ABSORBABLE INTRAMEDULLARY IMPLANTS
FOR HAND FRACTURES

ANIMAL EXPERIMENTS AND CLINICAL TRIAL

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Biodegradable implants made from polyglycolic and polylactic acid co-polymers undergo degradation by hydrolysis which results in loss of their mechanical strength. The degradation of 1.5 mm polyglycolide rods (Biofix) was studied after intramedullary and subcutaneous implantation in rabbits. Two weeks after implantation there was a 73% reduction in strength of the intramedullary implants and a 64% reduction in the subcutaneous implants.

Polyglycolide implants were compared with Kirschner wires for intramedullary fixation of extra-articular fractures in the hand. In one group of patients fractures were fixed with a 1.5 mm intramedullary rod and in a similar group a Kirschner wire was used. In both a wire loop was added for extra fixation. At six months there was no significant difference between the two groups. There were no allergic reactions to the polyglycolide implants.

The use of absorbable implants for fracture fixation has obvious clinical advantages. They do not have to be removed, but the gradual loss of their mechanical strength may render them too weak to resist normal mechanical stresses.

Biodegradable implants made from polyglycolic acid (PGA) and other polymeric composites have been used in clinical practice and PGA sutures have been in use since 1970 without any major problems of biocompatibility. PGA undergoes hydrolysis after implantation with gradual fragmentation of the implant which is eventually metabolised through Krebs' pathway (Hollinger 1983). To justify its clinical use such an implant must be biocompatible, retain sufficient strength until fracture healing has taken place, and undergo degradation with accompanying loss of strength at a known and acceptable rate.

Implants made from PGA are now available for commercial use. The rods, which are composed of well-formed fibres of a co-polymer of PGA and polylactic acid called polylactide, are embedded within a homogenous matrix of polyglycolic acid, a process of self-reinforcement which adds to their strength. They may be used in place of metal pins or Kirschner wires and are available in diameters of 1.5, 2, 3.2 and 4.5 mm and in lengths up to 70 mm (Fig. 1).

We have studied the degradation of 1.5 mm polyglycolide rods in rabbit bone and subcutaneous tissue and then compared the performance of bio-absorbable implants with that of Kirschner wires for fixation of fractures of the human hand.

ANIMAL EXPERIMENTS

Polyglycolic acid degradation in rabbit bone

Material and methods. We used adult rabbits weighing 3.5 to 4 kg. Polyglycolide rods (Biofix: Bioscience Ltd, Tampere, Finland) were implanted, one into each femoral medullary canal and one into the subcutaneous tissues on the inner aspect of each thigh. The animals were killed at intervals of four, seven, ten, 14 and 21 days. Sixty implants were retrieved, tested to failure using a three-point bending apparatus (Fig. 2) and their bending strengths calculated. All the rods retrieved after 21 days were found to be fragmented and none could be tested.

The mean values of the strength of the rods were calculated and plotted against the period after implantation to give strength-degradation curves for the intramedullary and the subcutaneously implanted specimens (Fig. 3). The loss in mechanical strength of PGA implants following immersion in a water bath at 37°C and after
Fig. 1

Polyglycolide rods 1.5 mm, 2 mm, 3.2 mm, 4.5 mm in diameter.

Fig. 2

Three-point bending apparatus used for testing cylindrical rods. S = supports, N = nose cone that applies load, F = maximum force recorded at time of implant failure, T = test piece.

Fig. 3a

Strength-degradation curves of polyglycolide rods at various intervals after implantation. Figure 3a – After intramedullary implantation. Figure 3b – After subcutaneous implantation.

Fig. 3b

Fig. 4a

Fig. 4b

Fig. 4c

Steps in the fixation of a fracture with a polyglycolide rod and a wire loop. Figure 4a – Rod inserted into longer fragment. Figure 4b – Fracture reduced and rod pushed distally. Figure 4c – Stable fixation achieved by tightening the wire.
subcutaneous implantation have previously been reported (Vainionpää 1986; Vainionpää et al. 1987).

**Results.** Before implantation rods of 1.5 mm diameter and 70 mm length had a mean bending strength of 450 MPa. There was a 73% reduction in strength after implantation for two weeks in bone (mean strength 120 MPa) and a 64.4% reduction after implantation subcutaneously (mean strength 160 MPa). The faster rate of degradation in bone is statistically significant (p < 0.05).

Three weeks after implantation none of the specimens was retrieved intact and the degradation curve was therefore extrapolated to zero (Fig. 3).

**CLINICAL TRIAL**

**Polyglycolide rods in fractures of the human hand**

Internal fixation is indicated for displaced, unstable fractures of the metacarpals and phalanges to allow early movement of the finger joints and to achieve the best functional results. The implants include simple pins, screws, and plates all of which should be removed after the fracture has healed. We performed a clinical trial to compare the efficacy of intramedullary polyglycolide rods with that of Kirschner wires.

**Patients and methods.** We studied two groups of 15 patients each with unstable displaced fractures of the metacarpal or phalangeal bones. Distal phalangeal fractures, fractures with severe comminution and intra-articular fractures were excluded. The choice of implant to be used was randomised by using instructions in sealed envelopes opened in the operating room just before the start of the operation.

Since the mechanical strength of the polyglycolide implants was known to decrease to zero in three weeks it was evidently unsuitable as the sole agent for internal fixation. We therefore added a wire loop. This combination had previously been found to be an effective method of fixing such fractures (Hung, So and Leung 1989). In the study group, the fractures were stabilised with a 1.5 or 2 mm diameter intramedullary rod and the wire loop applied as in Figure 4, or as a simple cerclage. In the control group the fractures were similarly treated, but a Kirschner wire was used instead of the rod.

Active finger mobilisation was started as soon as postoperative pain allowed. The patients were seen at weekly intervals and finally reviewed at 24 weeks. Joint motion was recorded at each visit and radiographs were taken at four, eight, 12 and 24 weeks. We looked carefully for signs of allergy, granuloma or sinus formation.

**Results.** The age distribution, sex and type of fracture were comparable in the two groups (Table I). Most of the fractures had been sustained at work and the sites of injury are shown in Figure 5.

**Bone union.** Six fractures united at four weeks, 15 at six weeks, 26 at eight weeks, 26 at 12 weeks and all had united by 16 weeks. One metacarpal fracture in the study group became displaced and had to be re-operated on five weeks after injury. This failure was attributed to faulty wiring technique. The fracture united in eight weeks but the metacarpophalangeal joint lost 40° of flexion. In one fracture in the control group the Kirschner wire migrated with loss of reduction. It was revised at four weeks and the fracture healed at eight weeks.

**Deformity.** Rotational deformity is a common complication of unstable fractures of the phalanges. There were

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**Table I.** Clinical details and fracture types in patients treated by polyglycolide rods or Kirschner wires

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<thead>
<tr>
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<th>Polyglycolide rods</th>
<th>Kirschner wires</th>
</tr>
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<tbody>
<tr>
<td>Sex M/F</td>
<td>13/2</td>
<td>15/0</td>
</tr>
<tr>
<td>Age range (years)</td>
<td>14 to 70</td>
<td>16 to 69</td>
</tr>
<tr>
<td>Fracture type*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Simple</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Compound</td>
<td>8</td>
<td>5</td>
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* four patients had two fractures and two had three

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Sites of fractures in the hand. Figure 5a – The group treated by polyglycolide rods. Figure 5b – The group treated by Kirschner wires.
two cases in the present series, one in the study and one in the control group. Re-operation was unnecessary as the deformities were slight. In the case in the study group the fracture healed with 20° dorsal angulation but the patient had no functional disturbance and it was not thought necessary to correct the deformity.

Stiffness. Three cases in the study group and four in the control group had 15° to 30° loss of movement in the joints distal or proximal to the fracture but these limitations of motion did not weaken the grip or the pinch strength of the affected finger. Three months after injury a decrease in grip and pinch strength of 5% to 10% was detected in seven cases, three in the study group and four in the control group.

Return to normal activities. All the patients were pleased with their treatment. They experienced pain only in the first one to two weeks after operation, and all except the two who required re-operation returned to work ten to 16 weeks after injury.

Allergic and tissue reactions. No allergic reactions were observed. Patients in the study group had a transient purple-coloured discharge from the wound and a mild tissue reaction. This subsided in seven to ten days and cultures were all sterile. Minor implant irritation was also observed in the controls and in one case the Kirschner wire had to be removed nine weeks after surgery.

DIscussion

Degradable implants need to remain strong for a known period after implantation to be useful in fracture fixation. It is equally important that the rate of degradation be known precisely so that the clinician can define the indications for their use and the margins of safety. Our study in rabbits showed a considerable loss of strength of the 1.5 mm polyglycolide rod within two weeks of implantation, whether in bone or subcutaneous tissue. Degradation took place faster in bone than in subcutaneous tissue and at a remarkably predictable rate. There was very little variation in implant strength between specimens retrieved at the same interval after implantation. The reliability and uniformity of degradation of implants made from the polyglycolide polymer thus satisfy one major clinical requirement.

The degradation of PGA and polyactic acid may not be just by hydrolysis. Williams (1979) described cellular enzymes which enhance degradation of the polymer and their presence may explain the faster rate of degradation in bone, a vascular environment that is rich in cellular elements, than in the relatively avascular surroundings of subcutaneous tissue. Our observations indicate that the PGA polymer induces a non-specific inflammatory reaction resulting in cellular infiltration and vascular proliferation around the implant. In addition, we have seen new bone formation consistently around the implants, also reported by Mäkelä et al (1987), but, in a separate controlled study, not around the metal pins in the control group.

The cellular infiltration and increased vascularity may have some effect on bone healing. Perhaps the rapid degradation of the implant may be compensated for by early new bone formation; this hypothesis needs further investigation.

Rapid loss of strength greatly limits the usefulness of a 1.5 mm polyglycolide implant as the sole means of internal fixation. The rate of degradation depends, however, on the diameter of the rod, and those of larger diameter should retain their strength proportionately longer.

In the rabbits, local reaction to the polyglycolide implant was observed only when the rod lay immediately beneath the skin and not when it was buried within the soft tissues. There were no such reactions with the intramedullary rods in rabbits or humans.

Our patients were carefully selected so that the study and the control groups could be compared directly. There was no difference between them in the rate of union or in the ultimate result in terms of joint motion, grip and pinch strength, and return to work. The polyglycolide implants were as good as Kirschner wires with the added merit that implant removal was unnecessary.

Certain technical aspects of these implants need to be emphasised. When the rods are not used in an intramedullary position, a pre-drilled track is necessary to introduce the rod across the fracture site, and, unlike Kirschner wires, they cannot be drilled or power driven, requiring careful handling to prevent breakage. A special applicator provided by the manufacturer did not eliminate the difficulty of inserting a rod obliquely across a phalangeal fracture. The technique was much simpler when the rod was used as an intramedullary device.

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REFERENCES


