A Retrospective Chart Review to Evaluate Clinical Outcomes of the BioBrace® Implant

Introduction:

A novel biocomposite scaffold (BioBrace®, CONMED) was developed as a biologic and mechanical augment to reinforce soft tissue where weakness exists. It is composed of a collagen sponge reinforced with PLLA microfilaments; these two materials act independently to promote the healing response and provide strength to the repair. Studies in ovine models have demonstrated tissue ingrowth by 6 weeks and which is as strong as the native tendon by 12 weeks post-implantation.[1,2] A Retrospective Chart Review was undertaken to evaluate safety and clinical outcomes of the BioBrace® Implant across various applications.[3]

Methods:

Medical records were reviewed with outcomes documented in 267 patients from four surgeons across four different United States health care facilities who underwent surgery between June 1, 2021, and March 31, 2023. This chart review was performed under a common protocol and Ethics Committee/ Institutional Review Board approval was obtained at each study site prior to the start of data collection. Patient demographics, pre- and post-operative clinical evaluations, and any patient-reported outcomes (PROMs) that the surgeon collected as part of their standard of care were documented. Outcome scores were collected pre-operatively, and at 3, 6, and 12 months post-operatively. Survey instruments used by the investigators are shown in Table 1.[4-20] As this review was retrospective with data collection completed through the common end date of March 31, 2023, patient follow-up duration varied based upon the time between surgery dates and this end date.

PROM	Range
UCLA Shoulder Assessment	0–35 (best)
ASES Shoulder Assessment	0–100 (best)
VAS Pain	0–10 (worst)
IKDC Knee Assessment	0–100 (best)

Table 1: *PROMs used by investigators* [4-20]

P-values along with the minimal clinically important difference (MCID) for each PROM were used to evaluate changes in PROMs over time. P-values less than 0.05 are considered statistically significant.

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Results:

Index procedures included in this study were grouped into 7 categories (Table 2).

Index Procedure Type	No.
Rotator Cuff Repair (RCR)	160
Tissue Graft Augmentation in ACLR	39
Hip (Gluteus Medius; Labrum)	21
Total Shoulder Arthroplasty (TSA)	21
Lower Limbs	11
Achilles Repair	8
Upper Limbs	7
Total	**267**

Table 2: *Number of procedures by procedure type*

Upper limbs procedures included biceps repair, triceps repair, and UCL reconstruction augmented with BioBrace®. Lower limbs procedures included ACL repair, patellar tendon repair, quadriceps tendon repair, and MPFL repair augmented with BioBrace®. The average follow-up time for all patients included in this chart review was 9.0 months (Range: 1.0 to 22.0 months). Patient reported outcomes are shown below in graphs.

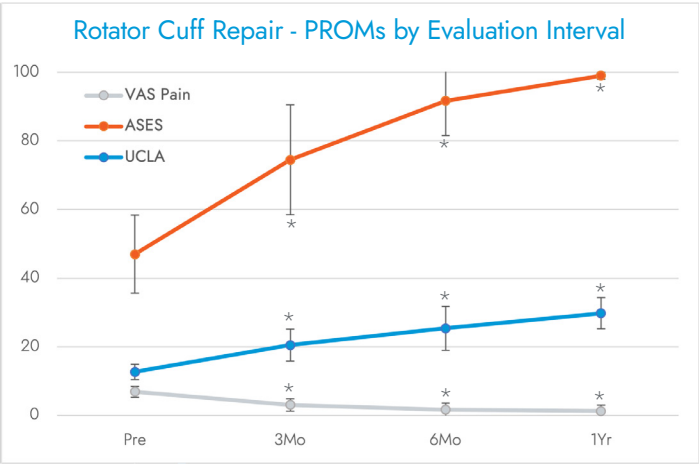

Figure 1: *PROMs for RCR over time; *p < 0.0001*

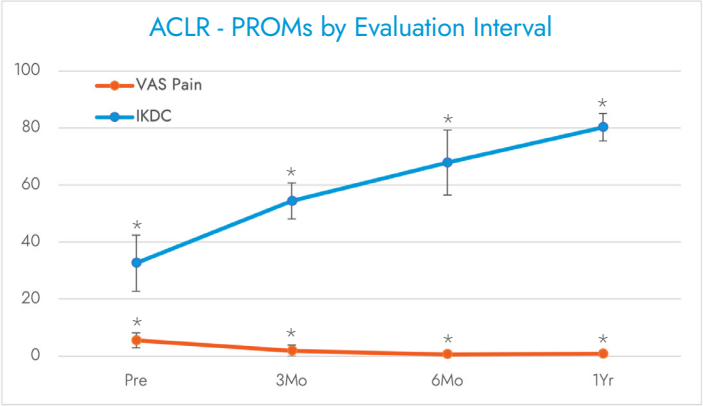

Figure 2: *PROMs for ACLR over time; *p < 0.001*

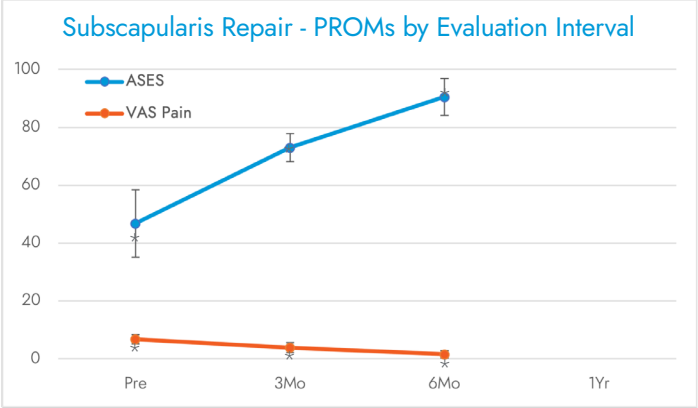

Figure 3: *PROMs for subscapularis repair; *p < 0.001*

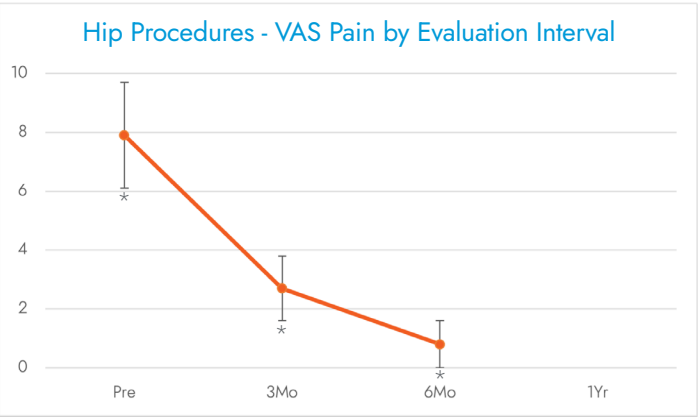

Figure 4: *PROMs for hip procedures; *p < 0.0001*

PROMS:

All changes in PROMs from baseline to each timepoint were statistically significant and greater than the MCID. In subscapularis repair and hip procedures, follow-up data beyond 6 months post-op was not available.

For Achilles Tendon repair, post-operative improvement in VAS pain at 3-month follow-up was statistically significant and exceeded the MCID. There was insufficient follow-up beyond post-operative Month 3 to calculate comparative statistics. Upper and lower limb procedure outcomes showed similar trends in terms of improvement over time.

Surgical Results:

There were no intra-operative complications or device malfunctions across all anatomies. For RCR, 6 out of the 160 resulted in a retear (3.8%). One retear resulted in revision surgery (0.6%). The retear occurred 6 months post-operatively and was medial to the BioBrace implant. In ACLR, 2 of the 39 resulted in a retear (5.1%), one of which resulted in revision surgery (2.6%). The other was a partial tear and was deemed stable enough to not require revision surgery. There were no retears or revision surgery in the subscapularis repair, hip procedures, Achilles tendon repair, upper limb, and lower limb procedure cohorts.

Discussion/Conclusion:

As seen in the literature, rotator cuff repair retear rate increases as tear size increases and can range anywhere from 7.2% to 94%.[21] One review found that even for small and medium tears, the average retear rate was 12.5%.[22] The retear rate for RCR augmented with BioBrace® in this chart review was 3.8%. While tear size was not documented and only symptomatic tears could be accounted for, the low retear rate in RCRs augmented with BioBrace® is very encouraging. Post-operative patient-reported clinical outcomes collected from validated survey instruments at three, six, and 12 months after the index surgery demonstrated statistically significant and clinically meaningful pain reduction and functional improvement across all seven indications.

Retear rates post-ACLR can range from 2% to 20%, based on a variety of factors including graft type, patient age, activity level, and more, as reported in the literature.[23] In this chart review, the retear rate for ACLR with BioBrace® was 5.1% and revision surgery rate was 2.6%. The low revision rate for ACLR with BioBrace® presented here is promising.

Safety of the BioBrace® Implant was demonstrated through review and documentation of all adverse events. No intraoperative adverse events or device malfunctions were reported and all index procedures with BioBrace® were completed successfully. None of the adverse events were determined by the surgeon investigators to be due to BioBrace® and there were no adverse reactions to the implant.

This evidence confirms BioBrace® can provide a clinical benefit across a variety of indications and does not pose a risk to patient safety. The data documented in this report may be used to expand regulatory approval of BioBrace® to countries outside the United States. Future clinical studies are underway to expand upon these results and bolster the clinical data supporting the use of BioBrace®.

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