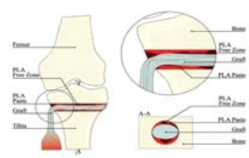
Bioresorbable Polylactide Implant Promotes Tendon Ossification in the Bone Tunnel in Ligament Reconstruction Surgery

Ficek K; Gogolewski S*
Galen Orthopaedics & Galen Foundation, PL-43-150 Bierun, Poland

Introduction: Reconstruction of injured ligaments is still a problem. The type of graft fixation is an important factor affecting success of the reconstruction. Inadequate fixation often results in tunnel widening, poor contact between the outer surface of the tendon and the surrounding bone and inadequate tendon ossification. Although various materials are being used experimentally to promote tendon graft-to-bone healing, their effectiveness has not been clinically proven.
In this study, microporous polylactide beads of controlled pore size impregnated with peripheral blood were implanted in bone tunnels in rabbits to assess their potential to enhance tendon graft osteointegration in ligament reconstruction surgery.

Methods: poly(L/DL-lactide) beads with a pore size in the range of 200 - 400 µm were produced from polymer purchased from PURAC Biochem, Gorinchem, the Netherlands. Twenty four male New Zealand rabbits 8-12 months old and 3-3.5 kg body weight were divided into 4 groups of 6 animals each: Group 1 (control), no PLA, implantation time 6 weeks; Group 2, PLA beads, implantation time 6 weeks; Group 3 (control), no PLA beads, implantation time 12 weeks; Group 4, PLA beads, implantation time 12 weeks (Ethic Committee approval 668/09, July 7, 2009). The animals were given antibiotic protection Linco-Spectin SS, 1 ml/5kg subcutaneously per 7 days before surgery (Pfizer Animal Health, UK), and kept in individual cages to adapt to the housing environment. No food was given during the day preceding surgery. The animals were anesthetized using atropinum sulfuricum 0,06 mg/kg, (Polfa, Poland), ketamine hydrochloride 40 mg/kg (Biowet, Poland), Xysilazine HCL 10 mg/kg (Biowet, Poland), administered intramuscularly. The bone tunnel with a diameter of 2.6 - 3.5 mm and length 8 - 12 mm was drilled in the proximal tibial metaphysis using a drill equipped with adequate drill bits. Next, the long digital extensor tendon of the right hind limb was detached from its lateral femoral condyle and implanted in the bone tunnel of the proximal tibial metaphysis applying appropriate tension. At this time, the PLA beads were mixed with blood from the bleeding part of the bone wall to form a homogenous paste and packed clockwisely into the bone tunnel around the tendon starting from its lateral entrance. After a tight lateral application, the procedure was repeated at the medial outlet. (Fig. 1). The average amount of PLA beads needed to fill the tunnel was 60 mg. The free end of the graft was fixed to the tibial periosteum at the opposite tunnel entrance with a 4-0 monofilament Prolene suture (Ethicon®). Subcutaneous wounds were closed in layers using 3/0 absorbable Safil Braun® braided polyglycolic acid sutures and the skin was closed with 4-0 monofilament Prolene suture (Ethicon®). The rabbits were placed in cages and allowed free movements until euthanization at 6 and 12 weeks after implantation using barbiturate overdose. The control and PLA implanted bones were harvested for histological evaluation. The 100 µm thick slices were stained with Masson-Goldner trichrome, hematoxylin-eosin and safranin O. The variables analyzed were: the presence of new bone, the type and density of cells, organization of collagen fibers, vascularization, cartilage orientation and healing of the grafted tendon along the longitudinal and the lateral cross-sections of the tunnels. In the latter case the slices were collected from the tissues harvested at the entrance, the midportion, and the exit of the tunnels. In addition, the specimens were examined for macrophage-like cells, lymphocytes, and foreign body cells.

Results: At 6 and 12 weeks postimplantation histological sections of harvested specimens showed significant tendon-to-bone healing in all animals with bone tunnels filled with PLA-blood paste. Abundant vascularized new bone was however formed almost exclusively in those areas where PLA-blood paste has been successfully delivered, whereas in other areas along the longitudinal tendon axis not reached by PLA-blood paste there was only a minute amount of bone or none at all. There was very little new bone formation in the control specimens for a comparable implantation time.



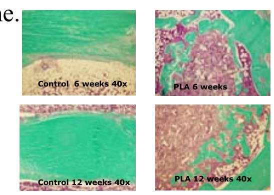


Fig. 1. Implantation setup. Fig. 2. Histological sections of the specimens harvested at 6 and 12 weeks after implantation. 1. Graft osteointegration, no PLA-blood paste was used, 6 weeks; 2. Graft osteointegration in the presence of PLA-blood paste, 12 weeks. 3. Well-developed blood vessels within the osteointegration zone in the presence of PLA- blood paste, 12 weeks. O - osteointegration; G - graft, B - bone, BV- blood vessel.

Conclusions: Adaptable, pliable paste consisting of microporous PLA beads and peripheral blood used to fill vacant areas between the tendon and bone in the bone tunnels promoted tendon-to-bone healing in rabbits subjected to surgery. This healing effect can be intensified by mixing PLA beads with autogenous marrow blood, platelet-rich plasma and/or growth factors. Nonuniform distribution of the PLA paste in the bone tunnel around the grafted tendon results in a patchy bone formation. The new bone is almost exclusively formed in those areas where PLA paste is in direct contact with both the tunnel bone and the outer surface of the tendon, thus creating conditions that facilitate bone regeneration. Further study is required to define optimal handling procedure to ensure uniform distribution of PLA paste throughout the bone tunnels.

*Formerly: Polymer Research, AO Research Institute, Davos, Switzerland