is calculated</td>
</tr>
<tr>
<td>Distractors are positioned at angle on the three-dimensional model with face-bow and insertion tool (optional)</td>
</tr>
<tr>
<td>Fixation plates are bent to fit on the three-dimensional model (optional) (Fig. 1)</td>
</tr>
<tr>
<td>Model operation is performed on articulator to make the guiding splint</td>
</tr>
<tr>
<td>Distractors are transferred to the operating situation in the required relation to the skull using a face-bow with a flange-connected insertion tool (Fig. 2)</td>
</tr>
</tbody>
</table>

![Fig. 1. Three-dimensional model with distractors fixed and activated.](image1)

![Fig. 2. Insertion tool with degree divisions for the caudal advancement angle $\beta$. The insertion tool can be flange-connected to a standard face-bow from the company SAM (Munich, Germany).](image2)
Surgical Procedure

First a high vestibular cut is made from regions 16 to 26. The N. infraorbitalis and the apertura piriformis are revealed. By means of soft-tissue tunneling, the fissura pterygomaxillaris is also revealed.

After a hole approximately 4 mm in diameter has been made on each side in the facial wall of the maxillary sinus, the distraction spindle (4 mm diameter) is inserted into the maxillary sinus lumen. The distractor is fitted to the facial wall of the maxillary sinus. It is set at the required angle $\beta$ using the insertion tool (Fig. 2) and the plates are adapted and screwed into place. The distractor pair is first fixed to the upper jaw, before osteotomy, with the screws and plates. The plates lying cranially are subsequently released again.

Osteotomy of the upper jaw is then performed in the Le Fort I plane and the jaw is mobilized (loosening from pterygoid process, downfracture, and loosening of nasal tubes, intranasal antrostomy as permanent drainage for the sinus). The upper jaw segment is subsequently brought back into the starting position and the cranial fixation plates are refixed using the prebored holes. After closure of the wound in two layers, only the distractor drive extends through the vestibular mucous membrane of the mouth. Transoral, transmucous activation can be carried out without difficulty (Fig. 3).

Treatment Sequence

Distraction is begun on the fourth postoperative day. It continues over a period of approximately 3 weeks, depending on the advancement distance, with a daily advancement of approximately 1 mm (two turns of the spindle). The distraction process is occlusion-guided. The movement of the upper jaw segment is directed in the horizontal plane by means of a guiding splint in which grooves have been made. From the starting position up to the target position, these grooves act as channels for the tips of the molars (Fig. 4). The splint also makes it possible to change a class III relation into a class I relation and to control the position of the upper jaw segment in three dimensions at any time during the distraction process. Clockwise (opening) rotation of the lower jaw may occur during the vertical movement of the upper jaw segment. Asymmetric sagittal movements are carried out by a different number of turns to the spindles. This is also controlled by the guiding splint (Fig. 4).

Removal of the Distraction Device

After a vestibular incision, the distraction devices can be easily removed because the screws of the plates are exposed on the anterior and lateral aspects of the maxilla. At first, the plates are separated from the head of the distraction device by removing the holding screws of the plates. Then each plate can be removed separately. The last procedure is to pull out of the sinus the body of the device, including the head and the spindle.

Patients in the Pilot Study

All patients had a cleft lip and palate and have had already undergone multiple operations. In four of the five patients, several attempts had already been made to advance the maxilla in a single-stage procedure. The average age of the patients at the time of the operation was 24.5 years. Three patients were female and two were male.
RESULTS

Development

To solve the problems of space, control, and positioning experienced with intraoral and extraoral distraction devices, we have developed a transantral upper jaw distraction device making use of the cavity of the maxillary sinus. The device acts in the planned direction of movement close to the center of force of the detached upper jaw segment. It allows good control of the planned movement in three dimensions. The submucosal part of the device on the facial wall of the maxillary sinus takes up only a small amount of space. The larger part of the distraction spindle is positioned in the cavity of the maxillary sinus. Distractor pairs are fixed to the bony buttress of the midface and the facial wall of the maxillary sinus using normal plates and screws (Synthes GmbH, Umkirch, Germany). We have also developed an insertion tool (Fig. 2) that enables the distraction spindles to be fixed at the target angle with respect to the Frankfort horizontal. The base plates of the distractors are adapted for fixation on the vestibular surface of the facial wall of the maxillary sinus. They can accept conventional miniplates as fixation plates. The distraction spindles are guided both by the vestibular base plate and by a bearing at the end of the distractor cover. When the distraction spindles are turned, the guided cranial base plates are pulled in a dorsal direction while the upper jaw segment moves in an anterior direction. The spindle drives past through the mucous membrane above the root tips of the premolars and crosses the soft-tissue cover of the maxillary cavity for a short distance. During the distraction procedure, not only a bony distraction is carried out, but also a soft-tissue expansion of the scarred tissue of the lateral and dorsal aspect of the maxilla.

Along with the development of the distraction device itself, a treatment plan was developed for its use. This is tailored to the individual situation and makes it possible to achieve the planned target position in three dimensions. The progress of the movement can be monitored during the distraction process using the guiding splint (Fig. 4) and can be corrected, if necessary, by appropriate alteration of the number of turns made to the spindles.

Distraction

Five patients have so far been operated on using the above procedure. The average follow-up period was 18 months. The parameters measured were the angle SNA and the distances N-A and S-A (Table II). The average increase in the angle SNA following distraction was 10.38°. After 1 year, this angle increased further, contrary to expectations, by 1.45° on average.

The average relapse rate after 1 year, taking SNA as the measure, was 1.74 percent. The average advancement forward and caudally (distance S-A) was 12.8 mm. This is approximately equivalent to the distraction distance c.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Cephalogram Preoperatively</th>
<th>Cephalogram Postoperatively</th>
<th>Cephalogram 6 mo</th>
<th>Cephalogram 1 yr</th>
<th>Result (%)</th>
</tr>
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<tbody>
<tr>
<td>Patient 1</td>
<td>SNA, degrees 79.1</td>
<td>89.2</td>
<td>90.0</td>
<td>90.5</td>
<td>+1.4</td>
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<tr>
<td></td>
<td>N-A, mm 67</td>
<td>66</td>
<td>67</td>
<td>69</td>
<td>+4.5</td>
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<tr>
<td></td>
<td>S-A, mm 91</td>
<td>98</td>
<td>97</td>
<td>100</td>
<td>+2.04</td>
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<tr>
<td>Patient 2</td>
<td>SNA, degrees 71.0</td>
<td>85.0</td>
<td>84.2</td>
<td>85.0</td>
<td>+0</td>
</tr>
<tr>
<td></td>
<td>N-A, mm 77</td>
<td>83</td>
<td>79</td>
<td>79</td>
<td>-4.8</td>
</tr>
<tr>
<td></td>
<td>S-A, mm 91</td>
<td>107</td>
<td>97</td>
<td>103</td>
<td>-3.7</td>
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<tr>
<td>Patient 3</td>
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<td>86.7</td>
<td>90.0</td>
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<td></td>
<td>N-A, mm 72</td>
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<tr>
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<td>S-A, mm 85</td>
<td>101</td>
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<td>Patient 4</td>
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<td>78.7</td>
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<td>79.9</td>
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<td>S-A, mm 90</td>
<td>99</td>
<td>—</td>
<td>103</td>
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<tr>
<td>Patient 5</td>
<td>SNA, degrees 74.1</td>
<td>87.4</td>
<td>86.1</td>
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<td>S-A, mm 90</td>
<td>106</td>
<td>105</td>
<td>103</td>
<td>-2.83</td>
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</table>
The relapse rate for this measurement was 0.68 percent.

The average caudal movement, the distance N-A, was 3.2 mm (minimum −1 mm, maximum +7 mm). The relapse rate for this distance was 0.32 percent. Both the results yielded by cephalogram analysis (Table II) and the clinical results after distraction were good, not only functionally, but also in terms of the aesthetic improvement achieved (Figs. 5 and 6).

**DISCUSSION**

The correction of dysgnathia in cleft patients is an important part of their rehabilitation. For advancement distances greater than 10 to 12 mm, it has been usual to move the lower jaw back in addition as a prophylactic measure against relapse, although the lower jaw’s position with respect to the base of the skull is usually correct. The effectiveness of this procedure is disputed because it appears that the relapse of the upper jaw cannot be significantly affected.\(^4\,22\) As with the use of pelvic bone material for the dorsal support of the upper jaw in the pterygomaxillary fissure area,\(^5\) whose effectiveness is also disputed,\(^9\) this procedure increases the extent of the operation as a whole. An insufficient advancement distance leads to a compromise, both aesthetically and functionally. In particular, it results in a deficit in the nasolabial area with too little advancement of the spina nasalis anterior and insufficient projection of the tip of the nose. This makes the consistent isolated forward and caudal advancement of the upper jaw segment the treatment of choice for both functional and aesthetic reasons.

From a methodological point of view, distraction is preferable because of the slow expansion of the scarred soft tissue,\(^19\) which seems to lead to lower relapse rates even for relatively large advancement distances.\(^19\,23\) The distraction apparatus used up to now has, however, been typified by discomfort for the wearer, peri-implant inflammation as a result of the arrangement of the equipment, and/or unsatisfactory three-dimensional control during the distraction process. When one-dimensional extraoral distraction devices are used, the planned direction of distraction can be only poorly controlled for methodological reasons. Hierl and Hemprich\(^24\) attempted to solve this problem.

The transantral distraction device was developed to achieve better patient acceptance and more precise planning and results.

For the planning of upper jaw distraction under three-dimensional control, a computed tomography scan of the region is required. Cleft patients often exhibit asymmetry of the maxillary sinus area if the sinus on the cleft side is very small. The same scan can also be used to produce a stereolithographic model for three-dimensional planning. The position

![Fig. 5. (Left) Lateral cephalogram of the initial situation. (Right) Lateral cephalogram after completion of the distraction process.](image-url)
and size of the fixation plates can be established using the model, ensuring that they can be fixed to sections of the facial wall of the maxillary sinus or midface framework where the bone is sufficiently thick. The roots of teeth can interfere with plate fixation, although this can be avoided by using appropriate plates or short screws. The plates attaching to the distractor are interchangeable, which can be helpful when the anatomic situation is unfavorable.

For the treatment of maxillary retrognathy in cleft patients, both the horizontal and vertical dimensions should be corrected simultaneously. This requires clockwise (opening) rotation of the lower jaw. The upper jaw complex must then be moved in both anterior and caudal directions, taking into consideration the new plane of occlusion and the planned front tooth exposure. The resulting vector yields the total advancement route. A simplified two-dimensional planning procedure using a digitized lateral cephalogram was developed in connection with this work, as was equipment making it possible to apply the planned values in the operating situation.

The necessary anterior and caudal movement of the upper jaw in the previously calculated osteotomy plane, after Austermann and Bollmann, means that only a small gap in the bone results. Although there are anatomic limitations to the positioning of cuts through bone, the bony gap requiring bridging is nevertheless kept as small as possible if the calculated values are applied.

According to Ahn et al., the ideal point of application of force for neutral movement of the maxilla is 14.6 mm above the occlusal plane mesial to the upper 6-year molars. In our case, the distraction forces act relatively precisely in this area, which explains the good control of the distraction process. With a point of application of force slightly above this, it is possible to avoid an open bite tendency, which is typical of linear distraction carried out in one dimension.

The scarred soft tissue dorsally and labially appears to be the main factor inhibiting advancement; slow stretching of the soft tissue is sufficient to reduce the forces causing relapse. In adult patients with maxillary retrognathy, the induction of bone by distraction osteogenesis is not the central problem. This is because it is possible to plan a small osteotomy gap if appropriate osteosynthetic systems are used and the osteotomy plane selected is at the required caudal advancement angle $\beta$. After immobilization, this gap can readily be bridged with bone. Distraction osteogenesis may nonetheless occur if the periosteal gap is not exactly...
aligned with the osteotomy line so that intact periosteum lies across the osteotomy gap.

The upper jaw stability necessary for bony consolidation can be achieved, even with relatively low bone availability, by using appropriate osteosynthesis methods with miniplates. This is possible because the forces causing relapse are reduced, and because the use of the guiding splint (Fig. 4) prevents incorrect loading. In no case was a loosening of the distractors observed. It is not yet clear whether the distractors exert an inflammatory influence on the maxillary sinuses in the course of the half-year during which bone consolidation takes place. As with conventional maxillary advancement, distraction also leads to velopharyngeal changes. Depending on the distance advanced, these can cause worsening of existing hypernasality or the return of hypernasality, which was hitherto compensated. In two of our cases, temporary hypernasality was observed, which was again compensated by patients within approximately 3 weeks of completion of active distraction. Neither speech therapy nor operative measures such as velopharyngoplasty were necessary.

Our distraction system (idea and technical development by Daniel and Horst E. Umstadt; production: Synthes GmbH, Umkirch, Germany) is concerned primarily with the soft-tissue conditions and the forces that they exert with advancement. This makes it possible to remove an important cause of predicted relapse in advance. With this distraction method and a movement rate of 1 mm per day after 3 days' postoperative pause, the possible occurrence of a callus bridge between the midface and the upper jaw segment is, however, also taken into account. Distraction osteogenesis in the classic sense is not a primary aim but can occur under optimal conditions. The greatest advantage concerning relapse of the maxilla seems to be soft-tissue expansion during our distraction procedure.

Although distraction is carried out at the level of the maxillary sinuses, it has so far been tolerated by patients without acute inflammation of the area. An acute infection of the maxillary sinus, caused by the distractor, is unlikely because an intranasal antrostomy is performed. The heads of the distraction drive spindles protrude into the vestibulum of the maxilla. The distractors are activated from here by turning the distraction spindles until the position preprogrammed into the guiding splint is reached. As a result of the angles calculated, the maxilla simultaneously reaches the planned vertical dimension. In the process, a clockwise rotation of the lower jaw slowly occurs, allowing the chewing musculature to adapt. The movement of the upper jaw can be controlled in three dimensions throughout the distraction process. Asymmetric movements are also possible right up to the target position by varying the rotation rates right and left.

Using the planning system and the transantral three-dimensional-controllable distraction system that we have developed, maxillary distraction can be carried out on cleft patients. The results are of similar precision to conventional upper jaw osteotomy performed in a single-stage procedure on noncleft patients but with lower relapse rates in comparison to one-stage procedures, which are up to 20 percent. The procedure can thus bring a substantial increase in rehabilitation quality for cleft patients.

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REFERENCES


