Bioabsorbable Plate and Screw Fixation in Orthognathic Surgery

Barry L. Eppley, MD, DMD

Indianapolis, Indiana, USA

This paper describes the author’s 10-year experience in using resorbable polymeric plates and screws in select cases of orthognathic surgery as well as a comprehensive review of all published reports on this technology for similar applications.

Key Words: Orthognathic surgery, jaw surgery, resorbable polymers, biodegradable fixation

The development of rigid internal bone fixation has revolutionized the treatment of craniofacial bone problems, albeit of congenital, traumatic, or oncologic etiologies. The amount of bone stability achieved with metal plates and screws has created a standard of stability that is unrivaled by other methods. This advance, however, has been associated with some complications. These include the potential for foreign body reactions from hardware loosening, sensitivity to cold temperatures when under thin skin cover, potential dental and sinus sensitivity resulting from the proximity of metal to these anatomic structures, and the need for secondary procedures to remove symptomatic hardware.

In the patient with a facial fracture, the incidence of secondary metal device removal in a recent clinical series was 33%, primarily attributable to discomfort related to palpability, cold intolerance, and pain. In orthognathic surgery, long-term removal rates of 10% to 12% have been cited in a predominantly young healthy cohort of patients in three recent series. As a result, the recognition of these metal plates and screw complications has long fostered the search for bioabsorbable rigid fixation devices for maxillofacial applications.

This article describes the author’s 10-year experience in using resorbable polymeric plates and screws in select cases of orthognathic surgery as well as a comprehensive review of all published reports on this technology for similar applications.

Surgical Technique

Plate and screw fixation devices were composed of a copolymer of poly-L-lactic and polyglycolic acid (PLLA/PGA) in an 82:8 ratio (LactoSorb; Walter Lorenz Surgical, Jacksonville, FL). These resorbable devices have an extensive clinical history in numerous craniofacial applications, particularly pediatric craniofacial surgery, without any adverse tissue reactions such as inflammation or osteolysis. The screw holes required tapping after drilling of an initial pilot hole and the plates were adapted to the bony contours of the cut maxilla either by digital bending or with the use of a heated water bath or water-activated heat pack for more exacting adaptation. Four 2.0-mm L-shaped plates with four 2.0 mm × 7-mm long screws per plate were used for the LeFort I osteotomies (Fig 1). In a few cases, a larger 2.0-mm mesh panel was used per side with staggering of screw placements. If a 2.0-mm screw stripped, it was replaced with a 2.5 mm × 7-mm long screw. No concern was given to the amount of screw protrusion into the maxillary sinus. All mandibular osteotomies were bilateral sagittal split osteotomies and were stabilized in a linear or inverted-L pattern per side with bicortical 2.5 mm × 15 or 17-mm long screws (Fig 2). Genioplasties were stabilized with a variety of methods, including a vertically placed adapted 2.0-mm plate with 2.0 mm × 5-mm long screws, X-plates with 2.0 mm × 5-mm long screws, or two or three 2.5 mm × 17-mm long screws in a lag screw fashion (Fig 3).

With this technique of resorbable “semirigid” fixation, no guidance elastics were used until after the third postoperative week regardless of the postoperative occlusal interdigitation.

Clinical Experience

Over the past 10 years, these surgical techniques have been used in orthognathic surgery cases that have had routine dentofacial deformities in which the bony discrepancy between the maxilla and mandible was
not highly significant. The exclusion criteria included cases in which the underlying deformity was from a cleft or craniofacial deformity (eg, hemifacial microsomia), when the maxilla needed to be segmentalized, maxillary advancements were greater than 5 mm, mandibular advancements were greater than 15 mm, there was significant maxillomandibular asymmetries, chin advancements were greater than 5 mm, and in patients whose postoperative compliance may be questionable (eg, syndromic patients).

In 24 maxillary osteotomies (17 advancements, six impactions, one downgrafting), no postoperative instabilities or problem with bone healing were encountered (Fig 4). Select long-term radiographs showed bone healing without osteolysis (Fig 5). In three patients, between 6 and 9 months postoperatively, paranasal swelling occurred. These were managed by antiinflammatory medication only and all resolved within 2 weeks.

In 13 mandibular osteotomies (nine advancements, four setbacks), complete bone healing and stability was obtained in all patients (Fig 6). Radiographically, screw holes persisted up to 1 year but were completely filled in at 2 years (Fig 7). No delayed foreign body reactions or any problems with mucosal wound healing over the ramus incisions were seen.

In seven genioplasties (five advancements, two vertical reductions), uneventful healing occurred in all cases. Good bone healing was seen radiographically without resorption of the downfractured symphyseal segment (Fig 8).

**DISCUSSION**

Despite the initial use of resorbable polymers as sutures for wound closure in the 1960s, the initial application of resorbable fixation in
the maxillofacial region did not occur until 1987. Most notably, Bos’ clinical series of zygomatic fracture fixation appeared, but less well-known was Dumbach’s initial efforts in orthognathic surgery. He reported the use of pins (3.5 mm) and screws (2.7 mm) for osteosynthesis of sagittal split osteotomies of the mandible with the retention of maxillomandibular fixation out to 4 weeks in all patients. Limited efforts in orthognathic surgery continued through the early to mid-1990s with limited reports by Champy in three patients, resorbable suture for LeFort I fixation by Obwegeser, and a single case of bimaxillary osteotomies by Haers in 1998.

The first clinical series was reported by Haers in 1998 in which he reviewed their experience with self-reinforced poly-L/DL-lactide (85:15, L/DL-lactide) plates and screws for osteosynthesis in 10 consecutive cases of bimaxillary procedures with simultaneous genioplasties without postoperative rigid intermaxillary fixation. None of the plates, which were bent at room temperature, broke. The screw heads broke or had an insufficient fit in the bone in 12 of 305 (3.9%) screws. By postoperative cephalometric analysis, the authors concluded that the application of this system in orthognathic surgery leads to a predictable short-term skeletal stability pattern that is comparable to titanium plates and screws.

Also in 1998, Edwards reported on their experience in 29 patients with resorbable fixation in LeFort I osteotomies. Over a 1-year period from October 1996 to November 1997, a combination of isolated LeFort I and bimaxillary procedures was performed using a traditional 4 L-plate and 16 screw fixation with 2.0-mm LactoSorb (82:18, PLLA/PGA) devices. Follow up ranged from 2 weeks to 1 year. No device, bone stability, or wound complications were encountered. The authors suggest that one’s initial cases should be preceded by a minilab experience or that you should operate with another surgeon who has experience with the technology, one-piece LeFort I osteotomies of no greater movements than 5 mm should be performed, and a series of specific technical steps in the application of the devices to the maxilla should be followed.

In 1999, Edwards reported on the suitability of resorbable screws for bicortical fixation in mandibular sagittal split osteotomies. In 37 patients, their sagittal split osteotomies were fixated with three 2.5-mm LactoSorb (82:18, PLLA/PGA) screws on each side. No postoperative maxillomandibular fixation was applied. Twenty-five patients had mandibular advancements, whereas 12 patients had setbacks. The average advancement was 6.5 mm (range, 3–17 mm) and the average setback was 5.2 mm (range, 3–8 mm). Intraoperative placements were uncomplicated and no screws were stripped during placement. No
problems in immediate postoperative stability were encountered and relapse was not evident in any patient. Follow up ranged from 3 to 17 months. The screw holes remained radiographically evident after 1 year. The authors concluded that resorbable screws of this composition appeared to offer clinical results comparable to metallic screw fixation.

Westermark in 1999 reported on 20 patients who had sagittal split osteosynthesis performed with three or four 2.5-mm resorbable screws on each side without additional fixation. The screws consisted of LactoSorb (82:18, PLLA/PGA) copolymer. Of the 20 patients, 17 had mandibular advancement, two had mandibular setback, and one underwent unilateral mandibular advancement after previous condylectomy. Six patients underwent simultaneous LeFort I osteotomy and four patients had simultaneous genioplasty. Postoperative training elastics were maintained for an average of 2.5 weeks. Six of the patients have been followed for 2 years, and 14 have been followed between 1 and 2 years without observable relapse and without clinical, radiologic, or histologic signs of healing complications.

Eppley in 1999 reported an experimental study to determine the suitability of biodegradable screws for fixation of mandibular sagittal split osteotomies.

**Fig 5** (A) Maxillary hypoplasia, preoperatively. (B) LeFort I osteotomy, postoperatively.

**Fig 6** (A) Mandibular hypoplasia, preoperatively. (B) Mandibular sagittal split advancement, postoperatively.
by in vitro biomechanical strength testing. In a urethane block model, biodegradable 2.5-mm LactoSorb (82:18, PLLA/PGA) screws were placed in an inverted L pattern and biomechanically tested. In static testing, the three screws sustained an average peak load of 131 kiloponds (Kp) (standard deviation, 5.2 Kp) with 5.5% strain at yield. In dynamic testing, the biodegradable screws tolerated a 45.3 Kp load for an average of 340,675 (22,783 standard deviation). Several of these test specimens did not ultimately fail and were further tested with an average load of 77.4 Kp until fixation failure occurred. These laboratory results indicate a relatively high resistance to biomechanical loads representative of mastication and indicate their potential effectiveness in fixation of the unrestrained sagittal split osteotomy.

Shand and Heggie in 2000 reported their initial experience with the use of resorbable fixation in orthognathic surgery. Thirty-one patients who had finished growing and who had dentofacial deformities that were not part of syndromes were treated by routine orthognathic repositioning procedures: maxillary (8), mandibular (9), or bimaxillary (14) procedures. All skeletal fragments were fixed with 2.0-mm (maxilla) or 2.5-mm (mandible) LactoSorb (82:18 PLLA/PGA) plate and screws. The follow up ranged
from 2 to 8 months (mean, 5 months). All patients recovered normally except for one who developed a localized buccal space infection. In the early postoperative period, six patients had mild mobility of the maxilla, but stability was within normal limits at 6 weeks after surgery. The authors summarize their experience as successful, although surgical technique has an important influence on clinical success. Most of these cases were maxillary advancements under 6 mm and superior maxillary repositioning.

Edwards in 2000 reported on their clinical experience with resorbable fixation in genioplasties in 2000. In 20 patients who had anterior mandibular osteotomies, fixation techniques with LactoSorb (82:18 PLLA/PGA) included either 2.5-mm lag screws or a 2.0-mm plate and screws. Sixteen patients had advancements, two patients had setbacks, and two patients had vertical reductions. Intraoperative stability was satisfactory in all patients and there were no postoperative infections or segmental instability up to 6 months after surgery.

In 2001, Edwards reported on the long-term outcome of copolymeric resorbable (PLLA/PGA; LactoSorb) devices used for maxillary and mandibular osteotomies. Twelve patients were evaluated, including sagittal split osteotomies (8), LeFort I osteotomy (2), and genioplasty (2). All mandibular osteotomies, that were fixed by three superior border or inverted L pattern placement of 2.5-mm screws, showed screw holes that by 18 months after surgery had near or complete trabecular bony fill by radiographs. One patient underwent a bone biopsy of a residual screw hole, which showed no residual polymer material. The maxillary sites, which were fixed by four 2.0-mm L plates and 16 2.0-mm screws, showed bone healing along the osteotomy lines and no evidence of residual fixation material or bone defects in the screw holes. No communication with the maxillary sinus was seen in the fixation sites. This patient series demonstrated complete resorption of the PLLA/PGA fixation devices without osteolysis in maxillary and mandibular bone sites by 18 to 24 months after surgery.

Also in 2001, Edwards reported on the potential effectiveness of resorbable (PLLA/PGA; LactoSorb) plate and screw fixation in simultaneously performed maxillary and mandibular osteotomies. Twenty consecutive patients underwent bimaxillary surgery that were fixed with bicortical screws (2.5 mm) at the sagittal splits, four L plates, and 16 screws (2.0 mm) for the maxilla, and the genioplasties were secured with two or three bicortical screws (2.5 mm). No postoperative maxillomandibular fixation was used and guidance elastics were applied at 2 weeks postoperatively. All surgeries were accomplished uneventfully and no problems in the immediate postoperative stability of the occlusion were encountered. Follow-ups ranged from 12 to 25 months. This clinical experience suggests that resorbable fixation is a viable alternative to metal for certain maxillomandibular deformities in which excessive bony movements are not performed.

The biomechanical characteristics of metallic versus polymeric fixation were shown in polyurethane models in which LeFort I advancements were done by Araujo in 2001. Both resorbable and metal systems tested showed load capacity magnitudes above 285 N (64 lbs) and more elastic resistance in the inferior-superior direction. The resorbable devices showed lower elastic stiffness than titanium but appeared to be adequate to withstand the forces of mastication.

In a clinical study of bilateral sagittal split osteotomies (BSSO) of the mandible in 20 patients, Ferretti and Reyneke placed bicortical LactoSorb
screws for fixation of advancements.\textsuperscript{20} Lateral cephalograms were studied out to 6 months postoperatively and compared with 20 other patients undergoing BSSO who had their advancements stabilized with bicortical titanium screws. There were no statistically significant differences in long-term stability between the two groups. No clinical or wound healing problems were encountered. The authors concluded that resorbable screw fixation for BSSOs is a viable alternative to titanium screws.

Similarly, Landes in 2003 performed mandibular osteotomies using two different formulations of resorbable plates in 18 patients with a variety of bone deformities and ages. Major bone movements were done, five having 8- to 10-mm movements and 13 having 10- to 12-mm movements. Ten plate specimens were subsequently retrieved in secondary operations up to 1 year after surgery.\textsuperscript{21} The current two resorbable plate systems showed sufficient stability for mandibular fixation after sagittal split osteotomy and repositioning when more than a 10-mm advancement was done when two plates were applied to each side. The complication rate was 27\%, including relapses. Disadvantages were cited such as cost, breakability, diameter, and the need to place the screws vertically to the plate, necessitating a bent instrument or transbuccal incisions.

In 2004, Norholt et al reported on a randomized, prospective study comparing LactoSorb miniplate fixation versus titanium in LeFort I osteotomies.\textsuperscript{22} A total of 60 patients were treated and then followed for 1 year after surgery. Cephalometrically, there were no statistically significant changes in the position of the maxilla from 6 to 12 months in either of the treatment groups. In the LactoSorb group, there were two cases of infection and wound dehiscence, whereas the titanium group required hardware removal in three cases.

In another randomized, prospective study comparing resorbable versus titanium fixation, a total of 60 patients with 177 osteotomies were evaluated by Cheung in 2004.\textsuperscript{23} Eighty-seven osteotomies were fixated with 196 titanium plates and 784 titanium screws in 30 patients, whereas 90 osteotomies were fixated with 165 resorbable plates and 658 resorbable screws in the other 30 patients. The postoperative infection rate was 1.53\% in the titanium group and 1.82\% in the resorbable group. Plate exposure rate was 1.02\% for the titanium patients and 1.21\% for the resorbable group. The plate removal rate in the first postoperative year in the titanium and resorbable groups was 1.53\% and 3.63\%, respectively. There were no significant differences in the subjective clinical parameters such as wound discomfort, stability of the osteotomized segments, plate palpability, and overall satisfaction of the results between the two fixation groups.

In 2005, 5-year experience in the use of LactoSorb fixation in maxillary surgery in 50 orthognathic and five preprosthetic procedures, performing LeFort I osteotomies in all cases, was reported.\textsuperscript{24} All operations were carried out without complications. Follow-up ranged from 6 months to 5 years. One postoperative infection was seen, which resolved with antibiotics. The authors concluded that resorbable fixation should be considered adequate for fixation in maxillary surgery.

A 5-year experience in 413 maxillary and mandibular resorbable plate osteosyntheses focusing on clinically apparent foreign body reaction as well as indirect and direct implant degradation was reported by Landes in 2006.\textsuperscript{25} Eighty fracture and reconstruction patients were osteofixated with either PLGA (139) or P(L/DL)LA (274). Average clinical and radiographic follow up was 29 months. Foreign body reactions were seen in 6\% of the treated patients. Both copolymers showed reliable biocompatibility and disintegration. PLGA (85:15) fixation degraded within 12 months and 70:30 P(L/DL)LA within 24 months. Burr holes reossified 12 months later.

Costa et al in 2006 evaluated skeletal stability after double jaw surgery for correction of class III malocclusions using either resorbable or titanium plates and screws.\textsuperscript{26} Twenty-two patients (12 titanium, 10 resorbable) had BSSOs for mandibular setbacks and low-level LeFort I advancements. Cephalometric analysis was taken out to 1 year postoperatively and both groups had excellent maxillary stability. The authors stated that resorbable fixation should be used with caution in maxillary movements greater than 5 mm.

**SUMMARY**

Biodegradable fixation devices have been used for a wide application of craniofacial bone problems, particularly in the past 10 years since they have become commercially available. Approximately one fourth of clinical reports address their use in orthognathic surgery and it is now becoming accepted that they may be successfully used with good patient selection and surgical technique. In controlled osteotomies such as a one-piece LeFort I and sagittal split mandibular osteotomies, when applied to nonsyndromic facial skeletal deformities in which the bony movements are limited, clinical outcomes can be comparable to those patients similarly treated with
titanium plates and screws. The key is good patient selection in which the bone stock is sufficiently good that adequate thread tapping can be done. Unlike metal fixation, patients should not be placed in immediate postoperative elastics to avoid potential early failure of the resorbable device–bone interface. Wait at least 3 weeks after surgery, regardless of the occlusal interdigation, to begin elastic therapy. At this point, adjustment of the skeletal bone is very similar to what occurs in bone distraction with a moldable callus.

There are numerous types of biodegradable fixation devices available composed of varying ratios of PGA and PLA mixtures. Whether significant differences exist in their biologic behavior and postoperative outcomes is not currently known. All must be placed similarly, however, with tapping of the screw threads and warm adaptation to the bone when necessary. The surgical technique with biodegradable fixation, in general, is more technique-sensitive than that of metal. Patience and motivation is the key to successful intraoperative application. Postoperative swelling (eg, foreign body reactions) can occur in a small number of patients in the paranasal region of the maxilla, presumably as a result of the thin overlying mucosal cover. The timing of these self-limited inflammatory reactions will depend on the resorption profile of the polymer devices used. They can be managed by antiinflammatory medications and operative reentry is not needed unless device exposure becomes evident with mucosal breakdown.

The long-term study of the use of bioabsorbable fixation in nonsyndromic maxillary and mandibular osteotomies indicates that its benefits are realized after the first postoperative year when the bone is completely healed, the occlusion stabilized, and the polymers eliminated from the body. Improvements in intraoperative application, particularly in plate adaptation and screw insertion, are needed before their use becomes more widespread.

REFERENCES