Scientific Foundations
Single-Stage Craniofacial Distraction Using Resorbable Devices

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We report on the use of a new type of internal bone distraction devices designed for craniofacial applications. These resorbable devices allow a single operative procedure for device placement, eliminating the need for a second open operative procedure for hardware removal. We report on three models of resorbable devices. The midface orbital frontal device was used for midface and monoblock advancement. The mandibular adolescent device was used in older children and adolescents. In neonates and young children, the mandibular infant device was used. Twenty-one patients (9 female, 12 male) aged 6 days to 15 years (mean = 53 months) underwent bony expansion of the craniofacial skeleton over a 2-year period. A total of 39 devices were implanted: 32 in the mandible, 3 in the maxilla alone, and 4 in the maxilla and frontal bones. Expansion distances ranged from 15 to 30 mm. Expansion took place at 1 to 2 mm/d. Latency periods ranged from 48 to 72 hours. There were no device structural failures and no major complications.

Key Words: Craniofacial distraction, biodegradable devices, poly L-lactic acid

There have been many advances in bone expansion of the craniofacial skeleton since McCarthy et al reported on human mandibular distraction osteogenesis in 1992. Early external devices were cumbersome and were subject to external trauma and pin site infections. In addition, the pins tracking through the skin often resulted in scar disfigurement. Subsequently, several authors reported on buried maxillofacial distraction devices, which minimized external scars and wound care. Although these internal devices were beneficial in terms of patient acceptance and decreased morbidity, they required a second open operative procedure for removal. Fibrous and sometimes bony ingrowth over the internal expansion devices made removal of these devices a formidable task.

Biodegradable hardware has largely replaced metallic and titanium implants in pediatric craniofacial applications. Recently, Cohen et al reported on a new partly biodegradable midface distraction device. This device requires a second operative procedure for partial removal and stabilization. Building on the advances in biodegradable plates and internal distraction technology, we began to investigate the possibility of developing a single-stage class of distraction devices in 1998. These efforts resulted in the development of three types of one-stage resorbable devices based on LactoSorb resorbable implant technology (Walter Lorenz Surgical, Jacksonville, FL). The first device we developed and used clinically was designed to allow distraction of the midface, orbits, and frontal bone (MOF device). The second device was a mandibular adolescent (MA device) suitable for older children and adolescents with adequate bone mass. The third device was specifically designed to allow for mandibular distraction in neonates, infants, and young children (MI device) having a relatively small amount of mandibular bone mass. We report on our experience with this new class of devices in 21 patients over 24 months.

Materials and Methods

Twenty-one patients underwent bony expansion over a 24-month period. Table 1 gives detailed patient data and indications for bone expansion. Seventeen patients underwent mandibular expansion, 1 underwent maxillary expansion, 1 had unilateral

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mandibular expansion and maxillary expansion, and 2 had monoblock advancement of the midface orbits and frontal bone.

Each type of expander consists of three parts, which vary in size and shape according to their intended application (Figs 1–3). There is a proximal plate for anchoring the device proximal to the osteotomy, a distal plate attached to the segment that is to be distracted, and a drive screw that joins the two. The proximal plate contains a threaded housing through which the expansion screw passes to join the distal plate. The expansion screw has several features. The proximal end is attached to a plastic-coated flexible cable that has a hexagonal distal end, where the expansion driver fits. The cables are available in various lengths. The central segment is threaded from the cable attachment to the distal tip, which is of slightly smaller diameter than the threaded shaft. The distal tip fits into a smooth receptacle in the center of the distal attachment plate, allowing it to turn freely as it pushes the distal plate forward during the expansion process.

Patients underwent general endotracheal anesthesia, and a cephalometric radiograph was obtained. The midface was approached through a combination of temporal incisions and intraoral incisions as has been previously described. The two patients who underwent monoblock osteotomies had a combination of coronal and intraoral incisions as has been previously described. The same device was used for midface and monoblock distraction (see Fig 3). The distal U-shaped plate was modified by trimming the upper limb of the plate for midface distraction applications. In the monoblock application, the upper limb was attached to the lateral orbital rim and frontal bone, whereas the lower limb was attached to the lateral and anterior maxilla.

All mandibular osteotomies were performed through small external submandibular incisions (Fig 4). The neurovascular bundle and tooth buds were

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Number of Patients</th>
<th>Type of Expander</th>
<th>Distraction Mean (mm)</th>
<th>Distraction Range (mm)</th>
<th>Wound Complications</th>
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</thead>
<tbody>
<tr>
<td>Pierre Robin syndrome</td>
<td>7</td>
<td>MI</td>
<td>17 mm</td>
<td>15–20</td>
<td>—</td>
</tr>
<tr>
<td>Craniofacial Microsoma</td>
<td>6</td>
<td>MI, MA</td>
<td>17 mm</td>
<td>15–20</td>
<td>2</td>
</tr>
<tr>
<td>Midface hypoplasia</td>
<td>3</td>
<td>MOF</td>
<td>27 mm</td>
<td>25–30</td>
<td>1</td>
</tr>
<tr>
<td>Treacher Collins</td>
<td>2</td>
<td>MA</td>
<td>28 mm</td>
<td>25–30</td>
<td>—</td>
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<tr>
<td>Nagers</td>
<td>1</td>
<td>MA</td>
<td>25 mm</td>
<td>25</td>
<td>—</td>
</tr>
<tr>
<td>Mandibular hypoplasia</td>
<td>2</td>
<td>MI, MA</td>
<td>23 mm</td>
<td>20–25</td>
<td>1</td>
</tr>
</tbody>
</table>

MA = mandibular adolescent device; MI = mandibular infant device; MOF = midface, orbits, and frontal bone device.

Fig 1  Mandibular infant device applied to skull model of neonate. Note narrow proximal and distal attachment plate design. The flexible expander cable (white) has been coupled to the drive screw.

Fig 2  Mandibular infant device applied to skull model of 5-year-old child. Note wider plate design for proximal and distal attachment plates. The drive screw (arrow) has not been attached to the flexible cable.
preserved by making monocortical osteotomies at the mandibular angle using a combination of reciprocating saw and osteotomes.

The design of the MA device incorporates a smaller rectangular distal plate in place of the distal U-shaped plate in the MOF device (see Fig 3). The MI device is considerably smaller than the MA device, with two different proximal and distal plate attachment plates (Figs 1, 2, and 5–7). The attachment plate design can be selected according to the height of the mandible at the proximal and distal osteotomy sites.

The sequence of expander placement was similar in all cases. After the desired osteotomies were performed, the appropriate distraction vector was determined and marked on the proximal and distal bone segments. The proximal and distal plates were then heated in a thermal pack and, when malleable, applied to the proximal and distal segments along the distraction vector. At least four LactoSorb screws were used to fixate the proximal and distal plates to the underlying bone in the MOF and MA devices, whereas the MI device used fewer screws. The proximal and distal plates were then joined by passing the distraction screw through their respective screw housings. Excess plate material at least one screw hole away from any anchored screw was removed with an eye cautery. The segments were then distracted 5 mm to ensure complete osteotomies and brought back to their original position. Wounds were closed with resorbable sutures after irrigation. Patients received a 1-week course of a first-generation cephalosporin and analgesics as needed.

Patients without preoperative airway compromise were observed for 24 to 48 hours and discharged home. Patients in this group began expansion at postoperative day 3 at a rate of 1 mm/d (0.5 mm in the morning and 0.5 mm in the evening) and continued expansion until the preoperative anatomical expansion goals were achieved. Those with preoperative obstructive apnea were maintained in the intensive care unit and intubated for 7 days to allow the edema to subside. The patients with airway compromise were expanded at a rate of 2 mm/d (1 mm in the morning and 1 mm in the evening) starting on day 2 for the first 5 days and were then extubated. Subsequently, expansion proceeded at 1 mm/d until

charges home.
significant relapses after expansion screw removal. All the patients with significant preoperative obstructive apnea demonstrated marked improvement in their clinical symptoms, with no postexpansion desaturations or obstructive episodes. Four patients with airway obstruction had complete preoperative and postoperative 12-channel sleep studies. Preoperative respiratory disturbance index measurements ranged from 18.5 to 8.5 (mean = 14.1). Postoperative respiratory disturbance index measurements ranged from 0.6 to 1.9 (mean = 1.0).

DISCUSSION

The pioneering work of Ilizarov\textsuperscript{9,10} defining the principles of gradual bone and soft tissue distraction led to the application of distraction osteogenesis in the craniofacial skeleton by McCarthy et al\textsuperscript{11} in 1992. The initial clinical reports led to a flurry of publications and seminars as the potential of this new and powerful technique was explored.\textsuperscript{11} Mo-

Fig 6 Photograph of infant in Figures 4 and 5 at 7 days after placement of mandibular infant device. At this point, the mandible has been expanded 3 mm.

complete. Preoperative and postoperative 12-channel sleep studies were obtained whenever feasible in patients with a history of airway obstruction. At completion of the expansion process, a 5-week consolidation period allowed for bony healing before removal of the expansion screw. The expansion screws were simply backed out, without anesthesia, in the office.

RESULTS

There were no major complications in this series of 39 bone distraction devices placed in 21 patients. Clinical expansion goals were achieved in all cases. Two patients experienced pain along a palpable edge of the distal plate requiring minor plate trimming. One patient with a mandibular expander required exploration for reattachment of the cable to the expander screw coupling. Two patients developed local scalp granuloma 4 months after completion of the expansion, with 1 requiring operative debridement. There were no structural device failures or clinically

Fig 7 Photograph of infant in Figures 4 through 6 at 6 weeks after mandibular infant device placement at the time of drive screw removal. A total of 20 mm of bone expansion was achieved.
lina as well as McCarthy and others contributed to the design of several uniplanar and multiplanar external bone expansion devices. Although satisfactory lengthening of the mandible with these techniques was achieved, the scars left by the attachment pins were less than ideal. In addition, the pin sites required meticulous attention to prevent infection, and the bulky nature of these devices often interfered with activities of daily living. Internal mandibular devices that could be placed through an introral or external approach soon followed. The rigid external device for midface distraction introduced by Polley and Figueroa allows for adjustments to the distraction vectors during the distraction period. This device requires a cranial halo application for proximal stabilization and is quite bulky, which may interfere with activities of daily living. Molina presented his midface distraction device in 1994 stimulating the search for a completely buried device. Chin and Toth reported on their initial use of buried internal devices in 1996 and a distraction device for use in LeFort III level osteotomies in 1997. Cohen and his colleagues subsequently developed a buried modular internal distraction system that could be configured for midface as well as mandibular distraction. The low-profile device was well tolerated, allowing for activities of daily living. All the external and internal devices required a second procedure for removal of hardware. The internal devices were often difficult to remove because of fibrous tissue ingrowth and occasional osseous integration of the device with the underlying bony bed.

In 1999, Cohen et al. introduced a partly resorbable device for midface expansion. This device required a second operative procedure for removal of the expander screw assembly and placement of a stabilizer plate during the consolidation phase. In addition, the design requires that a large amount of resorbable material remain implanted after the completion of the expansion process.

We wished to combine the patient acceptance of internal expanders with a single-stage device that required no second operation for removal or stabilization. Furthermore, we wanted to explore the possibility of using one basic design of devices for midface and mandibular expansion. Resorbable plates and screws have been used in a variety of clinical situations with good efficacy. The choice of resorbable material may be of some importance, because the resorption times vary widely. LactoSorb has the fastest resorption times of the current available biodegradable materials and thus is least likely to produce long-term problems such as local infections, granulomas, or skin irritation. It is ideally suited for application to the growing craniofacial skeleton. We have found the LactoSorb system ideal for use in pediatric cases. We chose to use the LactoSorb type of material in the manufacture of the bone expanders because of its relatively rapid resorption characteristics, easy malleability, and ease of application. Resorbable plates and screws are not completely inert; they are resorbed by hydrolyzation, fragmentation, and phagocytosis. We have observed that they can elicit an inflammatory response with granuloma formation and underlying bone resorption. We are constantly refining the current design, striving for maximal stability and strength while minimizing the amount of resorbable material. Although other types of resorbable materials offer a longer period of structural stability during the consolidation phase, we were concerned that a prolonged resorption period could interfere with normal growth in infants and young children.

The MOF device allows for ease of application in almost any osteotomy design and can incorporate orbital and frontal bone expansion (Figs 3, 8, and 9). The single drive screw can provide up to 40 mm of linear expansion. We found this device quite useful in monoblock osteotomies. It proved to be stable, reliable, and unobtrusive, allowing for a near-normal level of activity. The metallic drive screw was easily backed out without any incisions at the end of the consolidation period during an office visit. Two patients developed small areas of drainage over the plates during the resorption process, which required in-office local care in one patient and operative debridement in another. During the initial phase of resorption, the material begins to fragment in variably sized pieces, which can cause scalp or skin irritation and, rarely, secondary infection. To minimize particle migration with the undesirable sequelae, we recommend careful tailoring of the devices in situ. Any material that is more than two plate holes away from a screw should be trimmed during the application process to decrease the amount of potential inflammatory material. This does not significantly weaken the device.

The MA device was used in patients who were at least 10 years old and had adequate vertical dimensions to allow placement of the device (25 mm). This device is identical to the MOF device in the proximal plate assembly and drive screw. The distal plate is rectangular rather than the C-shaped plate used in the MOF device. This design feature allows for interchangeability of parts as required by the patient's bony anatomy. The device performed well, with good mechanical stability. Failure to properly trim the distal plate resulted in an area of skin irr-
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Fig 8 Preoperative photograph of 10-year-old boy with a diagnosis of Pfeiffer syndrome. The patient was noted to have pansynostosis with increased intracranial pressure, maxillary hypoplasia, and obstructive sleep apnea.

Fig 9 Postoperative photograph of patient in Figure 8 at 8 weeks after monoblock advancement of frontal bone and midface at the time of device screw removal. Note the midface and frontal advancement of 27 mm.

mentation through a 2-cm submandibular type incision and was small enough to fit on the neonatal mandible. This incision was particularly useful in this group in placing the osteotomy at the angle of the mandible so as to avoid damage to the tooth buds and alveolar nerve. The greatest challenge in this group was obtaining adequate bony anchorage for the fixation screws in the soft thin cortex of the infant mandible. We maximized the anchorage by using 1.5-mm (diameter) by 8-mm (length) screws without tapping, which allowed bicortical fixation. The 2-mm diameter screws were used as emergency screws if the 1.5-mm screws were stripped during the application process.

The overall design concept for all three types of expanders, proximal and distal attachment plates with a connecting drive screw, allows for maximal interchangeability of the three components. This flexibility allows the surgeon the option of converting an MI device from a 1.5-cm expansion to a 2.5-cm expansion by simply changing the drive screw at the

tation and pain requiring a second procedure to trim the protuberant plate in two patients. Careful attention should be paid to preventing protrusion of the plates outside the confines of the bony recipient bed so as to avoid our predicament. All the MA devices were placed through a submandibular type incision with the expansion cables brought out in the postauricular scalp. Although this approach left a small external scar, we believe that it allowed for the best visualization of the inferior alveolar nerve and prevented intraoral contamination. To date, all these incisions have healed in an acceptable manner. Theoretically, the single drive screw could allow for rotation of the distal bony segments, although this was not a problem in clinical practice. We postulate that the masticatory musculature prevents rotation of the distal segments while allowing relatively torsion-free function of the temporal mandibular joint.

The MI device was unique in that it could be easily applied in infants less than 1 week of age (see Figs 1, 2, and 4–7). The narrow profile allowed place-
time of application. In addition, the proximal and distal attachment plates can be easily modified by thermal contouring or trimming to almost any anatomical contour.

Our initial results are encouraging. We found that the strength, ease of application, and reliability of this new class of one-stage bone expander were equivalent to those of the various nonresorbable devices that we have used, while offering several distinct advantages. The cost and morbidity of second-stage removal are avoided. The MOF and MA devices have interchangeable parts, avoiding costly and complicated stocking of multiple devices. The resorbable components can be modified during the operation by simple in situ thermal molding to each patient’s anatomy, avoiding the need for multiple different sizes of devices. Interchangeable drive screws allow for intraoperative changes in total length of expansion without removing the anchoring plates. The same basic application process can be followed for all three devices. The relatively rapid resorption of the implanted components should not interfere with facial growth or provide a nidus for chronic infection. This class of one-stage resorbable devices is a step forward in the evolution of distraction osteogenesis.

REFERENCES