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Paper #140

Prospective Clinical Feasibility Study of a PLLA Scaffold for Primary ACL Reconstruction with Three-Year Follow-Up

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Summary:
Safety and feasibility of a PLLA scaffold for primary ACL reconstruction in a prospective, consecutive, clinical study

Abstract:

Introduction

Graft selection for anterior cruciate ligament (ACL) reconstruction continues to be debated. Autograft outcomes are affected by associated donor-site morbidity, while allografts have higher failure rates and inherently limited quality. To date, a demand remains for a safe, 'off-the-shelf' implant and tissue engineering is one approach that could provide a regenerative solution. Recently, a bioresorbable, acellular, poly(L-lactic acid) (PLLA) scaffold was developed, composed of 3D-braided polymeric microfilaments to guide cellular infiltration and new ligament tissue growth. Therefore, the objective was to assess the safety and feasibility of the PLLA scaffold for primary ACL reconstruction in a prospective, consecutive, clinical study.

Methods

Fifteen patients (ages 18 to 46 years old) with ACL ruptures were implanted with a PLLA scaffold for ACL reconstruction. The primary endpoint for the study was defined as the absence of graft failure or revision ACL surgery at one year. The study was performed in a highly active patient cohort, with 11 of 15 patients reporting a pre-injury Tegner score of 9 out of 10. Secondary endpoints were determined by safety rates per complications, subjective patient-reported outcomes (2000 IKDC scale, KOOS pain, Tegner, and Lysholm scores), clinical function (Lachman test, KT-1000, pivot shift, anterior drawer, and single leg hop test), and imaging measures (radiographic, MRI, and CT). In the case of graft failure, arthroscopic confirmation was performed prior to or on the same day as revision surgery. Biopsies were taken from the intra-articular region during revision surgery and processed for histological and molecular weight analyses.

Results

At the primary endpoint of one year, no infections, allergic reactions, or synovitis was reported indicating the safety of the implant. Patient-reported IKDC scores and additional patient-reported outcome measures showed progressive improvement over baseline values (60.2+/-12.7) at 6 months (82.8+/-14.6) and 12 months (90.1+/-13.5). Physician-reported clinical evaluations of knee function showed little to no laxity or knee instability at one year follow-up. After all patients returned to normal activity at 12 months, four graft ruptures occurred between 12 and 24 months follow-up, with one additional rupture at 35 months. Histological analysis of graft biopsies revealed a fully cellularized scaffold containing a synovial cell layer, neovascularization, and robust extracellular matrix. A mild, chronic

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inflammatory response, marked by foreign body giant cells, was observed adjacent to remnant PLLA. For the remaining patients, MRI revealed irregular outlines of the ligament and regional hyper-intensity that persisted through 18 and 24 months. Although these 10 individuals at 36 months follow-up continued to report normal ACL function, IKDC scores decreased at 18 months (83.8+/-20.1) and plateaued through 36 months (81.8+/-15.8) follow-up, though neither were statistically significant.

Conclusion

The first-in-man study of a PLLA scaffold for ACL reconstruction demonstrated the feasibility of an acellular, tissue-engineered scaffold. However, tissue regeneration was inconsistent, resulting in clinically unacceptable failure rates in this limited study. Outcomes indicated insufficient load-bearing capacity of new ligament tissue in the presence of a weakening scaffold, and further innovation is required to optimize scaffold properties to achieve long-term clinical efficacy.