Intramedullary fixation of cortical bone osteotomies with self-reinforced polylactic rods in rabbits

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Summary. Osteotomies of the femoral shaft in rabbits were fixed with intramedullary rods made of poly-L-lactic acid (SR-PLLA) and poly-DL/L-lactic acid (SR-PDLLA/PLLA). Follow up was from one week to 2 years. In the PLLA group, in 37 out of 40 osteotomies the fixation was firm and the bone was united. In the PDLLA/PLLA group, the fixation was firm in 30 out of 45, but in 13 of these angular deformity of more than 10° had occurred. The fixation had failed in 15. No inflammatory or foreign body reaction was seen in either group. This study demonstrates that SR-PLLA rods are suitable fixation for cortical osteotomies in rabbits.

Résumé. Les auteurs ont réalisé des ostéotomies de la diaphyse fémoreale chez le lapin, qu'ils ont fixées par des tiges intramédullaires faites d'acide poly-L-lactique (APLL) et d'acide poly-DL-L-lactique (APDLL). Les animaux ont été suivis de 1 mois à 2 ans. Dans le groupe APLL, la fixation a été solide et la consolidation obtenue dans 37 des 40 ostéotomies. Dans le groupe APDLL, la fixation a été solide 30 fois sur 45, mais dans 13 de ces cas il s'est produit une angulation de plus de 10°. Il y a eu 15 échecs de fixation. Dans aucun des deux groupes il n'a été observé de phénomènes inflammatoires ni de réactions à corps étranger. Cette étude montre que les tiges d'APLL permettent une fixation efficace de l'ostéotomie corticale chez le lapin.

Introduction

Polylactic acid (PLA) is an absorbable polymer which has been studied as a possible material for surgical fixation and in drug delivery systems. High molecular weight PLA is synthesised in the ring opening polymerisation of the cyclic diester lactide [12, 17]. In vivo PLA undergoes hydrolytic de-esterification into lactic acid which becomes incorporated into the tricarboxylic acid cycle and is subsequently excreted by the lungs as carbon dioxide [1, 15]. PLA has two enantiomeric forms, poly(-L-)lactic acid (PLLA) and poly(-D-)lactic acid (PDLLA) [32]. In experimental studies, the racemic form of polylactic acid, PDLLA, degrades and loses its mechanical strength faster than PLLA. Resorption time varied from 32 weeks to 18 months for PDLLA, and from 32 weeks to 4 years for PLLA [1, 4, 16, 22]. The biocompatibility of PLA is good [7, 8, 14, 15]. The cyclic diester, the lactide, can polymerise to a high polymer polylactide suitable for forming strong fibres and films [27]. In experimental studies, reinforced PLA sutures, non-reinforced PLA sheets, rods, screws and plates were used with success for the fixation of cancellous fractures in non-weight bearing bones [7, 8, 10, 16, 17, 24].

The mechanical properties of non-reinforced PLA implants are not sufficient for the fixation of weight-bearing bones. These materials are too brittle and may break before the fracture is consolidated [9, 29]. The PLLA or PDLLA matrix was self-reinforced (SR) with highly orientated PLLA fibres to form strong and tough PLA composites with higher strengths than in the earlier implants [29]. The SR-PDLLA/PLLA implants became weaker faster than the SR-PLLA implants [19, 23]. SR-PLLA and SR-PDLLA/PLLA cylindrical implants were used...
successfully in the fixation of cancellous bone osteotomies in rats [18].

The aim of this study was to find out whether SR-polylactic intramedullary rods were strong enough to fix osteotomies in weight-bearing bones of rabbits.

Material and methods

Implants

The intramedullary rods (4.5–4.8 mm by 50–60 mm) were made of self-reinforced polyactic acid. The SR-PLLA rod had a PLLA matrix reinforced with PLLA fibres, and the SR-PDLLA/PLLA rod a PDLLA matrix (40%) reinforced with PLLA fibres (60%). The molecular weight of the PLLA was 260,000 (CCA Biochem b.v., Holland) and the PDLLA 100,000 (Boehringer Ingelheim, Germany). The rods were gamma-sterilised with a dose of 2.8 Mrad.

Follow up

This was made at 1, 3, 6, 12, 24, 36, 48, 93 and 105 weeks; each group consisted of five rabbits, except the PLLA group at 6 weeks which was of six rabbits, with only one rabbit followed at 93 and 105 weeks. Two days before sacrifice by a lethal dose of medetomidine and ketalar, the rabbits were given oxytetracycline 50 mg/kg [20].

Examination of specimens

Both femurs were removed and dissected free of soft tissue. Anteroposterior and lateral radiographs were taken (distance 0.9 m, 40 kV, 12 mA and 0.03 sec). The osteotomy was tested manually, the intact left femur being a control. The shafts of both femurs were fixed in ethanol and embedded in methylmethacrylate [26]. Longitudinal coronal sections, 5 mm thick, were cut with a microtome (Polycut S, Reichert-Jung, Nussloch, Germany) and stained by the Goldner-Masson method [11]. Further sections, 80 μm thick, were cut with a Leitz saw microtome 1600 (Leitz GMBH, Wetzlar, Germany) for oxytetracycline fluorescence (HBO 220 UV lamp, BG 812/6 primary filter) and microradiographic studies (Kodak professional film SO 343; 50 kV, 9 mA, 12 min, at 22 cm distance).

Results

Failure of fixation occurred in ten rabbits, two in the PLLA group and eight in the PDLLA/PLLA group; they were sacrificed before follow up time was reached. The two failures in the PLLA group occurred 8 weeks after operation; the rods were not totally broken, but the SR-structure was delaminated and the rods were flexible. In the PDLLA/PLLA group, failure occurred from 2 to 18 weeks after operation.

All animals used their limbs normally after 3 weeks. On manual testing, the PLLA group were stable at 6 weeks and later, with one exception at 24 weeks. In the PLLA/PDLLA group, three osteotomies were unstable at 6 weeks, two at 12 weeks and one at 48 weeks.

Radiology

There was no failure of fixation in the PLLA group at follow up, compared with six in the PDLLA/PLLA group.

At 1–3 weeks. Fixation was firm without angulation in the PLLA group. There were three failures at 3 weeks in the PDLLA/PLLA group; angulation of more than 10° was seen in two at 1 week, and in all 5 at 3 weeks. Slight callus was present in all at 3 weeks.

At 6 weeks. Callus had increased and was greater in the PLLA compared with the PDLLA/PLLA group.