Background: When performing septorhinoplasty, deviated segments of septal cartilage can be straightened using cartilage or bone as splinting grafts. In some cases, autologous material is not available without an additional surgical procedure to harvest cartilage or bone. It is possible that resorbable plates can be used to splint and straighten deviated cartilage. Experience using bioreabsorbable rigid fixation devices on cartilage has been limited.

Objective: To examine early histopathologic changes of rabbit ear cartilage and adjacent soft tissue following implantation with bioresorbable plates.

Design: Nonrandomized, placebo-controlled trial.

Subjects: Twelve adult New Zealand white rabbits.

Materials and Methods: Ten adult New Zealand white rabbits (20 ears) underwent stenting of intact ear cartilage with LactoSorb plates (Lorenz, Jacksonville, Fla). Rabbits were killed 28 days after implantation, and the soft tissue, plates, and cartilage were harvested and prepared for histological examination. As controls, 2 rabbits (4 ears) underwent dissection and closure without stenting.

Results: Six rabbits experienced superficial skin breakdown on the ventral surface of the ear caused by excessive wound tension of the implant. The cartilage-plate interface and the surrounding soft tissues stenting the dorsal side of the ear remained free of inflammation or necrosis for all animals. Simple elevation of the perichondrium revealed no differences in the appearance of the cartilage between the control and test rabbits.

Conclusions: Resorbable plates have no deleterious effects on cartilage during the first month of implantation. While short-term studies have documented the safety and efficacy of using bioresorbable plates, further studies are recommended.

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Repair of the crooked nose deformity is often made difficult because of the inherent memory of the septal cartilage.1-3 Attempts at straightening deformed septal cartilage include techniques such as cartilage scoring, splinting with bone or cartilage grafts, and subtotal septal reconstruction (Figure 1).4,6 When grafting material is not available from the nose, autologous tissues, such as costal cartilage, auricular cartilage, or bone from the calvarium or iliac crest, are used. Harvesting these tissues incurs additional surgical morbidity and thus establishes the need for a rigid implantable material for splinting the septum.

Ideal material for splinting the septal cartilage should have the following properties: (1) The material should have adequate strength and stiffness to resist the forces of the septal cartilage. (2) The material should be malleable, yet maintain its original strength. (3) The implantable material should cause no local or systemic inflammatory reaction. (4) Ultimate resorption of the foreign-body implant should take place once the rigid properties are no longer needed. Resorbable rigid fixation plates have the potential to have these properties.

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Previously completed preclinical and clinical studies have documented the efficacy of resorbable fixation devices for procedures involving maxillofacial trauma and craniofacial reconstruction.7-11 However, few studies have examined the efficacy and/or histocompatibility of biodegradable rigid fixation devices when applied directly to a cartilaginous surface. The objective of this study is to examine early histopathologic changes that may occur following placement of a rigid...
MATERIALS AND METHODS

Ten adult New Zealand white rabbits underwent stenting of intact ear cartilage with bioresorbable plates. Procedures were performed on both ears in each animal, for a total of 20 ears. Two rabbits served as controls; the perichondrium on each ear was elevated and then closed without an implant. Prior to study initiation, all procedures were reviewed and approved by the Animal Care Committee of the University of Illinois at Chicago. The bioresorbable fixation devices used in the study were composed of polymerized esters (polymers) with approximately 82% polyactic acid (PLA) and 18% polyglycolic acid (PGA) (LactoSorb; Lorenz/Biomet Inc, Warsaw, Ind). The plates were rectangular (25 mm long, 5 mm wide, and 1.5 mm thick), with 6 holes for potential suture placement (Figure 2). The plates were fixed to the cartilage with resorbable suture.

Each rabbit underwent 1 surgical procedure under aseptic conditions. Ketamine hydrochloride (44 mg/kg) and xylazine hydrochloride (3 mg/kg) were administered intramuscularly as a preoperative anesthetic. The rabbits were then intubated and maintained on halothane to effect. Both ears were shaved and prepared with betadine and alcohol solutions, and the head and body were draped to expose both ears. Procedures were conducted bilaterally on all rabbits. Two 3-cm linear incisions were made through the skin to the underlying cartilage. One incision was initiated on the dorsal surface, while a separate incision was made on the ventral surface of each ear. Overlying soft tissue was retracted on both the dorsal and ventral surfaces to the level of wound closure.

Histological examination revealed no evidence of avascular necrosis or cartilage erosion in any of the specimens. There were no signs of infection or foreign-body reaction at the cartilage-plate interface or in the surrounding soft tissues (Figure 4). There was also no evidence of inflammatory response manifested by the presence of macrophages, polymorphonuclear leukocytes, eosinophils, or basophils at the site of contact between the plates and cartilage. A comparison between test sites with bioresorbable plates and control sites at which no plates were implanted and the perichondrium had been elevated and replaced revealed no gross or microscopic differences. There were no signs of cartilage inflammation, degradation, or injury in either the test or control group. Additionally, comparison of the cartilage in the test group with the rabbit ears in which no plates were placed revealed no appreciable difference under microscopic examination. At the time of harvest, a thin fibrous capsule enclosed each resorbable plate on the dorsal side of the ear. Additionally, no evidence of plate resorption was noted by either gross or histological examination after 28 days.

RESULTS

Twelve rabbits (24 ears) were evaluated. No evidence of wound infection or hematoma formation was noted in any of the study animals. On gross analysis, the resorbable plates remained intact and adjacent to ear cartilage in all rabbits. The skin on the dorsal surface of the ear remained intact in all rabbits; however, 6 of 12 rabbits had skin erosion on the ventral surface of the ear caused by plate volume and resultant tissue tension at the site of wound closure.

When performing septorhinoplasty, deviated segments of septal cartilage can be straightened using bone or cartilage grafts acting as splinting grafts. In some cases, cartilage or bone is not available without the additional surgical harvest of auricular or costal cartilage or calvarial/ilium crest bone. It is possible that resorbable plates can be used as splinting grafts to straighten deviated cartilage. However, resorbable plates exhibit a variety of chemical compositions (Table); with these varied chemical compositions come differing properties with respect to resorption, strength, tissue reactivity, and ability for full degradation. Ideal characteristics of a bioresorbable material include the following: (1) Strength should be retained long enough for the material to be effective. (2) There should be no systemic or local immune reactivity to the implant or its breakdown products. (3) Full degradation should occur without traces of implant residue. (4) No delayed-type hypersensitivity reaction should exist.12
The new bioresorbable products developed from poly–α-hydroxy acid polyesters are designed to maintain their strength and structural integrity well beyond the period required for normal bone healing. Additionally, bioresorbable plating systems are more malleable than metal systems. When warmed, the copolymer becomes pliable, allowing the surgeon to adjust the contour of the device to fit the desired application while the device maintains its original strength. Currently available bioresorbable plating systems are composed of a composite PLA/PGA mixture. The polymer products can either be combined with additional materials to reinforce the structural integrity of the plate or manufactured to be self-reinforcing. The self-reinforcing plates obtain their strength by allowing polymer fibers...
to interweave as the plates are formed. Polyglycolic acid is a dense polyester with a hydrophobic semicrystalline structure. When exposed to water, the ester groups of the PLA material are cleaved, resulting in slow degradation of the polyester. Polyglycolic acid polymers are chemically hydrophilic and therefore resorb at a faster rate than PLA products. Combining the PLA/PGA polymers in varying concentrations can alter the resorption rates of the fixation plates. The resulting copolymer resorbs at a rate that is dependent on the PLA-to-PGA ratio.

The homopolymers PGA and PLAs have been associated with more complications than the copolymers. Complications seen with the homopolymers include vigorous fibrous encapsulation (PLA), sterile sinus formation (PGA), and bone osteolysis (PGA). In addition, polyactic acid 910, a copolymer with a ratio of PGA and PLAs opposite to that of the LactoSorb ratio, was shown to cause sinus formation in the fixation of ankle fractures with bone pins.

Several animal studies have been conducted that examine the effects of resorbable sutures and plates on bone. Cutright et al used PLA sutures for internal fixation of mandibular symphysis fractures in 5 rhesus monkeys. The treated mandibles healed without complication, and no foreign-body reaction was noted in any of the test animals. Eppley and Sadove studied the effects of PLA/PGA copolymer mesh plates that were used to secure parietal bone grafts in 20 mature rabbits. Results of the study showed that the mesh plates resorb completely within 9 to 12 months. Two months after implantation, the plates showed no visible changes in morphological characteristics, and no peripheral inflammatory reaction was noted. At 6 months, the plates were still present; however, a significant decrease in plate mass was noted. Animals that were examined 9 months after implantation retained less than 1% of the resorbable plates, and at 12 months no evidence of polymer was seen either on the cranial surface or within the confines of the screw holes.

Kellman and colleagues examined the histological effects of resorbable plates on bone. They investigated the use of resorbable plates for fixation of bones of the face in 9 rabbits. These plates showed no adverse effects on the underlying bone. In particular, the inflammatory response was mild, consisting of a few inflammatory cells and rare foreign-body giant cells. Histological effects were serially evaluated until 32 weeks after implantation, not until plate degradation.

In addition to these animal studies, several studies examining the use of resorbable plates in humans have been conducted. A randomized controlled study, Rokkanen et al examined the use of polylactide glycolide rigid fixation implants for fixation of malleolar fractures compared with rigid fixation with metallic plates. Early results showed no difference in outcome between the 2 groups. In another study, poly-L-lactide plates were used for fixation of zygomatic fractures in 10 patients. It was reported that at 3 months no clinically detectable inflammatory reactions had occurred, and the plates were well tolerated by the body.

While several studies have examined the efficacy of resorbable plates for rigid bone fixation, few studies have examined the efficacy of resorbable plates for the fixation of cartilaginous structures. One such study, conducted by Weisberger and Eppley, demonstrated the successful use of resorbable fixation plates for the fixation of maxillofacial trauma and craniotomy flaps as well as 5 cases of laryngotracheal framework reconstruction. While histological examination was not performed, patients were noted to have no adverse reaction to the placement of the plates. Willner and Modlin successfully used polydioxanone plates for the treatment of tracheal stenosis in rabbits. The interface between cartilage and resorbable plates was also examined when self-reinforced polyglycolic acid was used as a mold for the growth of neocartilage. Polyglycolic acid rods had no harmful effects on the formation of the neocartilage.

Our study demonstrated that the short-term placement of LactoSorb bioreabsorbable fixation plates yielded no deleterious effects on either the underlying cartilage or the surrounding soft tissue. The absence of tissue inflammation at the interface site associated with resorbable plate placement is consistent with the findings of other previously completed studies. As noted earlier, 6 of 12 animals presented with auricular skin degradation along the ventral surface of the ear. The cause of the skin breakdown is attributable to both the thin ventral skin layer that is present in the rabbit ear and the additional tissue tension resulting from skin closure over the bioresorbable plate. Based on the results of this study, no breakdown of the thicker dorsal skin was noted in any of the animals. In order to decrease tissue tension at the implant site, thinner, low-profile (≤1 mm), more pliable bioreabsorbable plates have been designed for the nasal septum and are now available for clinical trial.

Cartilaginous changes were not observed in our study in either the control or test regions. These early results cannot predict long-term viability of the cartilage as the plate undergoes degradation. Further studies examining the longitudinal effects of the cartilage-plate interface and the ability for the plate to serve as a sufficient splint are needed.

### Conclusions

Several clinical applications involving the use of bioreabsorbable plates for fixation of cartilage are currently be-
ing considered. Stenting of septal cartilage fracture, fixation of cartilage grafts in ear and nasal reconstruction, and laryngotracheal reconstruction to repair subglottic stenosis are a few of the procedures that may benefit from the use of bioresorbable plate-cartilage fixation. While short-term studies have documented the safety and efficacy of using bioresorbable plates, further studies examining the long-term effects of plate exposure and plate resorption on cartilage and surrounding soft tissue are recommended.

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