Preliminary Results of Arthroscopic Superior Capsule Reconstruction with Dermal Allograft

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Purpose: The purpose of this study was to evaluate the short-term outcomes of arthroscopic superior capsule reconstruction (SCR) with dermal allograft for the treatment of irreparable massive rotator cuff tears (MRCTs). **Methods:** A multicenter study was performed on patients undergoing arthroscopic SCR for irreparable MRCTs. The minimum follow-up was 1 year. Range of motion and functional outcome according to visual analog scale (VAS) pain, American Shoulder and Elbow Surgeons (ASES) score, and subjective shoulder value (SSV) score were assessed preoperatively and at final follow-up. Radiographs were used to evaluate the acromiohumeral interval (AHI). **Results:** Fifty-nine patients with a mean age of 62.0 years had a minimum follow-up of 1 year. Twenty-five patients (42.4%) had a prior rotator cuff repair. Forward flexion improved from 130° preoperative to 158° postoperative, and external rotation improved from 36° to 45°, respectively ($P < .001$). Compared with preoperative values, the VAS decreased from 5.8 to 1.7, the ASES score improved from 43.6 to 77.5, and the SSV score improved from 35.0 to 76.3 ($P < .001$). The AHI was 6.6 mm at baseline and improved to 7.6 mm at 2 weeks postoperatively but decreased to 6.7 mm at final follow-up. Based on postoperative magnetic resonance imaging, 45% (9 of 20) of the grafts demonstrated complete healing. Forty-six (74.6%) cases were considered a success. Eleven patients (18.6%) underwent a revision procedure including 7 reverse shoulder arthroplasties. **Conclusions:** Arthroscopic SCR using dermal allograft provides a successful outcome in approximately 70% of cases in an initial experience. The preliminary results are encouraging in this difficult to manage patient population, but precise indications are important and graft healing is low in our initial experience. **Level of Evidence:** Level IV, case series.

See commentaries on pages 100 and 102

Massive rotator cuff tears (MRCTs) are a challenge, particularly in a younger population. With an arthroscopic approach, repair is possible in the majority of cases and functional outcomes are improved, particularly when a double-row repair can be achieved.[1] However, healing of MRCTs after repair may remain low, and failure of healing is associated with progression of arthritis.[2,3] Alternatives to repair such as reverse shoulder arthroplasty (RSA) are suitable in older patients but are associated with high failure rates in young patients.[4]

Superior capsule reconstruction (SCR) with fascia lata autograft has been proposed as a joint-preserving solution for irreparable MRCTs.[5,6] However, this technique increases surgical time and carries donor site morbidity. In an effort to reduce donor site morbidity, Hirahara and Adams subsequently proposed the use of dermal allograft for SCR as opposed to fascia lata.[7] Dermal allograft limits donor-site morbidity, has been used previously in augmentation of rotator cuff repairs, and has been used clinically for SCR. While several techniques have been proposed using dermal allograft,[7-10] no studies have reported on the outcomes with this technique.

The purpose of this study was to evaluate the short-term outcomes of arthroscopic SCR with dermal allograft for the treatment of irreparable MRCTs. The hypothesis was that SCR with a dermal allograft would

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lead to significant improvement in functional outcome in the short term.

Methods

A multicenter prospective evaluation was conducted of SCR performed at 4 institutions between November 2014 and January 2016. Inclusion criteria included an arthroscopic SCR performed with a dermal allograft. Exclusion criteria included revision SCR, an irreparable subscapularis tear, active infection, or neurologic pathology limiting shoulder function. The minimum follow-up was 1 year.

Functional and Radiographic Evaluation

Preoperatively and at 1 year postoperatively, American Shoulder and Elbow Surgeons (ASES) scores,[11] pain graded 0 to 10 on a visual analog scale (VAS), and subjective shoulder value (SSV)[12,13] were recorded. Range of motion was assessed by the treating surgeon at each site and included forward flexion in the plane of scapula and external rotation with the arm at the side measured with a goniometer and internal rotation estimated to the nearest spinal level. For final analysis, postoperative functional scores and range of motion were excluded in patients who were converted to RSA. At final follow-up patient satisfaction (yes or no), return to normal activities (yes or no), and any complications or revision surgery were recorded. In addition, the outcome was categorized as successful if the final ASES score was >50 based on a previous study[4] combined with a 17-point postoperative improvement in the ASES to meet a minimal clinically important difference for rotator cuff tears[14] and if the patient did not require RSA or revision SCR.

Radiographic evaluation included preoperative plain anteroposterior radiograph and a magnetic resonance image (MRI). Plain radiographic evaluation included the acromiohumeral interval (AHI) and Hamada classification on an anterior-posterior radiograph of the glenohumeral joint. The AHI was measured as the smallest distance from the inferior surface of the acromion to the superior aspect of the humerus. Measurements were also classified as <7 mm or ≥7 mm based on previous studies.[15,16] The radiographs were then graded according to the Hamada classification.[17,18] In the Hamada classification, the AHI is maintained in grade 1. In grade 2 the AHI is narrowed. Grade 3 includes acetabularization (concave deformity of the acromion undersurface) in addition to the grade 2 narrowing. Grade 4 includes narrowing of the glenohumeral joint. Grade 5 involves humeral head collapse. MRI evaluation included the degree of fatty degeneration and the tangent sign. Fatty degeneration was graded according to Goutallier et al.[19,20] All MRIs and radiographs were reviewed by a single author (P.J.D.).

Postoperative radiographs were also obtained at 2 weeks and 1 year postoperatively. A postoperative MRI was also obtained at 1 year postoperatively in patients willing to undergo an MRI. The graft status on postoperative MRI was categorized as healed or not healed, and the location of failure was classified as humeral sided, midsubstance, or glenoid sided.

Surgical Technique

The surgical technique has previously been described in detail and is summarized here briefly.[8] First, the subscapularis was evaluated and repaired as necessary followed by biceps tenodesis or tenotomy in every case unless the tendon was previously torn and completely retracted. Attention was then turned to the subacromial space, and a limited acromioplasty was performed with preservation of the coracoacromial ligament. The posterosuperior rotator cuff was then excavated and mobilized in an attempt to repair the tendon. The decision to perform SCR was made intraoperatively based on the inability to achieve a complete repair following mobilization.

The superior glenoid was prepped, preserving the superior labrum. At least 2 anchors were preplaced in the superior glenoid at the 10 and 2 o'clock positions, about 5 mm medial to the superior labrum. Next, 2 anchors were placed in the greater tuberosity adjacent to the articular margin in order to cover the span of the defect. The anteromedial anchor was placed 5 mm posterior to the bicipital groove. The posteromedial anchor was placed just anterior to the intact rotator cuff. The graft size was measured and extended 5 mm medially, anteriorly, and posteriorly to provide a margin and 10 mm laterally to cover the greater tuberosity. Sutures from each anchor were retrieved out of a lateral portal and passed through an acellular dermal allograft. Graft thickness was 1 mm in 5 cases, 2 mm in 2 cases, and 3 mm in all other cases. The sutures were then used to shuttle the graft into the subacromial space. The graft was first secured medially to the glenoid. Finally, the graft was secured laterally to the greater tuberosity (Fig 1). In all cases margin convergence sutures were placed between the graft and the remaining infraspinatus or teres minor posteriorly.

Postoperatively, patients were immobilized in a sling for 6 weeks without dedicated physical therapy. At 6 weeks postoperatively, the sling was discontinued, and passive forward flexion and passive external rotation were allowed. At 3 to 4 months postoperatively, active forward flexion and passive internal rotation were allowed and strengthening was initiated. Return to full activity was allowed at 6 to 12 months, including all sports activities without restriction.

Statistical Analysis

Continuous data was described by mean and standard deviations. A *t*-test was used to analyze the difference in pre- and postoutcome scores. Chi-square test was used

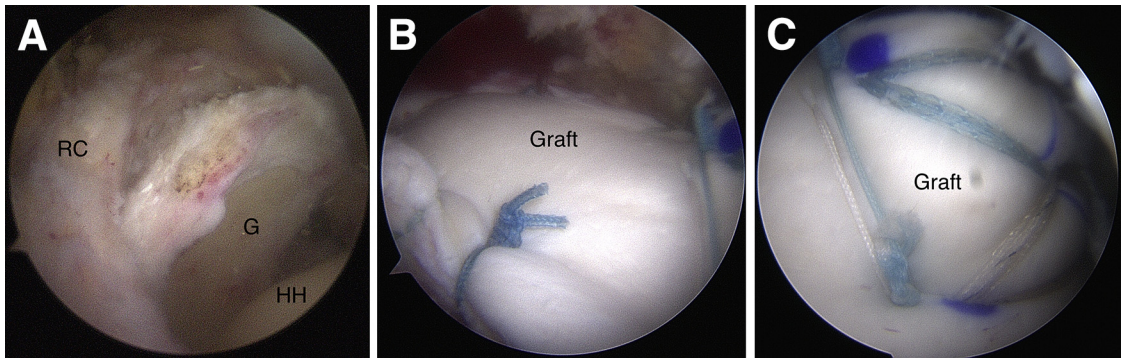

Fig 1. Right shoulder posterior viewing portal. (A) Diagnostic arthroscopy reveals a massive contracted rotator cuff tear with retraction of the rotator cuff (RC) medial to the glenoid (G). (B) Same view following superior capsule reconstruction with dermal allograft. (C) Fixation of the graft on the greater tuberosity. (HH, humeral head.)

to compare proportion differences. Two-tailed P values $< .05$ were considered significant.

Results

Study Population

Sixty-seven patients met the study criteria. No patients declined to participate in the study. Eight patients were lost to follow-up, leaving 59 patients (88.1%) available for the analysis at a mean of 17.7 months postoperatively (range, 12-29). Baseline patient characteristics and surgical data are summarized in Table 1. The mean age was 62.0 ± 8.7 years. Twenty-five (42.4%) had undergone a range of 1 to 3 previous rotator cuff repairs.

Preoperative radiographs and MRI scan were available for 57 (96.6%) patients. The AHI averaged 6.6 mm prior to surgery. According to the Hamada classification, the shoulders were grade 1 in 31 cases (54.4%), grade 2 in 16 (28.1%), grade 3 in 9 (15.8%), and grade 4 in one (1.8%). Fatty degeneration was grade 3 or 4 in the supraspinatus in 43 cases (75.4%) and in the infraspinatus in 37 cases (64.9%).

All patients had a complete supraspinatus tear, and 56 (94.9%) had a complete infraspinatus tear. Thirty-three (55.9%) patients had a subscapularis tear (mean 49% of footprint), which was repaired in all cases with a mean of 1.9 (range, 1-4) anchors. The dermal allograft was secured to the glenoid with a mean of 2.3 anchors (range, 2-4) and to the greater tuberosity with a mean of 3.9 anchors (range, 2-5). Additional procedures included an anterior interval slide in continuity in 27 cases (45.8%), posterior interval slide in 18 (30.5%), limited acromioplasty in 48 (81.4%), distal clavicle excision in 3 (5.1%), biceps tenodesis in 25 (42.4%), biceps tenotomy in 9 (15.3%), and a coracoplasty in 16 (28.1%).

Clinical Outcome

The functional outcome of the study group is summarized in Table 2. There were statistically significant improvements comparing preoperative to postoperative range of motion and all functional outcome scores. Forty-three (72.9%) patients were satisfied with the procedure, and 41 (69.5%) reported return to normal activity.

There were 4 (6.8%) complications including 2 falls in the postoperative period, one infection that required debridement and placement of an antibiotic spacer, and one case of persistent biceps pain after a proximal tenodesis that was managed with an open subpectoral tenodesis. Including the 2 aforementioned revision surgeries, one (18.6%) patient required additional surgery, 7 (11.9%) had an RSA, and 2 (3.4%) had a revision SCR.

Based on our criteria for successful treatment, 40 (67.8%) cases were considered a success. Only 2 (40%) of the 1 mm thick grafts resulted in a successful outcome. Excluding the 1 mm grafts the rate of successful outcome was 75.5% in Hamada 1 or Hamada 2 (34 of 45) versus 44.4% in Hamada 3 or 4 (4 of 9; $P = .065$).

Radiographic Outcome

Thirty-five patients (59.3%) had radiographs at 2 weeks postoperatively, and 44 patients (74.6%) had radiographs at 1 year postoperatively. The AHI was mean of 6.6 ± 3.0 mm as baseline and improved to

Table 1. Baseline Patient Characteristics

	Mean or Number ($n = 59$)
Age, years	62.0 ± 8.7
Male sex (%)	39 (66.1)
Previous repair (%)	25 (42.4)
AHI*	6.6 ± 3.0
FD-SS†	0:5:9:33:10
FD-IS†	1:9:10:18:19
FD-SSc†	11:23:14:4:5
Medial-lateral tear size, cm	5.2 ± 1.5
Anterior-posterior tear size, cm	4.7 ± 0.8

AHI, acromiohumeral interval; FD-IS, fatty degeneration of the infraspinatus; FD-SS, fatty degeneration of the supraspinatus; FD-SSC, fatty degeneration of the subscapularis.

*Data available for 60 cases.

†Data correspond to Goutallier grade 0, 1, 2, 3, and 4. respectively. Data available for 60 cases.

Table 2. Results of Arthroscopic Superior Capsule Reconstruction

	Preoperative Status (Mean ± SD)	Postoperative Status (Mean ± SD)	*P* Value
Active forward flexion	130° ± 48°	158° ± 32°	<.001
Active external rotation	36° ± 18°	45° ± 17°	.008
Internal rotation, spinal level	L3	L1	<.001
VAS pain	5.8 ± 2.2	1.7 ± 2.1	<.001
ASES	43.6 ± 18.6	77.5 ± 22.0	<.001
SSV	35.0 ± 19.9	76.3 ± 25.2	<.001
AHI	6.6 ± 3.0 mm	6.7 ± 3.0 mm	.889

AHI, acromiohumeral interval; ASES, American Shoulder and Elbow Surgeons; SD, standard deviation; SSV, subjective shoulder value; VAS, visual analog scale.

7.6 ± 2.7 mm at 2 weeks postoperatively ($P = .017$). However, the AHI was 6.7 ± 3.0 mm at final follow-up, which was not statistically significant compared with preoperative values ($P = .889$; Fig 2).

Based on postoperative MRI, 45% (9 of 20) of the grafts demonstrated complete healing. Eighteen of the grafts were 3 mm thick; one graft was 1 mm thick, which did not heal, and one graft was 2 mm thick, which did heal. Failure of the graft occurred on the humeral side in 7 cases, intrasubstance in 3 cases, and on the glenoid side in one case. Based on our criteria for successful treatment, 100% of the patients with grafts that healed had a successful outcome compared with 45.5% when the graft did not heal ($P = .009$). Additionally, in the group that healed, postoperative pain was lower (VAS, 0.7 vs 2.6; $P = .038$) and the ASES score was higher (90.0 vs 66.5; $P = .027$), while SSV trended toward higher values (88.7 vs 64.6; $P = .068$). There was no difference in the incidence of subscapularis tears between the 2 groups (66.7% vs 54.5; $P = .595$). However, preoperative subscapularis atrophy was lower in the group that healed compared with the group that did not heal (0.6 vs 2.2; $P = .006$). All of the patients who healed had grade 0 or grade 1 subscapularis atrophy.

Discussion

The findings of this study confirm our hypothesis that SCR with a dermal allograft leads to improvement in functional outcome in the majority of cases. Overall, approximately 70% of cases were considered successful based on our criteria of successful treatment. While the rate of secondary procedures was nearly 19%, the overall findings provide several insights into the indications and factors associated with success.

In the effort for joint preservation, a variety of materials have been proposed to augment or replace an irreparable rotator cuff tear. Dermal allograft, xenografts, or synthetic patches have all been reported primarily in a patch technique whereby the material is attached from the remnant rotator cuff to the humeral head or as an augment to rotator cuff repair.[21-23] More recently, the vital role of the superior capsule in glenohumeral mechanics has been recognized.[24] In a biomechanical model of an MRCT Mihata et al.[6] demonstrated that reconstruction of the superior capsule closely mimicked subacromial pressure and translation observed with an intact rotator cuff. Importantly, restoration of pressure and translation was improved with their SCR technique compared with patch grafting. Later, Mihata et al.[5] were the first to report on the

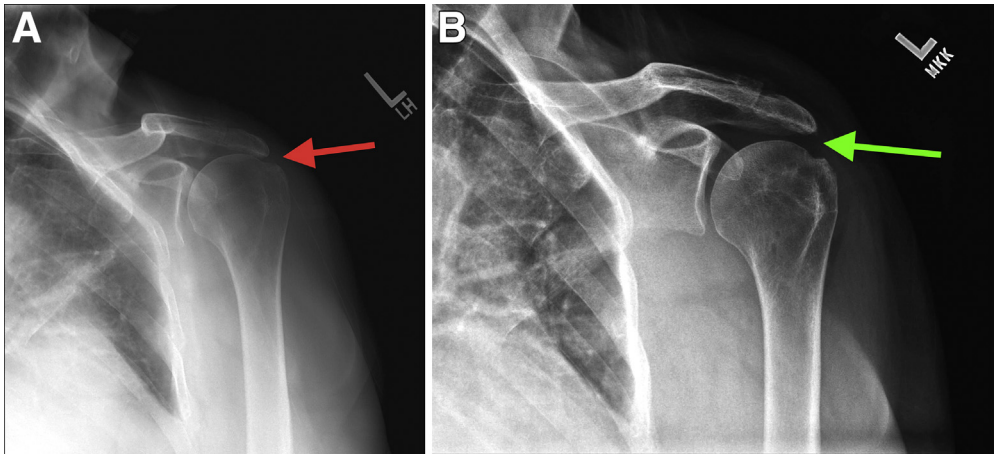

Fig 2. (A) Preoperative anteroposterior radiograph of a left shoulder of a 71-year-old man with an irreparable massive rotator cuff tear demonstrates superior migration and a decreased acromiohumeral interval (red arrow) or Hamada 2 changes. (B) One-year postoperative radiograph demonstrates recentering of the humeral head and normalization of the acromiohumeral interval (green arrow) following superior capsule reconstruction with dermal allograft.

clinical outcomes of 24 SCRs with fascia lata autograft at a mean of 24.1 months postoperatively. ASES scores improved from 23.5 preoperatively to 92.9 postoperatively ($P < .001$). We also observed statistically significant improvement in pain, ASES, and SSV scores following SCR with dermal allograft.

While the improvement we observed in functional outcome was lower and the rate of complication was higher than that reported by Mihata et al., our results are reasonable compared with other techniques for irreparable MRCTs. Gerber et al.[25] reported on 69 patients who had a latissimus dorsi transfer for an irreparable rotator cuff tear. At a mean of 53 months postoperatively, SSV scores improved from 28% preoperatively to 66% postoperatively. By comparison, our patients improved from 35% preoperatively to 76% postoperatively, thus demonstrating similar gains from preoperative to postoperative. Mulieri et al.[26] used RSA for irreparable rotator cuff tears without glenohumeral arthritis and reported that ASES scores improved from 33.3 to 75.4 and pain decreased from 6.3 to 1.9. They also noted a 20% complication rate. In our series, outcomes were similar. ASES scores improved from 43.6 to 77.5, pain decreased from 5.8 to 1.7, the complication rate was 6.8%, and 18.6% required additional surgery. On one hand, our rate of complications and revision surgery was high. But this must be placed in the context of a newer procedure and learning curve. An initial report of RSA, for instance, reported a complication rate of 50% with a revision rate of 33%,[27] but recent complications rates of RSA have decreased dramatically.[28,29] Therefore, comparing our results to those of alternative nonanatomic procedures, SCR appears to be a reasonable alternative for joint preservation in this difficult patient population, assuming appropriate indications.

Graft thickness may be important for optimizing the outcome of SCR with dermal allograft. Anatomically the normal thickness of the superior capsule ranges from 4.4 to 9.1 mm.[30] Based on biomechanical analysis Mihata et al.[31] have argued for using a thick graft for SCR. They compared 4 mm and 8 mm thick fascia lata grafts and noted that while both grafts decreased subacromial contact pressure, the 8-mm graft was better at reducing superior translation. In our study we had poorer outcomes with thin grafts. While the overall success rate was 68%, the rate of success with the use of 1 mm thick grafts was only 40%. Based on this finding we recommend using a 3 mm thick graft when dermal allograft is selected for SCR. One could argue that a 3-mm dermal allograft is thinner than the normal anatomical thickness of the superior capsule. However, 3 mm is the maximal thickness dermal allograft currently commercially available. Furthermore, while it is more expensive compared with fascia lata autograft, dermal allograft carries the advantage that it is less morbid and reduces operative time.

Table 3. Technical Pearls for Superior Capsule Reconstruction with Dermal Allograft

	Pearl
Indications	1. Best results are with Hamada 1 or 2; Avoid Hamada 3 or 4. 2. Repair the subscapularis to balance force couples, but avoid SCR with an irreparable subscapularis tear.
Technical	1. Use at least a 3 mm thick graft. 2. A flexible cannula is used to push the graft into the joint after all sutures are checked for tangles. 3. The graft can be pulled into the joint through a superior portal (Neviaser portal) to avoid pulling excessively on the medial glenoid anchors. 4. The majority of failures occur on the tuberosity; strong fixation is encouraged.
Postoperative	1. Strengthening is delayed until 12 to 16 weeks postoperatively.

The difference in our results based on the preoperative Hamada classification provides some insight into the indications for SCR. Excluding 1-mm grafts, in cases with a centered humeral head (Hamada 1) or with superior migration or decreased AHI (Hamada 2) our rate of success was approximately 75%. However, with adaptive changes of (Hamada 3) or joint space narrowing (Hamada 4), our rate of success was only 44%. We therefore believe the Hamada classification can be used to provide insight into the prognosis of SCR. This is echoed in Mihata's first report in which 22 of 24 (91.7%) patients were classified as Hamada 1 or 2.[5] Based on their findings and our findings the best indication for SCR appears to be Hamada 1 or 2. It appears best to avoid SCR in cases of Hamada 3 or 4.

Mihata et al.[5] reported that 83.3% of fascia lata grafts healed postoperatively based on MRI. In our limited MRI series, 45% of the dermal allografts were healed postoperatively. On the one hand, this could be viewed as a high rate of failure. On the other hand, this can be viewed as a 45% rate of healing in a population with an otherwise irreparable tear. Interestingly, most graft failures occurred on the humeral side despite being secured with more anchors than the glenoid side. We suspect this is because the humeral side of the graft experiences greater stresses with movement as well as greater abrasion via acromiohumeral contact. It is also important to note that graft healing was associated with higher functional outcomes scores and that the patients who healed were considered successful based on our criteria in 100% of cases compared with only 45% of cases that did not heal. This highlights the importance of graft healing in achieving a successful outcome with SCR. Mihata et al.[5] previously highlighted the importance of repairing the subscapularis prior to SCR. Based on our analysis, the preoperative status of the

subscapularis may be important in developing criteria to identify which patients are appropriate for SCR. While the presence of a subscapularis tear and tear size did not affect healing, patients in the group that healed had less preoperative atrophy of the subscapularis. Given this finding we advise caution in recommending SCR in patients with advanced preoperative atrophy of the subscapularis (i.e., grade 3 or 4). In addition, several possibilities may exist for improving healing from a technical perspective such as graft augmentation, alternative suture constructs, or biologic augmentation (e.g., platelet-rich plasma). Since graft healing appears important to achieving a good outcome, further study is warranted in this area.

It is important to note that these results represent our initial experience. While we suspect that there was a learning curve, a larger study group and longer study period are required to examine this factor. Previous studies have demonstrated that the learning curve plays an important role in complex procedures such as RSA,[32] and our surgical technique and indications continue to evolve. Nonetheless, based on our results and experience we have summarized our pearls for optimizing the outcomes of SCR using dermal allograft (Table 3).

Limitations

There are several limitations to our study. First, the results are short term. It is unclear based on these findings whether or not SCR will be viable as a long-term joint preservation option. Second, there was no a priori power analysis or comparative group such as a partial repair alone. However, it is known that the results of partial repair deteriorate with time, and based on this we are hesitant to settle for a partial repair in a young patient when there is potentially a more anatomic option in SCR. Third, few patients had postoperative radiographs and radiographs were not fluoroscopically controlled, which limited the evaluation of the AHI. Fourth, only a few of our patients had postoperative MRIs to evaluate graft healing. Fifth, there was no comparison of dermal allograft to fascia lata allograft as a graft source.

Conclusions

Arthroscopic SCR using dermal allograft provides a successful outcome in approximately 70% of cases in an initial experience. The preliminary results are encouraging in this difficult to manage patient population, but precise indications are important and graft healing is low in our initial experience.

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