# A REVISED SURGICAL CONCEPT OF ANTERIOR CRUCIATE LIGAMENT REPLACEMENT IN A RABBIT MODEL. PRELIMINARY INVESTIGATIONS

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## Abstract

*In this project the anterior cruciate ligament (ACL) replacement in a rabbit model was performed for the preclinical phase of investigations of a new form of biomaterial i.e. polymer beads (granules). This material, based on resorbable aliphatic polyester (polylactide - PLA) was used as a filler of the bone tunnels to enhance tendon-to-bone healing. The high specific surface area and well known biocompatibility of this material designated it as an osteoconductive agent in reconstructive ligament surgery. Additionally, a new surgical concept was proposed which retains the natural elasticity of the harvested tendon. This method ensures fixation of the grafted tendon within the bone tunnels in their entire length.*

***Keywords:*** *ACL reconstruction, tendon implant, resorbable material*

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## Introduction

ACL is the most frequently injured ligament in the knee. The treatment options for ligament ruptures include conservative management but the most broadly accepted procedure is reconstruction with intra-articular grafts [1-2]. The outcome of reconstructive ligament surgery is dependent on the quality of healing of the transplanted grafts in the bone tunnels. Different techniques ensure only a partial graft fixation in some areas of the bone tunnel [2-4]. A major part of the transplant anchored inside the bone is suspected to integrate with the bone by biological processes occurring naturally within the tunnels. Improper graft fixation may cause inadequate joint stability. In this study we tested a new form of material dedicated to filling the tunnels covering the transplanted grafts. The role of the polymer granules was to create a three-dimensional scaffold for osteoblasts to adhere to, enabling them to proliferate faster than they otherwise would in the blood of the bone tunnel (FIG. 1).

The aim of this experiment was to verify the effect of the bioresorbable material on the healing process between the outer surface of the tendon and the inner part of the bone wall to obtain entire intratunnel fixation.

## Materials and methods

Polymer granules were produced using commercial copolymer; poly L/DL lactide (L/DL; 80:20; PURAC) which was approved by FDA. Porous granules were obtained using leaching technique described elsewhere [5]. Specific surface area of the granules was about 20 $m^2/g$.

An in vivo experiment concerned 12 rabbits (Ethic Committee approval 668/09) which were divided into 4 groups of 3 animals each: Group 1 (control), no PLA, implantation time 6 weeks; Group 2, PLA, implantation time 6 weeks; Group 3 (control), no PLA, implantation time 12 weeks; Group 4, PLA, implantation time 12 weeks. Under general anesthesia the long digital extensor tendon of the right hind limb at the lateral femoral condyle was exposed and through its insertion (attachment) site, threads were applied without cutting the tendon off (FIG. 2a). The tunnels were arranged in proximal tibia methaphysis medially and in distal femur methaphysis laterally. The natural ACL insertions served as the footprints to drill the tibial and femoral bone tunnels. Bone tunnel diameters were 2.6-3.5 mm and were about 1 mm wider than their grafts. According to other authors, in the surgical set-up the long digital extensor tendon is exposed and immediately detached. Our innovative algorithm offers the alteration of the surgery to maintain the biological and physical properties of the tendon. The tendon was detached as late as possible to avoid its contraction, which might change its physical parameters and then implanted in the bone tunnel applying appropriate tension.

The grafted tendon was pulled through the tunnels and covered with the polymer granules. PLA material was evenly distributed around the graft, starting from its tibial distal entrance next to femoral proximal one. (FIG. 2c). Because of the electrostatic properties of the polymer granules, the majority of the porous beads were mixed with autogenous peripheral bone blood. This composition in a paste form filled the bone tunnels. The graft ends were sutured to the tibial and femoral periosteum with the non-absorbable threads (Prolene 2.0). The patella was reduced and the joint was closed and sutured in layers. 24 hours after surgery all rabbits returned to their normal activity. The animals were euthanized 6 or 12 weeks after surgery.

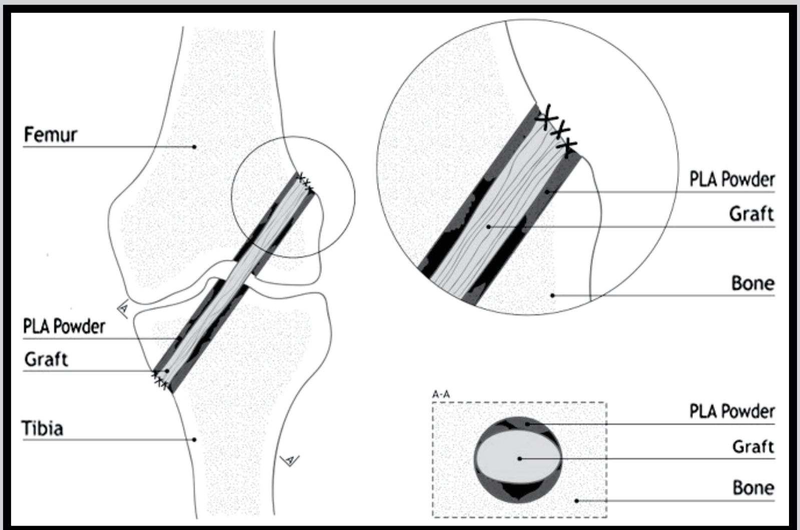


**FIG. 1. Model of graft implantation using PLDLA granules.**

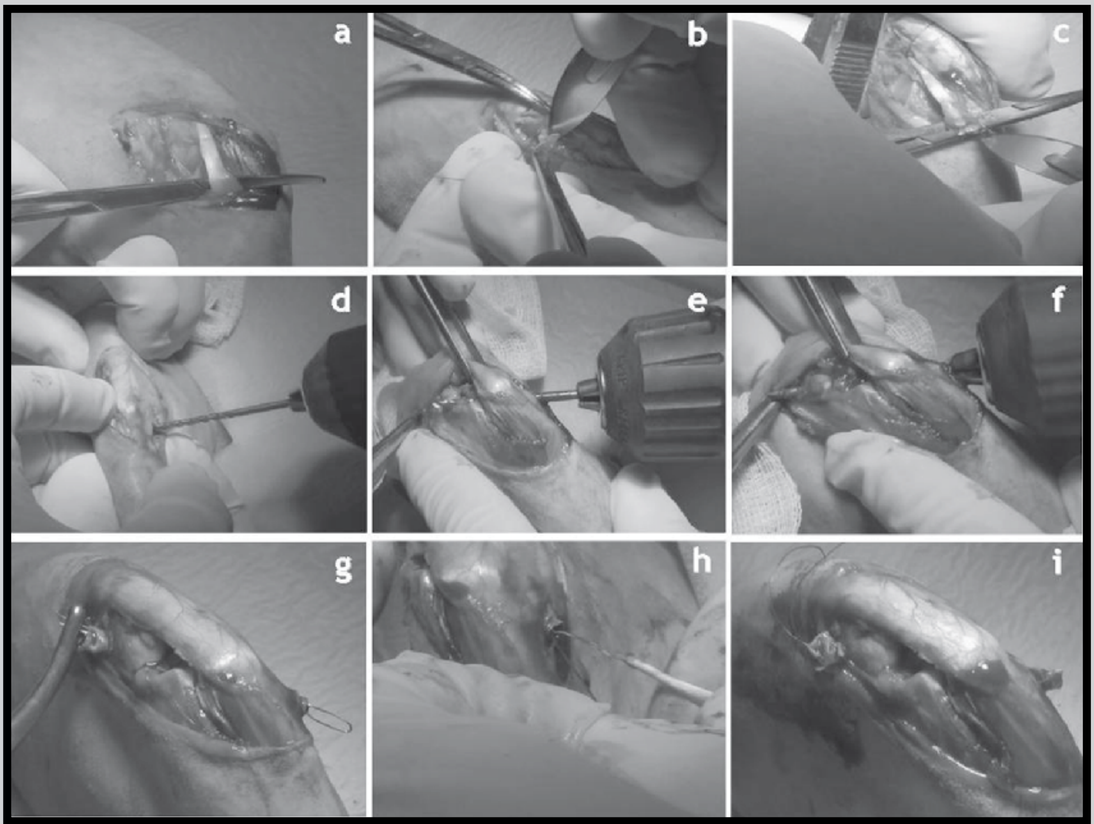


**FIG. 2. Surgical procedure; the long digital extensor tendon was detached (a-c), the natural ACL insertions served as the footprints to drill the tibial and femoral bone tunnels (d-f), the grafted tendon was pulled through the tunnels and covered with the PLDLA granules (g-i).**

## Results

The polymer granules applied in the experiment show a tendency to interact electrostatically, which makes the operation difficult. The polymer powder tightly covers the syringe needle and surface of the tools which hinder its introduction inside the bone loss. Moreover, introduction of the powder has only a local character and the powder is not homogenously distributed inside the bone tunnel. It may significantly influence the course of osteointegration process, which could be faster in areas reach in the polymer granules, and slower in areas where the granules are absent e.g. in a middle part of the tunnel. The granules with specific surface area of 20 $m^2$/g and size 1-10 µm are a sufficient carrier of active substances of blood e.g. pallet rich plasma. During the operation blood drawn from the patient's wound is mixed with the polymer granules. According to the literature [6] the main criterion of proportion between a natural (i.e. binder) and a synthetic component is consistence of the material which should be paste-like. In the case of the described treatment the rate between the polymer powder and patient's circulating blood was 3:1. Such paste in quantity about 3.5-4 ml was easily introduced into a syringe and then injected to the bone tunnel. It seems that, the applied method should provide a homogenous distribution of the paste within the defect area. An adaptable, pliable paste consisting of mesoporous PLA beads and blood marrow cells was used to fill vacant areas between the tendon and bone in the bone tunnels, which facilitated and enhanced tendon - to - bone healing. This protocol displays the alter, total grafted tendon fixation through the entire length of bone tunnels. Final confirmation of homogenous distribution of the paste and its influence on the ossification process rate will be possible after histopathological analysis.

## Conclusions

Total graft fixation in contrast to the commonly used partial one guarantees optimal joint stability after ligament reconstruction. Further study is required to attain better handling procedures in order to ensure uniform distribution of PLA paste within the bone tunnels. The healing effect can be intensified by mixing PLA beads with autogenous marrow blood cells or platelet - rich plasma and/or growth factors.

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