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Biodegradable fixation of rabbit osteotomies

Osteotomies of the tibial diaphysis were operatively fixed with biodegradable implants in 44 rabbits. Polyglycolic acid (PGA)/polylactic acid (PLA) copolymer implants reinforced with 7 per cent carbon fibre and overlaid with gold were used in 24 rabbits. Poly-beta-hydroxy butyric acid (PHBA) with carbon fibre reinforcement and gold surfacing were used in 20 rabbits. No external support was used. Unsatisfactory results were achieved with the PGA/PLA copolymer implants. Better results were achieved in 15 out of 20 rabbits whose osteotomies were fixed with carbon fibre-reinforced PHBA implants.

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The use of the biodegradable and biocompatible polymers polyglycolic acid (PGA), polylactic acid (PLA), and their copolymers in the fixation of fractures was suggested by Schmitt & Polistina (1969). The use of biodegradable polymers in the fixation of long bone fractures has been experimentally studied (Alexander et al. 1981, Christel et al. 1982), though without definitive success. The results of biodegradable fixation were better for fracture of cancellous bone as compared with cortical bone. Rokkanen et al. (1985) reported successful early results of biodegradable fixation of fractures of the ankle. We studied fixation of experimental osteotomies with carbon fibre reinforced and gold overlaid implants.

Material and methods

Fixation devices. Forty-eight carbon fibre reinforced pieces (25 × 5 × 3 mm) were made of biodegradable polyglycolic acid (PGA) polylactic acid (PLA) copolymer (Vicryl[R]) by compression moulding. The carbon fibre was commercial Grafil-carbon fibre, type XAS. The carbon-fibre content of the pieces was approximately 7 per cent. The carbon fibres formed parallel fibre bundles in the pieces. Two pieces were united with cyanoacrylate glue (Histoacryl[R]) to a T-shaped implant. The implant was overlaid with gold by a sputtering method (thickness of 30 nm). Twenty-four such implants were used as fixation devices in osteotomies of the tibial diaphysis in Group A. 40 pieces reinforced with carbon fibre (25 × 5 × 3 mm) were produced so that as matrix was biodegradable poly-beta-hydroxy butyric acid (PHBA). Twenty T-shaped PHBA implants with gold surface were used in Group B.

Experimental animals. Forty-four adult rabbits weighing from 2500 to 3400 g were used. The rabbits were anesthetized with subcutaneous Hypnorm[R] (Philiphs, Duphar) 0.5 ml/kg and diazepam (Diapam[R]) 3 to 5 mg/kg. The right hind led was shaved and scrubbed with Neo-Amisept[R]. A medial incision was made. The leg was osteotomized and then identically fixed with an implant as shown in Figure 1. The opening was closed with PGA sutures (Dexon[R]). During operation all the rabbits received 100,000 IU of

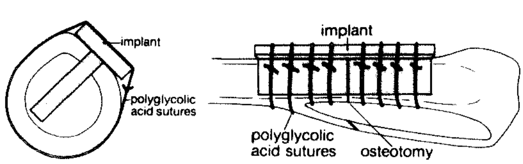

Figure 1. Operating technique. The oblong hole with rounded ends for the implant was made using a circular saw and drill in the medial side of the tibial diaphysis. The bone was cut with a circular saw in the middle part of the hole and the fibula was broken manually. Bone preparation was performed under flowing saline cooling to prevent heat injury (Eriksson & Albrektsson 1983). The T-shaped implant was placed into the hole and fixed to the tibia with absorbable sutures pulled around the bone.

procain penicillin i.m. After recovery from anesthesia, the rabbits were returned to their individual cages without external support and fed and watered ad libitum.

In Group A four rabbits were killed with an overdose of sodium pentobarbitone (Nembutal Vet.[R]) at 6 weeks, seven rabbits at 6 weeks, seven at 12 weeks and six at 24 weeks. In Group B five rabbits each were killed at 3, 6, 12 and 24 weeks after operation. For oxytetracycline (OTC) labelling, the rabbits were injected intramuscularly with 50 mg OTC (Vendarcin[R]) per kilogram of body weight 3 and 4 days before death.

Examination methods. The tibia was exarticulated, dissected, radiographed and inspected for signs of infection or other complications. The specimens were embedded in methylmetacrylate. For histologic studies, 5μ thick longitudinal sections were cut and stained by the Masson-Goldner method. Sections measuring 80 μm were taken for OTC fluorescent and microradiographic studies. In the microradiographic examinations, 50 kV, 9 mA, 12-min exposure time, and a 29.5-cm film-focus distance were used.

Figure 2. A. Osteotomy fixed with poly-beta-hydroxy buturic acid, is seen after 3 weeks. B. The osteotomy was united 12 weeks after operation.

Results (Table 1, Figure 2)

3 weeks. All four rabbits of Group A and four out of five rabbits of Group B walked without difficulty. Histologically, new bone was present periosteally in the posterior part of the osteotomy in all Group A rabbits and in three out of five Group B rabbits. Granulation tissue was observed periosteally at all osteotomies. Implant material was also seen at the osteotomy in all animals.

6 weeks. Four out of seven Group-A rabbits and three out of five Group-B rabbits used the limb operated on as if normal. In both groups four osteotomies were healed histologically; carbon fibres and/or implant material were seen at the osteotomy in half of the rabbits in both groups.

12 weeks. Four rabbits out of seven (Group A) and four out of five (Group B) were able to bear weight on the operated limb. In the radiographs, varus malalignment was observed in three Group A rabbits and nonunion in three cases (Group A) and in one case (Group B).

The remaining osteotomies had healed histologically. Carbon fibres were observed in most rabbits and implant material in six Group A osteotomies and in one Group B osteotomy.

24 weeks. Three out of six Group A rabbits and four out of five Group B rabbits were able to bear weight as if normal on the operated on limb. Varus angulation occurred in two Group A rabbits.

The osteotomy was ununited in three cases (Group A) and in one (Group B); all other osteotomies were healed histologically. Carbon fibres were seen at the osteotomy in two cases (Group A) and in three cases (Group B), but the polymer implants had disappeared.

Discussion

The use of PHBA in absorbable prosthetic devices and as surgical suture material was suggested in 1966 (British Pat. 1 034 123). The flexural and tensile strength of these polymers alone may not be sufficient for osteosynthesis of a fracture or osteotomy of the long bones (Christel et al. 1982). Therefore, carbon-fibre reinforcement was used here. Törmälä et al. 1986 showed that the tensile and flexural strength of PGA/PLA copolymer could be improved with a small quantity of carbon fibre and that gold surfacing slowed down the rate at which the strength of polymers decreased and was used in our study also.

The T-shaped implant, fixed by biodegradable sutures pulled around the tibia (Törmälä et al. 1984), was adopted because the use of a biodegradable implant shaped as a plate and fixed with screws to the bone has some disadvantages. Devices produced from polymers do not have the same elasticity as metals. Therefore, the strain of screw fixation around the screw hole may cause continuous small changes of shape in a biodegradable plate; the fixation will gradually loosen with increasing hole size or when microfractures appear in the plate. These problems were eliminated by using sutures for fixation of the implant.

The results were not satisfactory due to angulation of the tibia caused by too rapid biodegradation of the PGA/PLA copolymer; the final results was in many cases nonunion of the osteotomy. The results using PHBA implants were better than using PGA/PLA implants due to less angulation of the tibia and breaking of implants. We have now started investigations on the use of completely biodegradable polymer composites in the fixation of osteotomies of the long bones in laboratory animals.

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