FOOT & ANKLE INTERNATIONAL

Intraosseous Bioabsorbable Poly-L-Lactic Acid Screw Presenting as a Late Foreign-Body Reaction: A Case Report

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ABSTRACT

A 17-year-old woman complained of a localized painful swelling in her foot 30 months after internal fixation of a closed tarsometatarsal joint fracture with interfragmentary poly-L-lactic acid screws. Aspiration revealed a sterile abcess. Radiographs displayed an osteolytic lesion corresponding to a screw track in the first tarsometarsal joint. Formation of a draining sinus tract required surgical excision of a small granulomatous lesion. Histologic analysis found deposits of birefringent polymeric particles surrounded by a nonspecific foreign-body type reaction. This represents the first reported case of a draining sinus tract secondary to the use of polylactic acid screw fixation.

INTRODUCTION

Most investigations studying the use of polyesters as bioabsorbable fracture fixation have concerned polyglycolide implants.[4,7,9,12,13,16] The use of polyglycolide screws in the treatment of ankle fractures have demonstrated a high rate of union with no apparent adverse effect on fracture healing with the benefit of obviating the need for hardware removal at a later date. However, local inflammatory and osteolytic foreign-body reactions to polyglycolic acid implants have been well documented in the literature, occurring in 5 to 11 % of patients.[4,5,8,9,16] This usually presents as a late draining sinus secondary to sterile abcess formation. Rapid degradation of the polyglycolic acid polymer causes these adverse reactions to occur within two to four months after implantation, when the disintegration of the polymer has reached its final phase.[7,22]

Another synthetic biodegradable polymer used in fracture fixation implants is polylactic acid. In contrast to polyglycolic acid, the degradation time of polylactic acid is several years.[17,18] The use of polylactic acid implants has been rarely associated with local swelling or an inflammatory reaction.[2,13,14,15,17,18,20,21] Previously in the literature there had been no reports of development of a draining sinus or sterile abcess formation related to their use. Recently, a late foreign-body reaction of an intraosseous bioabsorbable polylactic acid screw was reported 52 months after implantation for an ankle fracture.[19] Histological examination revealed polymeric debris surrounded by a foreign-body type reaction.

We report the case of a patient in whom a late local inflammatory reponse, associated with a draining sinus tract, occurred to a polylactic acid screw over two years after the initial fixation of a tarsometatarsal joint fracture.

CASE REPORT

A seventeen year old female sustained a closed, tarsometatarsal joint fracture / dislocation of the left foot after falling off a teeter-totter in July, 1996. Two weeks after the initial injury she was treated with open reduction and internal fixation of the first through fourth tarsometatarsal joints with four absorbable 3.5 mm polylactic acid screws (Biofix, Tampere, Finland) at another institution. (Fig. 1) She remained nonweightbearing in a short leg cast with crutches for 10 weeks and then was allowed to weight bear as tolerated. She was ambulating pain free at six months and had returned to regular activities including sports at one year postoperatively.

Two years and 6 months after the initial surgery, she returned to a local orthopaedic surgeon with complaints of a painful cyst on the dorsomedial midfoot which had been present for several months. The mass was thought to be a ganglion cyst and was aspirated on two

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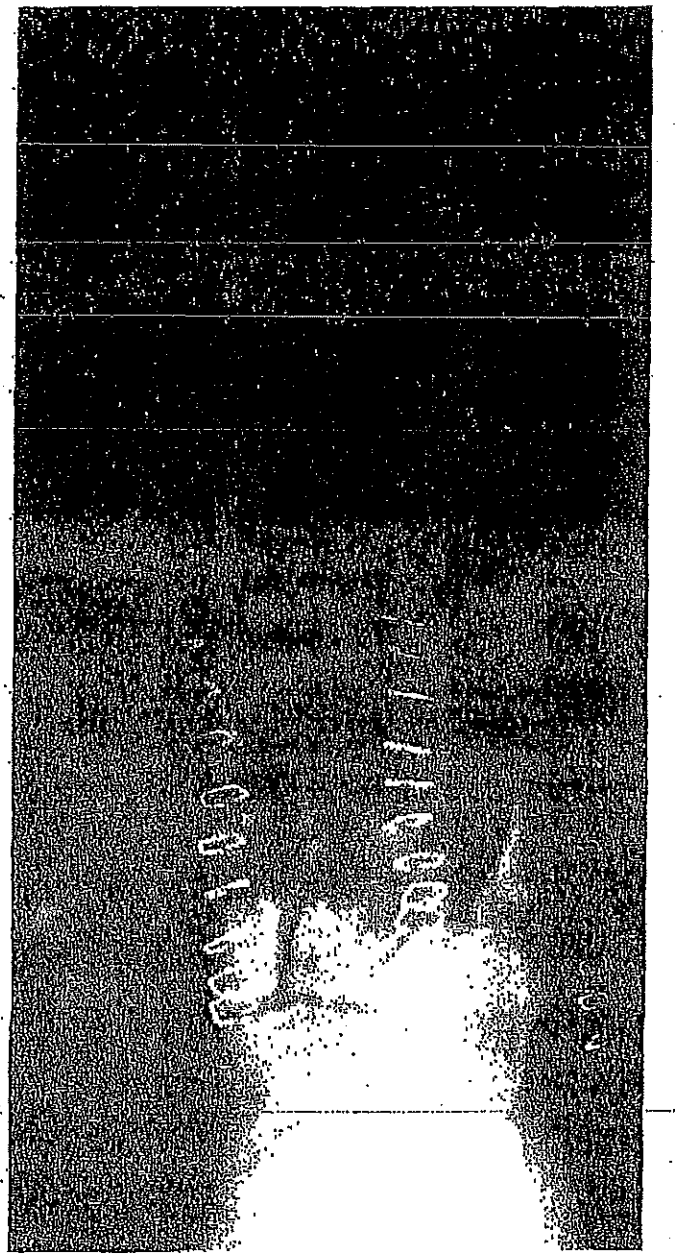

Fig. 1. Postoperative anteroposterior radiograph of the left foot. The closed tarsometatarsal joint fracture dislocation was treated with interfragmentary screw fixation with poly-L-lactic acid screws.

occasions. However, after each aspiration the mass returned. On presentation to our clinic, physical examination revealed a small 1 cm by 1 cm, mildy erthythematous soft tissue mass over the middle dorsal incision at the level of the second and third tarsometarsal joints. There was a punctate, nondraining hole over the center of the mass. This was aspirated under sterile conditions and yielded 1 cc of purulent looking fluid. She was placed on a two week course of oral antibiotics for a subcutaneous abcess after aspiration of a ganglion cyst. Aerobic and anaerobic cultures from the aspiration revealed no microorganisms. Radiographs taken at that time showed anatomic reduction of the lisfranc joints with no signs of post-traumatic arthritis. During the two weeks interim the mass began to drain a clear fluid with no surrounding erythema or obvious infection. The mass continued to drain for another two weeks despite another course of oral antibiotics. Further inspection of the radiographs revealed an osteolytic lesion corresponding to the screw track in the first tarsometatarsal joint (Fig. 2). At that time a sterile abcess secondary to her previous absorbable screw fixation was suspected.

She was taken to the operating room for an excisional biopsy of the subcutaneous mass of the left foot under local anesthesia. A granular fibrous nodule approximately 5 by 4 mm in diameter was found in the subcutaneous tissue and was sent to pathology. On division of the mass, no obvious foreign body or rem-

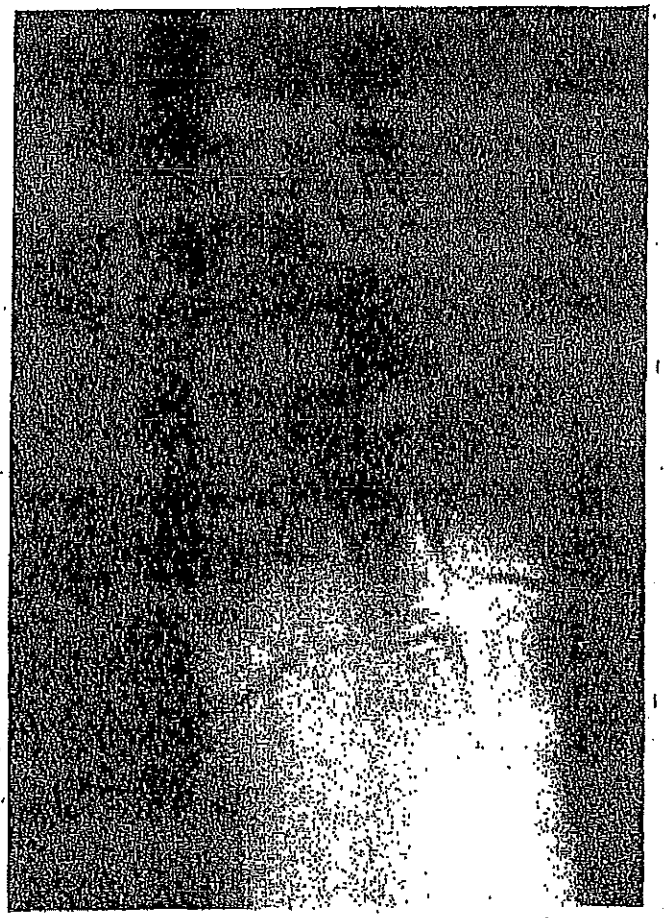

Fig. 2. Anteroposterior weightbearing radiograph of the left foot 30 months postoperatively. An osteolytic lesion (arrows) remains at the site of the polylactic acid screw tract across the first tarsometatarsal joint.

nant of the absorbable screw was seen. Further inspection of the local soft tissues revealed no other masses or sinus tracts to bone or joints. The wound was irrigated and closed with interrupted nylon sutures. Two weeks postoperatively, the wound had completely healed with no return of the subcutaneous mass and the patient was allowed to be full weight-bearing as tolerated to the foot. At six weeks postoperatively, the patient had returned to full activities without pain or recurrence.

Histological examination of the soft tissue mass was performed using a hematoxilyn and eosin stain under polarized and standard light microscopy. The mass revealed polarizable foreign material with a surrounding foreign-body type granulomatous inflammation (Fig. 3).

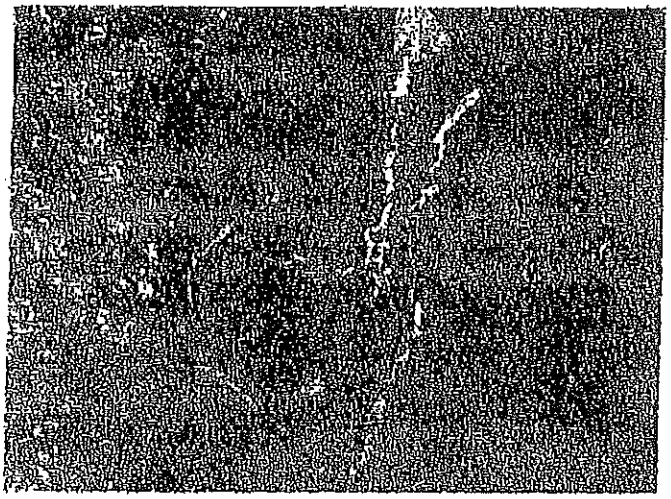

Fig. 3. Histologic appearance of the late foreign-body granulomatous reaction using hemotoxilyn and eosin stain viewed at 100x. Large deposits of translucent refractile material are seen in the extracellular compartment (asterisk). Numerous smaller polymeric particles are located within histiocytes (arrow) and multinucleated giant cells.

There were numerous translucent homogeneous deposits that were birefringent under polarized light located in the extracellular compartment. Numerous smaller polymeric particles were located within histiocytes and foreign-body type giant cells.

At final follow-up one year after surgical excision of the soft tissue mass, there has been no recurrence of either the mass or a draining sinus tract. There was no residual pain at the site of excision and the osteolytic lesion in the first tarsometatarsal joint was unchanged in appearance.

DISCUSSION

Polylactic acid is produced by anionic ring-opening polymerization of the cyclic diester lactide under influence of a catalyst.[1] Polylactic acid is a pale polymer with different stereoisomeric compound forms, depending on the L- and D- configuration of the lactic moieties forming the polymer molecules. It biodegrades mainly by hydrolytic scission of the ester bonds in the polymer chain, and to a lesser extent, through a non-specific enzymatic action.[3] The resulting lactic acid monomer can then be oxidized to pyruvic acid by lactate dehydrogenase.[1,3] Decarboxylation of pyruvate then yields acetyl-CoA which enters the tricarboxcylic acid cycle for further degradation to carbon dioxide and water.

In the early stage of the bioresorption, the depolymerization results in a decrease in the molecular weight of the polymer but no change is seen in the appearance of the implant and no cellular response is elicited.[1] Reduction of the molecular weight also corresponds to a decrease in the mechanical strength of the implant.[3,18,20] Further reduction of the molecular weight causes is associated with disintegration of the polymer into small particles. It is these small particles that incite the nonspecific inflammatory or foreign-body reaction.[1] The small particles become surrounded by macrophages forming giant cells which ingest the polymer debris, and leukocytes. When the polymer bioresorption is complete, the inflammatory cells disappear, leaving scar tissue.

The rate of bioresorption is dependent on the molecular weight, crystallinity, thermal history, and geometry of the implant.[1,3] In general, the larger implants degrade more slowly than smaller implants, and copolymers faster than homopolymers. Rate of bioresorption is also site-dependent, occuring more rapidly in soft tissues than in bone.[1,3] A bioresorption time of several years is needed for polylactic acid implants, depending on the chemical structure and size of the implant.[17,18] The exact rate of degradation of poly-L-lactic acid implants has not been determined. In an experimental study, poly-L-lactic acid rods implanted in the medullary cavity of rabbit femora to evaluate their degradation process.[17] After 18 months, histiocytes were found, and their phagocytic activity continued for up to 42 months, with the maximum activity observed between 24 and 36 months. Complete resorption took 62 months and implants were replaced by bone marrow cells, with only a small amount of residual tissue reaction. In addition, poly-L-lactic acid plates were shown to be present as long as 5.7 years after internal fixation of a zygomatic fracture.[2]

The unique complication of these bioabsorbable implants is the delayed inflammatory reaction that occurs during degradation.[2,10,14,17,18,21] This usually presents with the use of polyglycolide implants after the immediate postoperative period when the patient has experienced no initial problems with the wound healing. This is followed by a tender, erythematous, fluctuant

swelling over the healed incision, and may or may not be associated with the appearance of an osteolytic lesion within the bone at the site of the implant.[4,10,13,19] The mean interval between fixation of the fracture and the clinical manifestation of the inflammatory response is twelve weeks for the glycolic acid implants.[1,3,5,6] A draining sinus from the sterile abcess or liquid remant of the polyglycolide often forms as well.[9] Draining sinus formation may occur as frequently as 5-11% with the use of bioabsorbable implants in the ankle, yet it does not usually interfere with the short-term recovery or long-term functional results of treatment.[1,3] The occurrence of the reaction does not seem to be influenced by the volume of the implanted polymer or by location.[1,3,5,6]

Though the use of glycolic acid implants has been routinely associated with the occurrence of sterile abcesses and draining sinus tracts, the majority of reports on the use of polylactic acid implants have not. Rarely has local swelling consistent with an early postoperative inflammatory response been reported associated with the use of poly-L-lactic acid implants for fracture fixation.[2,13,14,15,17,18,21] Bucholz et al. evaluated the use of poly-L-lactic acid screws for the use of internal fixation of medial malleolar ankle fractures.[13] One patient out of eighty-three (1%) developed a sterile nondraining abcess at the site of the absorbable implant. Bergsman et al. found painless intermittent local swelling with the use of poly-L-lactic acid plates for internal fixation of zygomatic fractures.[2] Yoshino et al. discovered delayed aseptic swelling after the use of a poly-L-lactic acid rod for fixation of a talar neck fracture.[21] Eitenmuller et al. reported the same type of response with the use of poly-L-lactic acid plates for the fixation of lateral malleolar ankle fractures.[14] Close to 50% of patients experienced a delayed inflammatory reaction, as late as three years postoperatively. They also noted that with a decrease in the size of the plates, they were able to eliminate the clinical manifestation of the inflammatory reaction.[15] These focal areas of inflammation tend to resolve over several weeks with no specific treatment, and all occurred within 2 years of operation.

There has only been one report in the literature to date of a late foreign body reaction to an intraosseous bioabsorbable poly-L-lactic acid screw.[10] This occurred 52 months after internal fixation of a lateral malleolar ankle fracture with the development of a painful sterile abcess. Its location corresponded to an osteolytic lesion in the distal fibula at the site of the poly-L-lactic acid screw tract. Though no draining sinus tract formed, persistence of the local inflammatory response resulted in its surgical excision. A small granulatomous lesion was found at the entrance to the screw track in the fibula. Histologic examination revealed polymeric particles that were birefringent under polarized light with a surrounding non-specific foreign-body reaction. Surgical excision resulted in resolution of the lesion without recurrence but residual tenderness remained over the lateral malleolus.

To our knowledge, this is the second report of a late foreign body reaction or sterile abcess formation to a poly-L-lactic acid screw after internal fracture fixation. It is also the first report of a late foreign body reaction with development of a draining sinus tract to a poly-L-lactic acid screw. These findings support the fact that sterile abcesses and draining sinus tracts can also occur secondary to the use of poly-L-lactic acid screws despite their longer bioresorption times. This may happen more frequently once longer follow-up studies are performed with the clinical use of these bioabsorbable implants for fracture fixation. This is particularly important in light of the fact that the clinical use of poly-L-lactic acid implants are increasing and expanding into new applications.

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