Resorbable PLLA-PGA Plate and Screw Fixation in Pediatric Craniofacial Surgery: Clinical Experience in 1883 Patients

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The need to provide rigid bony fixation in the surgical treatment of craniofacial deformities has inspired an ongoing evolution of surgical innovations and implants. Because of the young age of many treated craniosynostosis patients and the unique pattern of cranial vault growth, the extensive implantation of metal devices is potentially problematic. The use of resorbable plate and screw devices offers all of the benefits of rigid fixation without many of their potential risks. Since the introduction of resorbable plate and screw devices in 1996, tens of thousands of craniofacial patients have received implants, but long-term results from a large series have yet to be reported. A combined prospective and retrospective analysis was done on 1883 craniosynostosis patients under 2 years of age treated by 12 surgeons from seven different geographic locations over a 5-year period who used the same type of resorbable bone fixation devices (poly-L-lactic-polyglycolic copolymer). Specifically, the incidence of postoperative infection, fixation device failure, occurrence of delayed foreign-body reactions, and the need for reoperation resulting from device-related problems were determined. Technical difficulties and trends in device use were also noted.

From this series, significant infectious complications occurred in 0.2 percent, device instability primarily resulting from postoperative trauma occurred in 0.3 percent, and self-limiting local foreign-body reactions occurred in 0.7 percent of the treated patients. The overall reoperation rate attributable to identifiable device-related problems was 0.3 percent. Improved bony stability was gained by using the longest plate geometries/configurations possible and bone grafting any significant gaps across plated areas that were structurally important. The specific types of plates and screws used evolved over the study period from simple plates, meshes, and threaded screws to application-specific plates and threadless push screws whose use varied among the involved surgeons.

This report documents the safety and long-term value of the use of resorbable (LactoSorb) plate and screw fixation in pediatric craniofacial surgery in the infant and young child. Device-related complications requiring reoperation occurred in less than 0.5 percent of the implanted patients, which is less frequent than is reported for metallic bone fixation. Resorbable bone fixation for the rapidly growing cranial vault has fewer potential complications than the traditional use of metal plates, screws, and wires. (Plast. Reconstr. Surg. 114: 850, 2004.)

The development and widespread application of internal metallic bone fixation over the past 20 years has been one of the most significant advances in craniomaxillofacial surgery since the basic concepts of secure bone fixation and primary bone healing were introduced several decades previously. With the extensive use of fixation technology in pediatric craniofacial surgery in particular, it is now apparent that there are several potential postoperative complications that may occur. Given the young age at which the pediatric craniofacial procedures are performed, it is likely that some patients will require device removal in their lifetime as a result of skin irritation, infection, or exposure of the underlying plates and screws. More significantly, the development and bone apposition/resorptive pattern of skull growth create the potential for growth restriction and eventual metal device translocation to the endocranial surface. The points of screw tips against the dura or apposed to the cerebral cortex impose a risk of creating...
a parenchymal injury and seizure focus, although no actual case occurrence has been reported.

These potential risks with metal fixation in infants and children make the use of resorbable polymer fixation devices a logical choice. The ability to achieve good intraoperative bone stability while allowing postoperative device resorption would eliminate all potential future device-related complications. The primary author has previously reported on an initial series of patients who received resorbable poly-L-lactic-polyglycolic (PLLA-PGA) plates combined with metal screws (because of the unavailability of small-sized resorbable screws at that time) for pediatric cranial fixation in 100 consecutive patients in 1997. Since that report, a complete resorbable fixation system has been used, including plates and screws, and a much larger patient series has undergone implantation and been followed by numerous surgeons. This follow-up reports on the long-term follow-up of these resorbable PLLA-PGA fixation devices in pediatric cranial vault applications.

PATIENTS AND METHODS

Resorbable Fixation Devices

All patients reviewed in this clinical series were treated with plates and screws composed of a unique combination of co-polymers, PLLA-PGA (82 percent-18 percent; LactoSorb, Walter, Lorenz Surgical, Jacksonville, Fla.), which has the properties of retained fixation strength that persists up to 6 weeks after implantation, with complete resorption of the devices between 9 and 15 months after surgery. The fixation devices had plate profiles of 1.5 mm and screw diameters of 1.5 mm. The screws were placed by initially drilling a 1.1-mm pilot hole; the bone threads were then cut with a hand-held tap. Later in this patient series, some authors replaced the threaded screws with a threadless push screw that required only a 1.25-mm pilot hole before insertion.

Patient Evaluation

This clinical series was confined to patients with cranial vault deformities from either sutural synostosis (frontal) or deformational (occipital) causes. All of the patients were all under 2 years old so as to represent a primary surgical repair and to keep the patient population as uniform as possible. The patient experiences came from solicited surgeons known to have used this specific PGA-PLLA copolymer bone fixation devices in significant numbers from 1997 to 2002. They were retrospectively asked to complete a demographic questionnaire detailing their patient population and clinical experience. The questionnaire specifically focused on intraoperative application issues and the occurrence of postoperative complications (infection, bone instability, foreign-body reactions, and reoperation). A smaller subset of reviewed patients came from a separate prospective study (1995 to 1997) in which the same information was gathered as part of a Food and Drug Administration clinical study protocol.

RESULTS

Patient Population

A total of 12 surgeons from seven different metropolitan areas in the United States provided information on 1883 pediatric cranial vault reconstruction cases in which the specific resorbable fixation devices were implanted. A portion of the reported patients represented a part of a clinical trial that was done prospectively as part of another study (227 patients, 12 percent). The remaining patients of the reported operations (1656 patients, 88 percent) were retrospectively obtained. Of the 1883 patients, most of the operations performed were for frontal craniosynostoses (1532, 81 percent), whereas surgery for occipital deformational causes represented the minority of reported cases (351, 19 percent) (Figs. 1 and 2).

Intraoperative Application

Placement of the resorbable plates and screws was consistently reported to be uncomplicated, other than the need for hand-tapping of the screw threads before their insertion. Hand-cutting the threads was reported as onerous and resulted in some wrist fatigue when done in large numbers, but it consistently produced screw threads that allowed good engagement of the screws. A recent change in screw placement technique has been in the use of a threadless push screw. This requires a larger pilot hole (1.25 mm), as the screw is simply pushed into position. Despite this innovation, the majority of this study's surgeons (nine of 11, 82 percent) still preferred a tapped threaded screw. Application of the plates was reported as the simplest part of the procedure. The flexibility of the resorbable plates and the
curvilinear shape of the cranial vault did not usually require any complex plate bends that the inherent flexibility of the plates did not allow. Heating of the plates through a water bath or water-activated heat pack allowed any shape to be obtained, but this was very rarely used. As experience with the resorbable implants increased, some authors more frequently used longer plates to join more distant bone segments (Fig. 2).

Postoperative Complications

Postoperative infections were reported in eight patients (0.4 percent) in this series. Of these eight patients, five had local wound infections that were treated with oral antibiotics and were followed to resolution as outpatients. In two patients, infections were treated and satisfactorily resolved with hospital admission and intravenous antibiotics without surgery. Only one patient required reoperation for drainage and irrigation followed by intravenous antibiotics. A significant infection rate, defined as hospital readmission with intravenous antibiotics or surgery, was therefore 0.2 percent. All infections were noted to have occurred within the first 6 weeks after surgery, with an average time of onset of 16 days. No long-term occurrence of infections (months to years) was reported.

Resorbable device failure with loss of bony position occurred in the immediate postopera-
Fig. 2. Occipital cranial vault reconstruction in a 10-month-old boy with a severe unilateral occipital deformational plagiocephaly after failed helmet therapy. (Above, left) Preoperative view; (above, right) 6-year postoperative view; (below) intraoperative view.

tive period in five patients (0.3 percent) requiring re-operation in the early postoperative period (up to 6 weeks postoperatively). The majority of these cases (four) had an associated history of head trauma resulting from either a fall (three) or a direct blow (one). During the reoperative surgery, it was noted that the devices failed primarily because of breaking or fracturing of the plates as opposed to screw pullout.

Delayed foreign-body reactions (>3 months from initial operation) were reported to have occurred in 12 patients (0.7 percent); these were seen as localized areas of scalp swelling or cyst formation without redness. The earliest presentation was at 4 months after surgery, with the latest reported incident at 10 months. All of these resolved without the need for antibiotics within 2 to 4 weeks after their development. Only one patient (0.06 percent) had a percutaneous drainage, which demonstrated clear fluid without bacterial growth.

Reoperation resulting from device-related problems (eliminating infection, which could not be confirmed as directly device-related but rather operation-related) was required in four patients (0.23 percent).

DISCUSSION

Modern pediatric craniofacial surgery has undergone a multitude of advancements and innovations in surgical techniques over the past two decades. Early in the development of craniofacial surgery, it became apparent that a method of bone fixation was needed to provide both intraoperative stability and postoperative maintenance of the desired change in bone
shape and contour. Numerous creative methods of loop suture and stainless steel wire ligatures were initially used, but their lack of three-dimensional stability left these methods wanting. The development of metallic plate and screw fixation, particularly the adaptation to a smaller size, provided rigid bone fixation that was ideal for maintaining new bony configurations. With widespread use, however, certain concerns surfaced because of the young age of the implant recipients and the unique pattern of cranial vault growth. These issues primarily revolve around the potential need for secondary removal resulting from device loosening, skin irritation, and device exposure. Uniquely, intracranial translocation to the endocranial surface and dural violation pose the more grave potential risks of causing secondary headaches and/or creating a seizure focus. Of less concern is the potential for growth restriction, although this has been shown to have only a relatively minor local effect that is restricted to the area of the implantation site. An ideal system for pediatric craniofacial bone healing would provide rigid fixation during the initial phase of healing, then be eliminated from the body through natural processes after it is no longer needed. Plate and screw fixation devices composed of resorbable polymers appear to most closely match the requirements needed for this application and have been under experimental investigation for decades. Resorbable bone fixation implants have been clinically available since 1996 and have been implanted in tens of thousands of patients; the vast majority of them have undoubtedly been implanted in young pediatric patients. These devices have been composed of various combinations and formulations of polylactic acid and polyglycolic acid polymers (family of polyorthoesters) because of their long history of use and safety as the primary constituent of most resorbable sutures. When used alone, polylactic acid in its L-isomer forms a crystalline lattice that is quite hydrophobic and resistant to degradation. This makes polylactic acid implants quite strong, but their resorption is slow, if it ever occurs at all. Such slow or nonexistent degradation may eventually cause a foreign-body reaction requiring secondary removal, thus defeating their primary benefit. Conversely, pure polyglycolic acid produces a rapidly resorbing implant because of its enhanced hydrophilicity. Such rapid water uptake results in early weakening of the implant because of loosening of the polymer bonds. It is because of these chemical properties that copolymers of polylactic acid and polyglycolic acid are often used in an effort to create better strength and resorption profiles than exist in the homopolymers alone. Almost all currently used resorbable fixation devices employ this blended or composite approach to a resorbable implant composition. Commercially available resorbable fixation devices have numerous compositions in addition to PLLA-PGA, including PLLA-PDLLA, PDLLA, and PLLA-TMC. Whether truly significant clinical differences in handling and effectiveness exist among these polymer compositions is unclear, but all seemed to have captured the most important property to ensure eventual material resorption, an amorphous (minimally crystalline) polymer structure.

Despite their clinical availability since 1996 and their potential benefits in the pediatric cranial vault, only scattered reports of small patient series exist. These early reports present their initial enthusiastic clinical use, which documents their intraoperative applicability, but long-term results after implantation have yet to be reported. As degradable polymer devices change postoperatively, the issues of fixation stability and potential foreign-body reactions are relevant, particularly as to how they would be compared with static titanium metal devices or stainless steel wire ligatures. After more than 7 years of clinical availability and the large number of children who have received implants, it is prudent to evaluate whether the theoretical benefits of resorbable fixation in children have been realized. The incidence of infection in craniofacial procedures has been previously reported to be between 2.5 and 6.5 percent. Dissection of the patient populations in these reports (differentiating primary versus secondary surgery and patient age), however, shows that the infection risk in the primary craniosynostosis patient is substantially lower, less than 1 percent. Infant age, unscarred tissues and wound bed, and lack of frontal sinus development all contribute to an exceedingly small surgical infection risk. Although no formal studies have been conducted in the pediatric craniofacial population, the use of any form of metal bone fixation has not been associated with increased risks of infection. Although polymer device (plastic surfaces) have a known higher affinity...
for bacterial adhesion than metal, the small number of infections seen in this series (0.2 percent) does not show any increased risk of intraoperative bacterial inoculation into the reconstruction site. The stability offered by a plate form of fixation is intuitively more appealing than that of any form of creative ligature placement or osteotomy design. Although metal is clearly stronger than any form of amorphous polymer, most resorbable devices compensate for this material difference by taking the liberty of adding more material to their mass. In essence, the material goals of metal versus resorbable devices are diametric. Metal fixation devices are paired down to the minimum amount of material for stability because they are permanent, whereas polymer devices do the opposite because they are resorbable. For this reason, most resorbable plates feel as stable as metal, particularly in the low load-bearing requirements (resistance to compression from scalp closure in frontal procedure, laying on the back of the head in occipital procedures) of the cranial vault. Because they are not permanent, most surgeons likely use more resorbable fixation devices than they would if they were using metal, thus further contributing to the stability of the reconstruction. Because of the rapid healing of the cranial vault, there would be no reason to suspect significant differences in the maintenance of cranial contours and the long-term aesthetic outcome, whether the bone is fixed by polymer or metal devices. Strength differences do exist, however, in exposure to high-energy loading situations (such as blows from falling). The resorbable polymer becomes more brittle at high loading rates. All failed cases in this series showed loss of stability, with resultant malpositioning of the reconstruction and fracture through the holes of the plates. In contrast, metal devices rarely fracture, as a result of their malleability, but respond to such stresses by plastic deformation, resulting in bending of the hardware with or without screw pull-out.

The issue of foreign-body reaction to degrading polymeric material is of the greatest postoperative interest. This problem has plagued the development efforts of resorbable fixation devices in the past. Foreign-body reactions represent a local intolerance (inability to metabolize) either to the type of polymer or to the volume of polymer debris at a specific site. As previously mentioned, the alteration of polymer compositions from crystalline to more amorphous (noncrystalline) structures has been the single greatest advance in resolving this problem. Although this eliminates the potential for severe adverse granulomatous reactions years later, there still remains the question of whether smaller localized reactions to polymer loads may still occur within the time frame of the device's resorption profile. As can be seen in this patient series, this occurrence is small (<1 percent) and appears only as an occasional cyst formation underneath the scalp. It is important to realize that this cystic swelling is only temporary and does not represent an infection that needs to be treated. Contained within the cyst is only clear noncellular fluid. It is a transient response to the degrading polymer, is painless to the patient, and is self-limiting by ongoing local metabolism. With the specific PLLA-PGA copolymer used in this series, the cyst develops between 3 and 9 months after surgery, the most active phase of degradation and clearance of the polymer devices. This specific response to resorbable bone fixation devices will vary depending on their polymer composition. As such, longer-resorbing resorbable materials will likely develop this response much later than was seen in this series.

It is important to point out that the majority of the data gathered in this survey is retrospective. As a result, errors of convenience commonly occur, particularly in the recollection or documentation of postoperative complications. The net result of these errors is an underestimation of complication occurrence. This is inherent in all such surgical survey data and undoubtedly is part of all conducted studies including this one. The overall complications rate reported in this series, however, is substantially lower than that historically reported with the use of differing polymer bone fixation systems in orthopedic surgery, where spontaneous drainage in the protracted postoperative period can be as high as 25 percent. This is most likely attributable to the young age of the patients, a more favorable resorption profile of the polymer devices used, and the excellent blood supply of the craniofacial region.

**Summary**

Long-term experience in large numbers of patients demonstrates that resorbable poly-L-lactic-polyglycolic plate and screw fixation in pediatric cranial vault reconstruction is as safe
and effective as metal devices, with no added risks of infection or reconstruction instability. They eliminate the need for any secondary device-related procedures; this is their major advantage. There is a very low occurrence of isolated foreign-body reactions as the material is metabolizing; these are self-limiting and require no treatment.

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REFERENCES


