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Healing of partial-thickness rotator cuff tears following arthroscopic augmentation with a highly-porous collagen implant: a 5-year clinical and MRI follow-up

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SUMMARY

Background. The purpose of this study was to review patients with intermediate- and high-grade partial-thickness rotator cuff tears at 5 years following insertion of a highly-porous collagen implant on the bursal surface of the cuff to determine the durability of the clinical results and structural integrity of the healed tendons compared to their previously reported 2-year results.

Methods. Eleven of the original 13 patients were examined after 5 years. Clinical scores (Constant and ASES) and MRI evaluations of tendon integrity and quality were compared to the two-year results.

Results. All patients demonstrated statistically significant improvement in clinical scores compared to preoperative values. Mean Constant and ASES pain and function scores improved at 5 years but were not statistically different from the two-year scores. Eight of the 11 patients demonstrated no negative change in tendon quality on MRI. However, 3 patients had developed new, asymptomatic tears (1 low-grade articular, 2 low-grade intra-substance) of the supraspinatus tendon.

Conclusions. This 5-year follow-up confirms the ongoing clinical benefit of this implant in the treatment of partial-thickness lesions of the rotator cuff and demonstrates ongoing structural tendon improvement, with most repaired tendons intact at five years.

KEY WORDS

Collagen Implant; Rotator cuff tears; Surgical treatment; Tendon healing; Arthroscopic shoulder surgery

INTRODUCTION

Many partial-thickness rotator cuff tears (PTRCT) are known to enlarge and eventually progress on to full-thickness tears with time. In a longitudinal study over a five-year period, Yamaguchi et al. demonstrated that 39% of PTRCTs showed tear progression with no patients showing a decrease in tear size (1). They also noted that 51% of asymptomatic PTRCTs became symptomatic after a mean 2.8 years.

The potential for partial-thickness and small, full-thickness tears to heal has been considered by a number of authors, (2,3) however, other factors such as subacromial impingement, degenerative changes, age and increased shear stresses within the tendon may interfere with a purposeful repair.

(4) Some studies have alternately suggested that there is no active repair occurring at the site of a tendon injury (5,6). Differential shear stresses within the tendon have been thought to contribute to the development of partial-thickness tears within the tendon and may lead to further impaired healing, tissue degeneration and increase in tear size (7-10).

Earlier clinical studies have demonstrated that placing a highly-porous, oriented collagen implant onto the bursal surface of the supraspinatus tendon which had a partial-thickness tear (bursal-sided, intra-substance, or articular-sided) induced both a neo-tendon layer of more than 2 mm of tissue and also led to apparent partial or complete healing of the tendon defects, as judged by MRI, of the tendon defects in most cases (11, 12). These studies followed patients for one year post-surgery (12) and up to two years post-implantation (11) with favourable results both clinically and on MRI assessment and no significant complications.

The purpose of this paper is to follow-up a cohort of patients reported earlier (11) to determine if the improved clinical outcomes and MRI outcomes in that series were maintained at 5 years post-implantation.

MATERIALS AND METHODS

Following Ethics Committee approval and registration with the Australia New Zealand Clinical Trials Registry (Trial ID: ACTRN12611001082998) patients with partial-thickness tears of the supraspinatus tendon were recruited. The study also meets the ethical standards required by this journal (13). A highly-porous collagen implant (Smith & Nephew, Plymouth, Minnesota) was arthroscopically attached to the bursal surface of the tendon and its effect on tissue induction, tendon quality and integrity, and clinical outcomes evaluated over a 5-year period. Informed consent was obtained for all patients. All patients (aged 40-67 years old at time of surgery) had a partial-thickness tear of Ellman (14) Grade II or III with chronic shoulder pain lasting longer than 3 months (resistant to analgesics, anti-inflammatory medication, and physical therapy). Patients with recent steroid use (oral or injected), insulin-dependent diabetes, genetic collagen disease, heavy smoking, chronic inflammatory disease, as well as previous cuff surgery, shoulder instability, grade 3 or greater chondromalacia, or grade 2 or greater fatty infiltration of the supraspinatus muscle were excluded. The implant is contraindicated for patients with a known hypersensitivity to bovine collagen.

Thirteen consecutive patients with partial-thickness tears of the supraspinatus tendon, with the articular- and bursal-sided tears confirmed at surgery and the intra-substance tears confirmed by preoperative MRI, met the criteria and were enrolled in the study and underwent surgery by one of four authors (DJB,DHS,BC or AAY). Eleven of these patients participated in the 5-year follow-up.

Surgical Technique and Collagen Implant

The surgical technique for insertion of the implant was previously described and performed arthroscopically under general anesthesia in either the beach-chair or lateral decubitus positions (11). At the time of surgery all patients had a detailed inspection of the glenohumeral joint and subacromial bursa. A bursectomy and acromioplasty was performed in all patients and if indicated other procedures such as biceps tenodesis / release and labral debridement were also performed. The implant, which is made from highly-purified, type I collagen from bovine tendons (Collagen Matrix, Inc., Oakland, New Jersey), was fixed to the supraspinatus tendon using custom-designed PLA staples with 5 mm of overlap on the bone of the greater tuberosity being fixed with custom-designed PEEK staples (Smith & Nephew, Plymouth, Minnesota). The patients were instructed to discard their sling 1 week after surgery and progress from passive to active-assisted to active motion as tolerated. Active forward was limited to 100° for the first 4 weeks and resistance exercises were commenced at 6 weeks. After 6 weeks there were no further restrictions on the use of the arm.

Clinical Assessment

Clinical assessments of the patients included the Constant-Murley shoulder score (not age or gender adjusted) and the American Shoulder and Elbow Society (ASES) shoulder Scale. These validated shoulder-specific assessments were administered both preoperatively and at 2 and 5 years postoperatively.

MRI Assessment

MRIs were performed on all patients preoperatively and at 2 and 5 years postoperatively. The scans were done on 3 Tesla scanners using 2 mm slices, with proton density (PD) and T2 weighted scans, with and without fat saturation. All of the MR imaging for both the initial and this study was performed at one of two institutions and read by a single musculoskeletal radiologist blinded to the clinical outcomes. All of the measurements were made on the PD fat suppressed images using a technique described in earlier reports (11,12). The tear size was estimated by analyzing the entire sequence of images from the coronal, sagittal, and axial scans.

In every patient the follow-up measurements were made as close as possible to the location where the preoperative

measurement was made. The size of the cuff defect, whether the tear had progressed, remained the same, or reduced in size, the change in thickness of the tendon, and the quality of the tissue were assessed by MRI. An evaluation of the adjacent tendon areas was also performed to determine whether degenerative changes would develop remote from the implanted tendon.

Statistical Analysis

Differences in tendon thickness over time were analyzed using a repeated measures ANOVA and differences between individual time periods were evaluated using post-hoc analyses. A dependent paired t-test was used to look for differences in clinical scores between the 2- and 5-year follow-up periods. Statistical significance was considered at $p<0.05$.

RESULTS

There were 13 patients at the commencement of this study with an average age of 53.8 years (range 42-67). The clinical and MRI findings of the initial 13 patients have been previously reported (11) and relevant data have been used within this paper as the baseline for the outcomes of the results of the 11 patients available for 5-year follow-up. The 2 patients lost-to-follow-up at the 5-year mark had high-grade tears at time of surgery – one articular-sided and the other intra-substance. Both of these patients had demonstrated apparent complete healing of their partial tears at the 2-year follow-up.

The mean length of follow-up of the 11 patients with 5-year follow-up was 60.3 months (range 59.1-62.1 months). The mean age of these patients at the time of surgery was 54.0 ± 8.3 years (range 42.5-67.0 years). 7 patients were male and 4 female, with 7 right and 4 left shoulders. 5 patients had high-grade tears, while 6 had intermediate-grade tears. The character of these tears was 3 bursal-sided (1 high-grade, 2 intermediate-grade), 4 articular-sided (1 high-grade, 3 intermediate-grade) and 4 intra-substance (3 high-grade, 1 intermediate-grade).

MRI assessment of tendon thickness

MRI assessment of tendon thickness 2 years following surgery demonstrated new tissue induction indistinguishable by MRI from the underlying tendon in all patients with a significant increase in mean tendon thickness from 4.28 ± 0.32 mm preoperatively to 5.91 ± 0.33 mm ($p< 0.0001$), at 2 years. At 5 years post-surgery there was a significant decrease in the mean tendon thickness to 5.16 ± 0.27 mm ($p=0.0012$) when compared to the thickness at 2 years. However, the thickness at 5 years was still significantly greater than the preoperative thickness ($p<0.0001$) (**Figure 1**).

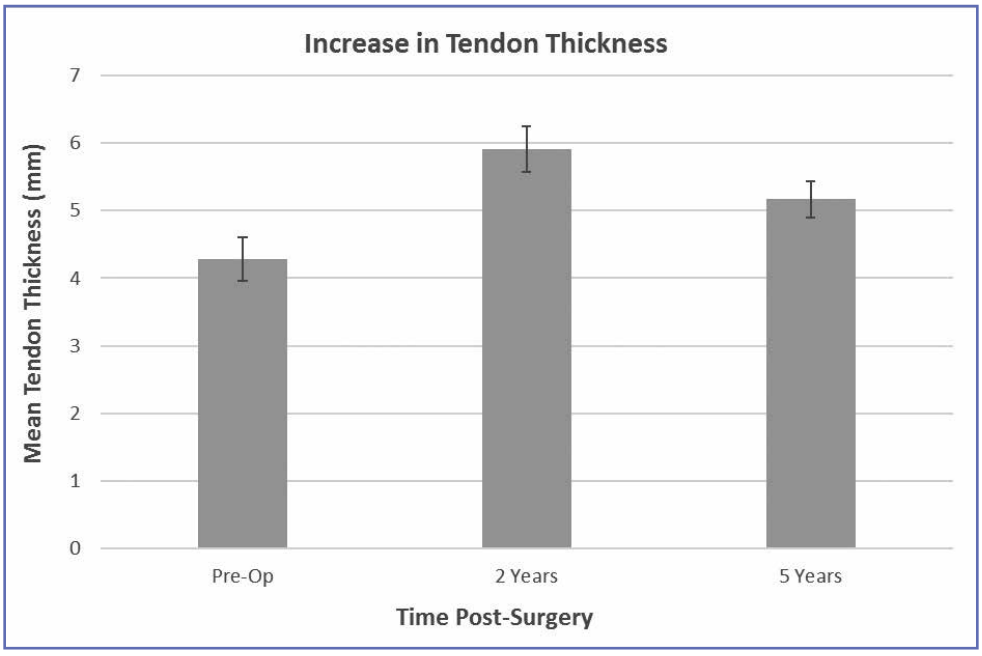

Figure 1. Chart demonstrating increased tendon thickness over the 5-year follow-up period. (Error bars indicate ± 1 SEM)

MRI assessment of tendon integrity

MRI evidence demonstrated that 8 of the 11 patients had no negative change in the apparent quality of the tendon between 2 and 5 years post-surgery. **Figures 2** and **3** show representative examples of healed tendons that remained healed through the 5-year follow-up.

Two patients demonstrated a negative change in the healing quality of the defect. One of these patients originally had a high-grade, articular-sided tear that was completely filled in by 6 months and remained filled in at the 2-year assessment. At 5 years, however, a new, low-grade, articular-sided defect was noted at the posterior edge of the implant site, adjacent to the original, high-grade defect (**Figure 4**). The other patient originally had a high-grade, intra-substance tear that was healed completely at 2 years, but developed a low-grade, intra-substance tear at 5 years in the region of the original defect (**Figure 5**). It was not possible to distinguish between "new" and "recurrent" pathologies.

One patient who originally had a high-grade, bursal-sided tear that appeared completely healed at 2 years developed an intra-substance delamination at 5 years that was quite medial to (i.e. distinct from) the original tear (**Figure 6**).

Clinical Assessment

Constant and ASES scores in all 11 patients showed persistent improvement throughout the 5-year follow-up period with no significant changes compared to the 2-year results (**Figures 7** and **Figure 8**). There were significant improvements in overall Constant score ($p \leq 0.01$), Constant pain score ($p \leq 0.001$), ASES total score ($p \leq 0.001$), and ASES pain score ($p \leq 0.001$) compared to the preoperative scores.

Complications

Complications were previously reported and detailed at the 2-year follow-up with one patient experienced excessive swelling of the shoulder during the arthroscopic procedure necessitating conversion to a mini-open approach. One

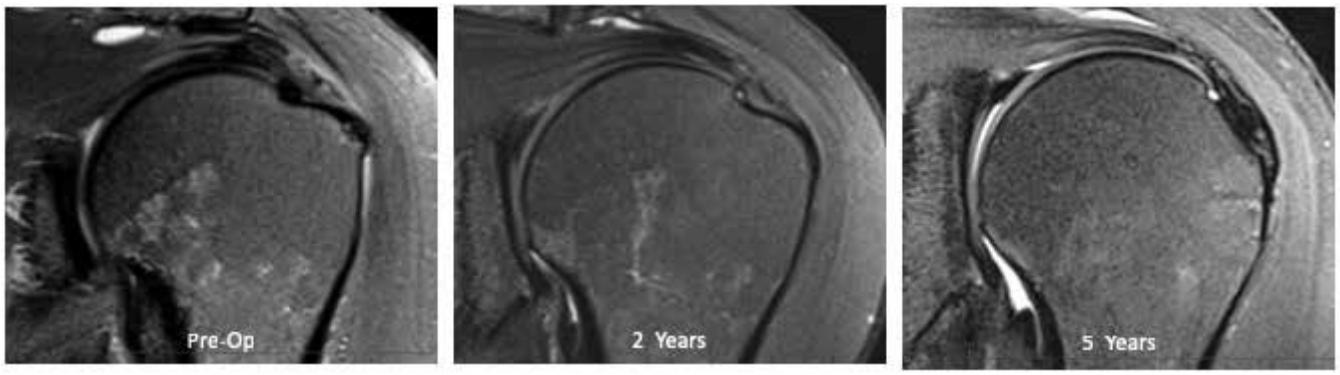

Figure 2. MRI images of an intermediate-grade, bursal-sided tear, which was completely healed at 2 years and remained completely healed at 5 years.

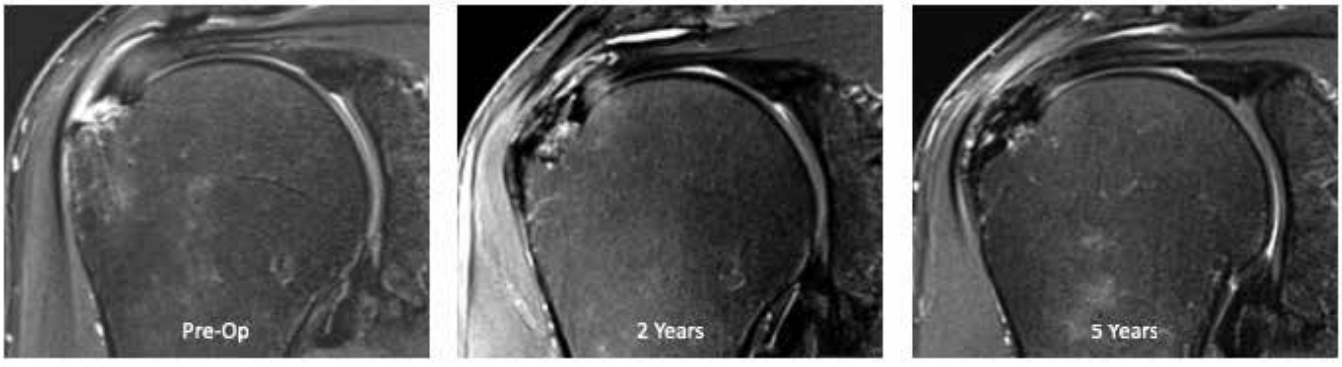

Figure 3. MRI images of high-grade, intra-substance partial-thickness tear followed over 5 years.

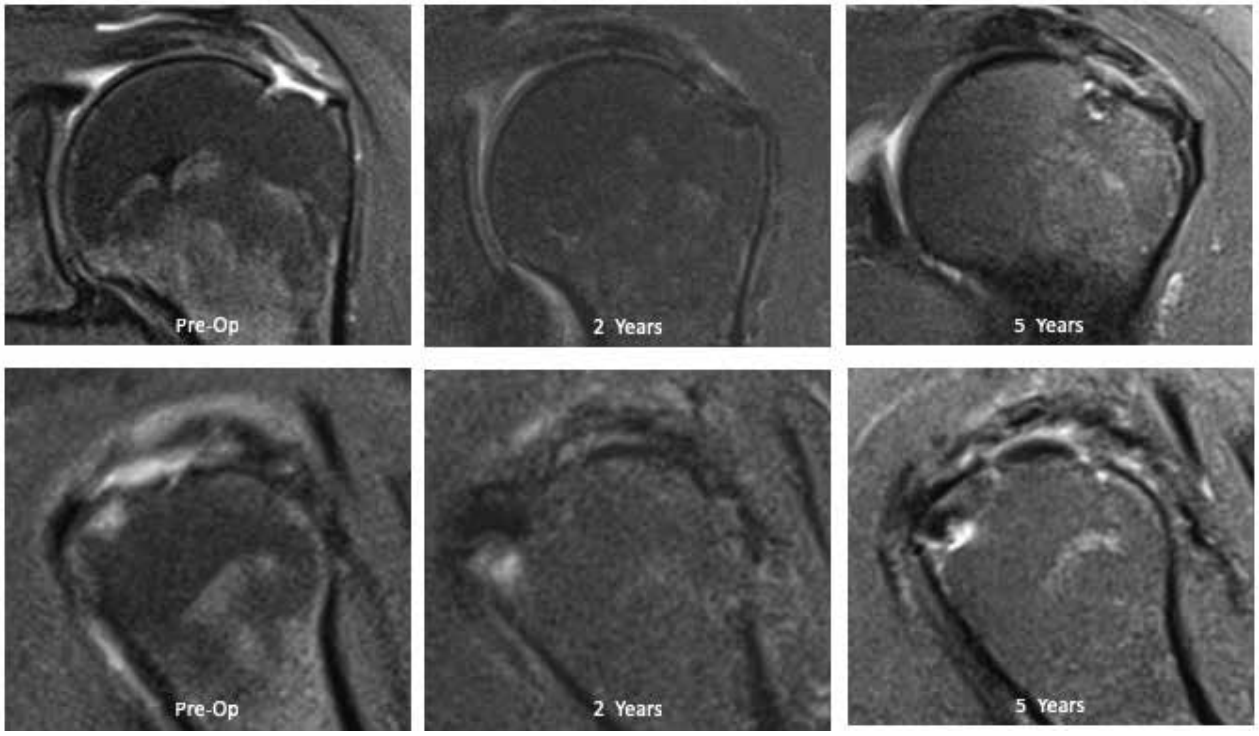

Figure 4. MRI images of high-grade, articular-sided partial-thickness tear. At 5 years a new, small defect was noted at the posterior edge of the implant site, while the original, very large defect was more toward the anterior edge.

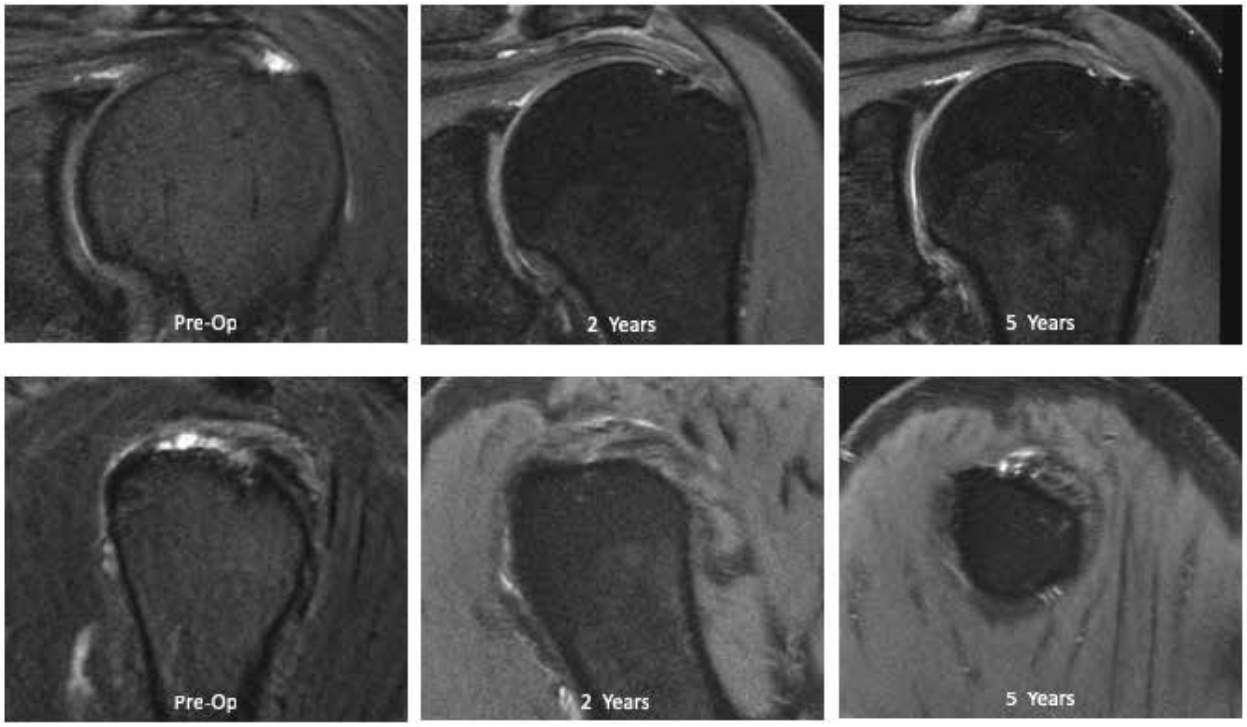

Figure 5. Patient with high-grade, intra-substance tear that was completely healed at 2 years. At 5 years a new, small intra-substance defect was observed.

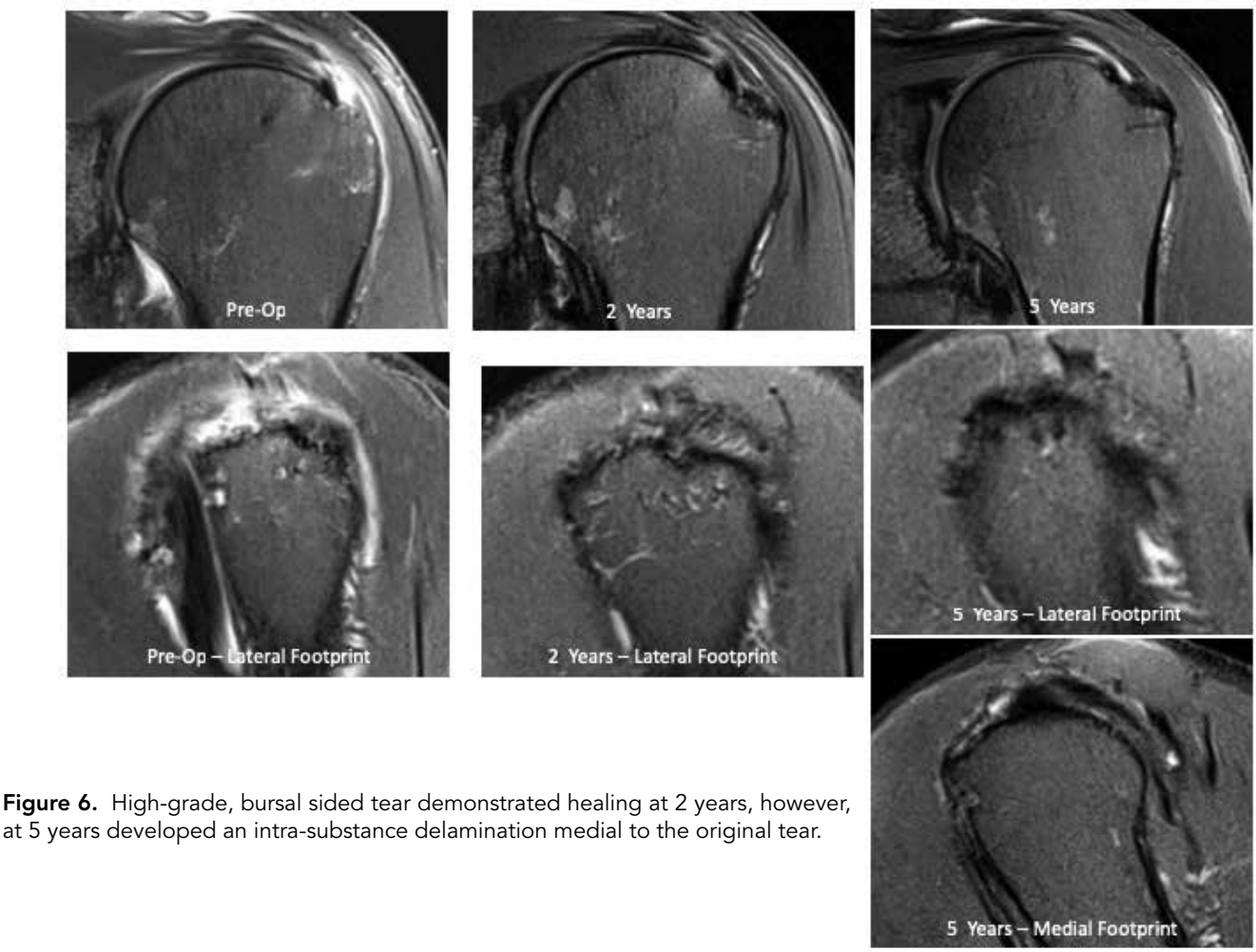

Figure 6. High-grade, bursal sided tear demonstrated healing at 2 years, however, at 5 years developed an intra-substance delamination medial to the original tear.

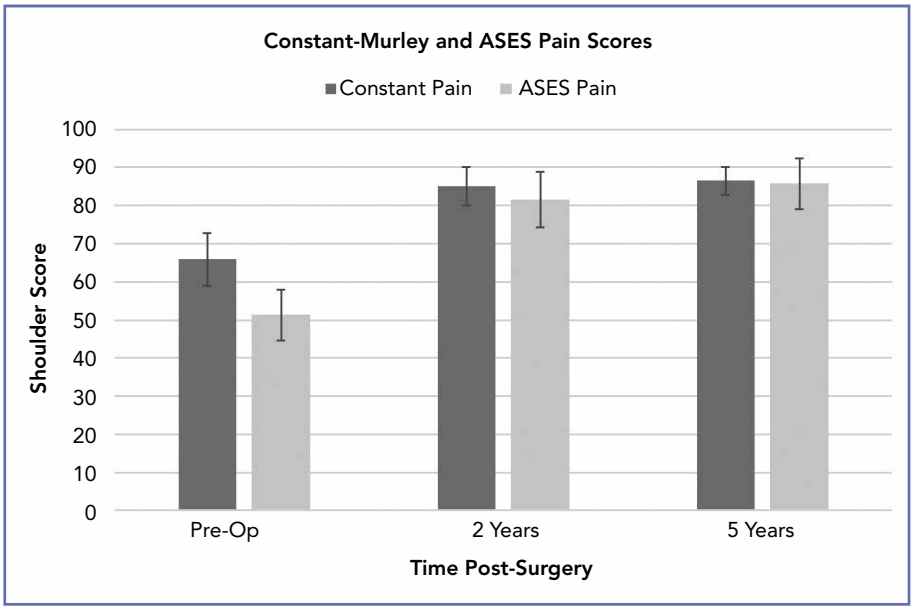

Figure 7. Constant and ASES scores over 5-year follow-up period. (Error bars indicate ± 1 SEM)

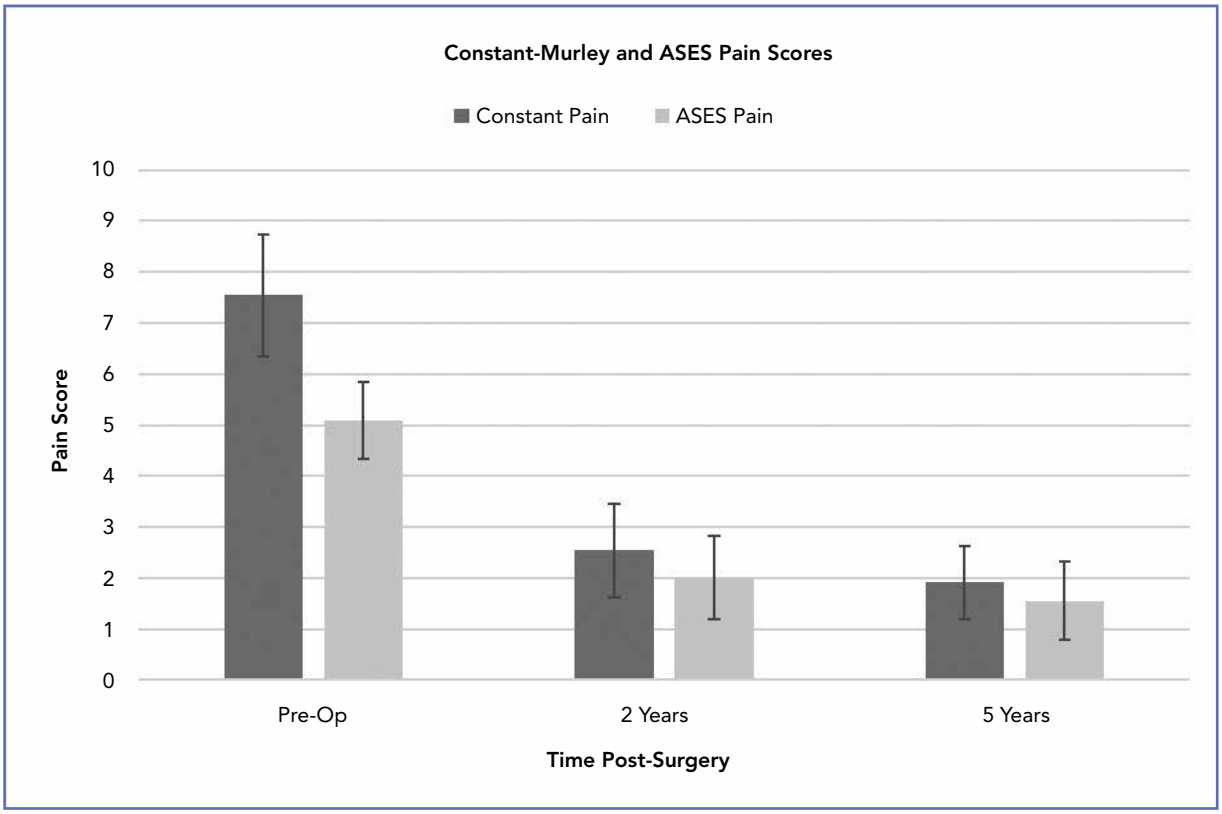

Figure 8. Constant and ASES Pain scores over 5-year follow-up period. (Error bars indicate ± 1 SEM)

patient developed adhesive capsulitis, one biceps tendinitis and one a bursitis with these issues believed to be unrelated to the device. There were no postoperative infections and no adverse events associated with the device. Between the 2- and 5-year follow-up assessments no further complications or clinical issues reported by the patients or noted by the reviewers.

DISCUSSION

Surgical treatment options to manage patients with partial-thickness rotator cuff tears include arthroscopic debridement, trans-tendon repair or completing the partial tear to a full-thickness defect and then repair of the entire tendon. Kartus et al., in a 5 years follow up, have shown that arthroscopic decompression and debridement of partial-thickness rotator cuff tears does not protect against further cuff degeneration (15).

Conversion of a partial cuff tear to a full-thickness defect and then repair has been advocated by many authors. (16-18) However, this involves cutting intact cuff tendon which when repaired may result in an altered footprint with potential length-tension mismatch of the repaired rotator cuff (19). Satisfactory results have been reported with over 83% being good or excellent (18, 20) despite an ultrasound study demonstrating a 12% re-tear of the repaired tendon (16). Alternatively, arthroscopic trans-tendon repair of the partial-thickness, articular surface tear has been recommended (19, 21). This maintains the lateral insertion of the rotator cuff and potentially reduces the possibility of tendon failure. In a systemic review, Strauss et al. reported no difference in outcome for tear completion and repair versus trans-tendon repair (22).

An alternative to these options is the implantation of a porous collagen implant on the bursal surface overlying the rotator cuff tear, whether it be bursal-sided, intra-substance or articular-sided. Finite element analysis suggests that the addition of 2 mm of tissue to the bursal surface of a partial thickness tear can significantly decrease peak intra-tendinous strain by 40% in articular-side and 47% in bursal-side partial-thickness tears (11). Sheep studies by Van Kampen et al. have shown that placing a highly-porous collagen implant on the bursal surface of the infraspinatus tendon would induce the formation of a fibrovascular tissue resem-

bling tendon and result in a significant and consistent thickening of the infraspinatus tendon (23). Following the animal experiments and the finite element studies, the porous collagen implant was used in humans to treat partial thickness cuff tears, and also as an augment to the treatment of full thickness cuff tears (11, 24). Subsequent published tissue retrieval studies confirmed that the histological changes seen in human specimens corresponded precisely with the findings of the sheep study of Van Kampen et al. (23, 25).

Use of the collagen implant as an alternative to completion of the tear and performing a repair has the advantage of requiring only 1 week in a sling and return to unrestricted activities at 6 weeks postoperative. In contrast, a traditional repair procedure usually involves 6 weeks in a sling and restriction of activities for 3 - 6 months.

Schlegel et al. (12) reported on 33 patients who underwent implantation of the collagen device for both intermediate- and high-grade partial-thickness tears involving articular, intra-substance and bursal-sided tears and noted an increase in tendon thickness of 2.0 mm. The MRI scans showed considerable reduction in defect size or complete healing in 94% of their patients. Paralleling this, ASES and Constant-Murley clinical scores and ASES pain scores were also significantly improved.

Our earlier report on 2-year follow-up of 13 patients with intermediate- and high-grade partial-thickness tears treated with the highly-porous collagen implant showed that there was a significant improvement in ASES and Constant-Murley clinical and pain scores (11). The tendon thickness was increased by 2.2 mm and the MRI appearance of the tears demonstrated significant improvement with all patients having either complete healing or only a residual low-grade tear. Our findings in these patients at the 5-year point of follow-up demonstrated that their clinical and pain scores remained excellent with no deterioration.

MRI evaluation of tendon thickness showed a decrease in the tendon thickness between 2- and 5-year post-operatively. The increase in tendon thickness at 2 years was 1.63 mm and at the 5-year mark this had reduced to 0.88 mm greater than the preoperative thickness, which remained statistically significant increase compared to preoperative measurements. This decrease in tendon thickness is associated with the normal remodelling phase of tendon healing in response to functional loading (26). Henry Davis in 1867 postulated that biological soft tissues were capable of functional adaptations to a changing mechanical environment and soon after Julius Wolff suggested a similar relationship for bone. Together both Davis's and Wolff's laws support the concept that both soft and hard tissues may be designed to promote mechanical optimality (27). The growth and remodelling of this neo-tendinous tissue on the bursal surface of the rotator cuff may reflect the complex mechanical behaviours of load bearing collagenous soft tissue and its ability to adapt to the mechanical loads within the rotator cuff.

Evaluation of the MRI character of the tendon tears showed that between the 2- and 5-year there had been no detrimental change in 8 of the 11 patients (72.7%). This suggest that the remodelled host generated tissue was able to maintain a homeostatic balance between the biological and biomechanical environment of the healed tendon.

Despite persistently excellent clinical results, two patients who had demonstrated apparently complete healing of their tendon defects at two years now showed low grade intrasubstance tears at five years. We presume that this reflects continuation of the underlying degenerative process. The collagen implant has not permanently reversed the tendon disease, but it has enabled the rotator cuff defects to heal, and has restored better tendon quality and integrity for an extended time. The one patient with a high-grade bursal sided tear appeared to have healed completely at five years, but to have developed an intrasubstance delamination. Again, although the bursal defect 'healed', underlying degenerative disease appears to have progressed, albeit in another part of the tendon.

All patents within this study originally had degenerative rotator cuff tears, this reversal of the healing process may reflect the ongoing intrinsic nature of the rotator cuff disease within these patients. The neo-tendinous tissue again was replicating the character of the underlying degenerative tendons assimilating to the original tendon environment and adopting the patients' tissue characteristics. We know that patients with repaired rotator cuff tears have a failure rate in the first 1-2 years (16, 28). Zumstein et al. also showed that with follow-up of patients longer term, there was an increasing rate of cuff failure (29). At 3.1 years they had a 37% re-tear rate, which increased to 57% at 9.9 years even though their clinical results remained the same. Hence the continuation of the degenerative disease process within the rotator cuff leads to further changes and deterioration in tendon quality with time. The collagen implant used in this study has not permanently reversed tendon disease, but did enable the rotator cuff to heal the defects and restore better tendon quality and integrity for an extended time despite the presence of ongoing rotator cuff degeneration.

There are both strengths and weaknesses within our study. We acknowledge that the number of subjects is low and definitive conclusions can only be loosely drawn from our findings. The lack of a case-matched control group would have strengthened our findings, however this is a unique and detailed study with meticulous follow up of a small cohort and offers important insights as to the medium term outcomes and overall safety for our patients with

partial-thickness rotator cuff tears treated with the highly porous collagen implant. There is the need for randomised controlled studies in the future to further validate our findings. Also, there is a substantive body of scientific and clinical literature which highlights the difficulties in managing these tears and none of these papers have documented the significant and sustained increase in tendon-like tissue and potential healing of the partial-thickness tears as seen in our patient cohort.

CONCLUSION

A 5-year follow-up is reported of 11 patients from an initial cohort of 13 who underwent insertion of a highly-porous collagen implant on the bursal surface of their supraspinatus tendons for intermediate- and high-grade partial-thickness tears. All patients maintained their earlier excellent clinical and pain score improvements. MRI scans demonstrated remodelling of the neo-tendinous tissue though it still was significantly thicker than preoperatively. The quality of tendon healing, as determined by MRI, was maintained in 8 of the 11 patients. No patient demonstrated regression of their tendon tears to their preoperative levels but 3 patients demonstrated new degenerative changes within their tendons. These observations suggest that the application of the collagen implant does result in new tendon-like tissue, and that both 'old and new' tendon are susceptible to degradation over time.This study supports the use of the collagen implant for patients with intermediate- and high-grade partial-thickness rotator cuff tears and demonstrates the durability of the tissue induction and continued clinical benefits resulting from the improvement of their underlying rotator cuff disease over a 5-year period. The radiological improvements on MRI initially noted for this implant can be expected to be maintained for many years past the primary surgical insertion.

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