The Integrity™ Implant System:
Early Outcomes Following Rotator Cuff Repair

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Introduction

Rotator cuff tears (RCTs) are one of the most common musculoskeletal pathologies, resulting in pain, loss of function, reduction in quality of life, and significant economic burden.[1,2] The principal etiology is age-related degenerative processes followed by trauma.[3,4] RCTs have little intrinsic ability to heal on their own, with conservative treatment having limited success, hence, rotator cuff repair (RCR) is typically performed in symptomatic patients with the goal of reattaching the injured tendon to its enthesis.[3] However, retear rates have been reported to be 10-48%, with those associated with large/massive tears exceeding 90%.[5-8]

One strategy to facilitate RCR is to augment the repair with a scaffold, or patch, to provide an environment conducive to healing as well as mechanically reinforce the repair.[9] While numerous types of scaffolds are available, the ideal scaffold for RCR has not yet been identified.[9]

A novel scaffold, the Integrity™ Implant System (Anika Therapeutics, Bedford, MA), has been developed to augment soft tissue healing, including use in RCR. The implant is a composite, porous, knitted scaffold of 80% benzyl ester of hyaluronic acid (HYAFF® technology, Anika Therapeutics, Inc., Bedford, MA) that prolongs the residence time of HA in the body, and 20% nonabsorbable polyethylene terephthalate (PET). The HA derivative takes advantage of the tissue regeneration properties of HA while the PET moiety enhances the mechanical properties of the knitted construct.[10-12]

The purpose of this study was to evaluate the early clinical outcomes of the Integrity Implant System for the repair of partial thickness and full thickness rotator cuff tears.

Methods

The Integrity Implant System includes the implant (20x25mm or 25x30mm), as well as absorbable poly (L-lactic-co-glycolic acid) tissue tacks (7mm and 8mm) to fix the scaffold to the tendon and nonabsorbable polyether ether ketone (PEEK) bone staples to fix the scaffold to bone – **Figure 1**.

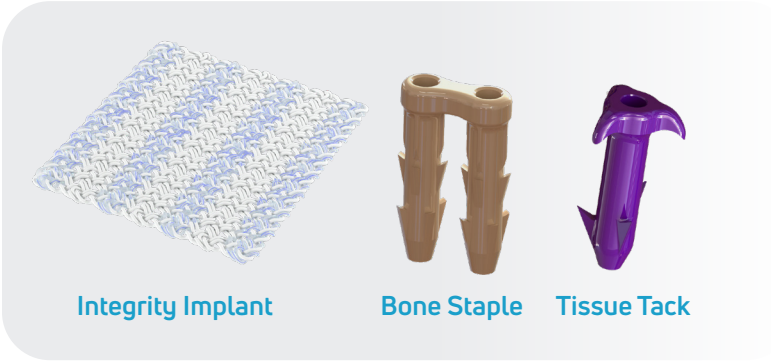

Figure 1. Integrity Implant System (not to scale)

Rotator cuff tears in a series of 36 patients were treated from November 2023 to May 2024. 7 patients were lost to follow-up and were thus excluded. Patient demographics are listed in **Table 1**.

Parameter	Value
Number of Patients	29
• Partial tear	20
• Full tear	9
Age, years Ave ± SD (range)	45.7 ± 13.5 (range: 18-71)
Gender – Male (Female)	14 (15)
BMI (kg/m^2) Ave ± SD (range)	28.1 ± 4.9 (range: 19-39)

Table 1. Patient Demographics

All patients underwent standard RCR utilizing the 20x25mm scaffold. The final construct included one bone staple and multiple tissue tacks.[13] Follow-up was performed at 3 months and 6 months evaluating flexion, external rotation, VAS pain (0-10 scale), and strength. Strength was measured per the Medical Research Council (MRC) as 0: no visible contraction, 1: visible contraction without movement of the limb, 2: movement of the limb but not against gravity, 3: movement against gravity over (almost) the full range, 4: movement against gravity and resistance, and 5: Normal.[14] All complications were recorded.

Continuous data was compared by ANOVA and a post hoc Tukey test and categorical data with the Fisher's Exact test, with significance taken as $P < 0.05$.

Results

Figures 2–5 show the flexion, external rotation, VAS pain scores, and strength scores, respectively.

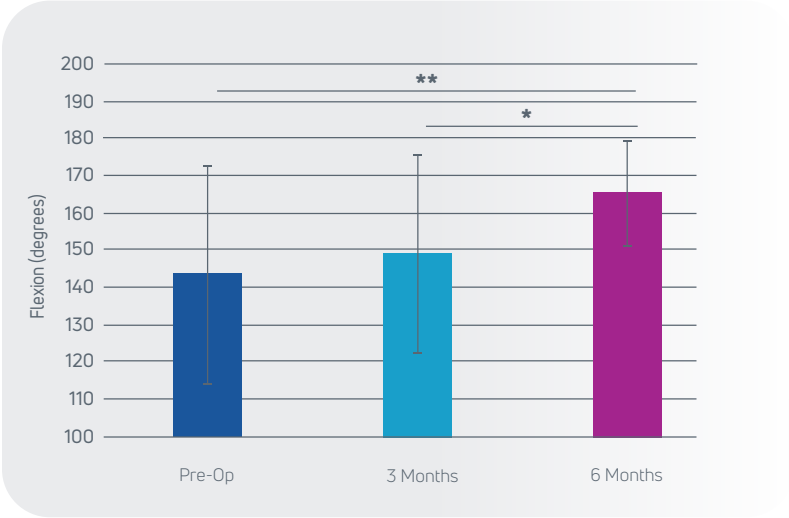

Figure 2. Flexion vs. follow-up interval.
*P = 0.039, **P = 0.0042

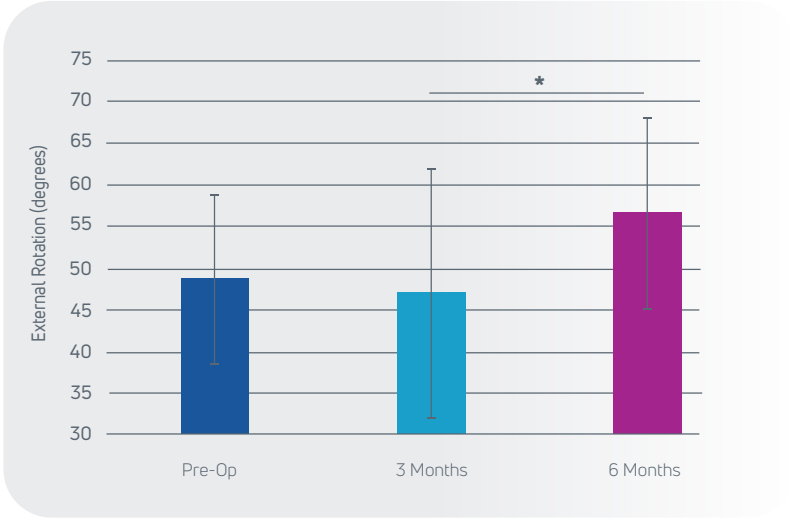

Figure 3. External rotation vs. follow-up interval.
*P = 0.017

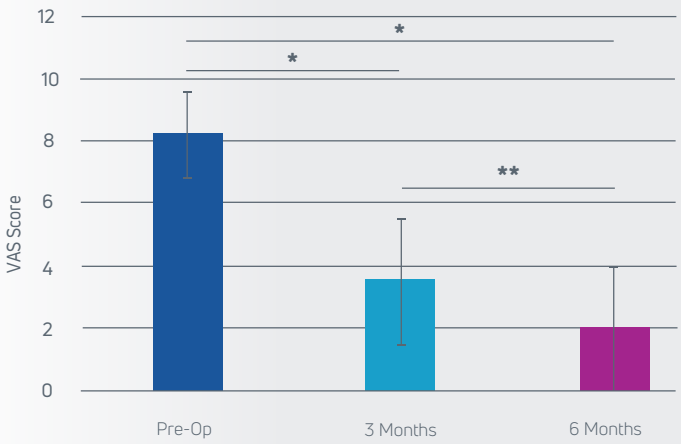

Figure 4. VAS pain score vs. interval. *P < 0.001, **P = 0.015

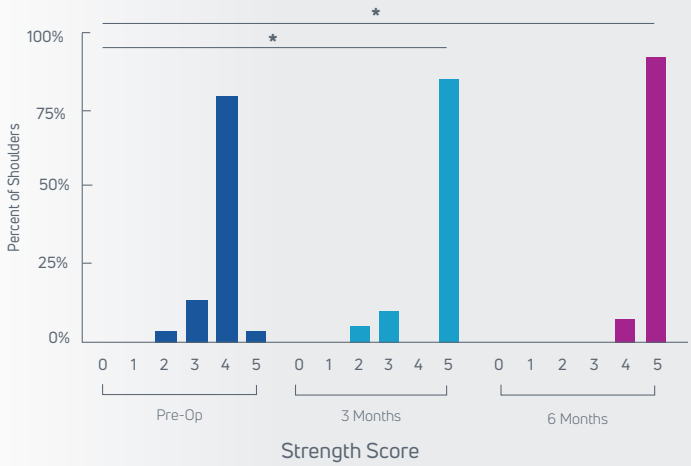

Figure 5. Strength score - percentage of shoulders. *P < 0.001

Four patients (13.8%) developed adhesive capsulitis at 2, 6, 6, and 12 weeks, respectively, all treated by corticosteroid injection. One reoperation was performed to treat a biceps tendon retear that occurred due to post-op trauma. There were no clinically manifest rotator cuff retears.

Discussion

Overall, outcomes improved from pre-op to 3-month follow-up with further improvement to 6-month follow-up. In particular, 3-month follow-up yielded a significant decrease in pain and increase in strength compared to pre-op, with no significant change in flexion or external rotation. From 3-month to 6-month follow-up there were significant improvements in flexion, external rotation, and pain with a trend toward additional strength improvement. Finally, at 6-month follow-up there were significant improvements in flexion, pain, and strength, with an improvement trend in external rotation compared to pre-op.

Adhesive capsulitis, or frozen shoulder, was the most prevalent post-operative complication. It occurs in 5% to 32% of shoulder surgeries and can be primary with a contributive medical history, secondary to shoulder surgery, or idiopathic.[15] Its rate of 13.8% in our study was well within that reported in the literature and appeared to be unrelated to use of the scaffold.

A recent meta-analysis found that retears were influenced by both patient-related and patient-unrelated factors with rates of 15% at 3 months, 21% at 3–6 months, 16% at 6–12 months, 21% at 12–24 months, and 16% after 24 months.[7] As such, it is encouraging that there was no clinical evidence of retears at 6 months.

Conclusion

The Integrity™ Implant System includes a porous, knitted implant comprised of an HA derivative to potentiate tissue regeneration and nonabsorbable PET polymer to enhance strength. RCR utilizing this system resulted in improvement in function and pain over 6-month follow-up with no clinical evidence of retear or complications attributable to the device.

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