ACL Reconstruction with Novel Reinforced Implant: A Preliminary Study

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Introduction

Recovery following tendon and ligament injuries remains a challenge for patients and surgeons. Optimizing healing and shortening rehabilitation time would have significant clinical impact. A reinforced implant, de-signed to participate in the healing process through tissue ingrowth and remodeling has been shown in an extra-articular model to improve rotator cuff tendon healing in large animals. The current study extends the use of the BioBrace® to augment autograft in an intra-articular model of anterior cruciate ligament (ACL) reconstruction in sheep. We hypothesize that the reinforced implant would induce new host tissue proliferation in an intra-articular application.

Methods

The implant (BioBrace®, CONMED) is a highly porous type I collagen matrix, reinforced with bioresorbable PLLA micro-filaments, to provide an open 3-D biologic implant with strength. ACL reconstructions were performed in 6 skeletally mature wethers following ethical clearance using an established model. Three animals were allocated to Autograft control and three animals allocated to Autograft + Implant. The medial extensor tendon served as the autograft tendon. The harvested extensor tendon and saline-hydrated BioBrace® were combined with #2 suture **(Fig 1)**.

The BioBrace® was placed on the inside of the doubled over extensor tendon graft. The knee was approached with a medial incision, patella subluxed and the ACL transected and removed. The ACL origin and insertion were used for anatomical land- marks for 6 mm tunnels. Suspensory fixation was used on the femoral side while PEEK interference screws (outside – in) were used for tibial fixation with the knee in ~20 degrees of flexion prior to screw insertion. Animals were euthanized at 6 weeks (n=3) and evaluated with gross dissection, radiographs, micro computed tomography, 3D T2-weighted MRI, mechanical testing, and paraffin histology. The ACL was manually segmented from 3D MR images using open-source software (BioImage Suite) to quantify and compare ACL tissue volumes between groups. Segmented ACL tissue volumes excluded the tibial and femoral insertions. Mechanical testing was performed in anteroposterior draw using a calibrated servo-hydraulic testing machine between 10N and 100N at 0.5Hz with 10 cycles followed by 60 seconds of relaxation and a ramp to failure at 10 mm/min. Micro-CT of the femoral and tibial tunnels were examined for bony response in the axial, coronal, and sagittal planes. Histology evaluated local cell and tissue responses within the BioBrace® and autograft tendon within the tibial and femoral tunnels as well as the intra-articular graft.

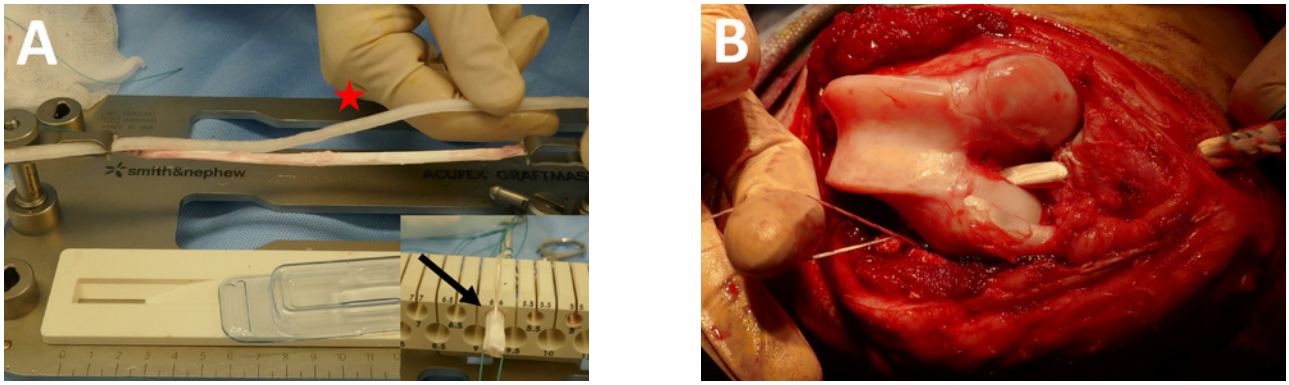

Figure 1. *The harvested extensor tendon and saline-hydrated BioBrace® **(star)** were whip stitched together **(A)** and placed into 6 mm tunnels in the femur and tibia **(B)**. The BioBrace® on the inside of the doubled over graft construct **(arrow)**.*

BioBrace

Results

All animals recovered uneventfully following surgery with no adverse reactions based on gross dissection and radiographs. Micro computed tomography demonstrated well placed tunnels and evidence of healing at the tunnel margins. No adverse bone reactions were noted. Volumetric analysis of MR imaging revealed significantly more intra-articular graft volume for the Autograft + BioBrace® group versus Autograft control (Autograft + BioBrace®: 1074.0 ± 79.1 mm3; Autograft control: 751.0 ± 80.6 mm3, p = 0.008) **(Fig 2c)**. MRI signals were consistent with formation of new tissue within the BioBrace® **(Fig 2a,b)** and early remodeling of the intra-articular graft which was confirmed in histology at 6 weeks **(Fig 3a)**. Femoral and tibial bone tunnel histology revealed new tissue integration into the BioBrace® as well as a healing interface with the host autograft **(Fig 3b)**. Scattered multinucleated cells were present on PLLA of the BioBrace® along with new vasculature and aligning neo-ligament connective tissue within the BioBrace®. Mechanical properties of the Autograft + BioBrace® group outperformed the Autograft control (peak load 141.3 ± 62.0 N versus 113.6 ± 46.0 N) at 6 weeks.

Discussion and Conclusion

The results of this intra-articular ACL model are in line with the previously reported findings of the reinforced implant used in an extra-articular rotator cuff repair. The common theme in both studies was the ability of the BioBrace® to support and encourage new tissue ingrowth and remodeling regardless of anatomic site (extra-articular, intra-articular, and bone tunnels). Clinically, a BioBrace® and the resultant host tissue ingrowth may serve to optimize the balance between the local biomechanical and biological healing environments. This study is limited in the short follow up and small sample sizes. Further work is warranted.

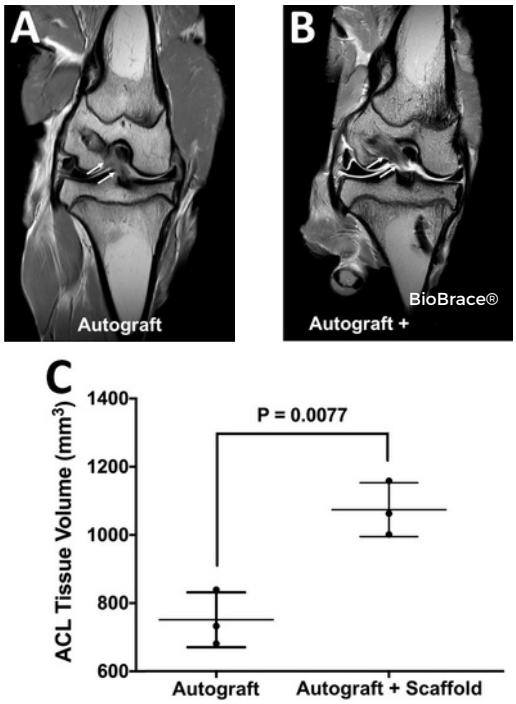

Figure 2. *Representative MR imaging of the joint space at 6 weeks in Autograft alone **(A)** and Autograft + BioBrace® **(B)**. The Autograft + BioBrace® group had significantly more intra-articular graft volume compared to the Autograft control **(C)**.*

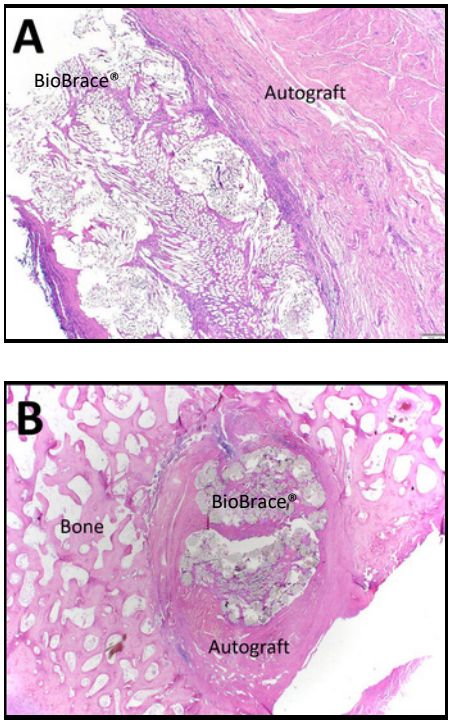

Figure 3. *Longitudinal H&E histology at 6 weeks of the intra-articular Autograft + BioBrace® graft, showing new connective tissue formation around and within the porous BioBrace® **(A)**. Cross-section H&E histology at 6 weeks within the tibial tunnel, showing open architecture of the BioBrace® inside the graft and tissue integration **(B)**.*

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