Failed Dermal Allograft Procedures for Irreparable Rotator Cuff Tears Can Still Improve Pain and Function

The "Biologic Tuberoplasty Effect"

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Background: Acellular dermal matrices (ADMs) have been used in the treatment of shoulders with massive rotator cuff tears (MRCTs). Despite clinical improvement, correlation of clinical findings with ADM integrity on imaging has not been investigated.

Hypothesis: The pain in shoulders with MRCTs is partially due to bone-to-bone contact between the tuberosity and acromion. Coverage of the tuberosity with an intact graft or a graft that is torn in a way that the tuberosity remains covered will act as an interpositional tissue, preventing bone-to-bone contact and leading to clinical improvement.

Study Design: Case series; Level of evidence, 4.

Methods: Between 2006 and 2016, a total of 25 shoulders with MRCTs underwent a procedure with an ADM. Pre- and postoperative visual analog scale (VAS) results, American Shoulder and Elbow Surgeons (ASES) score, Hamada grade, and Goutallier classification were reviewed. A postoperative magnetic resonance imaging (MRI) was obtained in 22 (88%) shoulders. The status of the graft was divided into the following categories: type I, intact graft; type II, graft tear with tuberosity covered; and type III, graft tear with tuberosity uncovered (bare).

Results: The mean patient age was 61 years (range, 49-73 years), and the mean follow-up was 25.6 months (range, 10-80 months). Mean length from surgery to postoperative MRI was 13.9 months (range, 6-80 months). The graft was torn in 59% (13/22 shoulders). Significant improvements were found in VAS and ASES scores (7 vs 0.7 and 32.6 vs 91.2, respectively; $P < .01$) for type I grafts and in VAS and ASES scores (8.1 vs 1.3 and 26.3 vs 84.6, respectively; $P < .01$) for type II grafts. No difference was found in postoperative VAS and ASES (0.7 vs 1.3 and 91.2 vs 84.6, respectively; $P = .8$) between type I and type II grafts. No improvement was seen in VAS (7.3 vs 5.7; $P = .2$) or ASES (30.6 vs 37.2; $P = .5$) for type III grafts.

Conclusion: MRI appearance of the graft has a significant impact on functional outcomes. Patients with an intact graft or a graft tear leaving the tuberosity covered have lower pain and higher functional scores than those in whom the torn graft leaves the tuberosity uncovered.

Keywords: bridging repair; acellular dermal matrix; massive rotator cuff tear; human dermal graft; rotator cuff integrity; superior capsule reconstruction; biologic tuberoplasty

Massive rotator cuff tears (MRCTs) are one of the most challenging problems treated by shoulder surgeons.[3] Controversy still exists as to the best nonarthroplasty treatment option for these complex tears, including debridement with biceps tenotomy or tenodesis,[1] tendon transfers,[6,7] acellular dermal matrices (ADMs) as a bridging procedure (BRI),[2,10,14,15,29,31] and superior capsule reconstruction (SCR).[4,20]

BRI entails suturing an ADM to the rim of the retracted rotator cuff tendon and securing the ADM to the greater tuberosity. SCR has become a popular treatment option for MRCT, as it is thought to improve centering of the humeral head and superior stability of the glenohumeral joint.[21] Mihata et al[20,21] described the SCR technique in a laboratory setting, followed by a clinical study. A major change to their initial technique has been the type of graft used in the surgery today. The procedure was first described using tensor fascia lata (TFL) autograft, and since the inception of the procedure, American surgeons have transitioned to use of ADM. Few studies[4,10,17,18,23] have correlated clinical

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findings with graft integrity on postoperative imaging studies. The purpose of our study was to correlate clinical findings with graft integrity when using an ADM.

METHODS

After obtaining approval from the Kaiser Permanente Southern California Institutional Review Board, we retrospectively reviewed patient data that were prospectively collected from October 1, 2006, to November 30, 2016. In total, 14 patients (15 shoulders) underwent a BRI procedure and 10 patients (10 shoulders) underwent SCR for MRCT with a dermal allograft by a single surgeon. The ADMs used included GraftJacket Max Force Extreme (Wright Medical Technology Inc) for the first 2 shoulders in BRI procedures and ArthroFlex (LifeNet Health) for the remaining 23 shoulders. All grafts had an average thickness of 2 mm for BRI procedures and 3 mm for the SCR procedures. ADMs are approved by the US Food and Drug Administration for use in rotator cuff augmentation but not as an interposition graft. Therefore, the use of ADMs in our technique is "off label" (please refer to www.fda.gov for further details on regulations regarding the use of extracellular tissue matrices for rotator cuff repair).

Inclusion criteria included any patient with shoulder pain and a massive, retracted 2-tendon (supraspinatus and infraspinatus) rotator cuff tear (RCT) medial to the glenoid on magnetic resonance imaging (MRI) in whom at least 6 months of nonoperative management had failed (including corticosteroid injection, oral anti-inflammatories, and physical therapy), those who did not wish to have an arthroplasty, and those with Hamada[11] grades 1 (no superior migration of the humeral head) or 2 (superior migration of humeral head with acromiohumeral distance $\leq$5 mm). The senior author (R.M.) performed an intraoperative assessment of the rotator cuff tendon quality, mobility, and ability to be repaired during shoulder arthroscopy and determined that the RCT was irreparable. Patients were required to comply with the postoperative protocol and rehabilitation program. Exclusion criteria included patients with severe glenohumeral arthritis, RCT arthropathy with Hamada grades higher than 2, inflammatory arthritis, or infection. None of the patients in our study had a partial repair or tendon transfer performed as an adjunct to the BRI or SCR.

All patients underwent standard clinical preoperative and follow-up examinations. Postoperative MRI studies were performed in 22 of the 25 (88%) shoulders. Statistical analysis of the functional and pain outcomes was performed only in shoulders that had postoperative imaging. Both a musculoskeletal-trained radiologist and the senior author interpreted all postoperative MRIs. Preoperative and postoperative outcome measurements included the American Shoulder and Elbow Surgeons (ASES) score, visual analog scale (VAS) score, acromiohumeral distance (AHD), Hamada grade,[11] and preoperative Goutallier stage.[8]

The AHD was measured on a true standing anteroposterior (Grashey) view of the shoulder with the arm at the side in neutral rotation.[9,28] Graft tear was classified as type I, intact graft; type II, graft tear with tuberosity covered; or type III, graft tear with tuberosity uncovered (bare).

Surgical Technique

For the BRI procedure, a mini-open incision was made over the anterolateral deltoid, incorporating the lateral portal. Multiple No. 2 FiberWire sutures (Arthrex) were passed through the rotator cuff rim in a mattress fashion and then through the ADM. The SCR was performed all-arthroscopically. The ADM was secured with 3 anchors to the glenoid (at the 10-, 12-, and 2-o'clock positions). In both procedures, the graft was secured to the tuberosity with a double-row, transosseous-equivalent repair.

Postoperative Protocol

The arm was placed in a padded postoperative shoulder immobilizer for 6 weeks. After the initial 2 weeks, gentle, daily pendulum exercises were initiated. Only passive range of motion was allowed for the first 6 weeks. The sling was removed at 6 weeks, and formal active and active-assist range of motion without restriction was initiated at 6 weeks. Gradual strengthening was initiated at 12 weeks, and resistance training was incorporated as tolerated by the patient.

Statistics

Statistical analysis was performed by use of Stata v 15.1 (StataCorp). All variables were tested for normality of data distribution through use of the Shapiro-Wilk test. The Student *t* test was used for normally distributed data, and the Wilcoxon rank-sum test (Mann-Whitney *U* test) was used

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TABLE 1
Number of Shoulders by Hamada Grade and Goutallier Classification

Preoperative Hamada Grade	n (%)	Preoperative Goutallier Classification	n (%)
1	13 (59.1)	0	2 (9.1)
2	9 (40.9)	1	8 (36.4)
3	0 (0.0)	2	8 (36.4)
4A	0 (0.0)	3	2 (9.1)
4B	0 (0.0)	4	2 (9.1)
5	0 (0.0)		

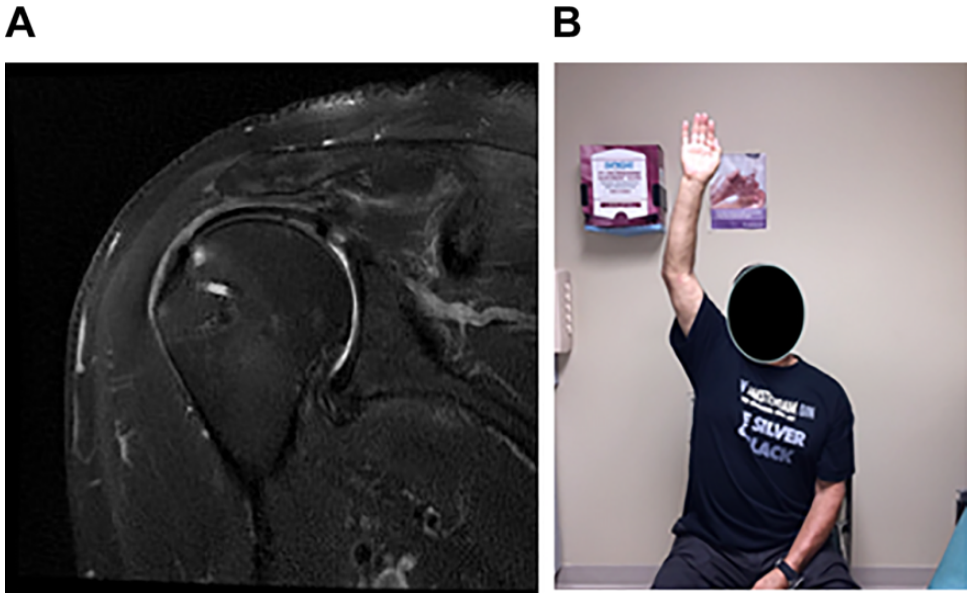

Figure 1. (A) Magnetic resonance imaging at 6 months postoperatively of a type I graft (healed to tuberosity and glenoid) with superior capsule reconstruction. (B) The patient is able to actively elevate his right shoulder.

for nonnormally distributed data. A P value less than .05 was considered statistically significant.

RESULTS

In the 24 patients (25 shoulders) who met the inclusion criteria, clinical follow-up occurred at an average of 25.6 months (range, 10-80 months). There were 18 males and 6 females with an average age of 61 years (range, 49-73 years). A postoperative MRI was obtained in 22 of 25 (88%) shoulders. The mean time from surgery to MRI was 13.9 months (range, 6-80 months).

In 19 of 25 (75%) shoulders, a concomitant procedure was performed. An isolated mini-open, subpectoral biceps tenodesis was performed in 15 shoulders, and a subscapularis repair and subpectoral biceps tenodesis was performed in 3 shoulders; 16 (64%) shoulders had no prior operations. A prior rotator cuff repair was performed in 8 shoulders, and 1 shoulder had 2 prior arthroscopic capsular releases for adhesive capsulitis. The average preoperative Goutallier stage of the supraspinatus was 1.9 (range, 0-4), and the average preoperative Hamada grade was 1.4 (range, 1-2) (Table 1).

An overall graft tear rate of 59% (13/22) was found. Overall, significant improvements were noted in VAS score (7.5 vs 1.6, $P < .01$) and ASES score (29.7 vs 81.1, $P < .01$). Postoperative MRI demonstrated 10 type I, 9 type II, and 3 type III graft tears.

Patients with an intact graft (type I) had significant improvements in ASES scores (32.6 vs 91.2, $P < .01$) and VAS scores (7.0 vs 0.7, $P < .01$). Figure 1 shows an MRI and photograph of a patient with a type I graft.

Patients with a graft tear leaving the tuberosity covered with ADM (type II) demonstrated improved ASES scores (26.3 vs 84.6, $P < .01$) and VAS scores (8.1 vs 1.3, $P < .01$). Figure 2 shows an MRI and photograph of a patient with a type II graft.

No difference was found in the postoperative ASES and VAS scores in type I compared with type II grafts (Table 2).

No significant improvement was seen in VAS or ASES score in shoulders with type III grafts (7.3 vs 5.7, $P = .2$, and 30.6 vs 37.2, $P = .5$). Figure 3 shows an MRI and photograph of a patient with a type III graft.

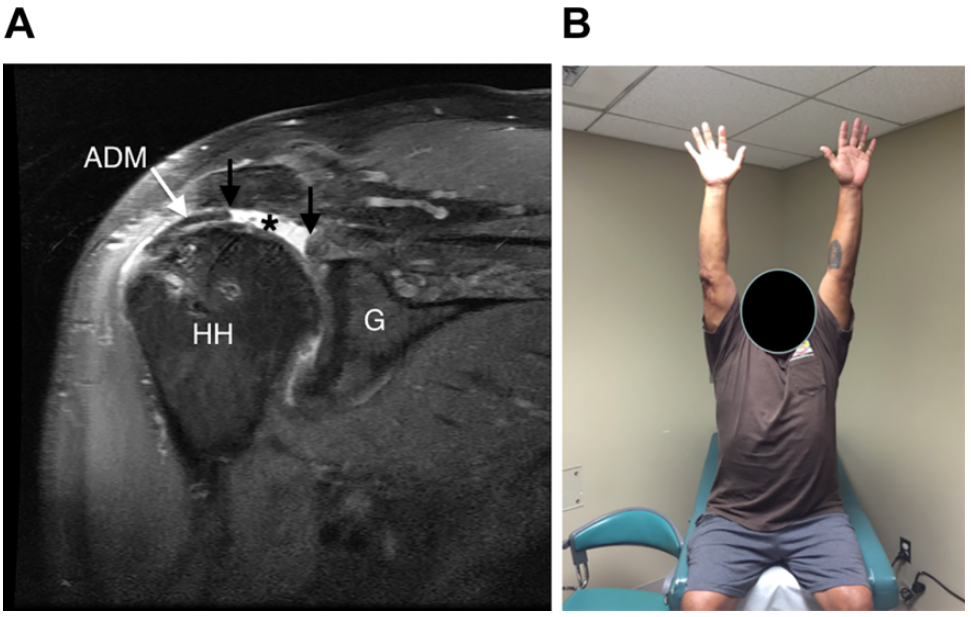

Figure 2. (A) Magnetic resonance imaging at 7 months postoperatively of a patient who underwent a superior capsule reconstruction demonstrating a type II graft tear (healed to tuberosity, torn from glenoid). Black arrows indicate the ends of the graft. Asterisk indicates gap or defect between graft and rim of cuff. (B) The patient is able to fully, actively forward elevate his right shoulder without any pain. ADM, acellular dermal matrix; G, glenoid; HH, humeral head.

TABLE 2
Postoperative VAS and ASES Scores in Shoulders Where the Graft Covered the Tuberosity (Types I and II)[a]

	Postoperative VAS	Postoperative ASES
Type I graft	0.7 (0-30)	91.2 (71.7-100)
Type II graft	1.3 (0-90)	84.6 (11.7-100)
P value	.8	.8

[a]Data are reported as mean (range). ASES, American Shoulder and Elbow Surgeons; VAS, visual analog scale.

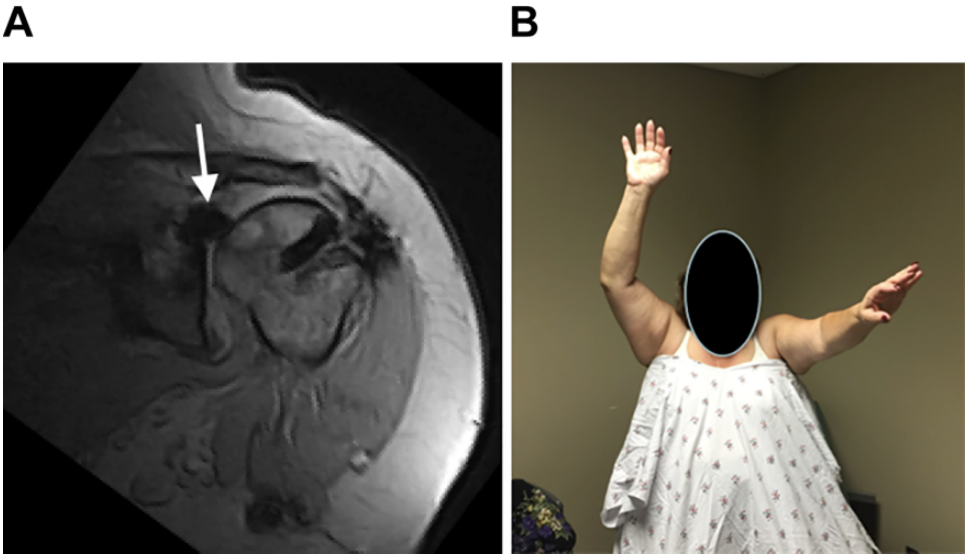

Figure 3. (A) Postoperative magnetic resonance imaging of a patient with a type III graft. The acellular dermal matrix is torn from the tuberosity and retracted to the glenoid (white arrow). (B) The patient continues to have pain and is unable to actively elevate her arm.

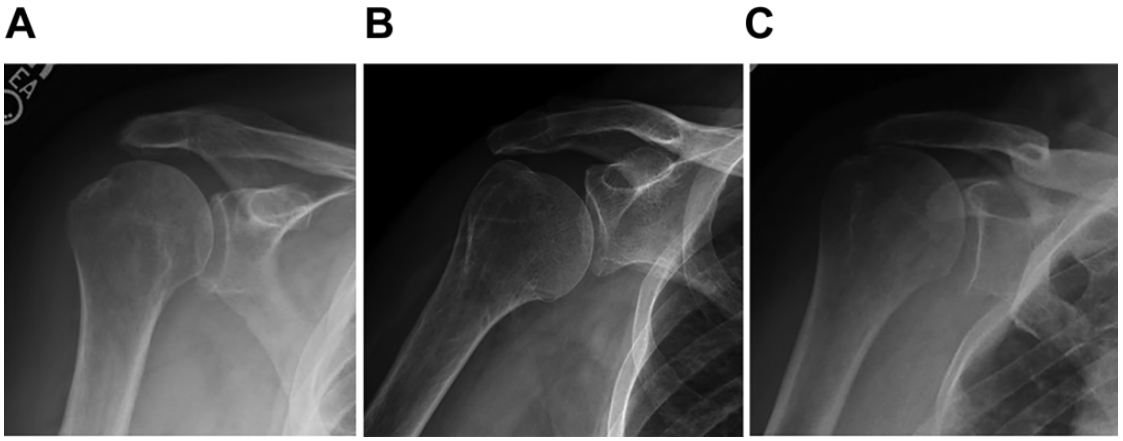

Figure 4. (A) Anteroposterior Grashey view of patient with a massive rotator cuff tear with the arm at rest by his side. (B) 10° active abduction view of a patient with an intact rotator cuff (note: no contact between tuberosity and acromion). (C) 10° active abduction view of same patient as in Figure 4A (note: bone-to-bone contact between tuberosity and acromion).

Statistically significantly improved VAS and ASES scores (0.9 vs 5.7 and 37.2 vs 88.1, respectively, $P < .01$) were found in shoulders where the graft was intact or graft tears left the tuberosity covered (types I and II, combined) compared with shoulders in which the graft tear left the tuberosity uncovered (type III).

DISCUSSION

The results of our study indicate that graft tear location has a significant impact on functional outcomes. Patients with either an intact graft or a graft tear leaving the tuberosity covered have lower pain and higher functional scores than those in whom the torn graft is not covering the tuberosity.

The question of where pain comes from in a shoulder with MRCT should be explored. Several sources have been implicated, including biceps tenosynovitis, glenohumeral synovitis, and capsulitis, leading surgeons to perform debridement and biceps tenotomy/tenodesis.[1,4,12,25] One source of pain that has not been explored in detail is bone-to-bone contact of the bare tuberosity with the acromion. In a shoulder with an intact rotator cuff, as the deltoid is activated to abduct the arm, the rotator cuff acts as a dynamic centralizer of the humeral head, keeping the center of rotation on the glenoid. In this scenario, the head is depressed and also covered by the tendon, and bone-to-bone contact does not occur. In a shoulder with a massive, retracted RCT when the deltoid fires, the humeral head is pulled superiorly, shifting the center of rotation and leading to bone-to-bone contact between the tuberosity and acromion (Figure 4).

This theory has been investigated in the literature by performing tuberoplasty of the greater tuberosity, initially described by Fenlin et al.[5] Using mini-open techniques, the authors used a pineapple bur to recontour the greater tuberosity and all exostoses that were formed from extensive contact between the tuberosity and the acromion. Fenlin et al reported 95% satisfactory results at a mean 27-month follow-up. Since the original description, other authors have reported satisfactory outcomes with arthroscopic tuberoplasty, demonstrating that minimizing tuberosity-to-acromion contact can lead to pain reduction and improved function.[16,27,30] In patients with tears where the graft is covering the tuberosity, the dermal allograft prevents bone-to-bone contact with the acromion, thus eliminating pain. We believe that the ADM acts as an interpositional tissue, and we have termed this the "biologic tuberoplasty effect" of the graft.

Several options have been described for the treatment of MRCTs, including BRI and SCR introduced by Mihata et al[20] using an autologous fascia lata graft. The use of acellular dermal allograft has gained popularity in the United States, although few studies have had large sample sizes and long-term follow-up. In addition, few have correlated clinical outcome with graft integrity on postoperative imaging studies. Denard et al[4] reported on 59 patients who underwent SCR with an ADM. The indication for obtaining postoperative MRIs was "patients who were willing to undergo an MRI," may have added a bias toward patients who were symptomatic to obtain the MRI. In their cohort, only 20 patients underwent an MRI, with 11 demonstrating a tear; 7 from tuberosity, 3 midsubstance, and 1 from glenoid. The postoperative VAS and ASES scores were significantly worse in the tear group compared with the intact group. Because the majority of the tears were from the tuberosity, those patients fared worse.

In other studies, Pennington et al[23] reported results on 88 patients who underwent an SCR with an ADM. The authors stated in their methods section that "postoperative advanced imaging with MRI was only performed on those patients who expressed dissatisfaction with their level of pain, or who had insufficient functional improvement in terms of strength and range of motion." Only 4 patients underwent an MRI, 3 of whom demonstrated a tear from the tuberosity. Lim et al[18] reported outcomes of SCR using TFL in 31 patients who underwent routine postoperative MRI at 3, 6, and 12 months. The authors noted 9 retears, of which 2 left the tuberosity uncovered and 7 left the

tuberosity covered. No significant differences were found between the "intact" and the "graft tear" groups postoperatively with regard to VAS, ASES, Constant score, range of motion, or external rotation strength. The authors did not perform a subgroup analysis dividing the tear types into 2 subgroups; instead, they combined all types of tears into 1 group. One can argue that since the majority (77.8%) of the tears were the type covering the tuberosity, no differences were seen between the "intact" and "tear" groups. Lee et al[17] reported outcomes on 36 shoulders that underwent SCR with either autograft TFL or dermal allograft (the authors did not report the percentage of each). All shoulders underwent routine ultrasound at 3 months and MRI at 6 and 12 months. A tear was noted in 13 patients: 11 from the tuberosity and 2 from the glenoid. The authors reported that the shoulders with a tear (which were predominantly leaving the tuberosity uncovered) had significantly worse postoperative ASES and Constant scores, which is consistent with our findings and those of Denard et al.[4]

Recently, balloon arthroplasty has been introduced as another tool in the treatment armamentarium for MRCTs. Although several authors have reported favorable clinical outcomes following balloon implantation,[13,19,22,32] few have explained the mechanism of action. Some attribute the outcomes to the "frictionless gliding" of the balloon,[13,26,32] whereas others believe that favorable outcomes are due to normalizing mechanics and force couples of the shoulder.[13,22,24,32] One can argue that another mechanism of action of the balloon arthroplasty is to prevent bone-to-bone contact.

Our study has several limitations, including a small sample size, lack of a control group, absence of postoperative MRIs for all patients, and the combining of BRI and SCR procedures. However, our study was not intended to serve as an SCR outcomes study; rather, our purpose was to correlate graft tear location with functional outcomes. Another limitation is the lack of preoperative and postoperative shoulder range of motion data; however, we believe that ASES and VAS scores are a satisfactory record of patient functional range of motion.

CONCLUSION

The use of an ADM in BRI or SCR procedure for the treatment of MRCT results in good clinical outcomes and pain reduction. In shoulders with a tear of the ADM where the tuberosity remains covered, significant improvements in pain and function may be achieved. The ADM covering the tuberosity acts as an interpositional tissue and has a "biologic tuberoplasty effect," preventing bone-to-bone contact between the tuberosity and the acromion, thus eliminating pain. Attention should be paid to repairing the ADM to the tuberosity to ensure healing of the ADM for clinical success of the procedure.

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