Augmentation of a Posterosuperior Cuff Repair With a Bovine Bioinductive Collagen Implant Shows a Lower Retear Rate but Similar Outcomes Compared With No Augmentation: 2-Year Results of a Randomized Controlled Trial

Miguel Angel Ruiz Ibán, M.D., Ph.D., Miguel García Navlet, M.D., Santos Moros Marco, M.D., Jorge Diaz Heredia, M.D., Ph.D., Arancha Hernando, M.D., Raquel Ruiz Díaz, M.D., Carlos Vaquero Comino, M.D., Salvador Alvarez Villar, M.D., and Jose Luis Avila Lafuente, M.D.

Purpose: To assess the clinical and radiologic outcomes of the addition of a bioinductive collagen implant (BCI) to repair of medium to large posterosuperior rotator cuff tears at 24-month follow-up. **Methods:** This study was an update of a randomized controlled trial that was extended from 1- to 2-year follow-up. A total of 124 subjects with symptomatic full-thickness posterosuperior rotator cuff tears with a fatty infiltration grade of 2 or less per the Goutallier classification were randomized into 2 groups in which a transosseous-equivalent repair was performed alone (control group) or with a BCI applied over the repair (BCI group). The outcomes reassessed at 2-year follow-up were as follows: Sugaya grade, retear rate and tendon thickness on magnetic resonance imaging (MRI), and clinical outcomes (pain level, EQ-5D-5L score, American Shoulder and Elbow Surgeons [ASES] score, and Constant-Murley score [CMS]). **Results:** There were no relevant differences in preoperative characteristics between the groups. There were no additional complications or reinterventions in the second year of follow-up. Of 124 randomized patients (59 male and 55 female patients; mean age: 58.1 years [standard deviation (SD), 7.35 years]), 114 (91.9%) underwent MRI evaluation at 25.4 months (SD, 1.95 months) after surgery. There was a lower retear rate (12.3% [7 of 57]) in the BCI group compared with the control group (35.1% [20 of 57]) ($P = .004$; relative risk of retear, 0.35 [95% confidence interval, 0.16-0.76]). The Sugaya grade was also better in the BCI group (2.58 [SD, 1.07] vs 3.14 [SD, 1.19]; $P = .020$). Clinical follow-up was performed in 114 of 124 patients (91.9%) at 25.8 months (SD, 2.75 months) and showed improvements in both groups ($P < .001$), with 87% achieving the minimal clinically important difference for the CMS and 90% doing so for the ASES score; however, there were no differences between the groups. Among subjects who underwent both MRI and clinical assessment (n = 112), those with an intact tendon presented better CMS values ($P = .035$), ASES scores ($P = .015$), and pain scores ($P = .006$) than those with a failed repair. **Conclusions:** Augmentation of a transosseous-equivalent repair with a BCI in posterosuperior rotator cuff tears clearly reduces the retear rate at 2-year follow-up without increased complication rates and with similar clinical outcomes. Subjects with failed repairs had poorer clinical outcomes. **Level of Evidence:** Level I, randomized controlled trial.

From the Shoulder and Elbow Unit, Orthopaedic Surgery and Trauma Service, Hospital Universitario Ramón y Cajal, Madrid, Spain (M.A.R.I., J.D.H., R.R.D., S.A.V.); Department of Surgery and Medicosocial and Sanitary Sciences, Faculty of Medicine, Universidad de Alcalá de Henares. Madrid. Spain (M.A.R.I., J.D.H., R.R.D., S.A.V.); Shoulder and Elbow Unit, Orthopaedic Surgery and Trauma Service, Hospital Asepeyo Coslada, Madrid, Spain (M.G.N., A.H.); Shoulder and Elbow Unit, Orthopaedic Surgery and Trauma Service, Hospital Maz Zaragoza, Zaragoza, Spain (S.M.M., J.L.A.L.); and Orthopaedic Surgery and Trauma Service, Hospital Ibermutua Madrid, Madrid, Spain (C.V.C.).

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Address correspondence to Miguel Angel Ruiz Ibán, M.D., Ph.D., Unidad de Hombro y Codo, Hospital Universitario Ramón y Cajal, Cta Colmenar Km 9.100, Madrid, Spain 28046. E-mail: drmri@hotmail.com

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Rotator cuff disease is a leading cause of pain and dysfunction in older adults.[1] When a tear develops, arthroscopic rotator cuff repair (ARCR) is often successful and yields good clinical outcomes, but repair failure can develop in 10% to 75% of repairs.[2-4] These failure rates have stayed relatively stable for the past 20 years despite the introduction of newer arthroscopic techniques such as double-row and transosseous-equivalent (TOE) repairs.[5] The high failure rates might be related to biological issues both at the bone-tendon junction (because of difficulty in achieving tendon-to-bone healing[6]) and in the tendon tissue itself (owing to underlying tendinopathy). Various biological alternatives, such as bone marrow stimulation, platelet-rich plasma, stem cells, and augmentation with different grafts (fascia lata and allogeneic or xenogeneic dermal tissue), have been shown to improve outcomes, in particular in terms of retear rate reduction.[6-8]

A bioinductive collagen implant (BCI) made of highly purified type I collagen, obtained from bovine calcaneal tendons, has been used to supplement ARCR.[9,10] The implant is placed over the repaired tendon and is infiltrated by tenoblasts from the native tendon, increasing its quality and thickness.[9,11,12] A recent randomized controlled trial (RCT) has shown that the use of this implant to supplement a repair of non-acute mid- to large-sized (1- to 4-cm-long) posterosuperior cuff tears reduced the retear rate dramatically at 1-year follow-up and increased the thickness of the tendon but without relevant differences in clinical outcomes.[13]

The purpose of this study was to assess the clinical and radiologic outcomes of the addition of a BCI to repair of medium to large posterosuperior rotator cuff tears at 24-month follow-up. The hypothesis was that at longer follow-up, the retear rate would still be lower in the BCI-augmented group and that this would lead to better clinical outcomes.

Methods

This was a 2-arm, multicenter, triple-blinded (patient−, outcome assessor−, and data analyst−blinded), parallel-group, pragmatic, randomized superiority trial, with 24-month follow-up. A detailed description of the methodology of this RCT can be found in the original report.[13] The study, as well as its extension to 2-year follow-up, was approved by the local institutional review board of Hospital Universitario Ramón y Cajal, Madrid, Spain. The protocol was preregistered on clinicaltrials.gov (NCT04444076). All subjects provided written informed consent for the initial inclusion and for the extension. The extension included full magnetic resonance imaging (MRI) and clinical assessment at 2-year follow-up.

Patients scheduled for primary elective posterosuperior cuff repair in 4 surgical centers were eligible for inclusion. The inclusion and exclusion criteria are detailed in Table 1. All patients were operated on under general anesthesia and an interscalene nerve block. The details of the procedure can be found in the initial publication.[13] In brief, after definition of the tear characteristics, the footprint underwent microfracture and a TOE repair was performed with 1 to 3 medial-row anchors and 1 or 2 lateral-row anchors. After completion of the repair and confirmation of eligibility criteria, patients were randomized into 2 groups: in the control group, the procedure was finished; in the BCI group, an implant (Regeneten Bioinductive Implant, large size; Smith & Nephew) was placed over the repaired tendon from the subacromial space, stretching 5 to 10 mm lateral to the footprint, and was fixed to the tendon with 5 to 8 absorbable anchors and to the bone with 1 to 3 PEEK (polyether ether ketone) anchors, per the manufacturer's recommendations. Both groups followed the same postoperative protocol.

Table 1. Inclusion and Exclusion Criteria for RCT

Inclusion criteria
Age ≥ 18 yr
Non-acute symptomatic (symptom duration > 3 mo)
Full-thickness posterosuperior cuff tear
Intraoperative anterior-posterior size between 1 and 4 cm
Fully repairable tear (>80% footprint coverage without tension confirmed during surgery)
Exclusion criteria
Pregnancy or risk of pregnancy
Retraction > 3 cm
Goutallier grade 3-4 fatty infiltration in any rotator cuff tendon on preoperative MRI evaluation performed <6 mo before surgery
Subscapularis or teres minor tendon tear that required repair during surgical procedure
Prior surgery or fracture in index shoulder

MRI, magnetic resonance imaging; RCT, randomized controlled trial.

Randomization was performed with a sealed envelope and a computer-generated random list of numbers with an allocation rate of 1:1. The surgeon was not blinded to the allocation. The patients, the clinicians responsible for the clinical and MRI evaluation, and the statistician who performed the statistical analysis were blinded to the group assignment.

The clinical and radiologic outcomes evaluated for the 2-year study extension were the same as those in the initial 1-year assessment.[13] MRI studies, performed 2 years after the procedure, were assessed for (1) tendon continuity using the Sugaya classification[14] (considering grade ≤ 3 as healed and grade ≥ 4 as retear); (2) retear location according to Cho et al.[15,16]; (3) supraspinatus tendon thickness (in healed tendons) in 3 zones (medial edge of footprint and 10 mm and 20 mm medial to it), and (4) degree of fatty infiltration of the supraspinatus and infraspinatus tendons per the

Table 2. Baseline Demographic Data, Clinical Characteristics, and Surgical Data for Each Group

	Bioinductive Collagen Implant (n = 61)	Control (n = 63)	*P* Value
Demographic data			
Age, yr	56.6 ± 6.86	58.7 ± 8.39	.140
Sex: male/female, n	31/30	30/33	.722
BMI	27.8 ± 4.69	27.2 ± 4.07	.501
Ethnicity: white/Hispanic/other, n	52/9/0	55/7/1	.521
Comorbidities			
Diabetes	7 (11.5)	8 (12.7)	.834
Tobacco use	14 (22.9)	16 (25.4)	.751
Hypercholesterolemia	21 (34.4)	15 (23.8)	.192
Steroid injection in past 6 mo	7 (11.5)	10 (15.9)	.481
Tear characteristics			
Side: right/left, n	44/17	42/21	.509
Tear shape			.180
Crescent	31 (75.8)	39 (61.9)	
L	8 (13.1)	11 (17.5)	
Inverted L	6 (9.8)	6 (9.53)	
U	16 (26.2)	7 (11.1)	
Tear size, mm	20.4 ± 6.83	19.7 ± 6.39	.541
Tear retraction, mm	16.5 ± 8.78	13.8 ± 7.22	.040*
Fatty infiltration on preoperative MRI: grade 0/I/II, n			
Supraspinatus	50/11/0	47/15/1	.267
Infraspinatus	56/4/1	55/8/0	.323
Functional data			
Preoperative pain level			
Maximum	6.7 ± 2.1	7.1 ± 2.3	.312
Minimum	2.4 ± 2.2	2.5 ± 2.5	.818
Mean	4.9 ± 2.1	5.0 ± 2.9	.763
Now	4.0 ± 2.7	4.6 ± 2.9	.306
Preoperative CMS	45.7 ± 16.9	45.6 ± 14.3	.980
Preoperative ASES score	44.6 ± 16.4	42.6 ± 16.5	.476
EQ-5D-5L score			
Health index (TTO)	2.43 ± 0.53	2.31 ± 0.58	.227
Health level (VAS score)	68.1 ± 21.9	64.4 ± 19.7	.343
Duration of surgery, min	90.5 ± 19.9	76.6 ± 17.6	<.0001*

NOTE. Data are presented as mean ± standard deviation for quantitative variables and as number (percentage of total) for quantitative variables. The statistical analysis results comparing the 2 groups for each variable are presented in the right column.

ASES, American Shoulder and Elbow Surgeons; BMI, body mass index; MRI, magnetic resonance imaging; TTO, time trade-off; VAS, visual analog scale.

*Statistically significant ($P < .05$).

Goutallier classification. The following clinical outcomes were assessed at 2-year follow-up: pain level with the Brief Pain Inventory, Constant-Murley score (CMS, which includes precise assessment of active range of motion and elevation strength at 90° of abduction), American Shoulder and Elbow Surgeons (ASES) score, EQ-5D-5L self-rated general health questionnaire, and time to return to work. The minimal clinically important difference (MCID) for the CMS and ASES score were calculated using half the standard deviation of the delta as suggested by Harris et al.[17] Further baseline information was also recorded (Table 2).

Sample size estimation was performed for the initial study using the healing rate, assuming a baseline rate of 70%. The trial was designed to identify a potential difference between groups of 20% with α error = 0.05 and power $(1 - \beta) = 0.8$. The normality of the variables had previously been ascertained using the Kolmogorov-Smirnov test. Dichotomous and qualitative variables were assessed with the χ^2 test, and quantitative variables were assessed with the Student *t* test. The Mann-Whitney *U* test was used to compare Sugaya grades. Outcome analysis was performed per protocol. The statistical threshold for significance was established at $P < .05$. The fragility index[18,19] and the S-value were also calculated.[20,21]

Results

Between June 2020 and February 2022, 165 subjects preliminarily met the inclusion and exclusion criteria before surgery (Fig 1). After ARCR, 124 were randomized (61 to BCI group and 63 to control group). The baseline data for the initial 124-subject cohort and for each initial randomized group can be seen in Table 2; only 7 patients were lost to follow-up. On assessment of

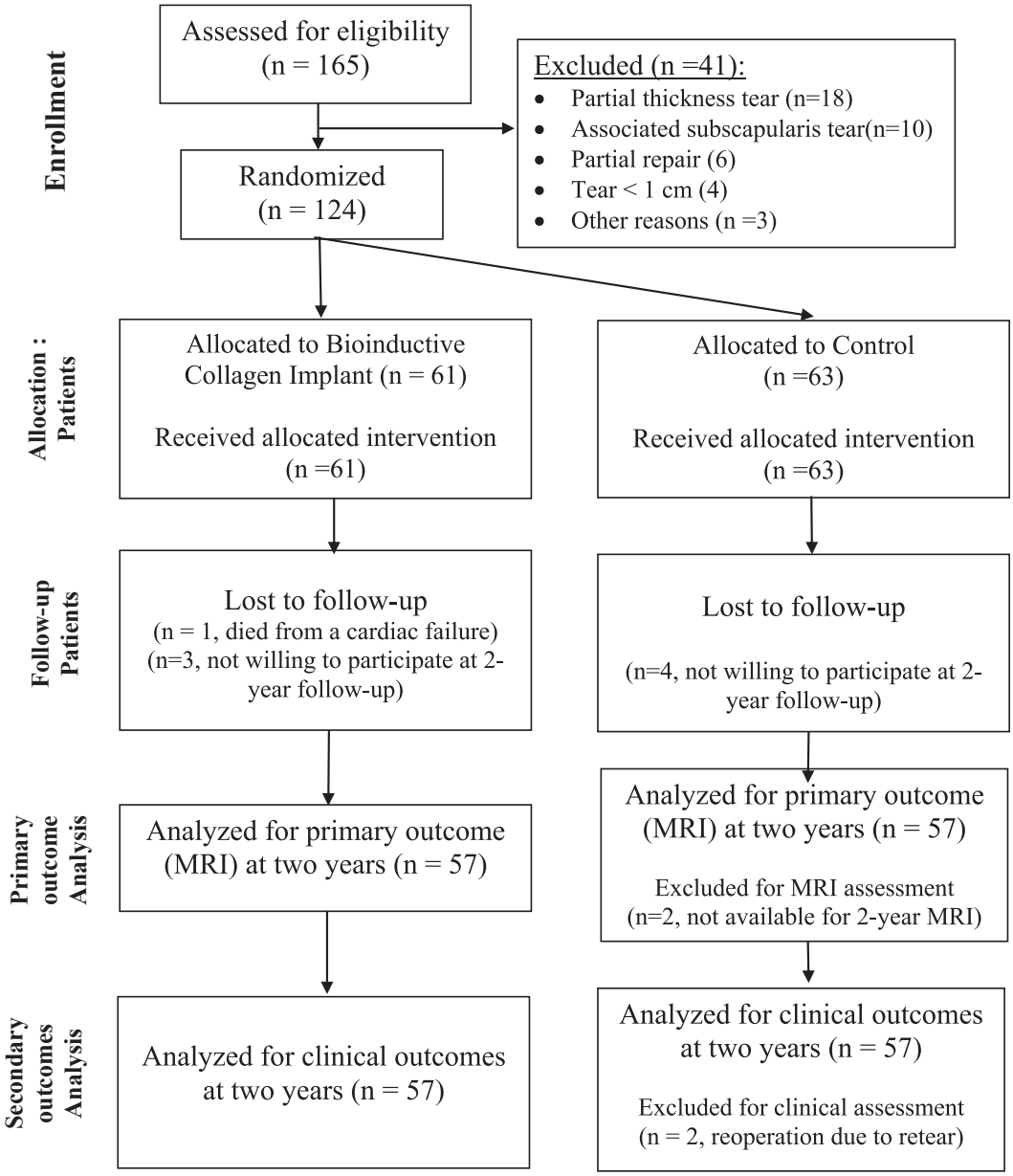

Fig 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram of study. (MRI, magnetic resonance imaging.)

the epidemiologic, preoperative clinical, preoperative MRI, and surgical data, the only factors showing differences between the groups were tendon retraction (higher in BCI group; mean difference, 2.7 mm; $P = .040$) and surgery duration (13.9 minutes longer in BCI group, $P < .0001$).

At the 2-year follow-up, 7 subjects were lost to follow-up and 1 died of cardiac insufficiency unrelated to the study. Two subjects (both in the control group) presented with poor functional outcomes and persistent pain at 5- and 6-month follow-up, presented with clear retears on MRI, and underwent revision ARCR. These 2 patients were excluded from the clinical assessment but were included in the MRI assessment. Two patients in the control group were available for clinical assessment but not for MRI assessment, thus leaving 114 subjects (91.9%) (BCI group, n = 57; control group, n = 57) available for secondary clinical variable assessment. MRI was evaluated in 114 subjects (91.9%) (BCI group, n = 57; control group, n = 57).

The MRI studies of 114 subjects performed 25.4 ± 1.95 months after surgery were assessed. There were 27 retears in 114 subjects (23.7%; 95% confidence interval [CI], 15.6%-34.5%) without relevant differences between male and female patients (22 of 59 [37.3%] and 11 of 55 [20.0%], respectively; nonsignificant difference [$P = .339$]). The BCI group had a decreased

retear rate: In the control group, there were 20 retears in 57 subjects (35.1%; 95% CI, 24%-48.9%), whereas in the BCI group, there were 7 retears in 57 subjects (12.3%; 95% CI, 6.01%-23.2%). This difference was significant ($\chi^2 = 8.20$, $P = .004$) with an odds ratio of 0.259 (95% CI, 0.099-0.675). The absolute reduction in retear risk was 0.174 (95% CI, 0.304-0.045). The relative reduction in retear risk was 0.35 (95% CI, 0.161-0.762). The number of subjects needed to treat with a BCI to avoid a retear was 4.4 (95% CI, 2.6-12.9). The fragility index of these results was 4. The S-value was 8.

The structural continuity of the repaired tendon according to the Sugaya classification was better in the BCI group ($\chi^2 = 11.7$, $P = .020$) (Fig 2). Among the 27 cases with a retear, a type 1 failure was found in 3 cases (11.1% of all retears, 2.63% of all repairs), all in the control group (no significant difference between groups, $P = .35$), whereas the 24 type 2 retears (88.9% of all retears, 21.1% of all repairs) developed mainly in the control group (17 in the control group vs 7 in the BCI group; significant difference between groups, $P = .022$). There were no differences in the degree of fatty infiltration of the supraspinatus or infraspinatus between the groups (Fig 3) at the final MRI evaluation. In the 87 patients with healed tendons, tendon thickness was greater in the BCI group in only 1 of the 3 measured zones: The thickness at the medial edge of the footprint was marginally higher in the BCI group than in the control group (3.9 ± 0.9 mm vs 3.5 ± 0.9 mm, $P = .035$).

Clinical assessment was performed 25.8 ± 2.75 months (range, 22-31 months) after surgery. There were general improvements in all secondary clinical variables compared with baseline data in both groups, but no differences between the groups were found during follow-up in terms of pain level, CMS and its subscales (Fig 4A), ASES score (Fig 4B), and EQ-5D-5L (Fig 4C) at any time point. There were no differences in clinical outcomes between sexes. For the 114 assessed subjects, the MCID for the CMS was established as 11.3 and the MCID for the ASES score was established as 13.1. Of these subjects, 87% reached the MCID for the CMS and 90% did so for the ASES score. There were no differences in these rates between the 2 study groups for the CMS (84% for BCI vs 86% for control, $P > .999$) or the ASES score (91% for BCI vs 88% for control, $P = .762$).

Some clinical divergence between the 2 groups was evident on visual analysis of the data on the CMS and ASES score during the second year of follow-up, so a post hoc analysis of the clinical function of the subjects according to the tendon healing status was performed. Among the 112 subjects with both clinical and radiologic outcomes available at 2-year follow-up, those with healed tendons at 2-year follow-up (n = 87) presented better clinical outcomes than those with failed repairs (n = 25) when assessed with the CMS (66.2 ± 27.6 in failed repair group vs 80.2 ± 19.0 in healed tendon group, $P = .0069$) (Fig 5A), ASES score (71.7 ± 30.2 in failed repair group vs 84.4 ± 21.2 in healed tendon group, $P = .0150$) (Fig 5B), and pain level (1.47 ± 1.63 vs 2.62 ± 2.27, $P = .0068$) but not with the EQ-5D-5L visual analog scale score (76.2 ± 20.6 vs 73.4 ± 19.3, $P = .53$). These differences exceeded the MCID values defined for these scores in the study (11.2 for CMS,

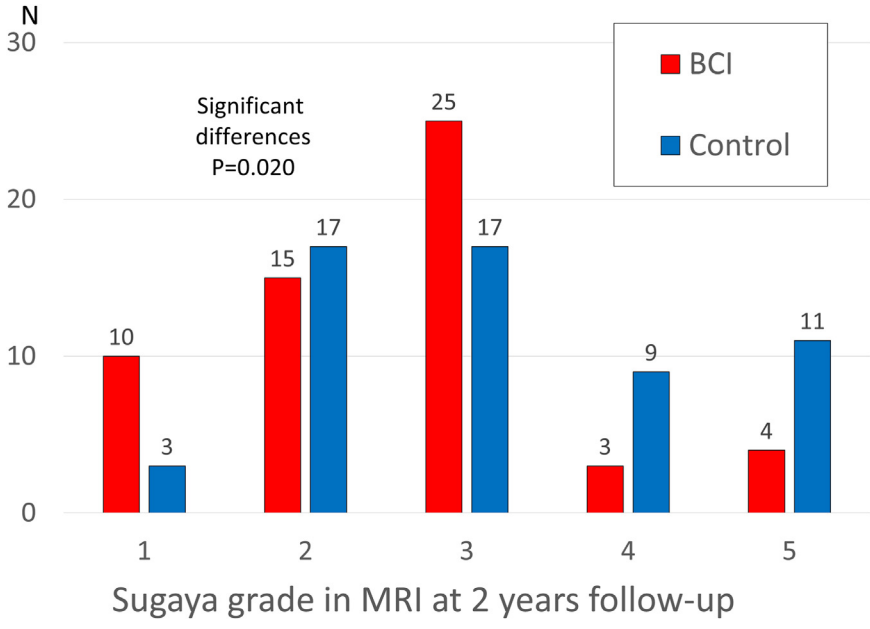

Fig 2. Assessment of rotator cuff integrity in 122 tendon repairs on 2-year postoperative magnetic resonance imaging (MRI) using Sugaya classification. (BCI, bioinductive collagen implant.)

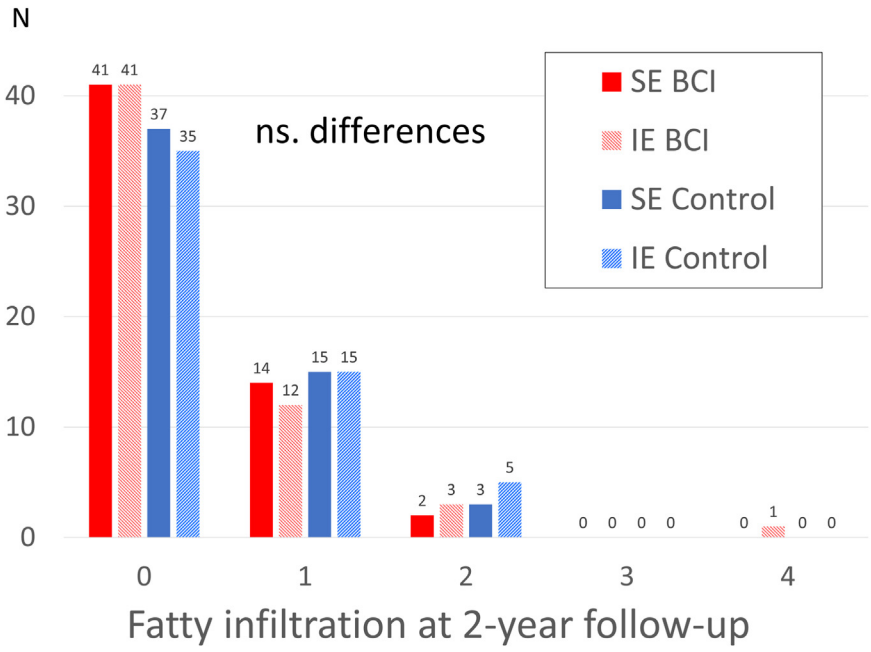

Fig 3. Degree of fatty infiltration of supraspinatus (SE) and infraspinatus (IE) muscles according to Goutallier-Fuchs classification analyzed on 114 magnetic resonance imaging (MRI) scans from control group and bioinductive collagen implant (BCI) group at 2 years postoperatively. (ns, nonsignificant.)

12.8 for ASES score, and 0.83 for pain level). An analysis of the differences in the subscales of the CMS and ASES score between the groups did not find a specific subscale responsible for the improvement because subjects with healed tendons had across-the-board improvements in pain, function, range of motion, and strength compared with those with failed repairs. Regarding the MCID, for the CMS, 86.2% of subjects with healed tendons and 65.3% of those with repair failure showed improvements larger than the MCID (nonsignificant difference, $P = .071$); for the ASES score, 91.9% of subjects with healed tendons and 64.0% of those with repair failure showed improvements larger than the MCID (significant difference, $P = .014$). Of the 96 patients who were in the active working population at the beginning of the study, 92 were able to return to work at 6.8 ± 3.4 months after surgery (6.86 ± 3.38 months in BCI group vs 6.87 ± 3.76 months in control group, $P = .99$); 4 subjects (2 from each group, $P > .999$) had abandoned the labor population.

Complications

In the first year of follow-up, complications were found in 10 subjects; of these, only 5 were major complications (1 postoperative deep infection in each group, 2 reinterventions due to early failure of the repair in the control group, and the aforementioned death). These have been reviewed in detail previously.[13] No patient presented with any further complication in the second year of follow-up or required a revision procedure for any cause.

Discussion

This RCT shows that the addition of a BCI to the repair of a medium to large posterosuperior cuff tear reduces the retear rate and improves the structural quality of the repaired tendon on 2-year postoperative MRI assessment without clear differences in clinical outcomes between groups at 2-year follow-up. Despite this finding, those subjects with healed tendons had better clinical outcomes than those with failed repairs, clearly indicating that increased failure rates are followed by worsening clinical outcomes that might lead to reoperation with time.

The MRI failure rate at 2-year follow-up was slightly higher than that found at the 1-year evaluation, at 24% (27 retears in 114 subjects) compared with 17% (21 failures in 122 subjects), with 6 additional failures identified during the study extension. This finding is in contrast to previous research that showed that cuff failures develop earlier after the surgical procedure: Miller et al.[22] found no further retears in the second year after surgery in a cohort of 22 consecutive patients with large rotator cuff tears followed up with serial ultrasound examination, and Chona et al.[23] performed a systematic review on the topic including 13 studies and concluded that retears generally developed until 10 to 15 months after surgery, after which retear rates were likely to level off. It is possible that degenerative disease of the cuff tendons evolves during the second year after surgery, accounting for the relative increase in tendon failures. Regardless, the 24% failure rate at 2-year follow-up observed in our study is well in line with the findings of other large studies such as the UKUFF

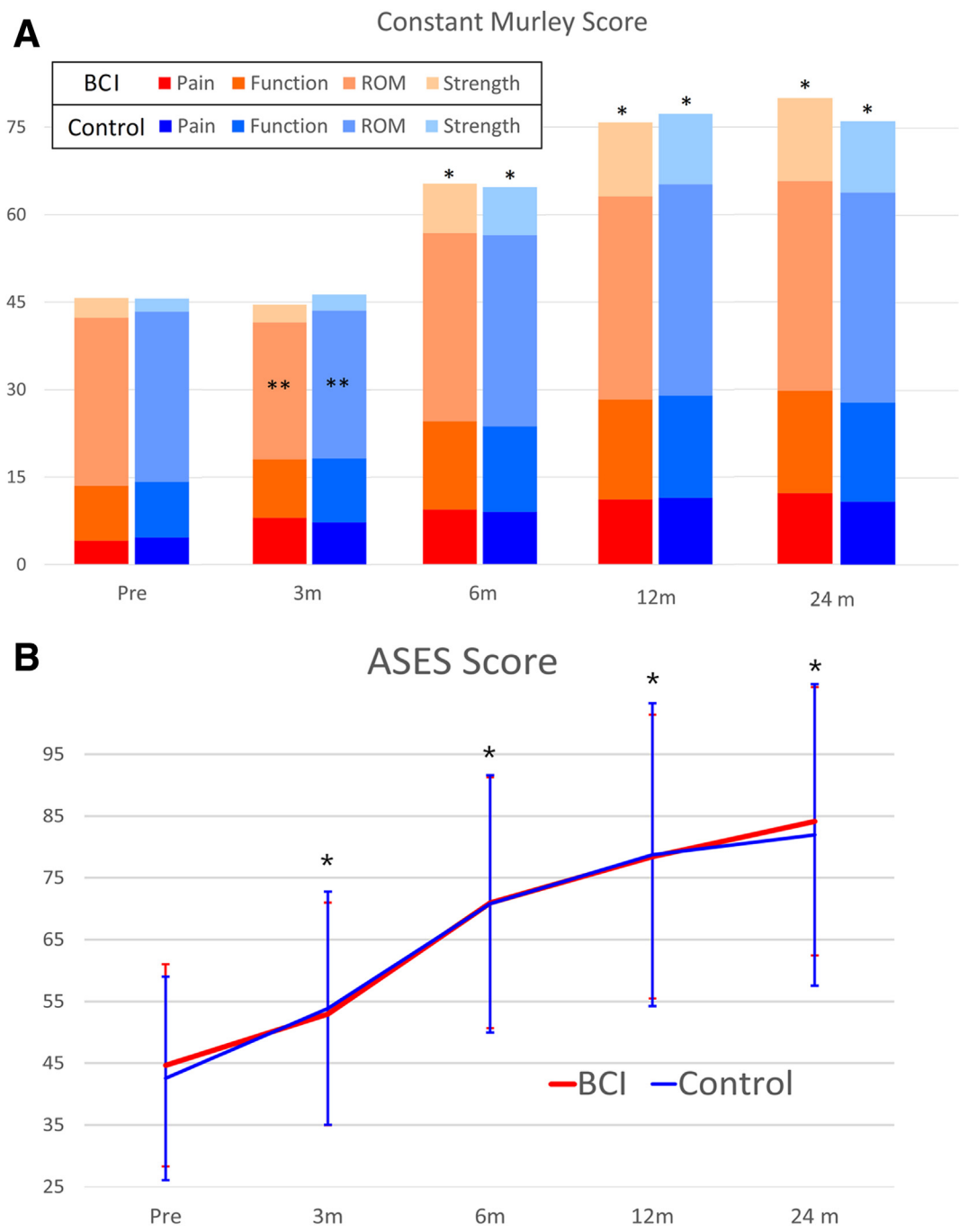

Fig 4. Evolution of Constant-Murley score (A), American Shoulder and Elbow Surgeons (ASES) score (B), and EQ-5D-5L visual analog scale (VAS) score (C) for 114 patients available during study. One asterisk indicates $P < .01$ for the scores, as well as every Constant-Murley subscale score, compared with baseline (Pre). Two asterisks indicates $P = .001$ for the range-of-motion (ROM) subscale at 3-month follow-up compared with baseline. (m, months.)

RCT, with a 43% failure rate at 2-year follow-up among 206 mainly small- and medium-sized tears,[24] or the meta-analysis of Hein et al.,[5] with a 20.3% retear rate among 920 one- to five-centimeter-long posterosuperior tears. Most of the tendon failures to heal in this study (21 of 24, 88%) were type 2 failures (medial to repair), in line with the rates of 72% to 92% found in other studies.[6,16,25]

The observed effect of the addition of a BCI on the integrity of the tendon found in our study is dramatic, showing a 3-fold reduction in retear rate, from 35.1% to 12.3%. This is in line with other authors' results at 2-year

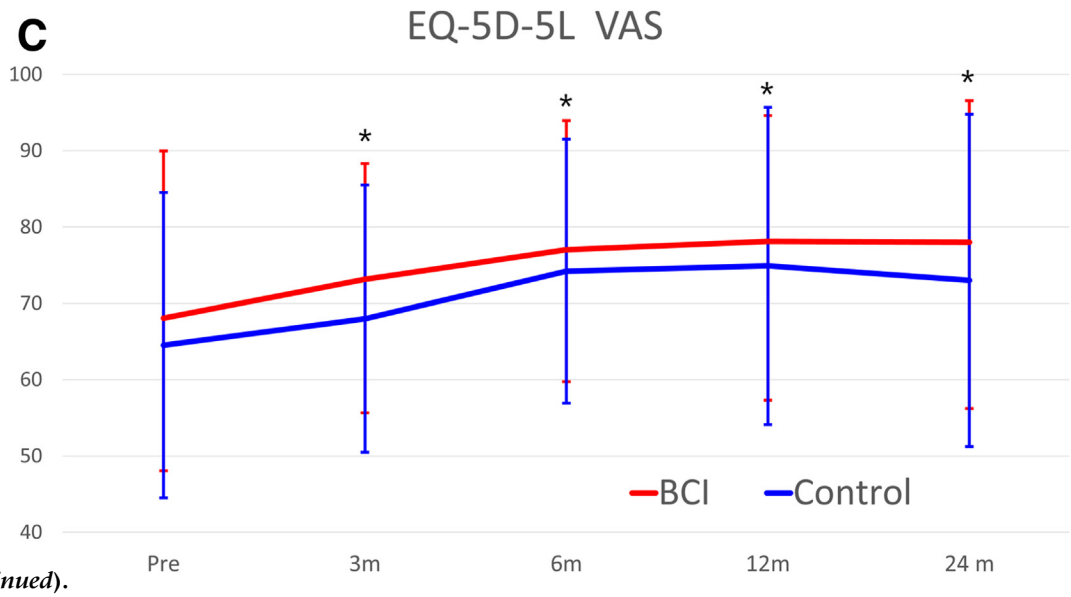

Fig 4. (*continued*).

follow-up: Bushnell et al.[26] reported a failure rate of 20.8% in a large group of 91 medium to large tears (1 to 5 cm long) repaired and supplemented with a BCI; and Thon et al.[27] found a retear rate of 9% among 23 large and massive tears (>3 cm). These studies and others have been incorporated into recent systematic reviews that have found clear evidence of lower retear rates with a BCI for full-thickness tears.[28,29]

The 2-year postoperative MRI assessment revealed improvement in the Sugaya grade in the BCI group, suggesting that the addition of a BCI not only avoids retears but also improves the quality of the tendon in the mid-term. There was, however, an across-the-board increase in fatty infiltration in the 2-year period of the study: Preoperatively, only 1.6% of cases presented with a fatty infiltration grade of 2 or more in the supraspinatus or infraspinatus, but at the 2-year follow-up, fatty infiltration was present in 9.8% of subjects. The tendon thickness increase of 0.4 mm at the footprint was not likely clinically relevant and negated the

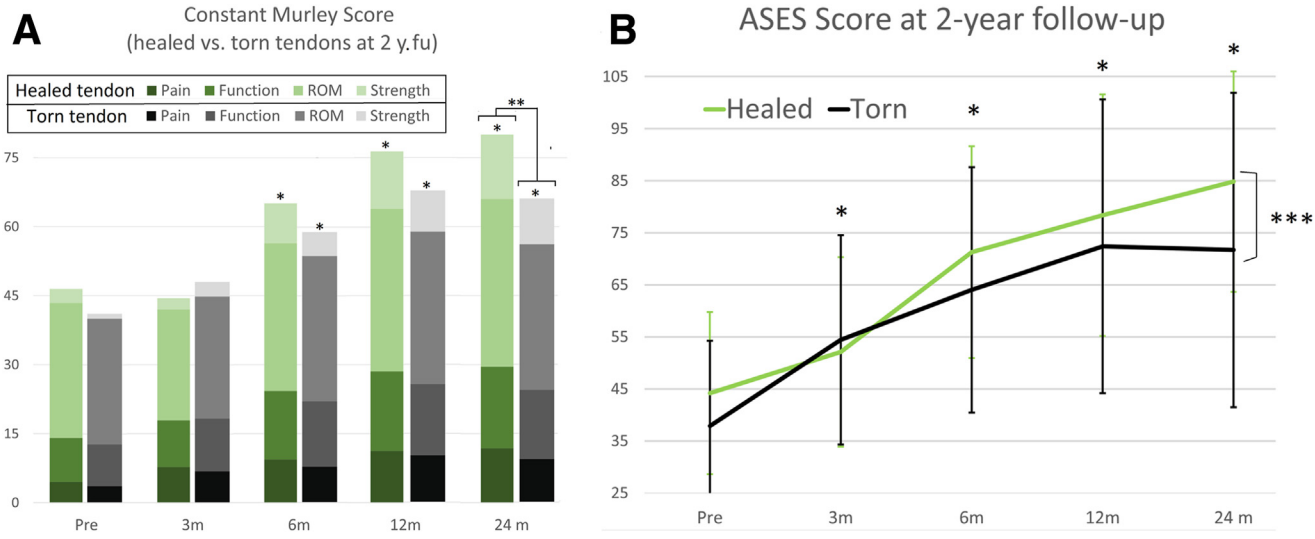

Fig 5. Comparison of Constant-Murley score (CMS) (A) and American Shoulder and Elbow Surgeons (ASES) score (B) between healed and failed (torn) repairs among 112 patients with both clinical and magnetic resonance imaging (MRI) data available during study. One asterisk indicates $P < .001$ for the total CMS (and every subscale) and ASES score at 6-, 12-, and 24-month follow-up compared with baseline (Pre); 2 asterisks, $P = .007$ for the difference in CMS values between healed and failed repairs at 2-year follow-up (2 y.fu); and 3 asterisks, $P = .015$ for the difference in ASES scores between healed and failed repairs at 2-year follow-up. (m, months; ROM, range of motion.)

relative thickness increases found at 1-year follow-up.[13] The change in tendon thickness suggests that the BCI integrates into the tendon in the early postoperative period as suggested by other authors,[9,11,12] but tendon maturity over time make these differences irrelevant. All these data suggest that the main long-term effect of the BCI is related to its ability to avoid early failure of the repair.

The "elephant in the room" is the absence of clear clinical improvements in the BCI group. Although patients from both the BCI group and the control group presented sustained clinical improvements at 2-year follow-up (with mean improvements far higher than the MCID for both the ASES score and the CMS), no clinical differences were found between the groups (Fig 4). That reductions in the retear rate are not necessarily followed by improved clinical outcomes has already been noted by other authors investigating other biological alternatives such as platelet-rich plasma,[30] microfracture,[31] and matrix augmentation.[32] This is due to the fact that retears seem to have little impact on outcomes in the short term, as shown in a systematic review of 41 studies by Holtedahl et al.,[33] in which retears were found to have a limited negative impact on pain and function at 18-month follow-up. However, in the long term, differences do develop: Yau[34] found that only after 5-year follow-up do clinical differences between healed and failed repairs develop in a cohort study of 105 ARCRs. Our current results support these findings given that the post hoc analysis comparing subjects with failed repairs and subjects with healed tendons at 2-year follow-up allowed substantial differences (larger than the MCID) to be identified for both the ASES score and the CMS (Fig 5). No clinical differences caused by the increased failures in the control group were found, this is partly understandable given that most patients in the control group (>65%) still had healed tendons, making whole group data heterogeneous. Thus, the clinical benefit of the BCI may be summarized as follows: If subjects in the BCI group have better healing rates than those in the control group and healing improves clinical outcomes at 2-year follow-up, then using the BCI will positively impact clinical outcomes. The clinical difference may be even more pronounced with longer follow-up because, as time passes, those patients with unhealed tendons have poorer functional scores,[33-35] increased fatty infiltration,[36] and higher reoperation rates.[37,38]

Limitations

We acknowledge several limitations in the extension of our RCT to 2 years. First, the number of patients lost to follow-up has increased, although the retention rate remains above 90%. Second, a more clear focus on the assessment of clinical outcomes based on substantial clinical benefit via patient-reported outcome measures might be better than focusing on only clinical scores and the MCID. Third, we did not record detailed information on participation in sporting activities, final active range of motion, or strength in external rotation—information that would have been useful. Finally, there are many clinical variables that can affect outcomes after rotator cuff repair, and our RCT did not directly control for all possible variables.

Conclusions

Augmentation of a TOE repair with a BCI in posterosuperior rotator cuff tears clearly reduces the retear rate at 2-year follow-up without increased complication rates and with similar clinical outcomes. Subjects with failed repairs had poorer clinical outcomes.

Disclosures

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