

**Title:** Treatment of Macroscopically Intact Biceps with Concomitant Superior Rotator Cuff Tears: A Single-Center Pragmatic Three-Arm Parallel Group Randomized Surgical Trial

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**Background:**

Long head of biceps (LHB) pathology is a common cause of shoulder pain with several surgical treatment options. However, evidence comparing different procedures such as tenotomy, tenodesis, or leaving the LHB intact (no-touch) remains limited.

**Methods:**

This monocentric randomized controlled trial included 87 patients undergoing rotator cuff repair. The participants were randomized into three groups: No-touch (n=29), Tenotomy (n=30), and Tenodesis (n=26). Patient-reported outcome measures (PROMs), range of motion (ROM), and adverse events were assessed at baseline, 6 months, and 12 months. This evaluation is an interim analysis.

**Results:**

PROMs scores were statistically comparable among the three groups at baseline, 6 months, and one year. At 1-year follow-up, there were no statistically significant differences between groups in ASES (pooled score of  $88 \pm 13$ ,  $p = 0.211$ ), Constant (pooled score of  $80 \pm 14$ ,  $p = 0.983$ ), LHB (pooled score of  $89 \pm 12$ ,  $p = 0.169$ ), SSV (pooled score of  $86 \pm 15$ ,  $p = 0.239$ ), and pain on VAS (pooled score of  $15 \pm 15$ ,  $p = 0.431$ ) scores. Comparable results were observed for external rotation ( $p = 0.185$ ). However, the tenodesis group demonstrated improved range of motion in both anterior elevation by  $10^\circ$  compared with the tenotomy ( $[0^\circ-20^\circ]$ ,  $p=0.010$ ) and no-touch groups ( $[0^\circ-15^\circ]$ ,  $p=0.038$ ). The tenodesis group also had greater internal rotation by 5 levels  $[0-5]$  compared to the no-touch group only ( $p = 0.009$ ). The no-touch group tended to have slightly more adverse events (24%) compared to groups the tenotomy (18%) and tenodesis (13%) groups, although this difference was not statistically significant ( $p = 0.518$ ). The most common complication in the no-touch group was cramping (n=3, 10%), whereas in both the tenotomy (n=2, 7%) and tenodesis (n=2, 8%) groups, the most frequent complication was the Popeye sign. Healing at 6 months according to the Sugaya classification tended to be lower in the no-touch group (n=24, 83%) than in the tenotomy group (n=26, 93%) or tenodesis group (n=22, 91%), although this difference was not statistically significant ( $p=0.122$ ). Finally, at one year follow-up, 92% (n=22) of the patients in the tenodesis group were very satisfied, compared with 75% (n=21) and 69% (n=20) in the tenotomy and no-touch groups ( $p = 0.335$ ).

**Conclusion:**

All three procedures showed satisfactory results. There were no differences in patient-reported outcome measures between the three groups at one year, but the tenodesis group showed improved anterior elevation and internal rotation. The tenodesis group also tend to have less complications and better patient satisfaction level at this interim analysis.