OSTEOLYTIC CHANGES ACCOMPANYING DEGRADATION OF ABSORBABLE FRACTURE FIXATION IMPLANTS

O. M. BÖSTMAN

From Helsinki University Central Hospital

We analysed the radiographs of 67 patients with displaced malleolar fractures treated by open reduction and internal fixation using absorbable polyglycolide rods. Seventeen patients developed a discharging inflammatory foreign-body reaction, a complication unique to these fixation devices.

In 34 patients ovoid osteolytic foci, usually 5 to 10 mm in diameter, appeared within the implant channels six to 12 weeks after the operation. The same lesion occurred in 14 of the 17 patients who developed a foreign-body reaction, whereas only 20 out of the 50 patients with an uneventful course showed osteolytic areas (p < 0.01). In patients with a foreign-body reaction the osteolytic foci tended to occur in the deepest parts of the implant channels. However, after one year the normal structure of the bone was restored.

Absorbable fracture fixation devices made of synthetic biodegradable polymers are a useful alternative method of internal fixation in certain fractures, although still in the development stage (Rokkanen et al 1985; Böstman et al 1987; Hirvensalo 1989; Jahn, Diederichs and Friedrich 1989; Leinxner, Moser and Poigenfurst 1989; Partio et al 1990). The histological appearance of the degradation and absorption of absorbable implants is well-known from experimental studies (Cutright and Hunsuck 1972; Vert et al 1984; Greve and Holste 1985; Hollinger and Battistone 1986; Vainionpää et al 1986; Böstman et al 1990b). However, preliminary evidence exists for certain differences in the tissue response between man and test animals (Böstman et al 1990a).

Inflammatory foreign-body reactions which include a discharging sinus without infection, have been encountered in nearly all clinical studies published on the use of absorbable fracture fixation implants made from polyglycolide or lactide-glycolide copolymer (Böstman et al 1987; Hirvensalo 1989; Hoffmann et al 1989; Partio et al 1990), yet no similar reaction has been reported in animal experiments. In patients a systematic histopathological survey of the tissue response is, of course, not possible. We sought indirect information of the absorption process through scrutiny of the radiographic changes accompanying degradation of the implant in ankle fractures, and related this to the clinical results.

PATIENTS AND METHODS

From 1985 to 1987, a total of 282 patients with displaced fractures of the lateral malleolus or bimalleolar fractures were treated by open reduction and internal fixation using polyglycolide rods. We studied two groups. The first comprised 50 consecutive patients with an uneventful course from the beginning of the investigation period. The second group consisted of 17 (6%) whose clinical course was complicated by a local inflammatory, non-bacterial reaction.

The implants used were cylindrical rods made of polyglycolide, 3.2 or 4.5 mm in diameter and 50 or 70 mm in length, in accordance with the size of the malleolar fragment to be fixed. At operation a channel was drilled across the reduced fracture in the cancellous bone and a rod of the same diameter was tapped into the channel (Fig. 1). The medial cortex of the distal fibular shaft was...
perforated accidentally on occasions when drilling the implant channel. Sometimes, this was only observed on subsequent radiographs.

Seventeen patients presented two to four months after operation with sudden painful swelling at the ankle; this discharged spontaneously through the skin, releasing sterile liquid with remnants of the degrading implant. The discharge continued for an average of four weeks. Microscopic examination of biopsy specimens from these patients revealed the histological picture of a nonspecific foreign-body reaction (Böstman et al 1990a).

Of the 50 patients with an uneventful course, 35 had a solitary fracture of the lateral malleolus and 15 had bimalleolar fractures. The mean age was 38.6 years. Of the 17 patients with a foreign-body reaction, 10 had a fracture of the lateral malleolus only, and seven had bimalleolar fractures. The mean age was 40.2 years. Of the seven patients with bimalleolar fractures five had discharging sinuses on both sides of the ankle and two on the lateral side only.

Standard anteroposterior, lateral and mortise view radiographs were obtained on admission and were repeated immediately after operation, at three weeks, six weeks, three months, six months, and after one year. The absorbable rods themselves are radiolucent but the outlines of the drilled implant channels were discernible up to six months (Fig. 2). The radiographs were examined for any abnormalities of the structure of the bone within and around the implant channels. The ankle region was divided into proximal, intermediate and distal zones in
Osteolytic Changes Accompanying Degradation of Absorbable Fracture Fixation Implants

The radiographs of 34 of the 67 patients showed ovoid osteolytic areas in the implant channels (Fig. 2). The diameter of these lesions varied from 5 to 10 mm but in the proximal parts of lateral malleolar implant channels the osteolytic areas were as much as 25 mm long, usually showing some cortical erosion (Fig. 3). No sclerotic zones were seen to surround the lesions.

Osteolytic foci were not seen earlier than six weeks after fixation, but in the majority (29 of 34 patients) they first appeared on the radiographs at three months. At six months the dimensions of the osteolytic lesions had decreased and the foci were more radio-opaque than at three months. After one year the structure of the bone was almost normal (Fig. 4).

The osteolytic areas were more common in patients with a foreign-body reaction (14 of 17) than in patients with an uneventful course, such lesions being present in only 20 of the 50 patients (p < 0.01). In three cases the radiographic appearance of osteolysis preceded the first clinical signs of a foreign-body reaction.

The 34 patients showed a total of 51 osteolytic foci, of which 35 were in the fibula and 16 in the tibia (Table I). In 10 cases there were two foci along the same implant channel (Fig. 4a). There was a significant difference in the location of the lesions between the patients with an uneventful clinical course and those with a foreign-body reaction (p = 0.001); proximal zone lesions were more common in patients with a foreign body-reaction (Table I).

In 12 patients the channel of the lateral malleolus was seen to have perforated the medial cortex of the distal shaft of the fibula. All these patients had an uneventful course, and no osteolytic lesion occurred.

**Table I. Site of osteolytic areas and clinical course**

<table>
<thead>
<tr>
<th>Zone*</th>
<th>Uneventful course</th>
<th>Foreign-body reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal</td>
<td>4</td>
<td>17</td>
</tr>
<tr>
<td>Intermediate</td>
<td>19</td>
<td>6</td>
</tr>
<tr>
<td>Distal</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

* see Figure 1

**DISCUSSION**

The depolymerisation of polyglycolide in tissues takes place mainly by hydrolysis. Rods made of polyglycolide lose one-half of their initial stiffness within two weeks but the physical appearance of the implants is macroscopically maintained for six weeks (Vasenius et al 1989). The time to ultimate degradation and absorption of polyglycolide implants varies from a few months to almost a year depending on the macromolecular structure and the thermal history of the polymer sample (Kopeček and Ulbrich 1983; Hollinger and Battistone 1986). The resultant glycolic acid molecules are metabolised via the citric acid cycle and finally eliminated by respiration.

In experimental animal studies, the local tissue response to implants containing polyglycolide has been shown to consist of an initial polymorphonuclear leukocyte reaction followed after a few weeks by the appearance of macrophages and multinucleated foreign-body giant cells (Vert et al 1984; Howard, McKibbin and Ráliš 1985; Hollinger and Battistone 1986).

In clinical studies a discharging reaction occurred in between 5% and 8% of the patients and commenced approximately 12 weeks after the operation (Böstman et al 1989, 1990b; Hirvensalo 1989; Partio et al 1990). Specimens obtained from patients with a clinical reaction as well as from those without any clinical signs of an inflammatory tissue response, all showed an identical histopathological picture of a nonspecific foreign-body reaction (Böstman et al 1990a). There was no adverse influence of the foreign-body reactions on union of the fractures.

In this study the presence of osteolytic areas seemed to accompany the decomposition of the implants between six and 12 weeks after implantation. There is a statistically significant association between the occurrence of an osteolytic focus and a clinical foreign-body reaction. Furthermore, the occurrence of a foreign-body reaction was clearly associated with an osteolytic lesion in the depths of the implant channel.

A foreign-body reaction of some degree to the implants obviously occurs in all individuals but the intensity varies for no obvious reason. An imbalance between monocyte-macrophage and fibroblast responses has been suggested as a possible explanation of a similar condition, the aggressive granulomatous reactions to the nondegradable polymers used in hip arthroplasty (Santavirta et al 1990).

The appearance of an osteolytic lesion at the end of an implant channel could be interpreted as a sign of increased intra-osseous pressure exerted by the liquid polymeric debris retained within the channel, and ultimately discharging at the orifice of the channel. In accordance with this concept, no osteolytic foci or manifest foreign-body reactions were seen when the implant channel perforated the bone at both ends, which may indicate that such perforation could be beneficial.

In contrast with the aggressive lesions encountered...
with polymethylmethacrylate cement, the osteolytic foci associated with polyglycolide resolved with restoration of normal bone structure. Awareness of the occurrence and behaviour of these lesions is necessary when absorbable fracture fixation implants are used.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

REFERENCES


