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Interposition of human amniotic membrane at the bone-tendon interface of a full-thickness rotator cuff repair

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Rotator cuff tears (RCTs) are a common problem leading to pain and dysfunction of the shoulder.[17,30,34] Despite clinical improvement after a rotator cuff repair (RCR), retear rates between 20% and 94% have been reported.[14] Current aim of RCR surgery is to reduce retear rates after RCR as it leads to better outcomes, especially in regard to strength.[5,7-10,22,29] Surgical factors such as using a transosseous equivalent double row repair technique[15] or augmenting with a dermal allograft[2] have been shown to reduce retear rates. More recently, biologics such as platelet-rich plasma,[23] adipose-derived mesenchymal stem cells,[27] and bone marrow aspirate concentrate[20] have been introduced to improve healing rates. Another method has been used to augment the bone-tendon interface with demineralized bone matrix[38] soaked with mesenchymal stem cells.[21]

On molecular level, several studies have demonstrated the presence of matrix metalloproteinase (MMP)-1,[36] MMP-3,[17] and MMP-9[36] at the site of RCTs and retears. MMPs belong to a family of 24 zinc-dependent endopeptidases, which can negatively impact the RCR tissue because these enzymes degrade components of the extracellular matrix in soft-tissue remodeling after injury.[10] Reduction of MMPs in animal models has been shown to reduce retear rates.[3,4] Human amniotic membrane (HAM) is a potent source of MMP inhibitor[19,28] but has been primarily used in the setting of scar inhibition.[13,16] The senior author (RM) chose to apply amnion matrix at the repair site to reduce MMP activity and to understand whether HAM administered at the tendon-bone interface at the time of RCR surgery would promote structural healing and improve patient-reported outcome scores.

Our hypothesis was that HAM interposition between rotator cuff tendon and bone would not interfere with healing of tendon to bone, even though amnion is known to inhibit scar and could potentially interfere with healing.

Methods and materials

Between November 2016 and April 2019, eight patients underwent RCR with amnion matrix interposition surgery by the senior author (RM). The patients were consecutively chosen to be augmented when we determined the tissue quality of the rotator cuff to be poor by the following technique. Because most RCR failures occur at the suture-tendon interface,[34] a #2 high-strength suture was passed through the cuff and pulled on. If the suture is ripped out of the tendon, that indicated poor tissue quality, and the decision to augment with HAM was made. Preoperative and postoperative American Shoulder and Elbow Surgeons, Oxford, visual analogue pain, and Single Assessment Numeric Evaluation scores were obtained. The amnion used in all cases was Arthrex Amnion Matrix (Arthrex, Naples, FL, USA), which is pure amnion and does not contain chorion. A postoperative magnetic resonance imaging (MRI) of the shoulder was obtained in all patients to assess rotator cuff integrity. The Sugaya classification was used to classify the postoperative MRI findings of the rotator cuff.[40] Type I indicates sufficient thickness with homogeneously low intensity; type II indicates sufficient thickness with partial high intensity; type III

Investigation was performed at Kaiser Permanente Southern California, Baldwin Park, CA, USA.
A subcommittee of the Kaiser Permanente Southern California Institutional Review Board approved this study.

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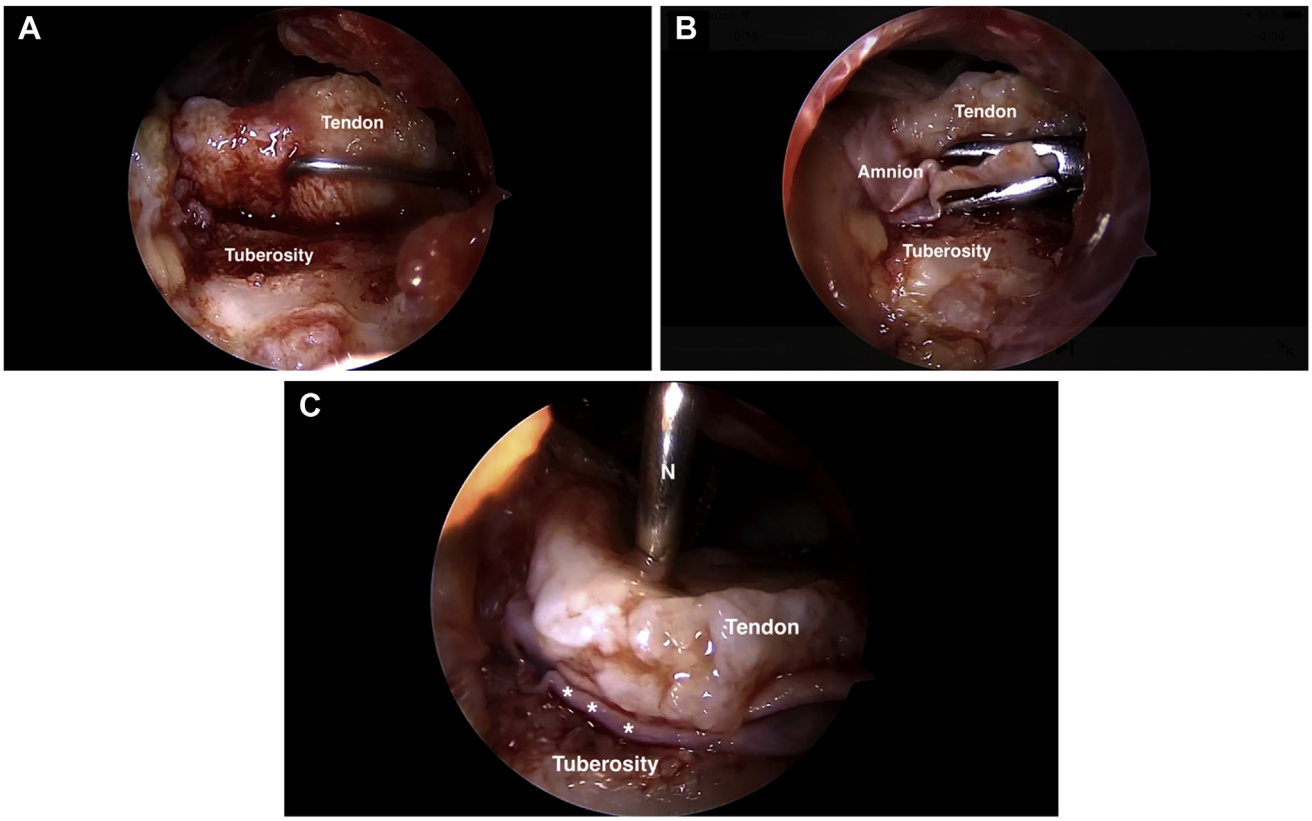

Figure 1 (**A**) A rotator cuff tear is demonstrated from the posterolateral viewing portal. The medial suture bridge has been created. A probe is used to elevate the tendon from bone for demonstration. (**B**) An amnion matrix is introduced from the posterior portal with a grasper. (**C**) The amnion matrix (*) is stabilized between the tendon and tuberosity with a spinal needle (N).

indicates insufficient thickness without discontinuity; type IV indicates presence of a minor discontinuity, suggesting a small full-thickness tear; and type V indicates the presence of a major discontinuity, suggesting a medium or large full-thickness tear. We chose to evaluate healing with MRI at 6 months because Miller et al[32] and Iannotti et al[24] have shown with serial ultrasounds and MRIs, respectively, that in their series, all retears occurred in the first 6 months and that no retears occurred between 6 months and 24 months.

Statistical analysis was performed to assess functional improvements using a paired student t-Test, with a P value of <0.05 set as significant.

Surgical technique

The procedure is performed arthroscopically with the patient in the lateral decubitus position. The arthroscope is moved to the posterolateral viewing portal. The greater tuberosity is prepared by lightly removing soft tissue from bone with a bur in reverse mode and without decorticating the tuberosity (Fig. 1, *A*). Two medial anchors (4.75 mm BioComposite Swivelock, Arthrex, Naples, FL) are placed at the articular margin. The FiberTape (Arthrex, Naples, FL) and #2 high-strength sutures from each anchor are passed through the rotator cuff tendon. The #2 high-strength sutures from each anchor are then tied to each other to create a medial suture bridge. This effectively seals off the medial row of the RCR and aids in keeping the graft onto the tuberosity. The saline is turned off, and the HAM is introduced from the anterior portal and placed between the tendon and tuberosity (Fig. 1, *B*). A spinal needle is introduced from the lateral edge of the acromion piercing the tendon followed by the amniotic membrane and securing the graft to the tuberosity (Fig. 1, *C*). The saline is then turned back on (Fig. 2, *A*), and a standard trans-osseous equivalent double-row repair is performed (Fig. 2, *B*). The spinal needle is removed once the repair is complete. The patient is immobilized for the first 6 weeks after surgery. At 6 weeks, a passive range of motion exercise program is initiated with strengthening beginning at 3 months continuing to 6 months.

Results

The mean age was 52.6 ± 6.8 years (42 to 61 years). There were 6 males and 2 females. The mean length of the tear was 21 ± 2 mm, and the mean width of the tear was 19.4 ± 3 mm. Table I summarizes the functional outcomes. There were significant improvements in functional and pain scores at a mean follow-up of 26 ± 3 months. Postoperative MRI obtained at a mean of 7.8 months (range: 6 to 14 months) revealed that the rotator cuff tendon had healed in all 8 cases (Fig. 3). There were 4 Sugaya type 1, 2 Sugaya type 2, and 2 Sugaya type 3 on postoperative imaging. Table II summarizes each patient's outcome scores with corresponding figures.

Discussion

The most significant finding in this series is that interposition of HAM between the rotator cuff tendon and bone did not interfere with healing of the RCR. Because rotator cuff healing occurs by initial scar formation and amnion is primarily considered a scar inhibitor,[13,31,39,42] our concern was that it may impede healing of tendon to bone when placed in that interface. This case series

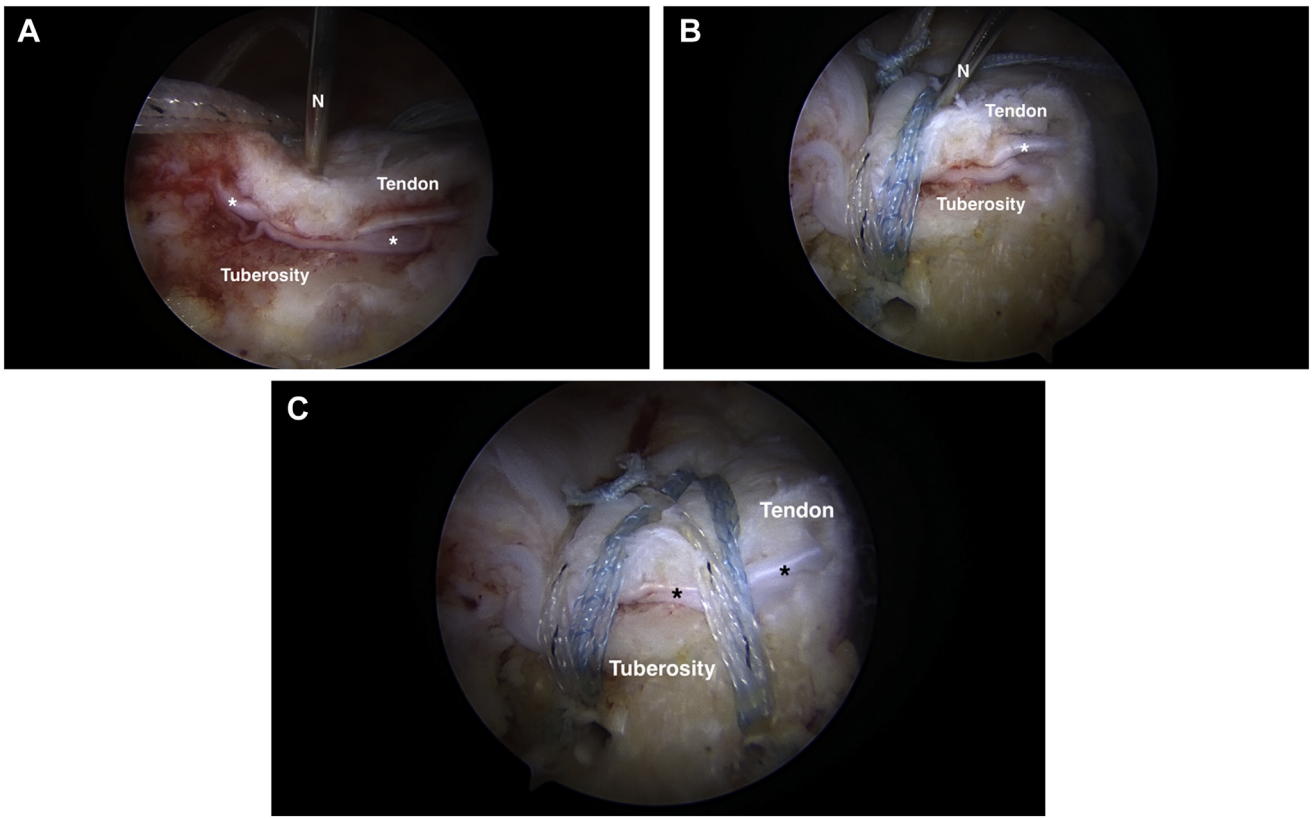

Figure 2 (**A**) The saline fluid is turned back on with the needle (N) still stabilizing the amnion matrix (*). (**B**) The first part of the lateral row fixation performed. (**C**) The completed trans-osseous equivalent repair with the amnion matrix (*) securely held in place by the repair construct.

Table 1
Summary of clinical outcome measures.

PRO	Preoperative	Postoperative	*P* value
ASES	24.1 ± 6.6	96.4 ± 3.1	<.00005
Oxford	22.8 ± 1.5	46.7 ± 1.4	<.00005
VAS	9 ± 0.9	0.3 ± 0.5	<.00005
SANE	31.7 ± 11.7	96.7 ± 5.2	.00001

ASES, American Shoulder and Elbow Surgeons; Oxford, Oxford Shoulder Score; *PRO,* patient reported outcome; *SANE,* Single Assessment Numeric Evaluation; *VAS,* visual analogue scale for pain.

shows that is no longer a concern when using amnion in the setting of RCR.

We cannot conclude whether the addition of HAM aided in or accelerated the healing of RCR based on this case series, but this finding can stimulate animal studies and larger randomized trials to evaluate whether it will reduce retear rates or accelerate healing.

HAM has been used in medical procedures for over a century. It has been used for corneal injuries and for burn wound coverage.[12,37,43] Amnion has anti-inflammatory properties, including downregulation of transforming growth factor beta, which can reduce perineural fibrosis and scarring.[13] Several animal models have demonstrated that amniotic tissue prevented scar formation. In a rabbit model, Kim et al[26] demonstrated that HAM wrapping of the ulnar nerve after a neurorrhaphy resulted in significant reduction in perineural fibrosis and scarring. This finding has also been demonstrated in human patients.[33] Meng et al,[31] using a rat model, transected and repaired sciatic nerves and found that those wrapped with HAM had significantly fewer adhesions and less scar formation than controls. In human subjects, application of HAM has been mostly used to reduce postoperative scarring and adhesion formation in prostate,[35] spine,[39,42] lung,[6] vaginal reconstruction,[1,41] and ocular surgery.[25] HAM has also been used in several orthopedic applications.[19] It has been used for tendon wrapping in foot and ankle surgery.[11,44] Zelen et al[45] injected micronized dehydrated human amniotic/chorionic membrane as an alternative to surgical intervention in the treatment of refractory plantar fasciitis. Hanselman et al[18] compared cryopreserved HAM injections to corticosteroid injections in plantar fasciitis patients. Gaspar et al demonstrated improved outcomes with the use of HAM in revision cubital tunnel surgery.[16]

On molecular level, several studies have demonstrated the presence of MMP-1,[36] MMP-3,[17] and MMP-9[36] at the site of RCTs and retears. MMPs belong to a family of 24 zinc-dependent endopeptidases, which can negatively impact the RCR tissue because these enzymes degrade components of the extracellular matrix in soft-tissue remodeling after injury.[10] Reduction of MMPs in animal models has been shown to reduce the retear rate.[3,4] Bedi et al performed an identical surgical repair in a supraspinatus tear in a rat model and randomized to two groups: controls and those treated with recombinant a-2-macroglobulin protein, a universal MMP inhibitor, at the repair site.[4] Significantly greater collagen organization and significant reduction in collagen degradation were observed in the a-2-macroglobulin-treated animals compared with controls at 4 weeks. In another study, Bedi et al created supraspinatus tears in a rat model and performed identical repairs in controls and rats treated with doxycycline, which has been shown to profoundly inhibit MMP by a mechanism independent of its antimicrobial activity.[3] The controls were compared to rats treated with doxycycline at various time points from preoperative up to 2 weeks postoperatively. They found that the healing enthesis of animals started on doxycycline preoperatively or at

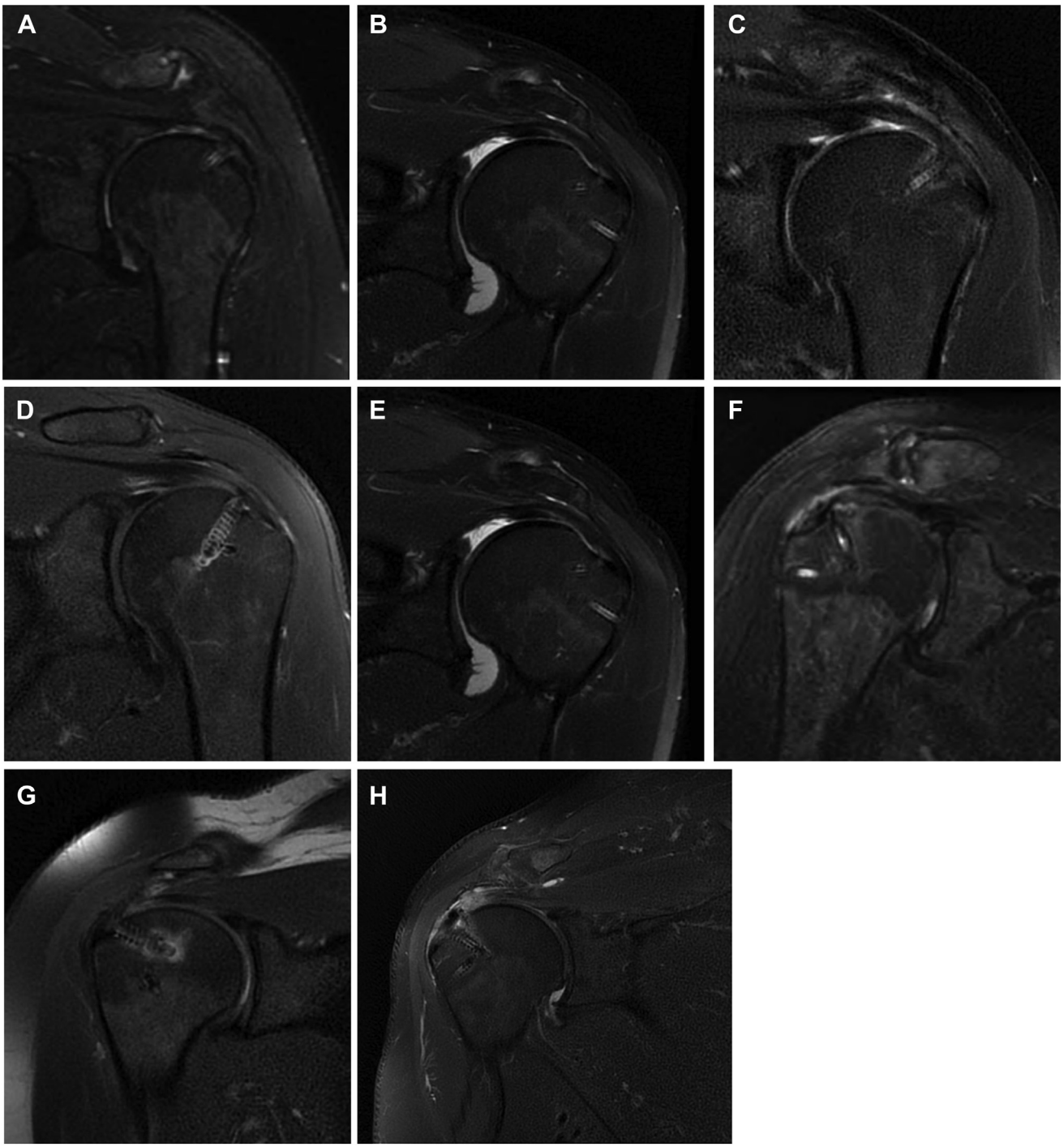

Figure 3 (**A**) T2 Fast spin echo of a *left* shoulder of a 58-year-old male 13.6 months after rotator cuff repair. (**B**) T2 Fast spin echo magnetic resonance arthrogram of a 49-year-old male 7.5 months after rotator cuff repair demonstrating no dye leakage into the subacromial space indicating a "water tight" repair. (**C**) T2 fat suppressed image of a 60-year-old male 6.8 months after rotator cuff repair. (**D**) Proton density fat suppressed image of a 51-year-old 8 months after rotator cuff repair. (**E**) Proton density fast spin echo image of a 56-year-old female 6 months status after repair. (**F**) T2 fast spin echo image of a 54-year-old male 7 months after rotator cuff repair. (**G**) Proton density fast spin echo image of a 42-year-old female 6 months after rotator cuff repair. (**H**) Proton density fast spin echo image of a 61-year-old male 7 months after rotator cuff repair.

postoperative day 5 had an increased load to failure compared with controls at 2 weeks.

HAM has been demonstrated to be a potent source of MMP inhibitor[19,28] but has been primarily used in the setting of scar inhibition.[13,16] Litwiniuk et al reported on 25 individuals with chronic venous stasis ulcers who were treated with amnion dressings.[28] They found that MMP-2 and MMP-9 activities in wound exudates revealed a decrease in activity in response to amnion application. This effect was due to the presence of the potent MMP inhibitors, tissue inhibitor of metalloproteinases-1, type-1 plasminogen activator inhibitor, and thrombospondin-1 in the amnion dressings, as shown by real-time fluorescence zymography and protein microarrays.

Table 2
Individual patient information with corresponding figure number and Sugaya[40] type on postoperative imaging.

Patient	Age	Sex	Preoperative ASES	Postoperative ASES	Preoperative Oxford	Postoperative Oxford	Preoperative VAS	Postoperative VAS	Preoperative SANE	Postoperative SANE	Figure	Sugaya classification
1	58	M	18.3	93.3	21	45	9	1	30	90	3A	1
2	49	M	25	94.9	24	48	8	0	40	100	3B	1
3	60	M	30	93.3	24	47	7	0	50	100	3C	1
4	51	M	20	100	22	48	8	0	20	100	3D	2
5	56	F	16.6	96.6	22	45	9	0	20	100	3E	3
6	44	M	26.6	100	21	48	8	0	20	100	3F	3
7	42	F	31.6	100	25	48	7	0	40	100	3G	1
8	61	M	28.3	95	23	47	8	1	30	90	3H	2

ASES, American Shoulder and Elbow Surgeons; Oxford, Oxford Shoulder Score; *SANE*, Single Assessment Numeric Evaluation; *VAS*, visual analogue scale for pain.

The question that still needs to be answered is why amnion, which dampens the cytokine storm and is a scar inhibitor, does not inhibit healing of the rotator cuff tendon. The answer is beyond the scope of the findings of our case series. Further histologic and biomechanical studies as well as clinical trials are needed to better understand the mechanism of rotator cuff tendon to bone healing and whether it can expedite healing and eventually reduce retear rates.

The limitations of this study are that there was a small sample size, and there was no control group.

Conclusion

In our series of 8 cases, interposition of HAM did not inhibit healing of rotator cuff tendon to the tuberosity. This is contrary to what is thought of HAM to act as a scar inhibitor. A potential role of HAM is that it is a potent MMP inhibitor, high levels of which have been found at the site of RCTs.

Disclaimers

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Patient consent: Obtained.

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