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Fixation of distal femoral osteotomies with self-reinforced polymer/bioactive glass rods: an experimental study on rabbits

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Abstract

Two self-reinforced poly(desamino tyrosyl–tyrosine ethyl ester carbonate), poly(DTE carbonate) or self-reinforced poly(DTE carbonate)/bioactive glass rods, (2 mm by 40 mm) were implanted into the dorsal subcutaneous tissue and osteotomies of the distal femur were fixed with these rods (2 mm by 26 mm) in 36 rabbits. The follow-up times varied from three to 100 weeks. After sacrifice, three-point bending and shear tests and molecular weight measurements were performed for subcutaneously placed rods. Radiological, histological, histomorphometrical, microradiographic, and oxytetracycline-fluorescence studies of the osteotomized and intact control femora were performed. The initial mechanical properties were higher with the SR-poly(DTE carbonate) rods, but the SR-poly(DTE carbonate)/bioactive glass rods lost their mechanical properties slower. At 100 weeks the bending strength had decreased to 21% of the initial value with the SR-poly(DTE carbonate) rods and to 49% with the SR-poly(DTE carbonate)/bioactive glass rods. The shear strength had decreased to 10% with the SR-poly(DTE carbonate) rods and to 23% of the initial value with the SR-poly(DTE carbonate)/bioactive glass rods. Two slight displacements and one delayed union and one failure of fixation were seen in the SR-poly(DTE carbonate) group. In the SR-poly(DTE carbonate)/bioactive glass group five delayed unions and seven slight displacements were seen. No signs of osteolysis or foreign body reactions were observed. Signs of resorption of the implants were seen at 100 weeks in the SR-poly(DTE carbonate)/bioactive glass group. The present investigation showed that the mechanical strength and fixation properties of SR-poly(DTE carbonate) and SR-poly(DTE carbonate)/bioactive glass rods are suitable for fixation of cancellous bone osteotomies in rabbits.

Keywords: Bioabsorbable rods; Self-reinforced; SR-poly(DTE carbonate); SR-poly(DTE carbonate)/bioactive glass; Osteotomy fixation; Experimental study

1. Introduction

During the past decade, bioabsorbable devices have gained popularity for the internal fixation of fractures and osteotomies [1–9]. According to previous experimental studies, bioabsorbable self-reinforced (SR-) polyglycolide (SR-PGA) pins [10] and self-reinforced poly L-lactide (SR-PLLA) pins [10,11] have shown sufficient fixation properties for fixation of cancellous bone fragments in rats. The ultimate degradation time of PGA is a few months [12] and of PLLA several years [13,14]. Despite a slightly weaker initial mechanical strength compared to SR-PGA pins, the mechanical strength of SR-PLLA is maintained at a high level longer than that of SR-PGA pins [15]. The mechanical strength and fixation properties of SR-poly(DTE carbonate) rods have also been suitable for fixation of cancellous bone osteotomies in rats [16]. Also, the tissue response to poly(DTE carbonate) was mild troughout a 570 day study [17]. Bioactive glass has been the object of interest due to its chemical bonding effect to bone [18]. It has been used, for example, in reconstruction of bone defects [19].

The aim of the present study was to examine the use of SR-poly(DTE carbonate) and SR-poly(DTE

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carbonate)/bioactive glass rods in the fixation of distal femoral osteotomies in rabbits.

2. Material and methods

Self-reinforced poly (desamino tyrosyl - tyrosine ethyl ester carbonate), poly(DTE carbonate) was supplied by Integra LifeSciences Corporation (NJ, USA), and the bioactive glass type 13 was supplied by Abmin Technologies (Turku, Finland). In this study SR-poly(DTE carbonate) with a molecular weight of 146 000 g/mol was used and mixed with 15 wt% of bioactive glass. Polymer in the form of powder was melt-extruded using a laboratory-scale single-screw machine equipped with a cylindrical die (Gimac micro-extruder ∅12 mm, Gimac, Carstronno, Italy). Extruded billets were die-drawn to SR-rods of 2 mm in diameter at temperatures close to the glass-transition temperature of the polymer. The rods were sterilized by Gamma-irradiation at a minimum dose of 25 kGy (Willy Rüsch AG, Germany).

2.1. Testing of SR-poly(DTE carbonate) rods

A total of 36 rabbits of both sexes were used in the study. There were 18 rabbits with a mean weight of 3947 g (range 3100–4860 g) in the SR-poly(DTE)carbonate group and 18 rabbits with a mean weight of 3561 g (range 2850–4050 g) in the SR-poly(DTE)carbonate/bioactive glass group. For every rabbit two cylindrical rods (length 40 mm, diameter 2 mm) were implanted into the dorsal subcutaneous tissue for evaluation of the strength retention properties, and a distal femoral osteotomy was fixed with two cylindrical rods (length 26 mm, diameter 2 mm) for evaluation of the bone fixation properties.

2.2. The surgical technique

The animal care complied with the guidelines of the national law on the care and use of laboratory animals. The rabbits were anaesthetized with subcutaneous injections of medetomidine (Domitor, Orion-Yhtymä Oy, Espoo, Finland) 0.375 mg/kg s.c. and ketamine (Ketalar, Parke-Davis, Solna, Sweden) 25 mg/kg s.c. and diazepam (Diapam, Orion-Yhtymä Oy, Espoo, Finland) 1.25 mg/kg i.m. During surgery all rabbits received 112 500 I.U. of benzathine penicillin and 112 500 I.U. of benzylpenicillin procain i.m. (Duplocillin LA, Intervet International B.V., Boxmeer, Holland). Small areas on both sides of the back were shaved and scrubbed with antiseptic fluid. The cylindrical rods were implanted into the dorsal subcutaneous tissue, and the incisions were closed in layers. The right hind limb was shaved around the knee and scrubbed with antiseptic fluid, and a medial parapatellar incision was made. The patella was dislocated laterally, and the articular part of the femur was exposed. Two drill channels of 2 mm in diameter were made from the postero-distal part of each condyle to the anterior part of the proximal intercondylar region through the cortex. An osteotomy was made with an oscillating saw from the antero-distal part of the femoral condyle to the posterior proximal direction (Fig. 1a–b). The posterior cortex was broken into a hinge. After reduction, the osteotomy was fixed with either two SR-poly(DTE carbonate) rods or two SR-poly(DTE carbonate)/bioactive glass rods. The rods were set at the depth of one millimetre from the articular surface and cut from the anterior surface of the femur with the saw. The incision was closed in layers. The rabbits received postoperatively buprenorphin (Temgesic®, Reckitt & Colman, Hull, England) 0.0375 mg/kg twice a day for three days. The rabbits were allowed to walk freely in their

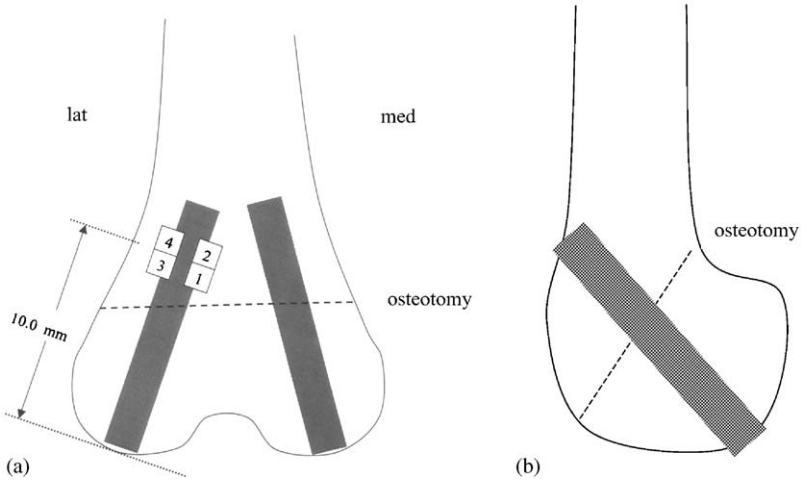

Fig. 1. Schematic anterior (a) and lateral (b) views of the distal rabbit femur showing positioning of the osteotomy, the implants, and the four standardized sample fields (1, 2, 3, 4) used in the histomorphometric analysis.