The author has used various designs of single-stage resorbable distractors to lengthen the mandible in 100 patients aged 7 days to 16 years (mean, 4.24 y; 49 girls, 51 boys) with predictable results and minimal morbidity since 2002. The range of distraction was 15 to 30 mm (mean, 25.4 mm). Indications for surgery included mandibular hypoplasia associated with Pierre Robin sequence, craniofacial microsomia, Treacher Collins, and Nagers syndrome. The history of the development of resorbable polymers for use in craniofacial surgery and the evolution of distraction osteogenesis are reviewed. The melding of these 2 innovative technologies has led to the development of a new class of single-stage resorbable devices. These devices are quite different from the titanium distraction devices that have been used in clinical practice for more than 15 years. Through continued clinical application, the surgical methodology for resorbable distraction has been refined and simplified, although still-evolving continued experience with resorbable distraction has greatly decreased operative time and improved results.

Key Words: Mandible distraction, resorbable, mandibular hypoplasia

The parallel development of resorbable surgical materials and the application of distraction osteogenesis to the craniofacial skeleton have led to the melding of these technologies in the development of single-stage resorbable distractors. Interest in bioabsorbable polymer materials has existed for more than 30 years, but widespread clinical application is relatively recent. Initially, it was recognized that polymers can be fashioned into medical devices that would eventually be resorbed by the body; however, the exact mechanism was unclear. Initially, pure homopolymers were used in orthopedic applications as pure polydioxanone, pure polyglycolic acid (PGA), and pure poly[l]-lactic acid. In a few early reports, copolymers such as PGA-poly l-lactide were used. Most complications in these early studies were reported with homopolymers. These complications included fibrous encapsulation, sterile sinus formation, and an intense inflammatory response. Fewer problems were noted with the use of the copolymer materials. These early resorbable polymers enjoyed some popularity, but because of the extreme length of time until resorption, the amount of inflammation caused by these polymers, and questions regarding their mechanical stability, they were never widely used. In the late 1980s and early 1990s, interest was again stirred in resorbable materials with the realization that mixing 2 different types of polymers would result in markedly different resorption characteristics depending on the proportions of each polymer.

These polymer macromolecules, when properly formulated, can serve a structural function and are then gradually degraded and resorbed by the body. A plethora of resorbable polymers were subsequently formulated for use in medical devices. The most extensively studied is the Lacto Sorb (Biomet Corporation, Indianapolis, IN), which is a random linear copolymer consisting of 82% poly l-lactide and 18% PGA. This compound resorbs during 12 months and loses strength during 3 to 4 months. It has intermediate resorption characteristics, which allow gradual resorption through hydrolysis and phagocytosis.

Until the introduction of these new copolymers, titanium plates and screws of various sizes had been used even in infants and children. This led to concern by many practitioners about plates and screws being carried through the bone and into contact with the dura and brain through the process of absorption and bony deposition. In 1992, the Lacto Sorb system of plates and screws was introduced for clinical
use, followed later by systems from several manufacturers, each having unique handling and resorption characteristics. In comparison to their titanium, these plates were significantly thicker because of strength considerations. Initially, plates were fashioned in the same shapes and sizes as titanium plates. As the unique properties of the resorbable materials were discovered, designs that took advantage of these characteristics were customized for specific clinical applications.

Paralleling the application of resorbable plate/screw fixation was the emergence of distraction in craniofacial surgery. The pioneering work establishing the principles of distraction osteogenesis was done by Dr. Ilizarov in Russia and was published in 1954. In 1973, Snyder et al reported on their work using gradual distraction for mandibular lengthening. Karp et al published their article on distraction osteogenesis in the craniofacial skeleton in 1990. McCarthy et al further defined both the scientific basis and clinical principles that set the stage for distraction of the craniofacial skeleton. This important work stimulated many others to apply this exciting technique. Initially, mandibular distraction devices were all external, modeled after orthopedic devices used for hand and wrist trauma. Although these devices offered excellent mechanical strength, there were also problems, including unsightly pin site scars, complications from pin site infections, dislodgement of devices, and other difficulties, which led surgeons to design internal mandibular devices. These metallic devices were inserted through either an oral or external approach and gave excellent mechanical strength to the distraction. The major drawback to these internal devices was that they had to be removed at the end of the distraction. Often, bone would tend to overgrow the device, making removal quite difficult.

In 2000, Cohen et al published his initial work using a maxillary distraction device made of a resorbable polymer. This device required a second stage for stabilization. The author, building on Dr. Cohen's experience, as well as on his own work with distraction, began working on a single-stage resorbable device in 2000. This work was done in conjunction with engineers at Biomet Corp. Combining the development of resorbable materials with internal distraction was a new frontier. Our efforts led to the design and development of several resorbable devices for use in craniofacial distraction osteogenesis. This new class of devices allowed for 1-stage distraction osteogenesis of the craniofacial skeleton. We reported our initial experience with a 1-stage resorbable distractor in 2002. This was followed by our report focusing on mandibular distraction in neonates and infants with Pierre Robin sequence in 2005. Since then, our experience has grown with application of various designs of mandibular distractors in 100 patients over 6 years. This experience has lead to the recognition that successful application of resorbable distraction requires technical modifications from the techniques used in the application of metallic distraction.

**Materials and Methods**

From 2000 to 2007, 100 patients have undergone single-stage resorbable distraction of the mandible. There were 49 girls and 51 boys ranging from 7 days to 16 years old (mean, 4.24 y). Thirty-two patients had unilateral distraction, and 68 had bilateral distraction. Indications for mandibular distraction include mandibular hypoplasia associated with Pierre Robin sequence (43 patients), craniofacial microsomia (37 patients), Treacher Collins (8 patients), and Naggers syndrome (4 patients), as well as various other indications (8 patients). Distraction distances range from 15 to 30 mm (mean, 25.4 mm).

To date, 10 patients have undergone more than 1 course of distraction to keep up with their growth. The current technique for mandibular distraction using a resorbable device is as follows (Figs 1-9). The distractor placement is accomplished through an external approach (Fig 9). A small incision is made approximately 2 cm below the mandible, and the platysma is divided. This is followed by subperiosteal dissection of the mandible. The proper vector is determined preoperatively, and the distractor cable is passed in the direction of the vector deep to the soft tissues. Most frequently, the distractor flex cable is brought out just

![Fig 1. A, Infant with Pierre Robin sequence and severe obstructive apnea. B, Same patient 2 years after 20-mm bilateral mandibular distraction.](image-url)
under the sideburn or under the ear (Figs 2 and 3). The proximal and distal portions of the distractor are then reassembled on the distractor drive screw. The distractor is applied to the mandible with a 3- to 5-mm gap between the proximal and distal portions to allow for the osteotomy. The author recommends using a self-tapping low-speed drill to avoid burning and thereby weakening the bone. Monocortical or bicortical screws can be used depending on the thickness of the bone. Once the device has been secured to the mandible, the drive screw is backed out into the proximal housing, and the osteotomy is performed. The most frequently used osteotomy technique is a monocortical osteotomy approximately at the angle of the mandible, which has been previously described.\textsuperscript{14,16} This involves using a small reciprocating saw blade, with great care being taken to only penetrate the cortical bone. A bone spreader is then used to open the osteotomy, preserving the inferior alveolar nerve. Alternatively, an inverted-L osteotomy or stepped osteotomy has been used depending on the size and shape of the mandible. In applying resorbable distraction to the mandible, several technical points have been found to be extremely helpful. These “pearls” are unique to resorbable technology and represent important technical differences from the standard techniques used to apply titanium devices (Table 1). These include the use of a combined drill and tap device that has quite a bit of torque but is low speed to prevent burning the bone. In addition, infant bone can be extremely thin and can be easily overdrilled using a high-speed bur. Application of the device before making the osteotomy allows for a more accurate prediction of the final vector and easier activation of the distractor. If available, a three-dimensional acrylic life-sized model of the skull that can be sterilized is extremely helpful (Fig 8). These models are manufactured from thin-cut computed tomographic scan data by Medical Modeling (Denver, CO). The location of the inferior alveolar nerve and tooth follicles is also shown on the model. The design of the osteotomy can be modified based on the shape of the mandible, location of the inferior alveolar nerve, or tooth follicles. The exact vectors can be planned on the model, and the distractor can be contoured to fit the mandible precisely before being applied to the patient. The model of distractor can be chosen based on the three-dimensional anatomy of the mandible. This technique eliminates the frustration of trying to thermally contour the device in situ. Each device should be activated 5 mm after application to confirm that the osteotomies are complete and that the segments are mobile. Once this has been done, the drive screws are backed out until bone-to-bone contact is achieved. Partial or incomplete osteotomies may result in device failure, asymmetric distraction, or both.

A 48-hour latency period is allowed before starting distraction at a rate of 2 mm/d until the desired amount of distraction is achieved. Patients are given 5 days of antibiotics, usually a first-generation cephalosporin, and allowed a soft diet. After completing the distraction, the drive screws are left in place for an additional 4 to 6 weeks to allow the

Table 1. Key Technical Points (pearls) for Resorbable Distraction

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<td>Low-speed drill</td>
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<td>Three-dimensional model</td>
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Fig 4 Patient with craniofacial microsomia. A, Before unilateral mandibular distraction (25 mm). B, One year after distraction. Note restoration of facial symmetry.

regenerate to consolidate. The drive screw is backed out in the office without sedation.

RESULTS

One hundred patients underwent distraction of the mandible. Sixty-eight patients had bilateral distraction, and 32 had unilateral distractions. The range of mandibular distraction was 20 to 25 mm (mean, 25.4 mm; Figs 1–7). There were 6 complications (6%). Two patients required debridement for exposed distractors, and 2 patients required removal for infection. The patients requiring removal for infection had completed the consolidation phase and retained the new mandibular length. These cases were early in the author’s series, and the material that protruded beyond the last screw was not trimmed sufficiently at the time of surgery. This resulted in pressure against the skin by this protuberant edge. In 1 early case, the mandibular distractor failed when the distal plate became detached from the mandible and had to be reapplied to complete the distraction process. In 1 infant case, the proximal mandibular segment separated into 2 fragments during distraction, and reoperation was necessary. The distractor was wired to the proximal segment, and distraction was successfully completed.

DISCUSSION

Resorbable I-stage mandibular distractors combine advances in resorbable materials and distraction to allow for predictable distraction with a single operation. Extensive studies of the safety and efficacy of resorbable fixation in children and infants...
can be used to lengthen the mandible or advance the maxilla, orbits, and even cranium without having to use bone grafts. This greatly shortens the time required for surgery and allows gradual stretching of the nerves, cartilage, and blood vessels, resulting in decrease in surgical morbidity. In addition, there is less relapse because distraction, done in a gradual manner, allows the soft tissues to adapt and prevents structural inadequacies seen with conventional methods.

Engineering resorbable distraction devices involves a whole new technology. Instead of conventional techniques such as milling, forging, and welding used in metallic distraction devices, resorbable distractors rely upon polymer science. Polymers of polylactic acid are formed in special molds or are machined/milled from plate blanks of resorbable material that are compression molded depending on the manufacturer. Sterilization is achieved by either γ irradiation or by ethylene oxide. This process is time-consuming and currently quite costly due to the early nature of the technology. Ounce for ounce, the polymers that we are currently using is not as strong as an equivalent volume of titanium. Therefore, resorbable devices tend to be somewhat thicker and bulkier. Rather than bending, as is done with titanium plates, the resorbable materials are thermally sensitive and can be molded into three-dimensional shapes after they are heated in a sterile water bath. It is important when thermally bending this class of device that any threaded portions have the drive screw or drive screw blank in place to avoid thermally distorting the threaded surfaces. After heating and bending, the drive screw should be activated to make sure that proper turning occurs. To have a truly 1-stage device, the drive screw must be removable at the end of the distraction but held in place long enough to allow the regenerate bone to provide...
It is important to choose a drive screw and cable length that will allow the desired distraction but not protrude excessively. The flexible extension can be protected from excessive bending using a cap, rubber tubing, or headband (Figs 2 and 3).

Many challenges remain in applying resorbable distraction of the mandible. These include making the devices thinner, smaller, and easier to use. Currently, resorbable distraction devices are only approved for patients younger than 2 years of age. We are still exploring the limitations and applications of resorbable distractors. Particularly gratifying results have been obtained in mandibular distraction for Pierre Robin sequence that saved the infants from requiring a tracheotomy. The results for mandibular distraction using 1-stage resorbable devices are comparable to those of Denny et al and others using metallic devices. Most of the complications were due to technical errors, including incomplete osteotomies, cortical fractures in the bone, and application of the distractor too close to the skin surface. Infections all occurred during the breakdown of the distractors when granules of the material extruded from the wound, causing an inflammatory reaction. Interestingly, as the surgeon’s experience has grown with this new technology, the number of complications has dramatically decreased. We are currently investigating combining distraction and morphogenic protein in patients who have very poor bone stock, require redistraction, have poor healing, or need distraction of greater than 25 mm.

Preliminary results in a half-dozen patients reveal that this combination of bone morphogenic protein with distraction may result in earlier bone healing and perhaps allow us to decrease the time for bone consolidation. In the last 30 patients, a torque-measuring device has been used to monitor the course of distraction. The torque measurement device is useful in assuring that excessive forces are not being applied during the distraction process as well as measuring the forces being applied from side to side (see related article in this issue). We are using a torque-limiting distractor driver that disengages the turning handle if torque more than 30 in. oz is applied, avoiding damage to the distractor. In addition, this driver is clearly marked for ease of use and comes with a combined instruction sheet and log table to record the progress of distraction. We have found that measuring and recording distraction torque can be helpful in determining the status of the distractors. For example, an extremely low reading on 1 side in a bilateral distraction case may indicate that the distractor has become detached from the bone.
CONCLUSIONS

This has been a very exciting time in the development of resorbable distraction. With growing experience, we have been able to develop more refined techniques specifically suited to this class of devices. Just as titanium plate and screw fixation in infants and children have largely been replaced by resorbable plates and screws, we feel that gradually, single-stage resorbable distractors will surpass their titanium predecessors. Although many challenges remain, we hope ongoing clinical and basic research will allow us to extend these applications to help children with complex craniofacial disorders.

REFERENCES