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

Barry L. Eppley, M.D., D.M.D., Louis Morales, M.D., Robert Wood, M.D., Jay Pensler, M.D., Jeff Goldstein, M.D., Robert J. Havlik, M.D., Mutaz Habal, M.D., Albert Losken, M.D., J. Kerwin Williams, M.D., Fernando Burstein, M.D., Arlene A. Rozzelle, M.D., and A. Michael Sadove, M.D.

Indianapolis, Ind.; Salt Lake City, Utah; Rochester, Minn.; Chicago, Ill.; Cleveland, Ohio; Atlanta, Ga.; Tampa, Fla.; and Detroit, Mich.

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.[1] 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.[2–4] 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.[5] 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