Polyglycolide Bioabsorbable Screws in the Treatment of Ankle Fractures

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ABSTRACT
Twenty-one patients with unstable medial malleolar, bimalleolar, or trimalleolar ankle fractures underwent open reduction and internal fixation of the medial malleolus with 4.5-mm polyglycolide screws. All lateral malleolar fractures were internally fixed with standard metallic implants.

Radiographic and clinical follow-up results were available on 16 of 21 patients. All fractures healed at an average of 3.4 months (range, 3-6 months), and there were no medial wound infections. Eight of 16 patients developed an inflammatory reaction to the biodegradable polyester at 3 to 4 months after implantation, including one who developed a sterile draining sinus tract. No surgical or nonsurgical treatment was required in those eight patients.

We conclude that whereas polyester screws yield union rates and functional results similar to those of metallic screws in the treatment of medial malleolar fractures, the use of polyglycolide screws is associated with an unacceptable rate of inflammatory reactions.

INTRODUCTION
Bioabsorbable implants offer potential advantages over metallic implants, including a reduced prevalence of soft tissue irritation from prominent retained hardware and a decreased necessity for hardware removal. Biodegradation of the implant also permits gradual stress transfer to the healing bone; thus, bioabsorbable implants may permit more complete remodeling of bone after injury. These theoretical benefits have encouraged clinical investigations into bioabsorbable polyesters for the internal fixation of fractures, most of which have been performed in Europe. Several different polyesters with different rates of hydrolysis and resorption have been investigated, including polyglycolide, polylactide, and copolymers of polyglycolide and polylactide in various ratios. Each of these polymers has a different rate of degradation related to its chemical composition. The compounds are drawn and molded into rods and screws for stabilization of fractures. The European experience has demonstrated a variable prevalence of sterile sinus tract formation in malleolar fractures fixed with polyglycolide rods, ranging from 5.9% to 8.1%. There is an undefined prevalence of inflammatory reaction without sinus formation to the polyester implants.

The purpose of this prospective study was to assess the efficacy and the complication rate of internal fixation of medial malleolar fractures with bioabsorbable polyglycolide screws. A specific goal was to define more precisely the prevalence of reactive soft tissue inflammation.

MATERIALS AND METHODS
Between October 1994 and March 1995, 21 consecutive adult patients with closed medial malleolar, bimalleolar, or trimalleolar ankle fractures were entered in this study. Polyglycolide screws are approved for use for internal fixation of medial malleolar fractures by the United States Food and Drug Administration, and the study protocol was approved by the institutional review board at Parkland Memorial Hospital, Dallas, Texas. The original protocol allowed for enrollment of 40 patients. On reviewing the preliminary results of the first half of the series, the enrollment was closed early because of the prevalence of soft tissue inflammation. Patients with a nondisplaced fracture, an open fracture, a large soft tissue injury, a small medial malleolar fragment that was not amenable to internal fixation of fractures, most of which have been performed in Europe. Several different polyesters with different rates of hydrolysis and resorption have been investigated, including polyglycolide, polylactide, and copolymers of polyglycolide and polylactide in various ratios. Each of these polymers has a different rate of degradation related to its chemical composition. The compounds are drawn and molded into rods and screws for stabilization of fractures. The European experience has demonstrated a variable prevalence of sterile sinus tract formation in malleolar fractures fixed with polyglycolide rods, ranging from 5.9% to 8.1%. There is an undefined prevalence of inflammatory reaction without sinus formation to the polyester implants.

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Open reduction and internal fixation of the ankle was performed as soon as the patient was stabilized from any associated injuries and as soon as soft tissue edema allowed. Severe swelling about the ankle man-
dated admission and elevation of the extremity for seven patients before surgery. Lateral fractures were approached through a standard lateral incision, and internal fixation was performed using one-third tubular plates and 3.5-mm cortical and cancellous screws inserted with standard AO technique.\textsuperscript{9,10} The medial fracture was exposed through a hockey-stick or straight medial incision. The medial malleolar fragment was then reduced, and either one or two polyglycolide 4.5-mm screws, depending on the size of the fragment, were placed for stabilization.

The polyglycolide screws (Biofix; Bioscience Ltd., Tampere, Finland) were fully threaded with an enlarged rectangular head over which a torque-limiting screwdriver fits for insertion. A 3.5-mm drill bit was first used to create the drill hole. The hole was then tapped its entire length with a 4.5-mm tap. The proximal fragment was not overdrilled, and the fully threaded screw inserted in this fashion does not apply interfragment compression. The prominent portion of the screw head was then removed using an electrocautery loop which cuts the polyester by melting it.

Postoperatively, all patients were managed non-weightbearing for a period of 6 weeks. Immobilization was achieved with a plaster splint or brace at the discretion of the surgeon. Patients were instructed to advance their weightbearing at 6 weeks.

Clinical, radiographic, and subjective follow-up was scheduled at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year. One patient with a medial malleolar fracture and an ipsilateral acetabular fracture died 2 days after surgery from a saddle pulmonary embolus despite deep venous thrombosis prophylaxis. Four patients were lost to follow-up before fracture healing. The remaining 16 patients returned for follow-up at a mean of 12 months (range, 8–16 months).

RESULTS

Of the 16 patients returning for follow-up, there were 8 men and 8 women. Eight left ankles and eight right ankles were fractured. The average age of the patients was 37 years (range, 19–61 years). There were four medial malleolar fractures, 10 bimalleolar fractures, and 2 trimalleolar fractures. All fractures demonstrated lateral displacement of the talus with a mean of 4 mm (range, 2–15 mm).

Two polyglycolide screws were placed in each of 14 fractures, while one screw was placed in each of the remaining two fractures. All screws were between 40 mm and 60 mm long. Two intraoperative screw fractures occurred. One was easily retrieved and replaced with a second screw. The other occurred after complete insertion of the screw and was left in place. A second screw was placed intact in this patient, and the fracture healed without sequelae.

Union and Functional Results

Fractures were considered healed when the fracture line was radiographically obliterated. All medial malleolar fractures healed with an average time to union of 3.4 months (Figs. 1 and 2). Three patients had a postoperative reduction judged to be 1 mm displaced. Two postoperative reductions were 2 mm displaced. The
remaining fractures were judged to be anatomically reduced. All fractures healed without loss of the initial operative reduction.

At most recent follow-up, three patients complained of mild pain with activities. No patients had pain judged to be moderate or severe. The average range of motion was 10° of dorsiflexion (range, 5° to 25°) and 40° of plantarflexion (range, 25° to 60°).

Complications

One patient with insulin-dependent diabetes and a bimalleolar fracture developed an infection of the lateral wound, which necessitated multiple procedures for irrigation and debridement and soft tissue coverage. The medial fracture healed without complication at 4 months after surgery.

Eight of the 16 patients developed an inflammatory reaction of the medial wound at 3 to 4 months after surgery. This reaction was characterized by erythema and edema, with a boggy, cystic fluid collection at the base of the wound. There was mild tenderness, and all eight patients complained of constant, dull pain on the medial side of the ankle. One of these patients developed a sterile sinus tract productive of hydrolyzed polyglycolide at 4 months after surgery. At the latest follow-up, the sinus closed without further treatment, the fracture healed, and mild residual edema with minimal erythema was present. No adverse affect was seen on fracture healing in these patients. The inflammatory reactions and the medial ankle pain resolved during the subsequent 6 to 12 weeks.

DISCUSSION

Bioabsorbable implants for the internal fixation of fractures offer several advantages over conventional fixation with metallic implants. First, because the implant is hydrolyzed and absorbed, there should be a reduced prevalence of soft tissue irritation from prominent hardware, requiring removal of the implant. Second, there is a gradual stress transfer to bone. This allows complete remodeling and healing without stress shielding. However, one major disadvantage unique to biodegradable implants has been encountered. Soft tissue inflammation and sinus tract formation, in response to the hydrolyzed product of some polyesters, have been reported in 6% to 8% of patients in the literature.

Histologic examinations of degrading polyglycolide have shown that they incite a nonspecific foreign body reaction. Cytologic studies demonstrate that polyglycolide is an immunologically inert compound that induces a monocytic migration and adhesion and a nonspecific lymphocyte activation. Breakdown of the polyglycolide is primarily by hydrolytic scission of the polymer into glycolic acid monomers that are converted to glycine. Subsequently, they are converted to acetyl-CoA and enter the Krebs cycle, where they are eliminated as carbon dioxide and water through respiration. Excretion in the urine plays a minor role.

The majority of clinical investigations in this field have been performed in Scandinavia using cylindrical
rods made of various polyesters and measuring 3.2 mm to 4.5 mm in diameter. Both polyglycolide and polylactide, as well as copolymers of the two compounds, have been tested. These studies have uniformly shown a high rate of union, with a variable rate of late spontaneous drainage of the polyester. In this country, there has been clinical success with the internal fixation of ankle fractures using a bioabsorbable screw composed of polylactide. There were no cases of late spontaneous drainage of hydrolyzed polylactide. However, the use of polyglycolide implants in Europe has revealed a variable prevalence of sterile sinus tract formation from the drainage of the hydrolyzed polyglycolide. Ankle fractures internally fixed with polyglycolide rods demonstrated a 6% to 8% prevalence of sterile sinus tract formation. There has been an undefined rate of reactive soft tissue inflammation without sinus formation.

Several factors appear to contribute to the incidence of late inflammation and sinus tract formation. First, the polymer composition affects the rate of degradation. Polyglycolide is a hydrophilic polyester that degrades more rapidly than polylactide, a hydrophobic polyester. It is thought that polyglycolide hydrolyzes over 6 months; polylactide requires 3 years or more for resorption when implanted in bone. Second, the surface area of the implant and load of polymer inserted affect the rate of reabsorption. Third, implants placed in soft tissue tend to resorb faster than those placed in bone. Finally, the anatomic site of implantation affects the development of sinus formation. Implants placed in the distal radius and scaphoid have the highest prevalence of reaction (25%) and ankle fractures the lowest (5–8%).

In the present study, the large prevalence of soft tissue inflammation developing at around 3 months after surgery necessitated the early closure of enrollment. Although the subsequent numbers in this study were small, 50% of the patients returning for follow-up developed a reactive inflammation to the degraded screws. All medial malleolar fractures healed without delay, as has been our previous experience with other bioabsorbable implants.

The lack of a concurrent control group of fractures internally fixed with metal screws is a weakness of this study. In a previous prospective study performed at our institution, however, a group of patients with comparable fractures treated with standard stainless steel cancellous screws showed no local inflammatory reactions. Our surgical technique and postoperative regimen have not changed in the interim between these two investigations.

We conclude from this study that polyglycolide screw fixation of medial malleolar fractures affords stable fixation without hindrance to fracture healing. However, an unacceptable prevalence of delayed inflammation of the soft tissues is seen in response to the degraded polyglycolide. Therefore, we do not recommend ankle fracture fixation with polyglycolide screws.

REFERENCES