Rotator cuff repair augmented with a reinforced bioinductive implant improves strength and reduces creep at time-zero in an ovine model

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Abstract:

Background: This study investigates cyclic creep and max load in a rotator cuff repair with and without augmentation using a reinforced bioinductive implant at time zero in an ovine model.

Method: Twelve ovine infraspinatus tendons were dissected down to simulate a full thickness rotator cuff tear. All repairs used the same single row technique, six were augmented with BioBrace® while the other six acted as the control group. BioBrace® was secured independent of the repair using free sutures medially and secured laterally with bone anchors. All specimens were cyclically tested and pulled to failure.

Results: BioBrace® augmentation reduced cyclic creep by 23% compared to the non-augmented control (p-val<0.01). Augmentation with BioBrace® increased the max load of the repair by 114N, or 34%, compared to the non-augmented control group (p-val=0.03).

Conclusion: Augmenting a rotator cuff repair with BioBrace increases time-zero strength and reduces cyclic creep, as observed in an ovine model. Reduction in cyclic creep and increased peak load supports that augmentation, as performed in this study, may alleviate stress from the tendon and potentially reduce rotator cuff repair failure at the suture-tendon interface.

Introduction:

Retear rate of the primary surgical repair site for large and massive full-thickness rotator cuff tears ranges from 34% to 94%[1,2]. Failure of the repair commonly occurs within the first 6 months post-op and is attributed to two main factors: insufficient biologic healing of the native tendon tissue and mechanical failure at the suture-tendon interface[3,4,5] .

Failure of the cuff construct biologically and mechanically must be addressed within the first 6 months post-op when most failures occur[4]. Augmentation with various scaffold technologies has recently gained interest. However, historically, augmentation has either focused on biologic healing or mechanical failure and none have proven to address both sufficiently[6,7,8].

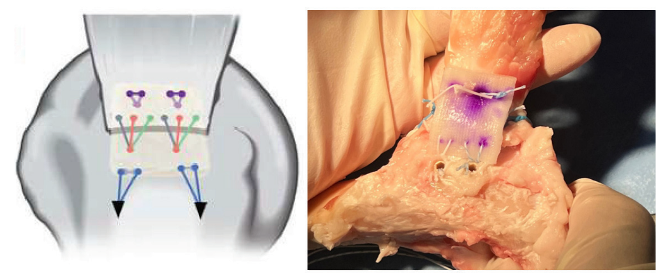
A novel reinforced bioinductive implant (BioBrace®, CONMED) was developed to achieve biologic and mechanical augmentation using a biocomposite approach: a highly porous collagen sponge for improved healing reinforced with PLLA filaments for strength. Previous publications have demonstrated rapid cellular infiltration and new tissue regeneration by 6 weeks with cuff strength at 12 weeks as strong as native tendon[9,10].

The strength of the repair over time has been demonstrated with this implant[9,10], however, load sharing at time zero to improve initial rotator cuff repair mechanics via augmentation has not been well investigated. Load sharing and increased repair strength may alleviate stress at the suture-tendon interface and reduce the incidence of early mechanical failures. This study investigates load sharing and cyclic creep in rotator cuff repair augmented with a reinforced bioinductive implant at time zero. We hypothesize the addition of this augment will reduce creep in the cuff construct and increase the repair strength overall.

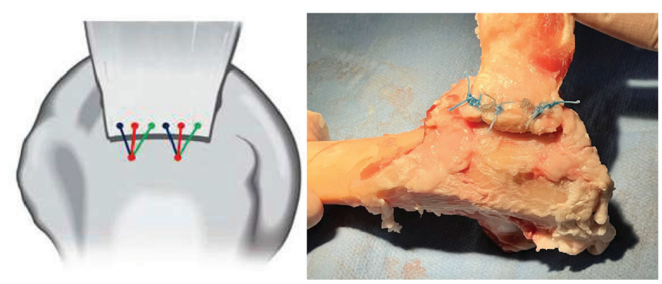
Methods:

Twelve ovine infraspinatus tendons were dissected down to simulate a full thickness crescent rotator cuff tear. All rotator cuff tears were repaired using a single row technique; six were augmented with BioBrace® while the remaining six served as a control group.

Two 5.5mm triple loaded suture anchors (CrossFT®, CONMED) were used to complete a single row repair of the rotator cuff. This completes the control group technique. Once the cuff is repaired, the augment was secured medially using two inverse mattress stitches (#2 Hi-Fi Suture) medial to the repair connecting the implant to the tendon. Two inverse mattress stitches were added to the lateral edge of the implant and secured to bone laterally using two 5.5mm knotless anchors (Argo®, CONMED) to independently tension the implants laterally.



Rotator Cuff Repair with BioBrace Augmentation



Rotator Cuff Repair Control

Figure 1: *Rotator cuff repair technique (A) with augmentation (B) Non-augmented control*

Once the cuff was repaired, the humerus was secured and the tendon belly cryo-gripped to a pneumatic fixture for pull to failure testing as seen in ***Figure 2***. Cyclic preconditioning from 10-100N for 500 cycles at 1Hz was performed before pulling to failure at 20mm/min until total evulsion[11]. Cyclic creep, load, displacement, stiffness, and failure mode were recorded.

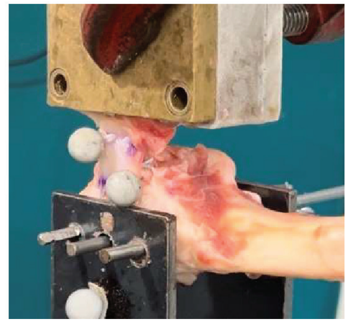


Figure 2: *Example of test setup with humeral head secured to fixture and tendon pulled to failure*

Results:

All repairs failed due to suture pull through the infraspinatus tendon. Max load and cyclic creep of the repair with and without augmentation are below in ***Figure 3.*** BioBrace® augmented repairs were statistically significantly higher in max load compared to non-augmented control (p-val < 0.01) (447 ± 70 N vs. 333 ± 51 N respectively). On average, augmentation increased the overall repair strength by 114N, or 34%. Cyclic creep in the augmentation group was significantly reduced by 23% compared to the non-augmented control (p-val = 0.03) (1.7±0.2 mm vs. 2.2±0.8 mm).

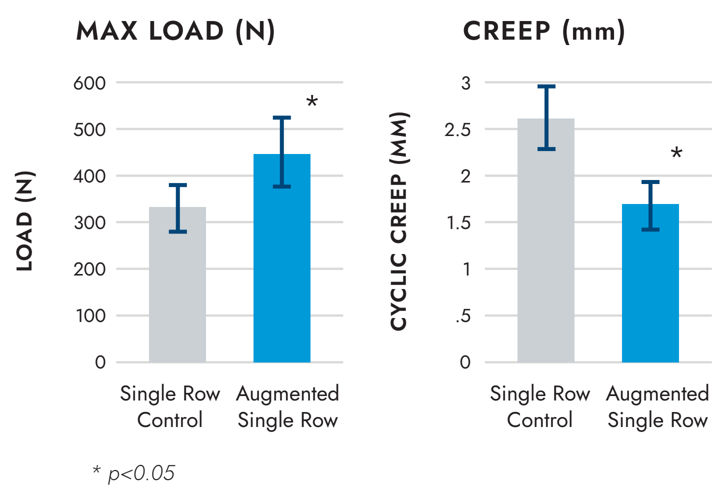


Figure 3: *(Left) Max load and (right) cyclic creep of augmented vs. non-augmented control.*

Discussion/Conclusion:

Augmenting a rotator cuff repair with a reinforced bioinductive implant increased the overall strength at time zero, and reduced cyclic creep as demonstrated in an ex-vivo ovine model. The increased max load demonstrates that the BioBrace® implant provides supplemental strength that may support the tendon in the early stages of healing when failures commonly occur. The reduction in cyclic creep demonstrates BioBrace® can load share alongside the tendon. These findings suggest that augmenting a rotator cuff repair with a BioBrace® improves strength of the construct and minimizes loss of contact between the repaired tendon and bone. The BioBrace® can load share with the primary repair, protecting it biomechanically, and potentially improving the chances for healing over time.

Rotator cuff failure occurs early on due to two main factors: poor healing and mechanical failure. This study proved augmentation with a reinforced bioinductive implant increases the repair strength and reduces cyclic creep. Previous publications have demonstrated that BioBrace® supports new tissue ingrowth[9,10]. Augmentation with the BioBrace® reinforced bioinductive implant addresses the two main modes of rotator cuff failure, suggesting it is an improvement over standard repairs without augmentation.

1. Rashid, M, C Cooper, J Cook, D Cooper, S Dakin, S Snelling, and A Carr. "Increasing Age and Tear Size Reduce Rotator Cuff Repair Healing Rate at 1 Year." Acta Orthopaedica 88, no. 6 (2017): 606–11. https://doi.org/10.1080/17453674.2017.1370844.
2. Neri, B, K Chan, and Y Kwon. "Management of Massive and Irreparable Rotator Cuff Tears." Journal of Shoulder and Elbow Surgery 18, no. 5 (2009): 808–18. https://doi.org/10.1016/j.jse.2009.03.013.
3. McCarron, J. A., Derwin, K. A., Bey, M. J., Polster, J. M., Schils, J. P., Ricchetti, E. T., & Iannotti, J. P. (2013). Failure with continuity in rotator cuff repair "healing". The American journal of sports medicine, 41(1), 134–141. https://doi.org/10.1177/0363546512459477
4. Iannotti, J. P., Deutsch, A., Green, A., Rudicel, S., Christensen, J., Marraffino, S., & Rodeo, S. (2013). Time to failure after rotator cuff repair: a prospective imaging study. The Journal of bone and joint surgery. American volume, 95(11), 965–971. https://doi.org/10.2106/JBJS.L.00708
5. Ponce, B. A., Hosemann, C. D., Raghava, P., Tate, J. P., Sheppard, E. D., & Eberhardt, A. W. (2013). A biomechanical analysis of controllable intraoperative variables affecting the strength of rotator cuff repairs at the suture-tendon interface. The American journal of sports medicine, 41(10), 2256–2261. https://doi.org/10.1177/0363546513499228
6. Bushnell, B. D., Connor, P. M., Harris, H. W., Ho, C. P., Trenhaile, S. W., & Abrams, J. S. (2022). Two-year outcomes with a bioinductive collagen implant used in augmentation of arthroscopic repair of full-thickness rotator cuff tears: final results of a prospective multicenter study. Journal of shoulder and elbow surgery, 31(12), 2532–2541. https://doi.org/10.1016/j.jse.2022.05.025
7. Zhang, T., Ajayi, A., Hajjar, M., Fleckenstein, C. M., Nolan, J., & Hasan, S. S. (2023). Arthroscopic Repair of Retracted Large and Massive Rotator Cuff Tears with and without Augmentation with a Bio-Inductive Collagen Implant Reveals Substantial and Comparable Clinical Improvement. Arthroscopy: the journal of arthroscopic & related surgery, S0749-8063(23)00868-X. Advance online publication. 1.https://doi.org/10.1016/j.atro.2023.10.024
8. Snyder, S. J., Arnoczky, S. P., Bond, J. L., & Dopirak, R. (2009). Histologic evaluation of a biopsy specimen obtained 3 months after rotator cuff augmentation with GraftJacket Matrix. Arthroscopy : the journal of arthroscopic & related surgery : official publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 25(3), 329–333. https://doi.org/10.1016/j.arthro.2008.05.023
9. Carter, AJ, V Lovric, P Morberg, J Ott, J Bendigo, J Komenda, M Aronson, K Rocco, S Arnoczky, and WR Walsh. 2021. "Characterization of a Novel BioInductive Biocomposite Scaffold for Tendon and Ligament Healing." Presented at the Orthopaedic Research Society (ORS) 2021 Annual Meeting; February 12-16, 2021, Virtual.
10. Walsh, WR, AJ Carter, V Lovric, J Crowley, D Wills, T Wang, G Kanski, R Stanton, S Arnoczky, and R Arciero. 2021. "Tissue-Engineered Augmentation of A Rotator Cuff Tendon Using A Novel Bio-Inductive Biocomposite Scaffold: A Preliminary Study In Sheep." Presented at the Orthopaedic Research Society (ORS) 2021 Annual Meeting; February 12-16, 2021, Virtual.
11. Maguire, M., Goldberg, J., Bokor, D., Bertollo, N., Pelletier, M. H., Harper, W., & Walsh, W. R. (2011). Biomechanical evaluation of four different transosseousequivalent/suture bridge rotator cuff repairs. Knee surgery, sports traumatology, arthroscopy : official journal of the ESSKA, 19(9), 1582–1587. https://doi.org/10.1007/s00167-011-1436-x

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