Craniofacial reconstruction with a fast resorbing polymer: a 6- to 12-month clinical follow-up review

STEVEN R. COHEN, M.D., RALPH E. HOLMES, M.D., HAL S. MELTZER, M.D., MICHAEL L. LEVY, M.D., PH.D., AND MILES Z. BECKETT, B.S.

Craniofacial Surgery Service, Children’s Hospital of San Diego; and Department of Pediatric Neurosurgery, University of California at San Diego, California

Object. Resorbable polymer implants have become a compelling option in the treatment of acquired and congenital craniofacial deformities. In particular, the resorbable polylactide and polyglycolide polymers have demonstrated excellent safety profiles in multiple in vitro, animal, and clinical studies and are currently being used in a wide variety of craniofacial applications. In pediatric craniofacial reconstruction a desirable attribute of fixation is early resorption, which may limit the duration of any effect on cranial growth. In this paper the authors discuss the biomaterial properties of a fast resorbing polymer (FRP) and the clinical results in a series of patients who participated in a 6- to 12-month study.

Methods. The authors performed craniofacial reconstruction by using FRP implants in 29 patients beginning in August 2002. All patients experienced maintenance of stable bone fixation followed by bone healing. Cosmetic results were rated satisfactory or excellent, except for one unsatisfactory cosmetic result caused by disease progression.

Conclusions. Results of this study support the effectiveness of an FRP implant in a variety of craniofacial surgical procedures including craniosynostoses, fibrous dysplasia, cranial defects, and encephalocoeles.

KEY WORDS • craniofacial • reconstruction • resorbable polymer • polylactide • polyglycolide

Polyactic acid and polyglycolic acid are part of a chemical family referred to as alpha esters. These alpha ester compounds have been used successfully as suture material over the past 30 years. Resorbable polymers, especially the alpha ester polymer group, have been used successfully in various orthopedic and craniofacial applications with increasing frequency over the past 15 years.

Polyactic acid and polyglycolic acid are made by condensation polymerization of lactic and glycolic acids. To achieve higher molecular weights, polymer chemists have developed a ring-opening polymerization method that starts with dilactide or diglycolide; hence the correct terminology is polylactide or polyglycolide. Because different forms of dilactides are possible (L or D or D,L forms), different polylactides can be produced; these include poly(L-lactide), poly(D,L-lactide), and poly(L-lactide-co-D,L-lactide). In general, the fixation devices made from these lactides retain approximately 70% of their initial strength after 9 months and approximately 50% after 12 months. Biodegradation of lactides can be accelerated by incorporation of a glycolide. When manufactured from an 85:15 ratio of D,L-lactide and glycolide, this FRP will retain approximately 70% of its initial strength after 2 weeks and approximately 50% of its strength after 6 weeks (Figs. 1 and 2).

When low–load bearing bones are reconstructed, the clinician can now choose between bioresorbable or permanent metallic implant materials. In addition to the obvious advantages of a temporary implant over a permanent metallic device, polymer implant materials may have the following significant benefits: 1) reduced risk of stress shielding, that is, the weakening of healing bone resulting from excessively rigid fixation; 2) clearer radiographic presentation of the reconstructed region due to the absence of radiographic scatter; and 3) elimination of the need for subsequent removal surgeries that are sometimes required for metallic devices.

CLINICAL MATERIAL AND METHODS

Materials: FRP Implants

The MacroPore/Medtronic Neurologic Technologies FRP implants were manufactured from commercially available 85:15 poly(D,L-lactide-co-glycolide) raw material by using traditional melt processing techniques. These devices were developed to service the needs of pediatric patients. The implant designs and delivery system are essentially the same as for the more slowly resorbing polymer, 70:30 poly(L-lactide-co-D,L-lactide).
The FRP implants used in this study were 0.75-mm-thick mesh sheets ranging in size from $25 \times 25$ mm to $100 \times 100$ mm, and screws were 1.8 and 2.1 mm in nominal diameter. The mesh can be contoured after brief heating in sterile water ($\sim 60^\circ$C), which brings the polymer above its glass-transition temperature ($\sim 55^\circ$C); it can then be easily cut into any desired shape. The desired contour is maintained once the implant cools to room or body temperature. The mesh provides numerous holes with countersinks to accept the screws for fixation.

Methods: Clinical Study

After regulatory clearance from the Food and Drug Administration in August 2002, a clinical series of craniofacial reconstructions in which FRP was used was initiated to verify the efficacy of the product. The surgical use of FRP (Fig. 3) was similar to that for more slowly resorbing polymer implants. Detailed clinical evaluation forms were completed after surgery and at each postoperative visit. Evaluation criteria included assessment of the maintenance of fixation, healing, cosmetic appearance of the reconstruction, swelling at the implant site, and a description of any complications.

RESULTS

At present, we have completed the 6-month postoperative evaluation in 18 patients and another 11 have undergone both their 6- and 12-month postoperative evaluation, for a total of 29 patients in this report. No patient was lost to follow-up review. At surgery the mean age of the patients was 2.1 years (range 2 months–7.5 years). The diagnosis in the majority of cases was craniosynostosis (18 patients). The remaining diagnoses included fracture and fibrous dysplasia (two patients each), and cranial defect, encephalocele, orbital bone cyst, orbital lymphangioma, plagiocephaly, trigonocephaly, and Treacher–Collins syndrome (one patient each).

At the 6- and 12-month assessment all patients displayed stable fixation and bone healing. In all patients the cosmetic appearance was satisfactory or excellent, except in one with an unsatisfactory rating in whom disease progression unrelated to the implant occurred, requiring further intervention. All patients were free of postoperative swelling. Postoperative complications occurred in five patients: of these incidents, two were due to falls (mild hematoma), one was related to the patient’s encephalocele (cerebrospinal fluid leak), and one was a minor bone defect (all five were treated without further surgical intervention). There was one infection following a revision, which was treated with surgical intervention. There were no material- or implant-related complications.

Fig. 1. Graph showing percentage change in tensile and shear strength for the MacroPore/Medtronic Neurologic Technologies FRP implant according to weeks of real-time aging.

Fig. 2. Graph showing percentage change in inherent viscosity and molecular weight for the MacroPore/Medtronic Neurologic Technologies FRP implant according to weeks of real-time aging.

Fig. 3. Intraoperative photographs showing the use of FRP mesh and screws for reconstruction of craniofacial defects in a patient who had a nasofrontal encephalocele. Upper: Full-thickness cranial bone graft enveloped with FRP mesh. Lower: Mesh stabilized in place with FRP screws.
DISCUSSION

Polylactide and polyglycolide resorbable polymers are biocompatible with most body tissues and have a long record of safe use in humans. In pediatric craniofacial surgery an FRP is desirable. In a series of children treated with 85:15 poly(D,L-lactide-co-glycolide) FRP implants, the 6- or 12-month postoperative evaluation was completed in 29, and all patients displayed maintenance of stable bone fixation followed by bone healing. Satisfactory or excellent cosmetic results were attained in all except one patient in whom an unsatisfactory cosmetic result occurred because of disease progression. Complications were mild and none were related to the implant. Compared with metal, the FRP implants were easier to contour, and there was no imaging interference. Theoretical advantages that need further validation include physiological load sharing and reduced growth restriction. The results of this study support the effectiveness of FRP implants in a variety of craniofacial surgical procedures including craniosynostoses, fibrous dysplasia, cranial defects, and encephaloceles.

Disclosures

Drs. Cohen and Holmes are consultants for MacroPore Biosurgery, Inc., San Diego, California, and for Medtronic Neurologic Technologies, Goleta, California.

References