Reprinted from THE JOURNAL OF CRANIOFACIAL SURGERY
Vol. 13, No. 6 November 2002
Lippincott Williams & Wilkins Printed in U.S.A.

Scientific Foundations

Single-Stage Craniofacial Distraction Using Resorbable Devices

Fernando D. Burstein, MD* Joseph K. Williams, MD* Roger Hudgins, MD† Leroy Graham, MD‡ Gerald Teague, MD‡ Michelle Paschal, PA-C* Catherine Simms, RN*

Atlanta, Georgia

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[1] 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.[2–4,5] 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.[6,7] Recently, Cohen et al [8] 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

From *The Center for Craniofacial Disorders, †Division of Pediatric Neurosurgery, and ‡Division of Pediatric Pulmonology, Children's Healthcare of Atlanta, Atlanta, Georgia.

Address correspondence to Dr Burstein, Atlanta Plastic Surgery, 975 Johnson Ferry Road NE, Suite 500, Atlanta GA 30342; e-mail: FBursteing@aol.com.

Table 1. Patient Data and Indications for Bone Expansion

Diagnosis	*Number of Patients*	*Type of Expander*	*Distraction Mean (mm)*	*Distraction Range (mm)*	*Wound Complications*
Pierre Robin syndrome	7	MI	17 mm	15–20	—
Craniofacial Microsomia	6	MI, MA	17 mm	15–20	2
Midface hypoplasia	3	MOF	27 mm	25–30	1
Treacher Collins	2	MA	28 mm	25–30	—
Nagers	1	MA	25 mm	25	—
Mandibular hypoplasia	2	MI, MA	23 mm	20–25	1

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

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.[3] The two patients who underwent monoblock osteotomies had a combination of coronal and intraoral incisions as has been previously described.[4] 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

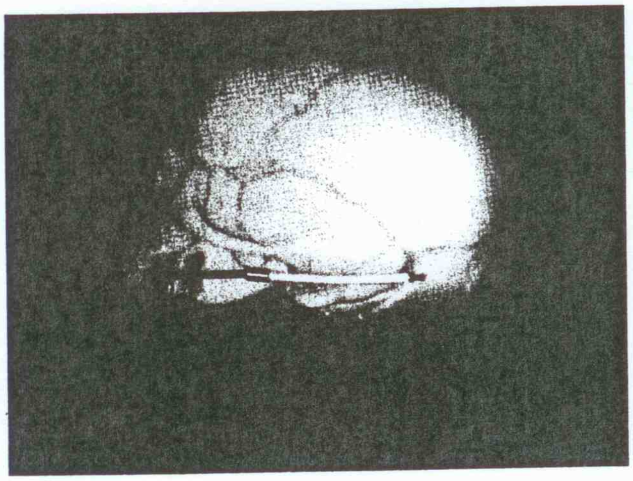

Fig 1 Mandibular infant device applied to skull model of neonate. Note narrow proximal and distal attachment plate design. The flexible expander cable (white) has been coupled to the drive screw.

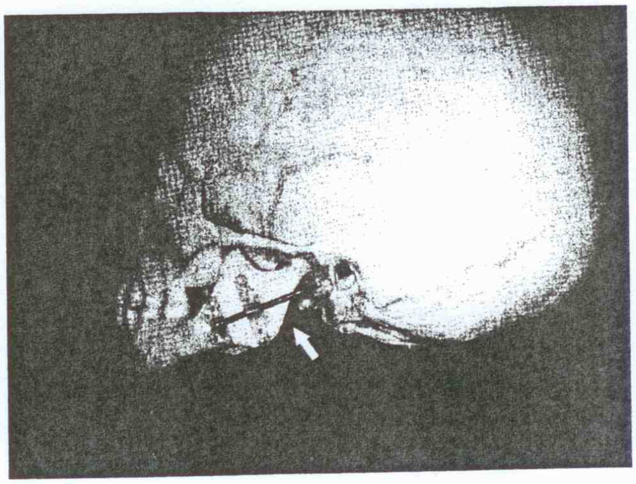

Fig 2 Mandibular infant device applied to skull model of 5-year-old child. Note wider plate design for proximal and distal attachment plates. The drive screw (arrow) has not been attached to the flexible cable.

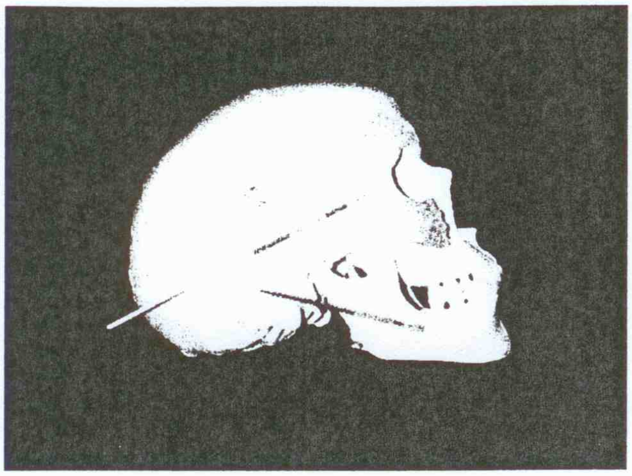

Fig 3 Adult skull model with midface orbital frontal device applied to maxilla and frontal bones. Mandibular adolescent device is applied to the mandible.

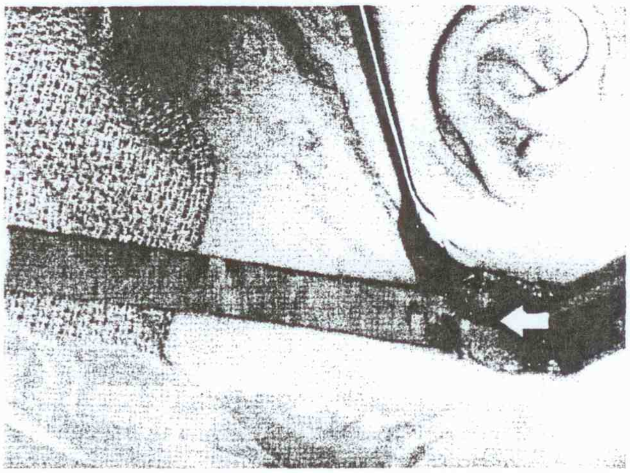

Fig 4 Photograph of 7-day-old infant with Pierre Robin sequence and severe obstructive sleep apnea at the time of mandibular infant device placement. The arrow demonstrates the neurovascular bundle, which has been preserved with monocortical osteotomy technique.

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

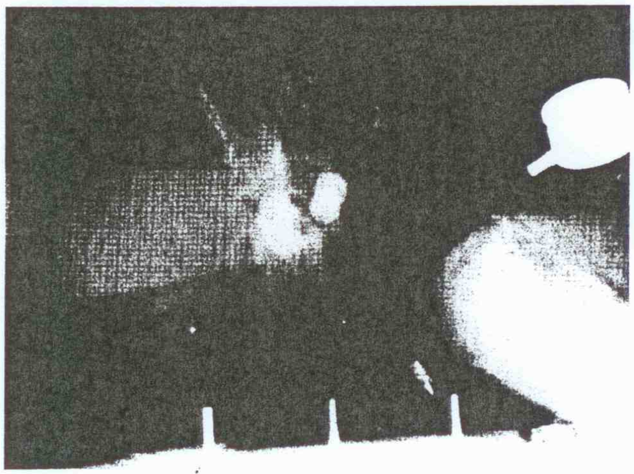

Fig 5 Intraoperative cephalometric radiograph of patient in Figure 4. Note the hypoplastic mandible.

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 5 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 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 [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[1] 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.[11] Mo-

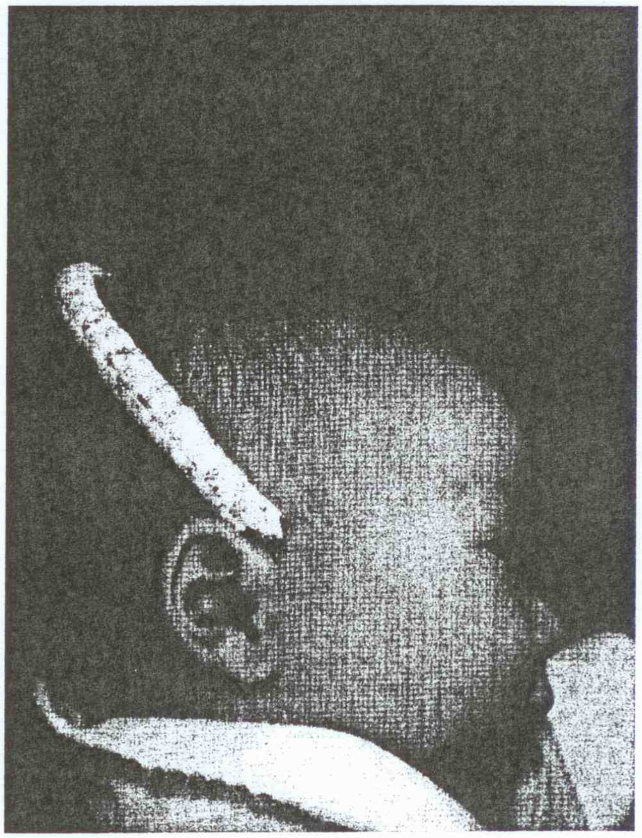

Fig 7 Photograph of infant in Figures 4 through 6 at 6 weeks after mandibular infant device placement at the time of drive screw removal. A total of 20 mm of bone expansion was achieved.