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Arthroscopic Biologic Tuberoplasty With a Dermal Allograft Leads to Significant Improvement in Functional Outcomes in Patients With Massive, Irreparable Rotator Cuff Tears

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Purpose: To present outcomes of patients who underwent arthroscopic biologic tuberoplasty (ABT) and evaluate differences in outcomes based on sex, Hamada grade, concomitant procedures, and length of follow-up with a minimum of 1-year follow-up.
Methods: Patients who underwent ABT between 2015 and 2022, with a minimum 1-year follow-up, were identified. Inclusion criteria were: (1) massive, irreparable rotator cuff tears, (2) active forward elevation $>90^0$, (3) intact or reparable upper border subscapularis tear, and (4) Hamada 1 to 3. ABT was performed with a 3- mm-thick dermal allograft. American Shoulder and Elbow Surgeons (ASES), Single Assessment Numeric Evaluation (SANE), and Visual Analog Scale for pain were recorded.
Results: Fifty patients (68% males) met the inclusion criteria. Mean follow-up was 22.9 ± 15.7 months (range: 12-109 months). The mean age was 64.8 ± 8.1 years (range: 46-79 years). There was a significant improvement in ASES (37.4 ± 14.1-85.8 ± 10.5, $P < .0001$), SANE (36.3 ± 16.7-83.5 ± 10.1, $P < .0001$), and Visual Analog Scale for pain (7.2 ± 1.8-1.4 ± 1.9, $P < .0001$). There was no significant difference in mean postoperative ASES based on sex ($P = .6623$), Hamada grade ($P = .1098$), and isolated ABT versus those with concomitant procedures ($P = .1087$). In addition, there was no difference in postoperative ASES between patients who had 1-year follow-up, those with 1 to 2 years follow-up, and those with >2 years follow-up ($P = .3887$). Minimal clinically important difference, substantial clinical benefit, and patient acceptable symptomatic state for ASES were 100%, 96%, and 80%, respectively, for SANE were 96%, 78%, and 46%, respectively, and for Visual Analog Scale were 98%, 84%, 92%, respectively. The maximal outcome improvement for ASES was 77.4 and for SANE was 74.1.
Conclusions: Excellent clinical outcomes can be achieved in patients undergoing ABT with significant functional improvement and pain reduction in patients with massive, irreparable rotator cuff tears. These outcomes can be equally achieved in males and females, and in shoulders that are Hamada 1 to 3. Outcomes of patients with >2 years follow-up were similar to those with 1-year follow-up and 1 to 2 years follow-up.
Level of Evidence: Level IV, retrospective case series.

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Massive, irreparable rotator cuff tears (MIRCT) are one of the most challenging problems to treat in the shoulder.[1] It is estimated that approximately 30% of rotator cuff tears are massive and irreparable.[2,3] Several options are available, but a gold standard does not exist.[4-7] Superior capsule reconstruction (SCR) using tensor fascia lata was introduced by Mihata et al.[6,8] In the United States, acellular dermal allograft has become popular and clinical results have been promising.[9-14] However, as the procedure is time-consuming, technically demanding, and costly, the popularity and number of SCRs being performed in the United States has declined.[15] In addition, several authors have reported high rate of graft tears following SCR,[10,16-18] raising questions about its mechanism of action. In fact, recent in vivo findings suggest that improved outcomes following arthroscopic superior capsule reconstruction are not associated with changes in shoulder kinematics as proposed and may be due to the spacer effect of the graft.[19-21]

Arthroscopic biologic tuberoplasty (ABT) procedure originated after one of the authors (R.M.) observed that, despite a large percentage of graft tears in his SCR cases on routine postoperative magnetic resonance images (MRIs), most patients did clinically well with a high satisfaction rate. The author observed that the location of the graft tear played a key role in the clinical outcome. Based on this observation, Mirzayan et al.[22] classified the graft tear patterns into 3 types: (1) intact graft; (2) "tuberosity covered," i.e., the graft is torn from the glenoid or in the midsubstance, leaving the dermal allograft healed to the tuberosity; and (3) "tuberosity bare"—the graft is torn from the tuberosity, leaving the tuberosity uncovered or bare. Mirzayan et al.[23-25] reported that those patients with graft tears leaving the tuberosity covered had significant improvements and equivalent outcomes in American Shoulder and Elbow Surgeons (ASES) and pain scores compared with those with an intact graft. However, those with graft tears leaving the tuberosity bare did not have significant improvements in ASES and pain scores. These findings have since been verified by two recent SCR studies. Shin and Lee reported that "patients with lateral graft failure ['tuberosity bare'] had inferior clinical outcomes than with medial graft failure after SCR using a dermal allograft."[26] Alzahrani et al. concluded that "graft failure at the greater tuberosity significantly influenced patient dissatisfaction."[27] These findings led several authors[28-32] to perform ABT as an isolated procedure instead of SCR, for patients with MIRCT by securing dermal allograft to the greater tuberosity with anchors, and foregoing securing the graft to the glenoid (Figure 1). Mirzayan et al.[25] coined the term "biologic tuberoplasty," as the biologic dermal allograft prevents bone-to-bone contact between the greater tuberosity and the acromion, thus eliminating pain.[33]

The purpose of this study was to present outcomes of patients who underwent ABT and evaluate differences in outcome based on sex, Hamada grade, concomitant procedures, and length of follow-up with a minimum of 1-year follow-up. Our hypothesis was that patients will have significant functional improvement as a primary outcome, and that there will be no difference in outcomes between sexes, Hamada grades, isolated ABT versus those with concomitant procedures, and that patients with 1-year follow-up will have similar outcomes to those with 1 to 2 years follow-up and those with greater than 2 years follow-up.

METHODS

Inclusion and Exclusion Criteria

After obtaining Institutional Review Board approval from all institutions, a multicenter (7 institutions, 8 surgeons—R.M., T.S.D., J.W.G., M.S., P.L.M., R.J.H., G.J.G., K.F.B.), retrospective evaluation of prospectively collected data was conducted of patients who underwent ABT between February 2015 and December 2022. Inclusion criteria for ABT were: (1) symptomatic, MIRCT who had failed nonoperative treatment for a minimum of 3 months; (2) active forward elevation over 90^0; (3) intact or reparable upper border subscapularis tear; and (4) Hamada ≤ 3.[34] Exclusion criteria included: (1) large or irreparable subscapularis tear; (2) Hamada ≥ 4; (3) arthritis of glenohumeral joint (diagnosed on preoperative radiographs or chondromalacia grade III or IV[35] at time of arthroscopy); (4) pseudoparalysis; (5) external rotation lag or significant weakness (<4/5 manual muscle strength test) in external rotation; (6) deltoid insufficiency; (7) inflammatory disease; and (8) infection. The minimum follow-up was 1 year.

We defined an MIRCT as a two-tendon tear of the supraspinatus and infraspinatus,[36] 4 cm or larger tear,[37] with tendon retraction to the glenoid[38] in all coronal sequences on MRI where the glenoid was visualized. Additionally, arthroscopic examination was performed to confirm that the rotator cuff rim could not be mobilized to the tuberosity.

Clinical Evaluation

Each investigator at their own institution obtained preoperative and minimum 1-year follow-up outcomes consisting of ASES scores,[39] pain graded 0 to 10 on a Visual Analog Scale (VAS), and Single Assessment Numeric Evaluation (SANE).[40] One investigator (R.M.) obtained postoperative MRIs in patients regardless of whether they were symptomatic. Clinically significant measures, including the minimal clinically important difference (MCID), substantial clinical

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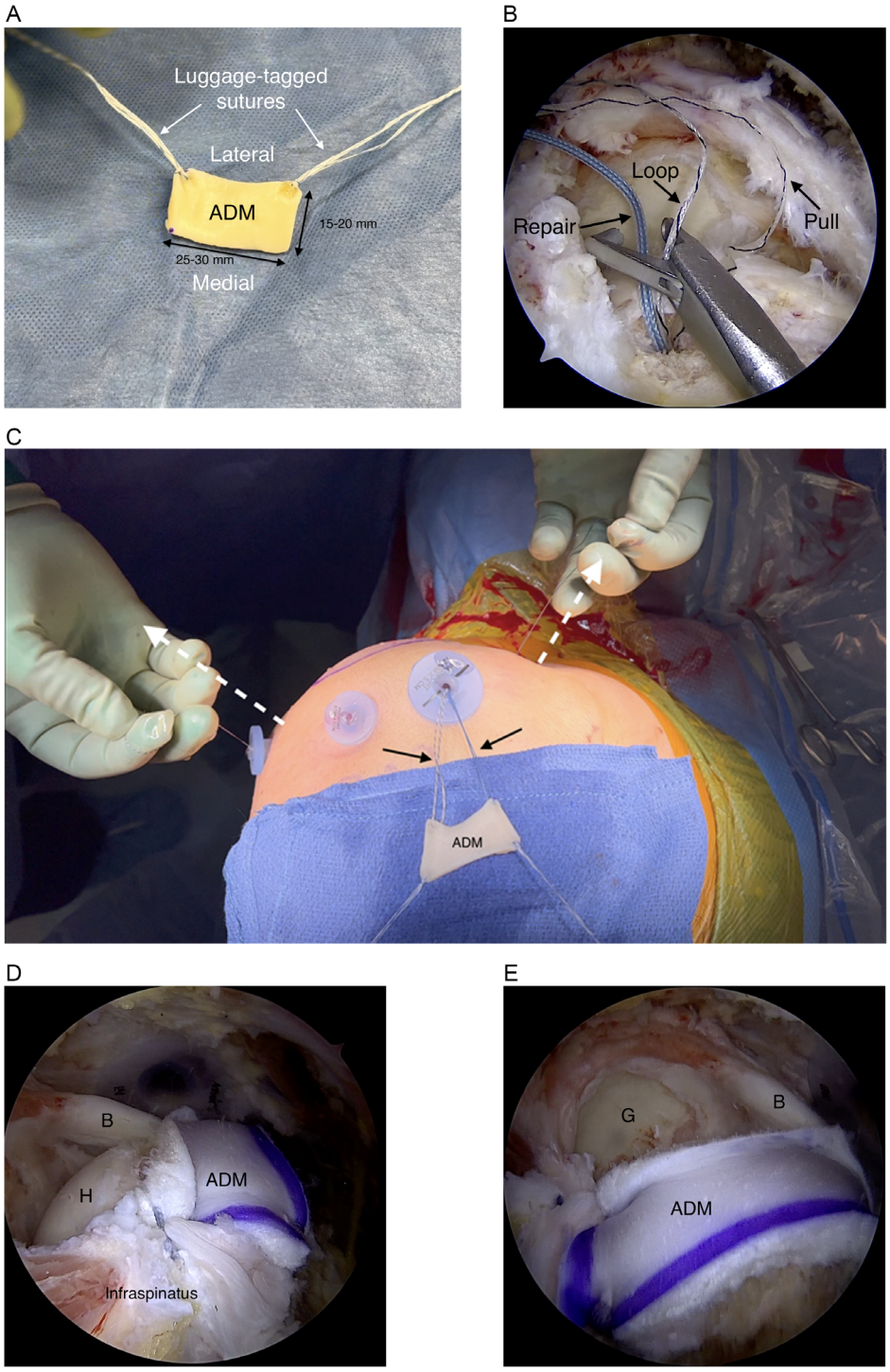

FIGURE 1 (A) Acellular dermal matrix (ADM) with luggage-tagged sutures in the lateral corners. (B) Posterior medial anchor placed anterior to the infraspinatus with the repair and loop sutures being retrieved. (C) The repair stitches (black arrows) are passed through the medial corners of the ADM and locked back into the anchors. The graft is reduced into the subacromial space by pulling on the pull stitches (white dashed arrows). (D) View from posterior and (E) lateral portal of a right shoulder showing the fixation of the acellular or dermal allograft to the greater tuberosity of the humeral head (H). B—long head of biceps tendon; G—glenoid.

benefit (SCB), patient acceptable symptom state (PASS), and maximal outcome improvement (MOI), were calculated to reflect patient clinical benefit and satisfaction after surgery. The MCID establishes the change in outcome score resulting in the smallest, appreciable or detectable clinical improvement after surgery. SCB is defined as the amount of change in a patient-reported outcome measure needed for a patient to feel significant improvement following surgery.[41] PASS is defined as the value beyond which patients consider themselves well.[41,42] Cohort-specific MCID thresholds

were calculated as half the SD (½ SD) of the improvement of the patient (delta scores from preoperative to final follow-up) in ASES, SANE, and VAS scores.

MOI is a patient's change in a given patient reported outcome, divided by their total potential improvement (e.g., [(postoperative ASES – preoperative ASES)/(highest possible ASES – preoperative ASES)] × 100).[43,44] It differs from MCID, PASS, and SCB in that the threshold for achieving MOI is normalized by the maximal possible improvement for each patient, rather than consisting of a fixed value applied to all patients and limits a ceiling effect.[43,45] According to Beck et al.,[43] achieving 69.5% MOI in the ASES score and 75% in the SANE score represents a threshold for defining excellent satisfaction after surgery.

Fifteen (30%) patients in this dataset have been previously published.[46,47] Suri et al.[47] published outcomes of 11 patients at a mean of 8.2 months, with only 5 patients at 1-year follow-up. Those 5 patients are included in this article with a minimum 2-year follow-up. Mirzayan[46] published outcomes on 10 patients with a mean of 21 months. All 10 patients are included in this study with a mean follow-up of 38.7 months.

Surgical Technique

The variations in technique have been previously described.[28,30,31,48] Briefly, the greater tuberosity is prepared by removing soft tissue. If large osteophytes exist from the tuberosity, they are excised with a bur. However, care is taken not to aggressively decorticate the tuberosity and to leave the shape and footprint of the tuberosity intact. The length and width of the tuberosity footprint is measured. A 3-mm-thick acellular dermal allograft (ArthroFlex, LifeNet Health, Virginia Beach, VA) is cut to size of the previously measured footprint. Two FiberLink sutures (Arthrex, Naples, FL) are "luggage tagged" in the anterolateral and posterolateral corners of the graft for future fixation of the lateral row (Figure 1A). Two anchors with a knotless mechanism (Knotless SwiveLock or Knotless FiberTak, Arthrex, Naples, FL) are placed off the articular margin anteriorly posterior to the bicipital groove and posteriorly anterior to the infraspinatus (Figure 1B). The repair stitch and the loop stitch from the knotless anchors are then retrieved through a 10 or 12 mm lateral cannula (PassPort, Arthrex, Naples, FL) with a divider to keep the anterior and posterior sutures apart. The repair stitch from the anterior anchor is then passed through the anteromedial aspect of the graft in a simple or mattress fashion. The repair stitch is then placed through the loop of the loop stitch from the same anchor. The pull stitch is pulled to bring the repair stitch into the anchor, locking it in a finger trap fashion. The same step is repeated with the posterior anchor sutures through the posteromedial aspect of the graft. When the pull stitches from the two medial anchors are pulled, the graft is reduced into the subacromial space through the cannula and secured to the medial row (Figure 1C). The two luggage tag sutures are then anchored laterally (PushLock or SwiveLock anchors, Arthrex, Naples, FL) (Figure 1D and 1E).

Postoperative Protocol

The patient is kept in a sling for 3 weeks. Beginning in the 4th week, the sling is removed and active and active-assist range of motion exercises are initiated without any limitations in range of motion. Between 4 and 6 weeks, once full range of motion is achieved, strengthening is initiated with resistance bands and advanced to weights as tolerated without any restrictions.

Statistical Analysis

Categorical variables were described using counts and proportions. Continuous variables were summarized using means and standard deviations. Comparison of the distributions of demographic and clinical variables were performed using chi-square for categorical variables and Kruskal-Wallis tests for continuous variables. Paired *t*-tests were performed to compare 2 measurements of the 3 outcome (ASES, SANE, and VAS) scores. Univariate regression analyses were performed to compare the 3 outcome (ASES, SANE, and VAS) scores among 3 groups. All analyses were two-sided and performed using SAS version 9.4 (Cary, NC). *P*-values $< .05$ were considered statistically significant.

RESULTS

During the study period, 54 patients underwent ABT. Four were excluded because they did not meet inclusion criteria (2 for preoperative elevation <90 degrees (i.e., pseudoparalysis), 1 had rheumatoid arthritis, and 1 for follow-up of only 3 months). Following the exclusions, 50 patients, 34 (68%) males, met our inclusion criteria. The mean follow-up was 22.9 ± 15.7 months (range: 12-109 months). The mean age was 64.8 ± 8.1 years (range: 46-79 years). The average anterior to posterior graft length was 25 mm (range: 18-30 mm) and medial to lateral width was 19 mm (range: 15-20 mm). In 5 patients, SANE scores were not obtained.

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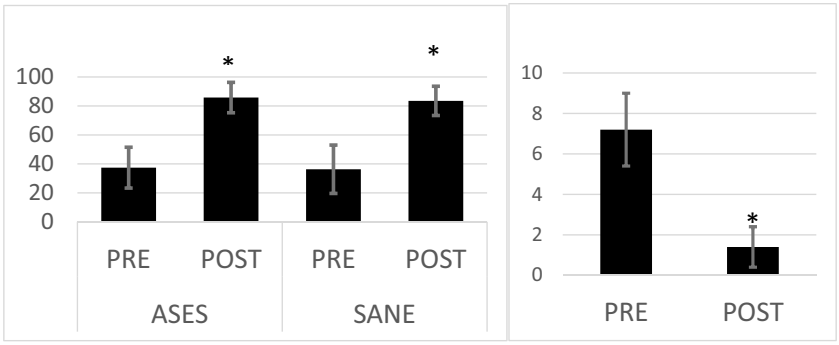

FIGURE 2 Pre- and postoperative American Shoulder and Elbow Surgeons (ASES), Single Assessment Numeric Evaluation (SANE), and Visual Analog Scale (VAS) for pain scores ($P < .0001$).

Overall, there was significant improvement in ASES (37.4 ± 14.1-85.8 ± 10.5, $P < .0001$), SANE (36.3 ± 16.7-83.5 ± 10.1, $P < .0001$), and VAS for pain (7.2 ± 1.8-1.4 ± 1.9, $P < .0001$) (Figure 2).

Outcomes Based on Sex

There were 34 (68%) male and 16 (32%) female patients (Table 1). When comparing the preoperative characteristics between the sexes, there was no significant difference in age ($P = .2841$), Hamada grade ($P = .8983$), ASES ($P = .6623$), and SANE ($P = .1147$). However, females had a significantly higher preoperative VAS pain score ($P = .0099$). Postoperatively, there was no significant difference between ASES ($P = .6623$), SANE ($P = .6216$), and VAS ($P = .0736$).

Outcomes Based on Hamada Grade

Thirty-six (72%) patients were Hamada 1, 8 (16%) patients were Hamada 2, and 6 (12%) patients were Hamada 3 (Table 2). When comparing the preoperative characteristic in these groups, there was no significant difference in age ($P = .7247$), length of follow-up ($P = .3414$), ASES ($P = .4392$), SANE ($P = .0.5632$), and VAS for pain ($P = .2878$). Postoperatively, there was no significant difference between ASES ($P = .1098$) and VAS ($P = .5425$). However, patients with Hamada 1 had a significantly higher postoperative SANE score than those who were Hamada 2 and 3 ($P = .0257$) (Figure 3).

Outcomes Based on Isolated ABT Versus Those With Concomitant Procedures

ABT was performed as an isolated procedure in 20 (40%) patients (Table 3). Concomitant procedures were performed in conjunction with ABT in 30 patients which

TABLE 1 Patient Characteristics Based on Sex

	Male (N = 34)	Female (N = 16)	*P*-Value
Age			.2841*
Mean ± SD	63.7 ± 8.1	67 ± 7.7	
Range	46 to 78	54 to 79	
Hamada, n (%)			.8983†
1	24 (70.6%)	12 (75%)	
2	6 (17.6%)	2 (12.5%)	
3	4 (11.8%)	2 (12.5%)	
Pre-op ASES			.6623*
Mean ± SD	40.9 ± 13.9	29.9 ± 11.7	
Range	22 to 85	17 to 57	
Post-op ASES			.6623*
Mean ± SD	86.6 ± 9.6	84.3 ± 12.3	
Range	64 to 100	55 to 97	
Pre-op SANE			.1147*
Mean ± SD	38.9 ± 12.7	30.9 ± 22.1	
Range	20 to 60	0 to 80	
Post-op SANE			.6216*
Mean ± SD	84.1 ± 9.9	82.2 ± 10.6	
Range	70 to 100	60 to 98	
Pre-op VAS			.0099*
Mean ± SD	6.8 ± 1.8	8.1 ± 1.4	
	1 to 9	4 to 10	
Post-op VAS			.0736*
Mean ± SD	0.9 ± 1.2	2.4 ± 2.7	
Range	0 to 4	0 to 8	

ASES, American Shoulder and Elbow Surgeons; Post-op, postoperative; Pre-op, preoperative; SANE, Single Assessment Numeric Evaluation; VAS, Visual Analog Scale.
*Kruskal-Wallis *P*-value ($P < .05$ = significant).
†Chi-square *P*-value ($P < .05$ = significant).

TABLE 2 Patient Characteristics Based on Hamada Classification

	Hamada			
	1 (N = 36)	**2 (N = 8)**	**3 (N = 6)**	***P*-Value**
Age				.7247*
Mean ± SD	65.1 ± 8.2	62.8 ± 9.4	65.5 ± 5.9	
Range	45.9 to 79	46 to 75	58 to 76	
Sex, n (%)				.8983†
F	12 (33.3%)	2 (25.0%)	2 (33.3%)	
M	24 (66.7%)	6 (75.0%)	4 (66.7%)	
Length of follow-up, n (%)				.3414†
1 yr	10 (27.8%)	2 (25.0%)	2 (33.3%)	
1 to 2 yr	16 (44.4%)	2 (25.0%)	4 (66.7%)	
>2 yr	10 (27.8%)	4 (50.0%)	0 (0.0%)	
Mean follow-up (mo)				.8463*
Mean ± SD	23.6 ± 17.5	23 ± 11.5	18.2 ± 6.1	
Range	12 to 108.8	12 to 39	12 to 23.7	
Pre-op ASES				.4392*
Mean ± SD	36.5 ± 15.5	38.3 ± 7.8	42 ± 12.5	
Range	16.6 to 85	28 to 49	25 to 55	
Post-op ASES				.1098*
Mean ± SD	87.5 ± 10.6	82.9 ± 8.8	79.8 ± 9.6	
Range	55 to 100	70 to 95	64 to 90	
Pre-op SANE				.5632*
Mean ± SD	34.1 ± 16.4	40.6 ± 17.8	41.7 ± 16.9	
Range	0 to 60	20 to 80	25 to 60	
Post-op SANE				.0257*
Mean ± SD	86 ± 10	78.6 ± 6.9	76.7 ± 9.8	
Range	60 to 100	70 to 90	70 to 95	
Pre-op VAS				.2878*
Mean ± SD	7.4 ± 1.9	6.9 ± 1.2	6.7 ± 1.6	
Range	1 to 10	4 to 8	5 to 9	
Post-op VAS				.5425*
Mean ± SD	1.4 ± 2.2	1.4 ± 1.1	1.5 ± 1.5	
Range	0 to 8	0 to 3	0 to 4	

ASES, American Shoulder and Elbow Surgeons; Post-op, postoperative; Pre-op, preoperative; SANE, Single Assessment Numeric Evaluation; VAS, Visual Analog Scale.
*Kruskal-Wallis *P*-value ($P < .05$ = significant).
†Chi-square *P*-value ($P < .05$ = significant).

included: 12 (40%) biceps tenodesis; 9 (30%) upper border subscapularis repair; 8 (27.7%) distal clavicle excision; and 4 (13.3%) biceps tenotomy. When comparing the preoperative characteristics between isolated ABT versus those with concomitant procedures, there was no significant difference in age ($P = .9447$), ASES ($P = .5792$), SANE ($P = .8193$), and VAS for pain ($P = .9526$). There was a statistically higher number of Hamada 3 shoulders in those

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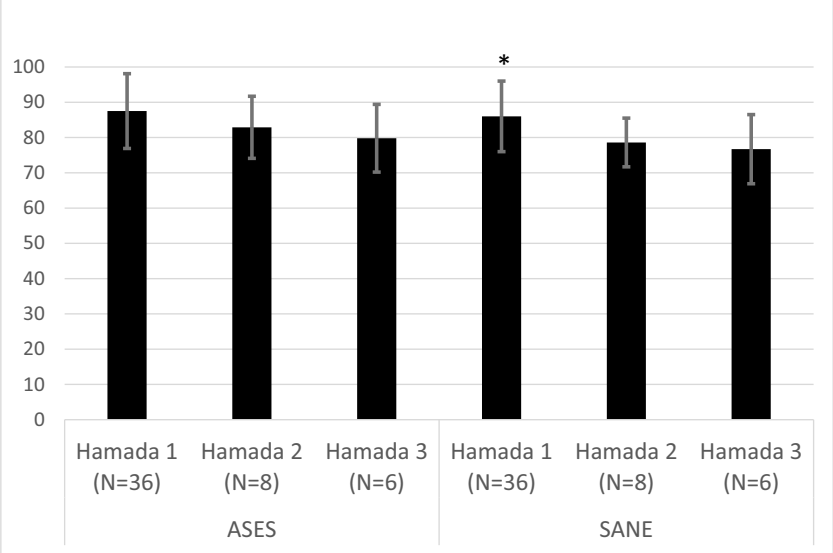

FIGURE 3 Outcomes based on Hamada grade. Postoperative American Shoulder and Elbow Surgeons (ASES) ($P = .1098$) and Single Assessment Numeric Evaluation (SANE) ($P = .0257$).

who underwent isolated ABT ($P = .0414$). Postoperatively, there was no significant difference in ASES ($P = .1087$) and VAS ($P = .8198$). However, patients who had concomitant procedures had a significantly higher postoperative SANE score ($P = .0251$).

Outcomes Based on Length of Follow-Up

Fourteen (28%) patients had 12 months follow-up, 22 (44%) patients had 13 to 24 months follow-up, and 14 (28%) patients had greater that 24 months follow-up (Table 4). When comparing the preoperative characteristic in these groups, there was no significant difference in age ($P = .7275$), Hamada grade ($P = .3414$), ASES ($P = .1080$), SANE ($P = .4973$), and VAS for pain ($P = .4324$). Postoperatively, there was no significant difference between ASES ($P = .3887$) and VAS ($P = .5605$). However, patients with greater than 24 months follow-up had a significantly higher postoperative SANE score than those with less than 24 months follow-up ($P = .0475$) (Figure 4).

MCID, SCB, PASS

The MCID was 8.7 for ASES, 11 for SANE, and 1.0 for VAS. An anchor-based SCB was calculated to be 25 for ASES, 35 for SANE, and 4 for VAS. PASS was calculated to be 79 for ASES, 85 for SANE, and 4 for VAS. Fifty patients (100%) achieved MCID for ASES, 48 patients (96%) achieved MCID for SANE, and 49 patients (98%) achieved MCID for VAS. Forty-eight patients (96%) achieved SCB for ASES, 39 patients (78%) achieved SCB for SANE, and 42 patients (84%) achieved SCB for VAS. Forty patients (80%) achieved PASS for ASES, 23 patients (46%) achieved PASS for SANE, and 46 patients (92%) achieved PASS for VAS. The MOI was 77.4 for ASES and 74.1 for SANE.

MRI Assessment of Graft Healing

One of the authors (R.M.) obtained MRIs in his series of 14 (28%) patients. Graft healing was evaluated on T2-weighted images and a lack of a hyperintense linear signal between the graft and the greater tuberosity. At a mean of 7.2 months, 100% (14 of 14) of the grafts had healed and incorporated to the tuberosity (Figure 5).

Complications

There were no revisions, no infections, and no inflammatory reactions. One patient who initially improved and was satisfied for the first 12 months developed pseudoparalysis. She did not have pain but could no longer elevate her arm past 30 degrees of elevation. She was converted to a reverse shoulder arthroplasty at 26 months after ABT. Intraoperative photographs show the incorporation of the dermal allograft to the greater tuberosity (Figure 6A). Histologic analysis showed complete replacement of the dermal allograft with highly organized fibrous tissue, no acute or chronic inflammatory cells, new blood vessel formation, and complete integration to underlying bone and adjacent articular cartilage of the humeral head (Figure 6B). More importantly, the thickness of this newly

TABLE 3 Patient Characteristics Based on Isolated Arthroscopic Biologic Tuberoplasty Versus Those With Concomitant Procedures

	Isolated (N = 20)	Concomitant Procedures (N = 30)	*P*-Value
Age			.9447*
Mean ± SD	65.5 ± 7.5	64.3 ± 8.5	
Range	46 to 79	46 to 78	
Hamada, n (%)			.0414†
1	11 (55%)	25 (83.3%)	
2	4 (20%)	4 (13.3%)	
3	5 (25%)	1 (3.3%)	
Pre-op ASES			.5792*
Mean ± SD	35.7 ± 13.9	38.6 ± 15.7	
Range	22 to 56	17 to 57	
Post-op ASES			.1087*
Mean ± SD	83.6 ± 9.5	87.3 ± 10.9	
Range	64 to 97	55 to 100	
Pre-op SANE			.8193*
Mean ± SD	35.8 ± 12.4	36.7 ± 19.7	
Range	20 to 60	0 to 80	
Post-op SANE			.0251*
Mean ± SD	79.8 ± 9.7	86.4 ± 9.6	
Range	60 to 95	70 to 100	
Pre-op VAS			.9526*
Mean ± SD	7.3 ± 1.5	7.2 ± 1.9	
	5 to 9	1 to 10	
Post-op VAS			.8198*
Mean ± SD	1.4 ± 1.9	1.4 ± 2.0	
Range	0 to 8	0 to 7	

ASES, American Shoulder and Elbow Surgeons; Post-op, postoperative; Pre-op, preoperative; SANE, Single Assessment Numeric Evaluation; VAS, Visual Analog Scale.
*Kruskal-Wallis *P*-value ($P < .05$ = significant).
†Chi-square *P*-value ($P < .05$ = significant).

formed fibrous tissue was 3 mm, which was the same thickness as the implanted dermal allograft.

DISCUSSION

Our findings support our hypothesis that ABT leads to significant functional improvement as a primary outcome, and that there are no differences in outcomes between sexes, Hamada grades, isolated ABT versus those with concomitant procedures, and that patients with 1-year follow-up had similar outcomes to those with 1 to 2 years follow-up and those with greater than 2 years follow-up.

Multiple treatment options are available for the treatment of MIRCT including debridement,[49] partial repair,[50,51] biceps tenotomy or tenodesis,[52] bridging grafts,[53] incorporation of long head biceps into partial repair,[54,55] tendon transfers,[56,57] subacromial balloon spacer,[5,58] superior capsule reconstruction,[59] and reverse shoulder arthroplasty,[60] but no gold standard exists. Superior capsule reconstruction has been popular for over a decade, but has since fallen out of favor in the United States for a multitude of reasons, including length and cost of the procedure as well as being technically challenging to perform.[15] In addition, high rates of graft tear have been reported.[10,16-18] Furthermore, studies using in vivo dynamic biplane radiography have showed that SCR did not restore the kinematics of the shoulder as previously shown in biomechanic studies[20,21] and that the graft is acting merely as a spacer.[19] Due to these findings and the initial observations that tuberosity-covered patients do as well as intact graft patients,[23,25,46] ABT emerged as a standalone procedure.

To better understand why ABT is successful in relieving pain and improving function, one must understand where the pain comes from in shoulders with MIRCTs. Using the suspension bridge model by Burkhart et al.,[61] in shoulders with MIRCT, deltoid contraction pulls the humeral head proximally, raising the center of rotation superiorly, leading to acromiohumeral articulation causing to bone-to-bone contact (Figure 7). Several biomechanical[62-65] as well as clinical[61,66-69] studies have since showed dynamic superior translation of the humeral head in a setting of rotator cuff tears with deltoid activation. Furthermore, higher deltoid forces are required for abduction leading to higher contact pressures at the acromiohumeral articulation.[65,70] Mirzayan et al.[25] coined the term "biologic tuberoplasty" as the healed dermal allograft to the tuberosity prevents bone-to-bone contact between the greater tuberosity and the acromion, eliminating pain and improving function.[25]

The addition of a dermal allograft arthroscopically without rounding of the tuberosity is what differentiates ABT from the tuberoplasty procedure described by Fenlin et al.[71] Fenlin's tuberoplasty was performed mini-open and created a congruent acromiohumeral articulation by rounding of the greater tuberosity. In his series of 19 patients, at a mean follow-up of 27 months, the modified University of California, Los Angeles (UCLA) score increased significantly from 9.3 to 27.7. However, a modified UCLA score of 27 to 30 (out of 30) is considered good to excellent,[72,73] so this cohort barely reached that criteria.

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TABLE 4 Patient Characteristics Based on Length of Follow-Up

	1 yr Follow-Up (N = 14)	>1 to ≤2 yr Follow-Up (N = 22)	>2 yr Follow-Up (N = 14)	*P*-Value
Age				.7275*
Mean ± SD	64.9 ± 7.1	63.7 ± 9.5	66.4 ± 6.5	
Range	46 to 74	46 to 79	54 to 78	
Sex, n (%)				.1405†
F	2 (14.3%)	10 (45.5%)	4 (28.6%)	
M	12 (85.7%)	12 (54.5%)	10 (71.4%)	
Hamada, n (%)				.3414†
1	10 (71.4%)	16 (72.7%)	10 (71.4%)	
2	2 (14.3%)	2 (9.1%)	4 (28.6%)	
3	2 (14.3%)	4 (18.2%)	0 (0.0%)	
Pre-op ASES				.1080*
Mean ± SD	45.1 ± 16.8	35.3 ± 12.6	33.1 ± 11	
Range	25 to 85	16.6 to 57	17 to 58.3	
Post-op ASES				.3887*
Mean ± SD	84 ± 11.8	85.5 ± 7.5	88.1 ± 13.1	
Range	64 to 100	68 to 97	55 to 100	
Pre-op SANE				.4973*
Mean ± SD	40.3 ± 12.9	35.2 ± 19.8	34.3 ± 15.4	
Range	20 to 60	0 to 80	0 to 60	
Post-op SANE				.0475*
Mean ± SD	80.8 ± 9.5	80.9 ± 10.3	89.1 ± 8.4	
Range	70 to 95	60 to 98	70 to 100	
Pre-op VAS				.4324*
Mean ± SD	6.5 ± 2.3	7.4 ± 1.6	7.6 ± 1.3	
Range	1 to 9	4 to 10	6 to 10	
Post-op VAS				.5605*
Mean ± SD	1.4 ± 1.5	1.7 ± 2.3	1.1 ± 1.7	
Range	0 to 4	0 to 8	0 to 6	

ASES, American Shoulder and Elbow Surgeons; Post-op, postoperative; Pre-op, preoperative; SANE, Single Assessment Numeric Evaluation; VAS, Visual Analog Scale.
*Kruskal-Wallis *P*-value ($P < .05$ = significant).
†Chi-square *P*-value ($P < .05$ = significant).

In addition, progression of superior migration of the humeral head can be seen, and long-term studies have shown borderline satisfactory outcomes.[74-77] Lee et al.[75] reported on 32 patients who underwent arthroscopic Fenlin tuberoplasty. At a mean follow-up of 40 months, the UCLA score improved from 15.4 points to 27.1 points out of a maximum 35 points. A UCLA score of 28 to 35 is considered good to excellent.[78] From the same institution, Park et al.[74] later reported on 16 patients (50% lost to follow-up) at a mean of 98 months follow-up. Although there was significant improvement, with the mean UCLA score improving from 10.3 to 27.2, the final score barely passed satisfactory outcome. In addition, since half their cohort (16 patients) was lost to follow-up, these results were skewed toward those who continued to do well at longer follow-up. Compared with these reports

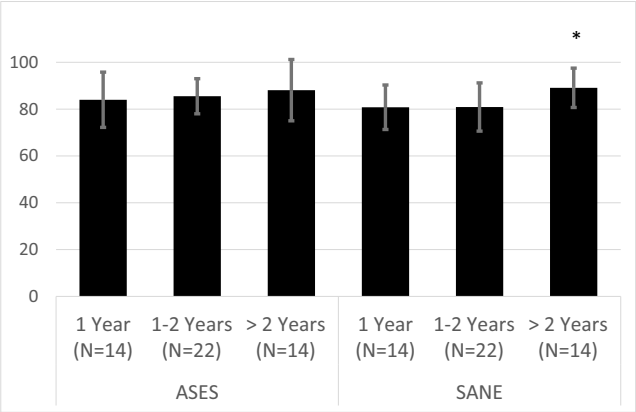

FIGURE 4 Outcomes based on length of follow-up. American Shoulder and Elbow Surgeons (ASES) ($P = .3887$) and Single Assessment Numeric Evaluation (SANE) ($P = .0475$).

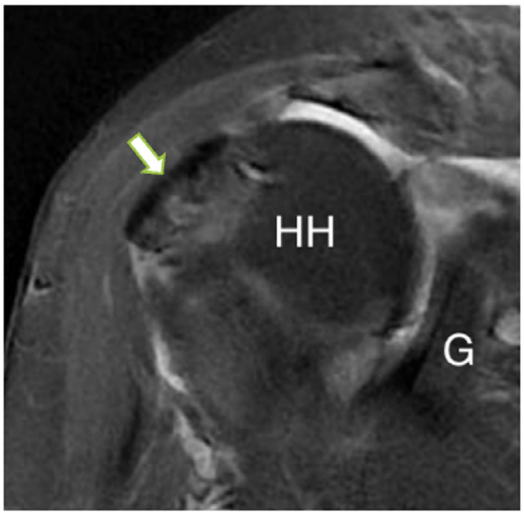

FIGURE 5 T2-weighted coronal oblique MRI of a right shoulder 7 months following surgery showing complete healing of the graft (arrow) to the greater tuberosity of the humeral head (HH). G—glenoid.

on the Fenlin tuberoplasty, our results had near excellent ASES and SANE scores, with minimal to no pain at follow-up. It appears that the addition of a dermal allograft to the tuberosity has an added advantage to tuberoplasty alone as evidenced by our cohort having a maximal outcome improvement of 77.4 for ASES and where anything over 69.5 is considered excellent satisfaction with the procedure.

In 2021, the Food and Drug Administration approved subacromial balloon spacer (SBS) in the United States for the treatment of MRCT.[79] The technique was first described by Savarese in 2012 and thought to work by "reducing friction during shoulder abduction" by lowering the humeral head and "facilitating gliding against the acromion."[80] However, SBS is made of a synthetic material which deflate in 3 months and completely degrade in 12 to 15 months.[79,81] So the question is how does SBS continue to provide pain relief and improve function once it has deflated and dissolved? There is no clear answer to that, but some authors have suggested rebalancing of force couples and retensioning of the deltoid may change the biomechanics of the shoulder.[82] A "balloon dip," which occurs in substantial proportion of SBS patients, is a transient deterioration in shoulder function and increased pain that occurs between 3 and 6 months after balloon implantation, which incidentally coincides with balloon degradation.[83,84] The results of balloon spacers in the literature are mixed, with some studies showing promising results,[5] while another study being aborted due to lack of efficacy.[85,86] Metcalfe et al.,[85] in a prospective, double-blind, randomized controlled trial (START:REACTS) found that SBS group did worse than subacromial decompression alone at 1-year follow-up. Haque et al. have recently reported the 2 years follow-up and confirmed their initial findings.[86] A study has shown that industry funding of studies of SBS significantly increased the study

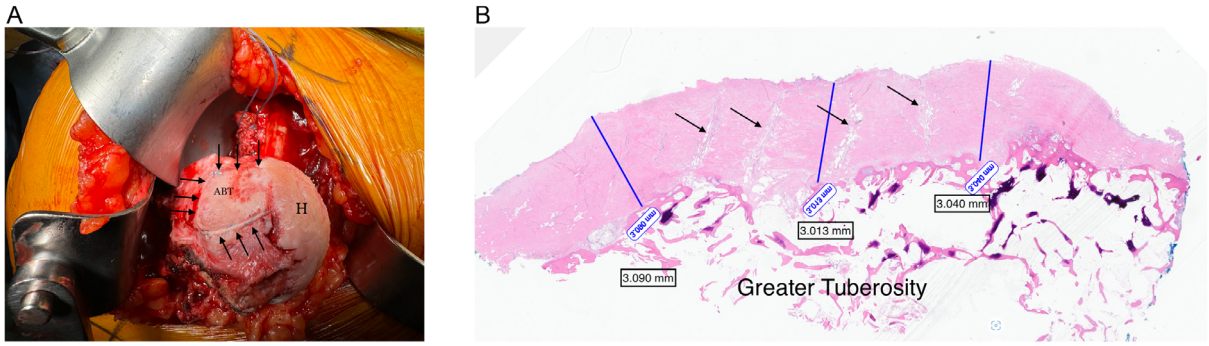

FIGURE 6 (A) Photograph of a right shoulder previously treated with an arthroscopic biologic tuberoplasty (ABT) 26 months prior, outlined by black arrows, showing complete integration with underlying bone and adjacent articular cartilage. (H—Humeral head). (B) Photomicrograph of the ABT sample with Hematoxylin and Eosin staining (X10) showing highly organized fibrous tissue, no acute or chronic inflammatory cells, integration with underlying bone, new vessel formation (black arrows), and maintenance of a 3 mm thickness from the dermal allograft (blue lines).

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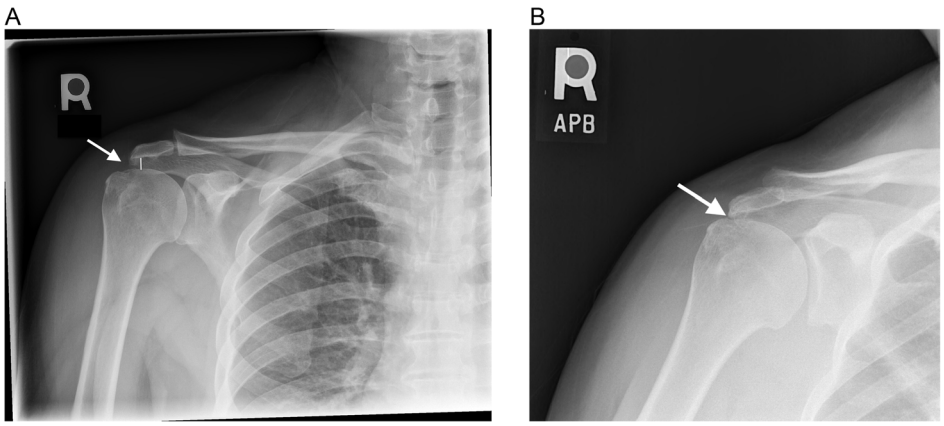

FIGURE 7 (A) Anteroposterior radiograph (AP) of the right shoulder of a patient with a massive rotator cuff tear in the resting position. White arrow showing a 9 mm acromiohumeral distance. (B) Anteroposterior, active abduction radiograph, of the same shoulder with deltoid activation showing bone-to-bone contact between the greater tuberosity and the acromion (white arrow).

reporting a "positive" outcome compared with nonfunded studies.[87] Those studies that do show significant improvement have mediocre Constant-Murley scores[88-90] or Oxford Shoulder Scores[91] at time of follow-up and often times have significant number of patients who are lost to follow-up.[88-90] Unlike these studies, the majority of patients in our study met the MCID and SCB for ASES, SANE, and VAS pain scores. In our cohort, the MOI for ASES was 77.4, which is considered excellent satisfaction. Lastly, the cost of a balloon is significantly higher than ABT (anchors and graft).

There may be concern that outcomes will be temporary due to dermal allograft deterioration. Histology obtained from one patient showed that the dermal allograft acted as a scaffold. The graft was completely replaced by highly organized and durable fibrous tissue, affirming our belief that ABT with a dermal allograft is a long-term biologic solution. The longevity of ABT was further supported by our data which showed equivalent outcomes in patients regardless of length of follow-up. The thickness of the graft may play a role in its durability, with the authors believing that thicker grafts are superior.

Our findings revealed that postoperative SANE score was statistically higher in patients with >2-year follow-up. This may not have clinical significance, as the MCID for SANE was 11 and patients with 1-year follow-up and those with 1 to 2 years follow-up had postoperative SANE scores less than 11 point difference. We also noted statistically higher postoperative SANE scores in patients who had concomitant procedures to ABT, but again, the difference was less than the MCID and therefore most likely not clinically significant. In addition, there were more Hamada 3 patients in the isolated ABT group than the concomitant group which may have affected their SANE scores. The postoperative SANE score was statistically higher in shoulders that were Hamada 1, this again being less than the MCID than those in Hamada 2 and 3, so may not have clinical significance.

Another key finding in our study is that in all patients where an MRI was obtained, the graft had healed to the tuberosity. This supports the short period (3 weeks) of immobilization which allows the graft to adequately heal. Unrestricted range of motion can begin at 3 weeks without concern for graft failure. We believe the consistent outcomes from 8 surgeons in 7 centers show procedural validity across diverse practice settings, reflect the real-world surgical variation and initial learning curve, and eliminate any single-center or single-surgeon bias.

Limitations

Our study has limitations. It is retrospective in nature and lacks a control group and follow-up is somewhat limited.

CONCLUSIONS

Excellent clinical outcomes can be achieved in patients undergoing ABT with significant functional improvement and pain reduction in patients with MRCT. These outcomes can be equally achieved in males and females, and shoulders that are Hamada 1 to 3. Outcomes of patients with >2 years follow-up were similar to those with 1-year follow-up and 1 to 2 years follow-up.

DISCLOSURES

The authors (R.M., T.S.D., J.W.G., M.S., G.J.G., E.S.S., K.F.B.) declare the following financial interests/personal

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