ACL Augmentation with a Reinforced Implant Improves Strength and Stiffness at Time Zero in an In-Vitro Ovine Model

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Abstract:

Background: This study investigates maximum load and stiffness in an anterior cruciate ligament (ACL) reconstruction with and without augmentation using a reinforced implant (BioBrace®, CONMED) at time zero in an in-vitro ovine model.

Method: Hamstring tendon ACL grafts were modeled by whip stitching the ends of ovine extensor tendons using #2 suture and doubling the grafts over a pin. Six of the grafts were augmented with the reinforced implant while the remaining six grafts acted as a non-augmented control group. All grafts were placed in a 6mm tunnel through 20pcf sawbones and fixed with a 6mm PEEK screw prior to pulling to failure at 20mm/min.

Results: Augmenting an ACL graft with a reinforced implant significantly increased the maximum load of the construct compared to non-augmented control (656 N vs. 457 N respectively) ($p<0.01$), a 200N, or 44% increase. The overall stiffness of the augmented tendon graft was 175 N/mm compared to non-augmented control of 124 N/mm ($p=0.09$) and represented a 50N/mm or 41% increase.

Conclusion: Augmenting an ACL tendon graft with a reinforced implant provided a 44% increase in strength and a 41% increase in stiffness of the graft construct at time zero. This suggests that BioBrace augmentation has the potential to reduce graft laxity and creep, and that augmentation may address the decrease in strength of soft tissue grafts during the early post-operative remodeling period.

Introduction:

As a reconstructed ACL graft remodels, the graft construct loses a significant amount of strength, having only 4% and 9% of its pre-operation strength at 6- and 9-weeks post-operation (see Figure 1 for more detail).[1] The strength of the reconstructed graft does not reach native ligament strength for well over one year.[1,2,3] Augmenting the strength of an ACL graft at the time of surgery may reinforce and protect the graft during the early post-operative remodeling period. This may help to reduce failures, accelerate rehabilitation, and improve return to activity.

Historically, augmentation of ACL procedures has attempted to improve the mechanical strength of the reconstruction or improve healing of the graft.[4,5] Current augmentation techniques are designed to act as a permanent seatbelt; providing mechanical reinforcement only when engaged. Thus, concerns may exist over stress shielding the ACL graft, over constraining and complex tensioning.[6,7,8,9] These techniques utilize materials that do not provide any biological or healing benefit and they do not degrade. The materials are present in the patient for rest of their life.

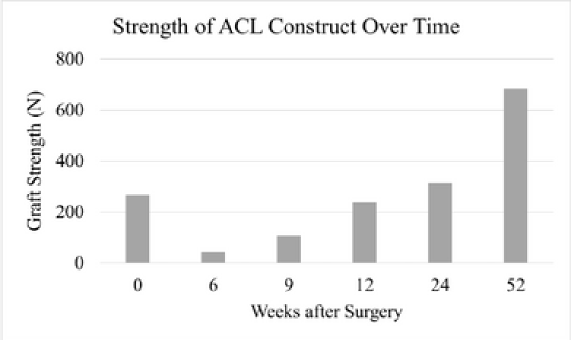

Figure 1: Average strength of graft construct in ACL reconstruction, adapted from Weiler et al 2002 [1].

A novel reinforced implant (BioBrace®, CONMED) was developed to achieve both mechanical and biological augmentation using a fully resorbable biocomposite approach: a highly porous collagen sponge for improved healing reinforced with PLLA filaments for strength. The BioBrace® implant provides supplemental strength and biology for up to 2 years before naturally resorbing. Previous studies have demonstrated rapid cellular infiltration and new tissue regeneration by 6 weeks with rotator cuff strength at 12 weeks as strong as the native tendon.[10,11,12] The goal of this study was to demonstrate the mechanical benefit of reinforced implant when augmenting an ACL tendon graft. We hypothesize that augmentation of the graft will increase the stiffness and maximum strength of the construct.

Method:

Hamstring tendon ACL grafts were modeled by whip stitching the ends of ovine extensor tendons using #2 suture and doubling the grafts over a pin. Six of the grafts were augmented with the 5mm wide reinforced implant by whip stitching the ends of the scaffold and doubling it over with the tendon graft. The remaining six grafts acted as a non-augmented control group.

All grafts were placed in a 6mm tunnel through 20pcf sawbones and fixed with a 6mm PEEK screw, as shown in Figure 2 below. All grafts were pulled at 25mm/min. Peak load (N), displacement at peak (mm), stiffness (N/mm), and failure mode were recorded. Peak load was defined as the maximum load registered while stiffness was defined as the slope of the linear region of the curve.

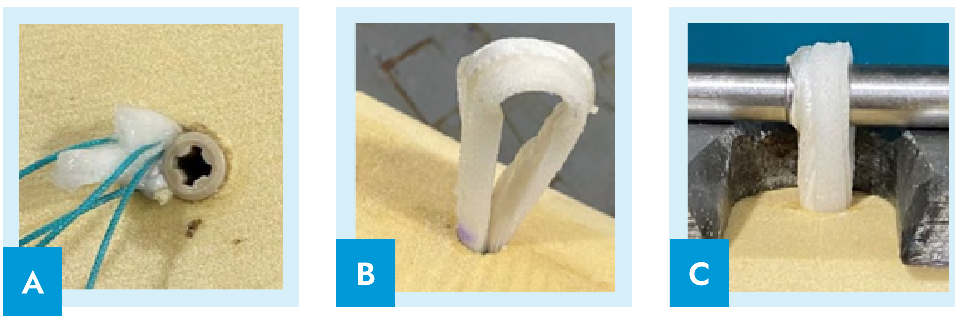

Figure 2: Tendon grafts augmented with the reinforced implant looped over a pin in a sawbones model. (A) Distal fixation of doubled over graft (underside of Sawbones block), (B) Tendon and reinforced implant loop, (C) Tendon and implant over a pin.

Results:

All constructs failed via the graft pulling out of the sawbones block. Maximum load and stiffness of the overall graft construct with and without augmentation are shown below in Figure 3. Augmenting an ACL graft with reinforced implant significantly increased the maximum load of the construct compared to non-augmented control ($p < 0.01$) (656 N +/- 87 N vs. 457 N +/- 40 N respectively). On average, augmentation with this implant increased the graft strength by 200N; a 44% increase. The overall stiffness of the augmented tendon graft was 175 N/mm +/- 22 N/mm, which was significantly higher than the tendon graft alone at 124 N/mm +/- 29 N/mm ($p = 0.09$) and represented a 41% increase. The displacement was not significantly different between groups indicating reinforced implant added supplemental strength at clinically relevant displacements ($p = 0.135$).

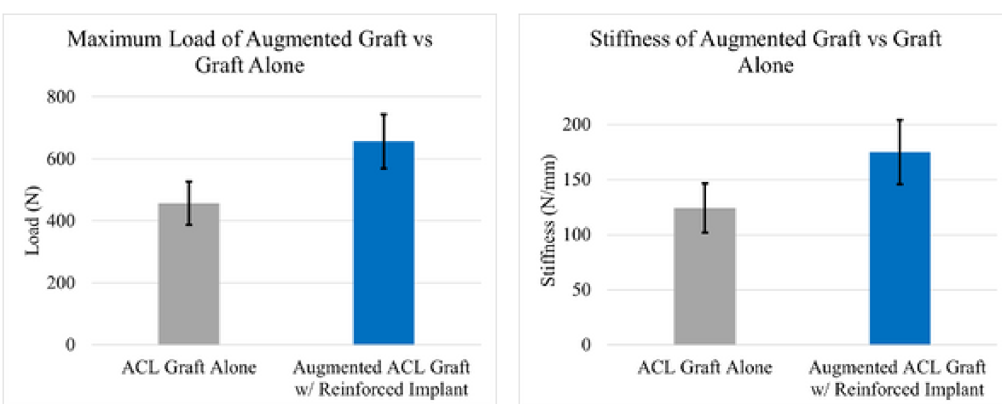

Figure 3: Maximum load and stiffness of the augmented ACL Tendon graft vs the ACL tendon graft alone. (* = p < 0.05)

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Discussions:

Augmenting an ACL graft with a reinforced implant increased the overall construct strength by 200N (44%) and increased the stiffness by 50 N/mm (41%). This indicates that at the time of surgery, the addition of the implant to an ACL graft will reinforce the graft construct, providing an increase of strength at time zero and throughout the early remodeling phase and increasing stiffness, potentially reducing graft creep and laxity. Figure 4 below demonstrates how 200N of supplemental strength from augmentation with a reinforced implant may affect the strength of the graft reconstruction during the first year of healing based on literature.[1] Augmentation with a reinforced implant may compensate for the decrease in graft strength observed during the first 12 weeks post operatively. This does not include the expected contribution to graft strength from rapid tissue ingrowth into the implant, as demonstrated previously.[10,11,12]

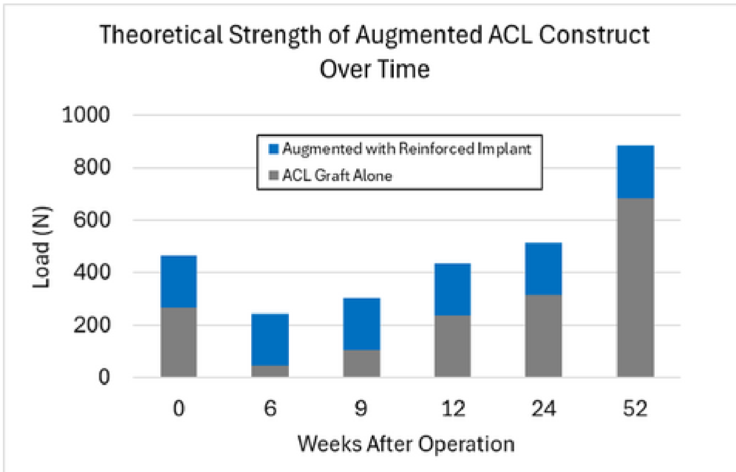

Figure 4: Theoretical strength of a reinforced implant augmented graft construct in ACL reconstruction during the first 2 years of healing [1].

Conclusions:

Augmenting an ACL tendon graft with BioBrace provided a 44% increase in strength and a 41% increase in stiffness of the graft construct at time zero. This suggests that BioBrace augmentation has the potential to reduce graft laxity and creep. Augmentation with BioBrace may address the decrease in strength of soft tissue grafts during the early post-operative remodeling period.

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