AUGMENTATION WITH A BIOINDUCTIVE COLLAGEN IMPLANT OF A POSTEROSUPERIOR CUFF REPAIR DECREASES FAILURES AT TWO-YEAR FOLLOW-UP. A RANDOMIZED CONTROLLED TRIAL.

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Introduction: Several augmentation options for rotator cuff repair (RCR) have been suggested to improve the healing rates and the clinical outcomes. One of the alternatives, placing a bioinductive collagen implant (BCI) over the repair, has been suggested to be cost effective, but published data are limited mostly to retrospective studies. This is a two-year follow-up update to the recently published one-year outcomes of a randomized controlled trial on the use of the BCI augmentation of transosseous equivalent (TOE)-RCR (1).
The aim of this study was to determine if BCI augmentation of a TOE repair of medium-to-large posterosuperior rotator cuff tears improved the healing rate determined by MRI at 2-year follow-up.

Material and Methods: A level-1 randomized controlled trial was performed in subjects with isolated, symptomatic, non-acute posterosuperior full-thickness (1-4 cm) rotator cuff tears that were reparable through TOE repair, and supraspinatus fatty infiltration ≤2. One hundred and twenty-four were randomized to two groups in which an arthroscopic TOE repair was performed alone (Control group) or with BCI applied over the TOE repair (BCI group). Retear rate (defined as Sugaya 4-5 as evaluated by MRI at 2-year follow-up) was the primary outcome. Tendon characteristics (Sugaya grade, and thickness of the healed tendon) and clinical outcomes (pain levels, EQ-5D-5L, American Shoulder and Elbow Society (ASES) and Constant-Murley scores (CMS)) were also assessed at 2-year follow-up.

Results: There were no relevant differences in preoperative demographic and clinical characteristics. The percentage of subjects with minor or major complications were similar between groups and no complications presented between the first and second year follow-up. Two subjects in the control group required a revision procedure due to persistent symptoms and radiological retear in the first-year follow-up but no further reinterventions were required in the second year of follow-up in either group.
One hundred and fourteen of the 124 randomized patients (91.9%; 57 in the BCI group and 57 in the Control group) were available for MRI evaluation a mean of 24.4±1.32 months post-intervention. Retear rate was lower (12.3% [7/57]) in the BCI group compared to the Control group (35.1% [20/57]) ($p=0.008$; relative reduction in risk of 0.35[CI-95%:0.16 to 0.76]). Sugaya grade was also better in the BCI group (Figure 1, $p=0.020$) and tendon thickness at the medial edge of the footprint was higher in the BCI group than in the control group (3.9±0.9mm vs 3.5±0.9mm, $p=0.035$).
One hundred and fourteen of the 124 randomized patients, (91.9%; 57 in the BCI group and 57 in the Control group) were available for clinical follow-up. There were significant improvements from preoperation in both groups in pain levels, EQ-5D-5L, ASES (Figure 2) and CMS ($p<0.001$) but there were no significant differences between groups at two-years follow-up. A posthoc analysis of patients with both MRI and clinical assessments (n=110) showed that an intact tendon was associated with better CMS (80.1±19.1 in the intact tendon group of vs. 69.9±25.2; $p=0.035$).

Discussion: At two years follow-up, BCI augmentation dramatically reduced the retear rates, with a better quality and thicker tendon, and did not increase this rate of post-operative complications compared to the Control group. Despite a lack of difference in clinical improvements, these data provide some reasons to believe that functional improvement exist, as the analysis of ASES and CMS show a trend for divergence between groups (Figure 2) that is difficult to overlook. Furthermore, subjects with retears in this study presented with worsening CMS of more than 10 points, which was well into the minimally clinically relevant difference for this score, suggesting, as expected, that clinical outcomes eventually follow radiological outcomes.

Conclusion: Augmentation with a BCI of a TOE repair in a medium to large posterosuperior rotator cuff tear reduces the retear rate at two-year follow-up by two-thirds, with better quality of the tendon and without increased complication rates.

(1) Ruiz Iban MA, et al. Augmentation of a Transosseous-Equivalent Repair in Posterosuperior Nonacute Rotator Cuff Tears With a Bioinductive Collagen Implant Decreases the Retear Rate at One Year: A Randomized Controlled Trial. Arthroscopy. 2023. 28:S0749-8063(23)01018-6. PMID: 38158165.

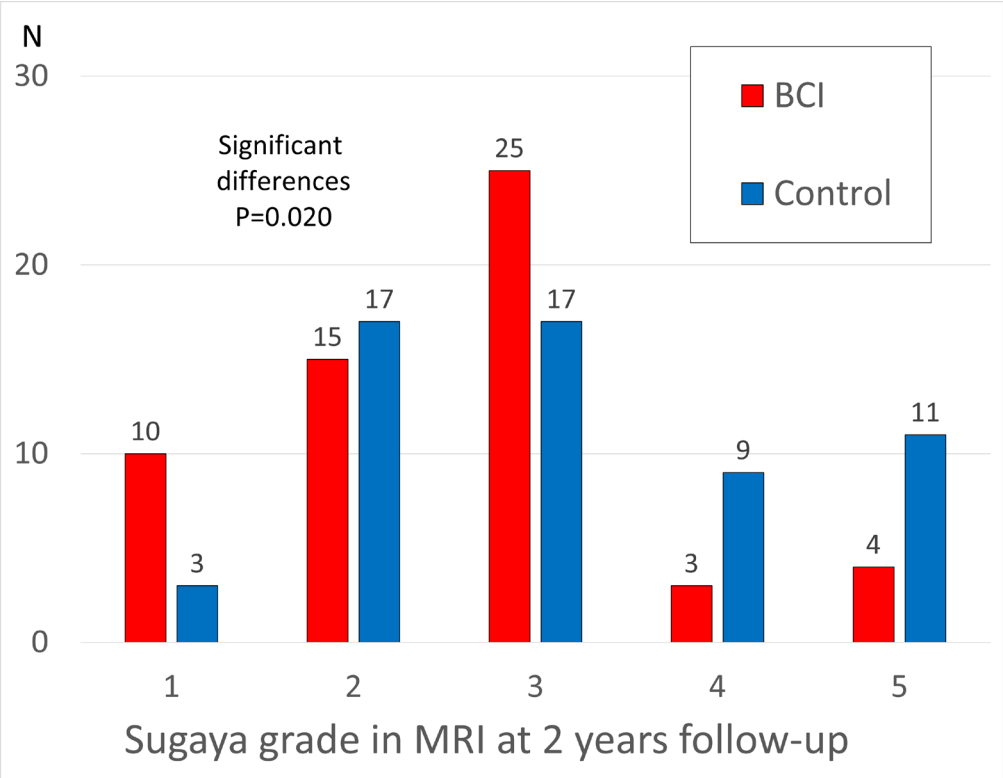

Figure 1: Frequency histogram of the 114 tendon repairs according to the Sugaya classification of postoperative cuff integrity, assessed in the MRI at 2-year follow-up. There were significant differences (p=0.020) between the Control group and the Bioinductive Collagen Implant (BCI) group.

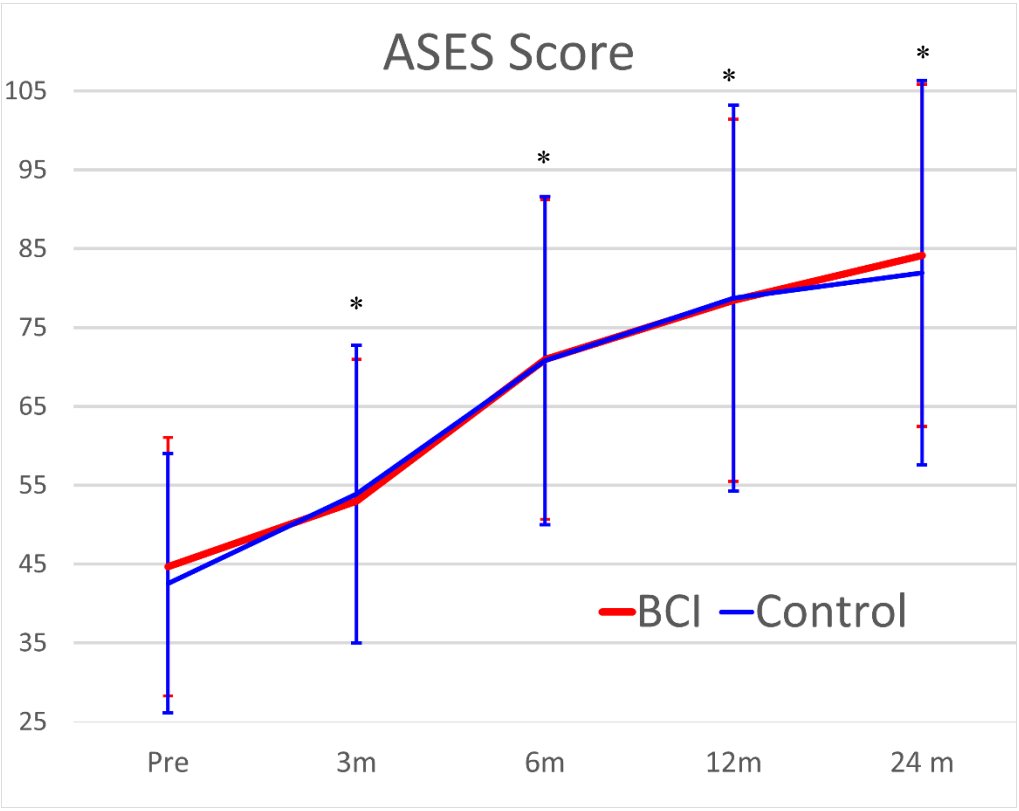

Figure 7: Evolution of the ASES score of the 114 patients available during the study. There were no differences between the Control and Bioinductive Collagen Implant (BCI) groups at any timepoint. * the ASES score improved significantly ($p<0.01$) at three, six, twelve and twenty-four months follow-up when compared to preoperative (Pre) values.