Comparison of absorbable poly-L-lactide and metallic intramedullary rods in the fixation of femoral shaft osteotomies: an experimental study in rabbits

JANNE VILJANEN1, HARRI PIHLAJAMÄKI1, JAAKKO KINNUNEN2, SÖREN BONDESTAM2, and PENTTI ROKKANEN1

1 Department of Orthopaedics and Traumatology, Helsinki University Central Hospital, 5 Topeliuksenkatu, Helsinki 00260, Finland
2 Department of Radiology, Helsinki University Central Hospital, Helsinki, Finland

Abstract An osteotomy of the distal femoral diaphysis was fixed with an intramedullary self-reinforced poly-l-lactide (SR-PLLA) rod in 22 and with a metallic rod in 38 skeletally mature rabbits. Histomorphometric and quantitative computed tomography (QCT) were performed to assess time-related changes in the consolidation process of the osteotomy of cortical bone and development of the external callus. The follow-up times were 8, 16, 24, and 48 weeks for radiologic and 16, 24, and 48 weeks for histologic studies; 19/22 of the SR-PLLA and 34/38 of the metallic fixed osteotomies healed during the observation periods. On microscopic evaluation, no difference was found in histologic parameters such as external callus area and fraction, and endosteal callus area and fraction between SR-PLLA and metallic fixed osteotomies. The total external callus area increased up to 16 weeks and subsequently decreased linearly over time in both experimental groups. However, the mean endosteal bone area and fraction decreased after 16 weeks in metallic fixated femora, while in the SR-PLLA fixated femora, both these values increased, being greater in the SR-PLLA group. The mean external callus QCT density decreased after 8 weeks in both experimental groups, the decrease being greater in the SR-PLLA group. Neither, no significant difference was detected between SR-PLLA and metallic fixed femora in any of the follow-ups. These results suggest that both SR-PLLA and metallic rods are suitable in the fixation of femoral shaft osteotomies in rabbits. Furthermore, SR-PLLA rod fixation seems to have a minor stress-shielding effect.

Key words Absorbable · Poly-l-lactide · External callus · Intramedullary fixation · QCT

Introduction

The development of bioabsorbable fixation devices offers solutions and new possibilities to overcome many problems which have been related to metallic implants in fracture fixation. This prospect will be even more important in the future as bioengineering and biomaterial technologies develop and as noninvasive technology opens new possibilities for the radiographic imaging of fracture healing. Although several studies have reported the good biocompatibility2,7–9,12,14,19 of self-reinforced poly-l-lactide (SR-PLLA) implants and the acceptable mineral density changes in trabecular5,18 and cortical bone20 after implantation of these devices, only little attention has been paid to well established comparisons of self-reinforced — poly-l-lactide (SR-PLLA) and metallic fixation alternatives using quantitative computed tomography combined with histologic data.

The present study was carried out to compare local structural changes in the endosteal bone and in the external callus between absorbable SR-PLLA and metallic fixation methods. Histomorphometrically, the aim was to investigate the nature of consolidation, to describe the nature of cortical bone secondary remodelling, and to provide experimental histologic data concerning the nature of secondary trabecular changes in the endosteal bone and external callus when absorbable SR-PLLA and metallic fixation is being used. Combining the mineral density evaluation using computed tomography with histomorphometric data may be the best method of describing these changes, especially in the external callus. In the previous literature no study that compares bioabsorbable and metallic fixation methods, using these parameters, can be found.

Materials and methods

Implants

An SR-PLLA rod or a corresponding metallic rod was used to fix an osteotomy of the rabbit femur (Fig. 1a,b).
According to data supplied by manufacturer (Bio-science, Tampere, Finland), the absorbable rods were 4.5 mm in diameter and 50 mm in length, with an initial bending strength of 275 MPa and shear strength of 100 MPa. These rods were manufactured from poly-l-lactide with an initial raw material viscosity average molecular weight of 664 000 (Purac Biochem, Gorinchem, The Netherlands) into self-reinforced (SR) fibers-in-matrix of the same polymer composite texture. The metallic AO/ASIF (Arbeitsgemeinschaft für Osteosynthesefragen/Association for Study of Internal Fixation) rods were 4.5 mm by 30–50 mm with initial modulus of elasticity about 200 GPa. The SR-PLLA rods were gamma sterilized with a dosage of 2.8–3.1 Mrad, and the metallic AO/ASIF rods were sterilized in an autoclave.

Surgical technique

Sixty skeletally mature rabbits with an average weight of 4.1 kg (range, 3.2–5.1 kg) were operated. Preoperatively they received subcutaneous (s.c.) atropine (Atropin; Orion, Espoo, Finland) 0.5 mg/kg and s.c. benzylpenicillin procaine (Procapen; Orion) 50 000 units/kg. The rabbits were anesthetized with s.c. ketamine (Ketalar; Parke-Davis, Barcelona, Spain) from 30 to 40 mg/kg, and s.c. medetomidine (Domitor; Lääkefarmos, Turku, Finland) from 0.2 to 0.3 mg/kg). The right knee was shaved and scrubbed with chlorhexidine gluconate (Klorheksidine; Lääkefarmos). A medial parapatellar incision was made and the patella was dislocated laterally. A hole of 4.5 mm in diameter was drilled with a titanium-coated drill bit from the intercondylar space to the medullary canal. No ferromagnetic device was in contact with the intramedullary cavity of the femur. Muscles of the distal femur were bluntly disected, and the distal third of the diaphysis of the femur was exposed. A distal cortical bone osteotomy was created with a circular diamond saw to the distal third of the femur. A bioabsorbable or metallic rod was tapped into the medullary cavity to fix the osteotomy. The proximal end of the SR-PLLA rod was shortened with an electric loop to match the shape of the patellar joint of the femur. In the metallic fixation, the distance of the drilling hole was measured before tapping and the right length of metallic rod was chosen. To establish sufficient stability for primary union and an experimental metallic fixation model comparable to that with absorbable SR-PLLA fixation, interlocking of the metallic rod was performed by locking both ends with Kirschner wires (Fig. 1b). On the basis of our pilot study, we knew that the anatomic shape of the rabbit femur results in inadequate friction in the nail-bone interface allowing detrimental motion at the osteotomy site, which leads to failure of fixation due to rotational instability. The wound was closed in layers, using polyglycolide sutures (Dexon; David and Geck, Gosport, UK). Unprotected weight-bearing was allowed as soon as the rabbits recovered from anesthesia. The rabbits were allowed to move freely in their cages after the operation. Follow-up times were 8, 16, 24, and 48 weeks for radiological studies and 16, 24, and 48 weeks for histological studies. Throughout the study, the rabbits were handled according to the Finnish law on animal experimentation.

Computed tomography (CT)

A fast CT scanner (GE, HiSpeed Advantage; General Electric Medical Systems, Milwaukee, WI, USA) was used. A slice thickness of 1 mm and matrix size of 512 by 512 were chosen. The exposure factors were 70 kV, 80 mA, and 2 s. Lucite calibration phantoms of Image (Irvine, CA, USA) were used to quantitate bone mineral density (BMD) in equivalent mineral density (mg/ml). Contiguous 1-mm-thick scans were performed, and the scanning length was 2 cm, centered at the osteotomy gap. Twelve specific regions of interest (diameter 1 mm) were analyzed, eight sites of the external callus and four sites of the SR-PLLA rod. The rabbits in the SR-PLLA groups were anesthetized during the CT examination at 8, 16, and 24 weeks, and killed at 48 weeks. To avoid artifacts in CT scans, the rabbits with metallic fixation had to be killed to remove the metallic rods prior to CT scanning.

Histologic and histomorphometric evaluation

After the animals were killed, both femora were exarticulated and dissected free of all soft tissue. The left distal femur was used as an intact control. The distal