

Osteoarthritis of the ankle after foreign-body reaction to absorbable pins and screws

A THREE- TO NINE-YEAR FOLLOW-UP STUDY

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Between 1985 and 1994, 1223 patients with malleolar fractures of the ankle were treated by open reduction and internal fixation with absorbable pins and screws, of whom 74 (6.1%) had an obvious inflammatory foreign-body reaction to the implants. Of these 74, ten later developed moderate to severe osteoarthritis of the ankle despite no evidence of incongruity of the articular surface. The implants used in these patients were made from polyglycolide, polylactide or glycolide-lactide copolymer.

The joint damage seemed to be due to polymeric debris entering the articular cavity through an osteolytic extension of an implant track. The ten patients had a long clinical course which included a vigorous local foreign-body reaction, synovial irritation and subsequent degeneration. At a follow-up of three to nine years, ankle arthrodesis had been necessary in two patients and is being considered for another two.

The incidence of these changes in the whole series was 0.8%, which is not high, but awareness of this possible late complication is essential.

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Soon after the large-scale introduction of absorbable implants for the internal fixation of fractures in the late 1980s, it was found that they were occasionally associated with an inflammatory foreign-body reaction at the site of implantation.¹⁻⁷ The characteristic features were osteolysis in cancellous bone seen around the implant and sterile skin sinuses discharging remnants of the fixation devices.⁸⁻¹² In the short term, this complication was regarded as benign and transient, occurring after union of the fracture, and not resulting in permanent tissue changes.^{1,8}

With greater experience of absorbable implants it is necessary to change that view. We report ten patients with foreign-body reactions to implants for internal fixation made from synthetic biodegradable α -hydroxypolyesters, who developed irreversible damage to the ankle.

Patients and Methods

From January 1985 to June 1994 we used absorbable pins and screws for the internal fixation of displaced malleolar fractures in 1223 patients (Table I). All the implants were produced by the same manufacturer (Bioscience, Tampere, Finland). During the first year, they were made from glycolide-lactide copolymer (PGA-PLA) in a ratio of 90:10. Later, pure polyglycolide (PGA) replaced the copolymer, and from 1989 they were made also from pure poly-L-lactide (PLA). The degradation time of PGA is a few months, whereas that of PLA in stereo-isomeric laevo form is several years. The two types of material were sometimes used together in the treatment of one injury (Table I). An example of this is a patient with a trimalleolar fracture: the malleoli were fixed with PLA screws, and the distal tibio-fibular syndesmosis was stabilised with a PGA pin.

All the implants were inserted into extra-articular pre-drilled channels of the same diameter, and the drill-holes for screws were tapped. The drill-holes were made in the usual places recommended for metal internal fixation¹³ and cast immobilisation was used for six weeks after operation.

There was an obvious foreign-body reaction in 74 of the 1223 patients (6.1%), first seen as a painful erythematous

Table I. Distribution of fracture types operated on and implant materials used in 1223 patients

	Number of patients	Percentage
Fracture type		
Unimalleolar	598	48.9
Bimalleolar	344	28.1
Trimalleolar	281	23.0
Implant material		
Polyglycolide (PGA)	941	76.9
Polylactide (PLA)	149	12.2
PGA and PLA in the same patient	85	7.0
Glycolide-lactide copolymer (PGA-PLA)	48	3.9

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Fig. 1a



Fig. 1b



Fig. 1c



Fig. 1d



Fig. 1e

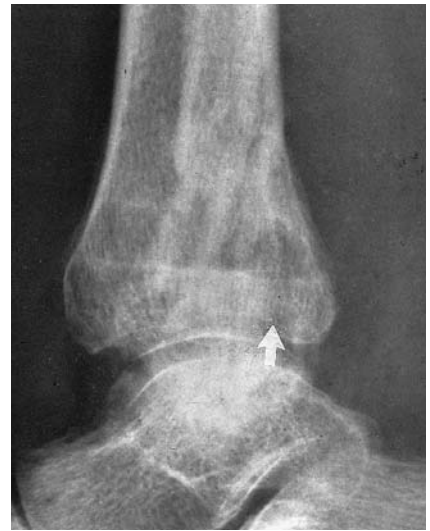


Fig. 1f



Fig. 1g



Fig. 1h

Case 2. Anteroposterior and lateral radiographs of the ankle of a 52-year-old woman with a displaced trimalleolar fracture. Figures 1a and 1b – Before operation. Figures 1c and 1d – After open reduction and internal fixation with PGA screws of 3.2 mm core diameter. The reduction of the fragments is accurate. Figures 1e and 1f – Thirteen weeks after operation, there is considerable osteolysis around the implant tracks with suspected direct communication between the osteolytic screw track in the medial malleolus and the joint cavity on the anteroposterior film (arrow) and between an extension of the screw track of the posterior triangle of the tibia and the ankle on the lateral film (arrow). The fracture fragments have united. Figures 1g and 1h – Three years later, the bony architecture of the osteolytic areas has been restored, but moderate osteoarthritis has developed.



Fig. 2a



Fig. 2b

Case 3. Figure 2a – Extensive sloughing over the lateral malleolus in a 35-year-old man with a severe foreign-body reaction to a PGA pin, 4.5 × 70 mm, three months after fixation of a fracture of the lateral malleolus. Figure 2b – Radiograph seven months after fixation of the fracture showing osteolysis around the implant track (asterisks), incomplete consolidation of the fracture and joint-space narrowing. The osteolytic implant track may communicate with the ankle through the ununited fracture.

papule or a discharging sinus at a median time of 11 weeks (7 to 18) after operation. Treatment was by aspiration of subcutaneous accumulations of tissue exudate and excision or debridement of discharging sinuses. In most cases, this resulted in the disappearance of the reaction within five weeks. During later years, however, some patients developed more prolonged symptoms with sterile synovitis and increasing pain.

We have studied ten such patients with joint involvement after a foreign-body reaction. At the latest assessment the mean follow-up was 49.6 months (36 to 109). We excluded patients with incongruity of the articular surface due to an inaccurate reduction or late mechanical failure of the fixation. To set this finding in context, we scrutinised the records of all the 1213 remaining patients for late referrals or visits. Because of the experimental nature of this method of treatment, which was known to doctors in the catchment area, patients with complications were usually referred to us without delay.

Moderate osteoarthritis was diagnosed when there was pain, limited ankle movement and joint-space narrowing on plain radiographs to 50% or more of the original values.¹⁴ When there was subtotal disappearance of the joint space, severe osteoarthritis was diagnosed.¹⁵

Continuous data were analysed by the Mann-Whitney U test and categorical data by the chi-squared test or Fisher's exact test.

Results

Clinical. In the ten patients, the delay between the operation and the first signs of a foreign-body reaction (Table II) did not differ from that in the other 64 patients having a

foreign-body reaction. All ten had developed a sinus discharging tissue exudate and polymeric debris within a few days. In seven of them, this was on both the lateral and the medial sides of the ankle. Bacterial cultures from the exudate showed no growth.

The first clinical signs of synovitis in the ankle appeared during the following weeks, but aspiration was avoided because of the danger of spreading secondary infection from open sinuses into the joint. By the time synovitis was evident, nine of the ten patients had union of their fractures (Fig. 1). Three patients required inpatient care for acute inflammatory reaction and two had debridement under general anaesthesia. One patient (case 3) required a skin graft for extensive sloughing over the lateral malleolus (Fig. 2). Biopsy specimens taken from the soft tissues at debridement operations showed changes typical of a non-specific foreign-body reaction, with abundant polymeric particles phagocytosed by multinucleated foreign-body giant cells.

In all ten patients, the acute reaction had subsided after four months, and was replaced by clinical and radiological signs of osteoarthritis (Figs 1 and 3). The median delay between injury and the diagnosis of osteoarthritis was 11 months (7 to 15). To date, two patients have had ankle arthrodeses (Table II), and this is being considered for two others.

Radiology. Plain radiographs at the onset of the tissue reaction showed osteolytic changes with cystic extensions of the implant tracks in all ten patients (Fig. 1). The fracture was ununited in only one patient (Fig. 2). Communication between one or several of the enlarged, extra-articular implant tracks and the ankle seems likely (Figs 1 and 2). The osteolysis regressed during a three-year period



Fig. 3a



Fig. 3b

Case 4. Figure 3a – Radiograph of the ankle of a 43-year-old woman with a bimalleolar fracture on admission. The displacement between the fragments is moderate. Figure 3b – Despite accurate reduction and union, severe osteoarthrosis developed within three years after a foreign-body reaction to the PGA screws. An ankle arthrodesis was eventually required.

(Fig. 1), but the osteoarthritic changes increased (Figs 1 and 3).

Statistics. The incidence of joint involvement, ten of 1223 patients, was 0.8% (95% confidence interval (CI) 0.3 to 1.5%). In the 74 patients with obvious foreign-body reactions the incidence was 13.5% (95% CI 6.7 to 24.5%). We found no statistically significant differences in the mean age or male-to-female ratio between the whole population with ankle fractures and absorbable implants and those developing articular damage, but patients with bi- or trimalleolar fractures were significantly over-represented in the osteoarthritic group ($p = 0.03$). A total of 1108 patients had an accurate reduction and no obvious foreign-body reaction, and none of them has required ankle arthrodesis. Two of the 74 patients with a foreign-body reaction have already needed this; the difference is highly significant ($p = 0.004$).

Discussion

Concerns have already been expressed about the biocompatibility of these absorbable implants^{3,5-7,10,16,17} despite the lack of long-term clinical data on large series. We found that the use of absorbable α -hydroxypolyester pins and screws for the internal fixation of displaced malleolar fractures led to an incidence of osteoarthritic changes in the ankle of approximately 1%, probably initiated by foreign-body reactions. This incidence is quite low, but the complication is a severe one, and thousands of patients are treated for these common types of fracture. After conventional metal internal fixation, the development of osteoarthritis is associated with inaccurate reduction and subsequent malunion,^{18,19} but we excluded such cases. We saw no severe osteoarthritis in patients treated with absorbable implants and accurate

Table II. Details of ten patients with articular damage after an osteolytic foreign-body reaction to absorbable fixation devices

Case	Age (yr)	Gender	Fracture	Implant material*	Time from operation to reaction (wk)	Follow-up time (mth)	State at latest follow-up
1	25	M	Bimalleolar	PGA-PLA	10	109	Moderate osteoarthritis
2	52	F	Trimalleolar	PGA	13	43	Moderate osteoarthritis
3	35	M	Unimalleolar	PGA	9	36	Moderate osteoarthritis
4	43	F	Bimalleolar	PGA	11	53	Ankle arthrodesis
5	31	F	Bimalleolar	PGA	11	42	Severe osteoarthritis
6	42	M	Bimalleolar	PGA and PLA	12	63	Ankle arthrodesis
7	54	M	Bimalleolar	PGA	10	37	Moderate osteoarthritis
8	54	F	Bimalleolar	PGA	13	39	Moderate osteoarthritis
9	45	M	Trimalleolar	PGA	10	38	Severe osteoarthritis
10	38	F	Trimalleolar	PGA	14	36	Moderate osteoarthritis

* see Table I

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