Absorbable polyglycolide screws in internal fixation of femoral osteotomies in rabbits

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In 20 rabbits, a transverse distal femoral osteotomy was fixed using a 4.5 by 30-mm absorbable screw made of polyglycolide. No postoperative external support was used. The consolidation of the osteotomy was investigated histologically, morphometrically, and microradiographically in groups of 4 to 6 rabbits that were followed for 3, 6, 12, or 36 weeks. Fourteen osteotomies showed solid bony union; and in 3, several bone trabeculae were seen to bridge a still partially ununited osteotomy. In another 3 rabbits, each with a follow-up time of 12 or 36 weeks, no convincing signs of progressing consolidation could be seen. Only 1 of these rabbits showed displacement of the distal fragment.

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For several years, absorbable pins and small rods made of polyglycolide have been in clinical use as implants for internal fracture fixation (Rokkanen et al. 1985, Böstman et al. 1987, Hirvensalo 1989, Hoffmann et al. 1989). The most common indication for the clinical use of these cylindric implants has been a displaced malleolar fracture. Despite the apparently rather limited control of fracture fragments that is possible with pins and rods, the retention of the position of the fracture fragments in the clinical series hitherto published has been good (Böstman et al. 1989, Frøkjær and Nue Møller 1989, Leixnering et al. 1989, Steinmann et al. 1990).

To extend the field of application of absorbable internal fixation devices, an implant of a more complex design than a simple cylinder is required. In this experimental study on rabbits, a transcondylar osteotomy of the distal femur was fixed with a polyglycolide screw. The aim was to determine the fixation properties of the screw by examining the consolidation of the osteotomy.

Material and methods

Twenty New Zealand rabbits of both sexes with closed epiphyseal lines, weight 3,200 ± 400 g, were anesthetized with subcutaneous injections of medetomidine, ketamine, and diazepam (Mero et al. 1989). A medial, longitudinal parapatellar incision was made in the right knee, the patella was dislocated, and the distal portion of the femur was exposed. A transverse, transcondylar osteotomy was made with a circular saw in the cancellous bone 10 mm proximal to the level of the knee joint (Figure 1). Then, the distal fragment was

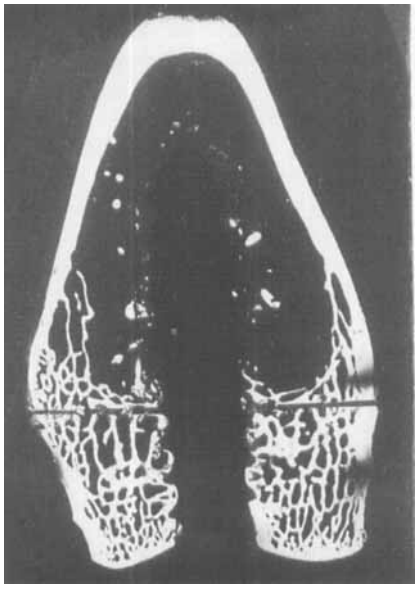

Figure 1. Coronal plane microradiograph of the distal rabbit femur showing the site of the osteotomy and the position of the polyglycolide screw after fixation.

exactly reduced, and a hole, 3.2 mm in diameter and 30–35 mm in depth, was drilled starting from the intercondylar notch of the intraarticular distal femur and passing through the distal fragment and the osteotomy surfaces up towards the diaphysis. The drill hole was tapped, and the osteotomy was fixed with a commercially available (Bioscience Ltd., Tampere, Finland) polyglycolide screw with a buttress thread profile—3.2 mm in core diameter, 4.5 mm in major thread diameter, 1.8 mm in thread pitch, and 30 mm in length (Törmälä et al. 1988). After fixation, the head of the screw was cut off. The incision was closed in layers with polyglycolic acid (Dexon®) sutures. Postoperatively, the rabbits were returned to their cages, were fed ad libitum, and were free to move around. No attempt to splint the extremity was made.

Groups of 4 to 6 rabbits were killed at 3, 6, 12, and 36 weeks. Forty-eight hours before the end of the follow-up time, the rabbits were injected with oxytetracycline (Vendarcin®), 50mg/kg i.m., to mark newly formed bone for tetracycline-labeling studies (Milch et al. 1958).

Both femora were inspected macroscopically, dissected free, and radiographed in anteroposterior and lateral projections. The left distal femur was used as an intact control. The distal third was taken as a specimen and fixed in 70 percent alcohol and embedded in methylmethacrylate (Schenk 1965). For histologic and histomorphometric analysis, 5-µm sections were cut in the coronal plane perpendicular to the osteotomy surface with a microtome and stained using the Masson-Goldner trichrome method. For microradiographic and tetracycline fluorescence studies, 80-µm sections were made. In the microradiography the technical factors were 50 kV, 9 mA, 12 min, and a tube-target distance of 29.5 cm.

Polarizing microscopy was used to identify birefringent polymeric material in the collected specimens. For histomorphometric measurements, a Leitz Diaplan microscope was linked via a television video camera to a semiautomatic imaging analysis system (Kontron MOP Videoplan, Munich, Germany). The microscopic field, overlaid with a graticule, was displayed on a television screen in the computer (Revell 1983).

To indirectly assess the stability of the fixation, the area of the periosteal callus was measured on each section. The degree of consolidation of the osteotomy was quantified by counting the number of the new-bone trabeculae crossing the osteotomy on the microradiographs. The number of longitudinally orientated trabeculae at the corresponding site on the intact control side, averaging 19.2 (15–23), was used as a reference. Solid union was regarded to have taken place if the number of trabeculae bridging the osteotomy amounted to two thirds or more of the trabeculae on the intact contralateral side. Incomplete union was deemed to be present whenever the number of the bridging trabeculae was less. For statistical analysis the Mann-Whitney two-sample rank sum test was used.

Table 1. Absorbable polyglycolide screw fixation of rabbit femoral osteotomy. Mean values (range)

Union	n	Proportion of bridging trabeculae	Area of periosteal callus (mm^2)
3 weeks	5		
incomplete	2	0.39 (0.17–0.61)	14 (10–17)
solid	3	0.87 (0.72–0.93)	8 (2–12)
6 weeks	5		
incomplete			
solid	5	0.81 (0.68–0.95)	13 (7–20)
12 weeks	6		
incomplete	2	0.08 (0.0–0.16)	43 (40–45)
solid	4	0.85 (0.70–0.95)	9 (5–13)
36 weeks	4		
incomplete	2	0.03 (0.0–0.05)	37 (25–48)
solid	2	0.90 (0.83–0.96)	4 (3–4)

Results

No postoperative infections or other disturbances of wound healing were encountered. At 3 weeks, solid union had occurred in three out of five osteotomies (Table 1). In 2 rabbits the medial side of the osteotomy showed bridging trabeculae, while the lateral side was completely ununited. The macroscopic appearance of the screw at 3 weeks was unchanged.

In the next group with a follow-up time of 6 weeks, all 5 rabbits had solid bony union of the osteotomy. The screw was decomposing; but no tissue replacement of the implant could be seen, and the polymeric material could still be removed in toto from the collected specimens.

In the 12-week group, 1 rabbit out of 6 showed frank nonunion with severe displacement of the distal fragment. Another rabbit had an incomplete union with abundant periosteal callus (Figure 2). In the other 4 rabbits, the osteotomies had united. The polyglycolide screw had degraded to a considerable extent and was being replaced by loose connective tissue. A continuous polymer was microscopically left only in the central portions of the implant cavity.

At 36 weeks, 2 out of 4 rabbits had osteotomies that demonstrated a fibrous nonunion. The largest individual area of periosteal callus, 48 mm^2 (19 percent of the total tissue area of the section), was measured in 1 of these rabbits. The other two osteotomies showed solid

Figure 2. Histologic section obtained at 12 weeks demonstrating an incomplete union of the osteotomy, the lateral side being nearly totally ununited (arrows). A large sleeve of periosteal callus is seen to surround the bone in the transitional area between cancellous and cortical bone. Masson-Goldner trichrome, ×4.

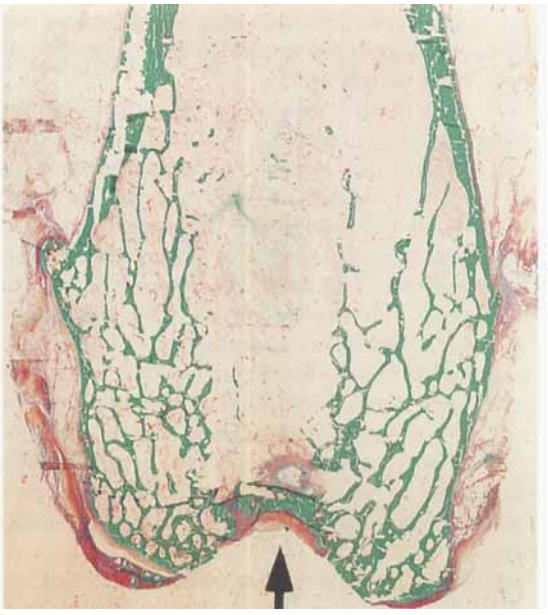

Figure 3. Histologic section obtained at 36 weeks showing solid bony union of the osteotomy, which no longer can be distinguished. Trabecular bone ingrowth into the implant cavity has occurred only in the subchondral area of the femur close to the intraarticular orifice of the screw channel (arrow).

union (Figure 3). Birefringent polymeric material could no longer be seen in the osteotomies after 36 weeks.

Considering the whole series, the mean area of periosteal callus in the 14 osteotomies with solid union was 9.4 (2–20) mm^2 and 31 (10–48) mm^2 ($P < 0.01$) in the six osteotomies with defective consolidation. Out of the six osteotomies with defective consolidation at the end of the follow-up, three showed some bridging bone trabeculae, whereas a hypertrophic nonunion was present in the remaining three osteotomies, one of which was in the 12-week group and two in the 36-week group (Table 1). The time-related changes in the area of periosteal callus among the osteotomies with solid union were insignificant.

Discussion

Polyglycolide is one of the few organic macromolecular compounds that are totally absorbable within the body and simultaneously are suitable to be manufactured into internal fracture fixation devices (Hollinger and Battistone 1986, Rokkanen 1990, Böstman 1991). To test the fixation properties of the polyglycolide screw, distal rabbit femur was chosen because of its principally cancellous nature, easy exposure and standardization of the osteotomy, and sufficient displacing forces to challenge the implant. Left unfixed, such an osteotomy in the rabbit has been found to result in immediate complete dislocation of the distal limb (Vihtonen et al. 1987). To allow simultaneous observations of the degradation process of the screw and of the tissue response to the polymer, union of the osteotomy was assessed by microscopic examination instead of loading the collected specimens to failure for biomechanical measurements.

The degradation of polyglycolide takes place mainly via hydrolytic scission and to a lesser extent via nonspecific enzymatic action. The resultant polyglycolide acid monomer molecules are metabolized through the tricarboxylic acid cycle to water and carbon dioxide. The ultimate main route of elimination is respiration.

Among absorbable polyesters, polyglycolide has a relatively rapid rate of depolymerization compared with, e.g., polylactide. In a previous study, rods of polyglycolide, 3.2 mm in diameter and 50 mm in length, lost approximately one half of their shear strength within 2 weeks when placed in the subcutaneous tissues of rat (Vasenius et al. 1989). However, in cancellous bone, with inherently rapid repair character-

istics, the degradation behavior of polyglycolide fixation implants does not necessarily seem to jeopardize retention of the fragments.

In the present study mimicking a transcondylar distal femoral fracture, the fixation properties of a polyglycolide screw were able to maintain reduction in 19 out of 20 osteotomies, with only one premature breakage of the implant and subsequent gross displacement occurring. In spite of good retention of the fragments, there were cases with defective union. The osteotomies with a limited number of bridging trabeculae after a short follow-up time might ultimately have proceeded to bony union. But, in addition to the case with severe displacement, there were two osteotomies with an established fibrous nonunion in situ. Incomplete union expectedly showed a clear correlation with the amount of periosteal callus in the transition area between cancellous and cortical bone in the distal femur.

Most of the experimental studies published on absorbable screws for internal fracture fixation have been concerned with maxillofacial fixations (Vert et al. 1984, Leenslag et al. 1987) or flake fractures (Gay and Bucher 1985). With regard to the mechanical demands made on the fixation devices, only one previous study (Eitenmüller et al. 1987) could match our study; and, indeed, in that study screws and plates made of polylactide were found insufficient to stabilize a diaphyseal osteotomy of the canine radius.

Parallel with the lively ongoing experimental research on absorbable screws for internal fracture fixation, screws made of absorbable polymers have already been tested clinically in both maxillofacial and orthopedic fracture surgery. The preliminary results of polyglycolide screw fixation have been reported in 217 patients with various injuries of the extremities, mostly malleolar fractures (Partio et al. 1990). There were seven failures of fixation necessitating reoperation; and there were 10 cases that had a clinically manifest, inflammatory, noninfectious foreign-body reaction, a complication unique to the absorbable implants (Böstman et al. 1990). In the present study, in accord with other previously published experimental studies, no inflammatory wound-healing disturbances were seen.

When considering the clinical relevance of the findings, it has to be recognized that the fixation model used was rather unsophisticated. Because only one screw was inserted and no compression was applied, the fixation cannot be directly compared with any actual clinical situation in humans. The present results would not seem to justify more than a cautious optimism with regard to the future applications of these devices. Further investigations are required before the introduction of polyglycolide screws into the internal fixation of fractures with high demands for mechanical strength.

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