

## Systematic Review

# Subacromial Spacer Implantation for the Treatment of Massive Irreparable Rotator Cuff Tears: A Systematic Review

Andrew S. Moon, B.S., Harshadkumar A. Patel, M.D.,  
Matthew P. Ithurnburn, P.T., Ph.D., D.P.T., Eugene W. Brabston, M.D., Brent A. Ponce, M.D.,  
and Amit M. Momaya, M.D.

**Purpose:** To synthesize and report the early clinical and radiographic outcomes associated with subacromial spacer use in patients with massive irreparable rotator cuff tears. **Methods:** A systematic search on MEDLINE, Embase, and Cochrane Library databases was performed during February 2018. Included studies were evaluated regarding the level of evidence and quality using the methodological index for nonrandomized studies. Patient demographics, intraoperative findings, clinical and radiographic outcomes, and complications were recorded for each of the included studies. **Results:** Seven eligible studies including 204 shoulders from 200 patients with subacromial spacer implantation were identified (6 Level IV studies and 1 Level III study). The mean methodological index for nonrandomized studies score for noncomparative studies was 11, whereas that of comparative studies was 15. The mean age of patients was 67.6 years, and the mean reported follow-up time was 19.4 months. All patients had Goutallier stage 3 and 4 fatty infiltration on magnetic resonance imaging. All studies reported consistent improvement in the total Constant score or American Shoulder and Elbow Surgeons score over the duration of follow-up. A total of 6 (3%) complications were reported in the included studies. Two studies detailed radiographic outcomes, with discrepant changes in the acromiohumeral interval. **Conclusions:** Patients undergoing subacromial spacer implantation for the treatment of massive irreparable rotator cuff tears have satisfactory outcomes at the 2- to 3-year follow-up with a low rate of complications. **Level of Evidence:** Level IV, systematic review of 1 Level III and 6 Level IV studies.

**M**assive irreparable rotator cuff tears (MIRCTs) present a challenging treatment dilemma for orthopaedic surgeons. Most treatment algorithms often start with conservative management, with the goal of reducing pain and dysfunction.<sup>1,2</sup> When conservative treatment approaches have failed, surgical options

include debridement with or without biceps tenotomy or tenodesis, partial tendon repair, tendon transfers, transplantation of allograft or synthetic graft materials, superior capsule reconstruction, arthrodesis, and reverse total shoulder arthroplasty (RTSA).<sup>3-10</sup> Despite multiple options, there is no consensus on optimal management, and clinical results reported in the literature are quite varied.<sup>11,12</sup>

In 2012, Savarese and Romeo<sup>13</sup> reported on a new surgical technique for the treatment of MIRCT using a biodegradable balloon spacer (InSpace Balloon; OrthoSpace, Caesarea, Israel), implanted between the acromion and humeral head. The proposed benefit of the device was to decrease subacromial friction and center the humeral head during dynamic movements, potentially helping restore force couples of the shoulder.<sup>13,14</sup> The spacer, which is made of a poly(L-lactide-co-ε-caprolactone) polymer commonly used in medical devices,<sup>15</sup> deflates within 3 months after implantation and biodegrades over a period of 12 months.<sup>16</sup> Since this original report, several authors have published their experiences with subacromial spacer implantation to treat MIRCT.<sup>16-22</sup> The

*From the Tufts University School of Medicine (A.S.M.), Boston, Massachusetts; and Department of Orthopaedics (A.S.M., H.A.P., M.P.I., E.W.B., B.A.P., A.M.M.) and Department of Physical Therapy (M.P.I.), The University of Alabama at Birmingham, Birmingham, Alabama, U.S.A.*

*The authors report the following potential conflicts of interest or sources of funding: B.A.P. is a consultant for Wright Medical and Acumed and receives payment for lectures and royalties from Wright Medical. Full ICMJE author disclosure forms are available for this article online, as [supplementary material](#).*

*Received April 6, 2018; accepted August 2, 2018.*

*Address correspondence to Amit M. Momaya, M.D., Department of Orthopaedic Surgery, University of Alabama at Birmingham, Highlands Hospital, 1313 13th St South, Ste 200, Birmingham, AL 35205, U.S.A. E-mail: [amomaya@uabmc.edu](mailto:amomaya@uabmc.edu)*

© 2018 by the Arthroscopy Association of North America  
0749-8063/18426/\$36.00

<https://doi.org/10.1016/j.arthro.2018.08.006>

number of patients in each of these studies has been small, and there has been no synthesis of these data with regard to clinical outcomes or complications.

The current study is a systematic review on subacromial spacer implantation in the setting of MIRCT. The purpose of this study was to synthesize and report the early clinical and radiographic outcomes associated with subacromial spacer use in patients with MIRCT. It was hypothesized that subacromial spacer implantation would result in improved clinical outcomes during short-term follow-up periods with low complication rates.

## Methods

The systematic review was performed following Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.<sup>23</sup> Studies were included if they reported clinical outcomes following subacromial spacer implantation for the management of MIRCT. The study must have clearly stated that the rotator cuff tear was massive and not fully repairable. Included studies were required to have reported follow-up data of  $\geq 3$  months and a follow-up rate of  $\geq 80\%$ . The following types of studies were excluded: (1) case reports ( $< 3$  patients); (2) reviews, editorials, or technique papers; and (3) non-English language publications.

MEDLINE/PubMed, Embase, and the Cochrane Library were searched for relevant publications. This online search was conducted in January 2018. The following terms were used in the search strategy for the PubMed and Embase databases: "subacromial spacer," "biodegradable spacer," "fluoroscopic guided spacer," "rotator cuff tear AND spacer," and "arthroscopic AND spacer." The search term used for the Cochrane Library was "subacromial spacer." Study titles and abstracts were reviewed to determine study eligibility. After nonrelevant papers were excluded, the full text of each of the remaining studies was reviewed. The references of these papers were also reviewed manually to identify any additional studies for inclusion. Study selection and extraction of relevant data were performed independently by 2 investigators (A.S.M. and H.A.P.). Any discrepancies between selected studies were settled by consensus between investigators with the help of the third author (M.P.I.). Each study was reviewed independently by 2 investigators (A.S.M. and H.A.P.) for study quality and bias according to the methodological index for nonrandomized studies criteria, with a maximum possible score of 16 for noncomparative studies and 24 for comparative studies.<sup>24</sup> Any discrepancies between scores were settled by consensus between investigators.

## Statistical Analysis

Patients' pooled demographic information, clinical features, radiologic findings, details of surgical

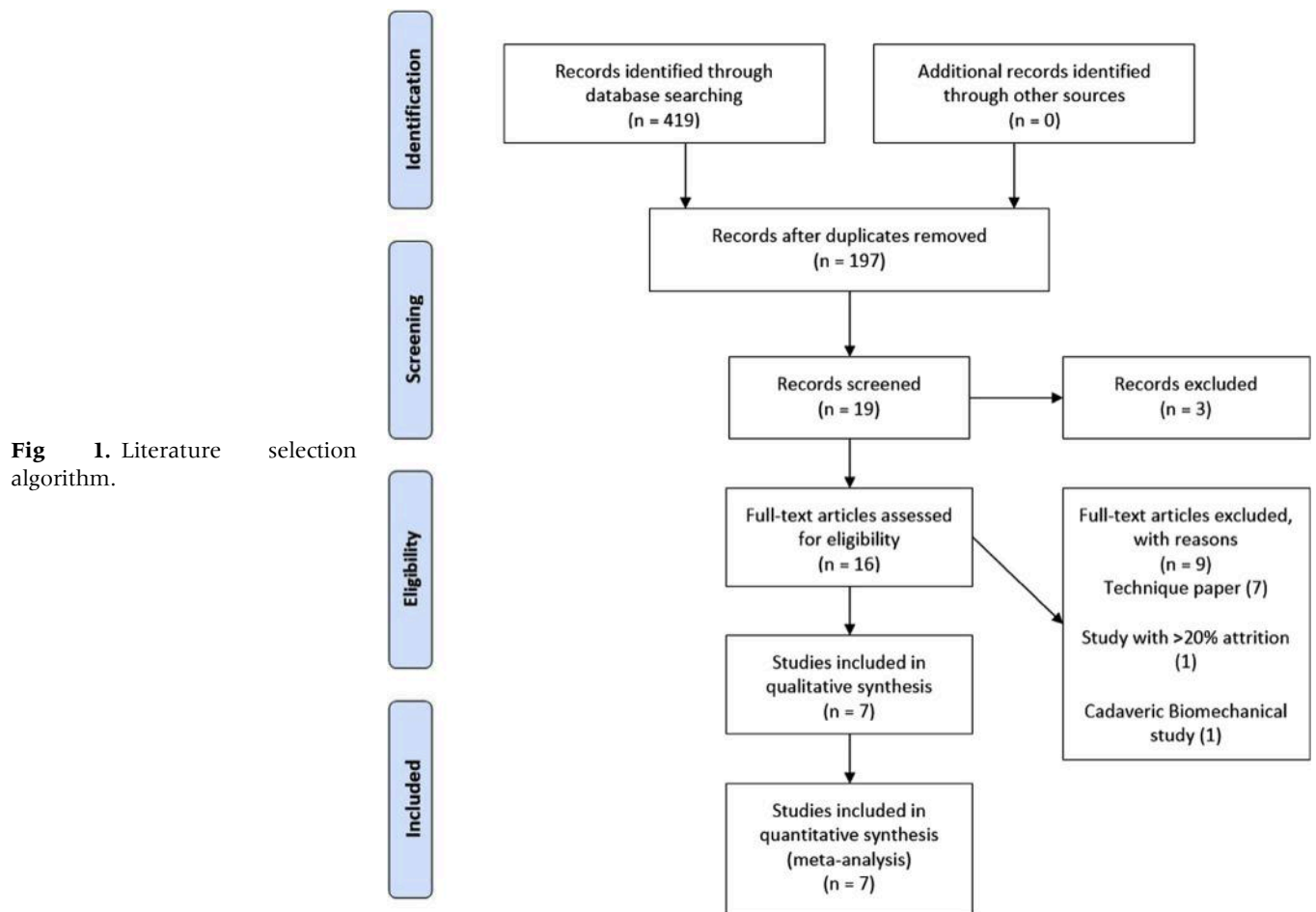
techniques, and intraoperative findings were reported. Outcome scores across the included studies were synthesized in a table format. Outcome measures reported in  $\geq 3$  studies were represented in a forest plot. Wherever data were found to be homogenous, pooled data were calculated using Microsoft Excel (Windows 8; Microsoft, Redmond, WA) Radiographic outcomes and overall complication rates were synthesized.

## Results

The combined MEDLINE/PubMed and Embase database search produced a total of 419 publications. After duplicates were removed, 197 publications remained. There were no papers on subacromial spacer use identified in the Cochrane Library. After screening titles for study relevance, 19 abstracts remained for review. From these abstracts, 16 full-text articles were obtained. After applying the inclusion and exclusion criteria, 7 articles were identified for inclusion in the systematic review. One study was a case-control study (Level III),<sup>16</sup> and the remaining 6 studies were case series (Level IV).<sup>17-19,20-22</sup> The methodological index for nonrandomized studies scores for the noncomparative studies had a mean score of  $11 \pm 1.1$  with a range of 11 to 13. The single comparative study had a score of 15. Interobserver reliability was 0.741. No additional studies were included after manual search of the references of the full-text articles (Fig 1). Table 1 summarizes each of the included studies.

The 7 studies meeting inclusion criteria included 204 shoulders from 200 patients, with 4 patients having received bilateral implantation. Mean age was 67.6 years. Six studies with 158 patients (162 shoulders) reported patient gender.<sup>16-20,22</sup> Of these 158 patients, 77 (48.7%) were male. Mean reported follow-up was 19.4 months (range, 3-36).

Duration of symptoms before surgery was reported in 3 studies (79 patients), with an average of 47.8 months.<sup>17,18,20</sup> Symptoms included persistent shoulder pain and loss of shoulder function. Use of imaging modalities included radiography in 3 studies,<sup>16,19,22</sup> ultrasonography in 3 studies,<sup>17,20,21</sup> computed tomographic arthrography in 3 studies,<sup>17,19,21</sup> and magnetic resonance imaging (MRI) in all 7 studies.<sup>16-19,20-22</sup> Four studies (102 patients, 104 shoulders) reported fatty infiltration on MRI, which was graded according to the Goutallier classification.<sup>17-19,22</sup> Two of these studies (54 patients) reported the actual Goutallier stages: stage 2 (3.7%), stage 3 (59.3%), and stage 4 (35.2%).<sup>18,19</sup> All patients in the remaining 2 studies had Goutallier stage 3 or 4 fatty infiltration.<sup>17,22</sup> Although patient criteria varied, most authors agreed that significant shoulder arthritis was a contraindication for spacer use. Specifically, Hamada grade  $> 3$  was reported as a contraindication.<sup>25</sup> Additional contraindications included subscapularis tears



owing to the possibility of anterior migration of the spacer<sup>19,20</sup> and pseudoparalysis.<sup>16</sup>

Gervasi et al.<sup>18</sup> used fluoroscopy-guided implantation with local anesthesia. In this technique, local anesthesia was first injected into the subacromial space and a 1.5-cm lateral incision was made to match the location of a lateral arthroscopic portal. The rolled spacer was

inserted and inflated using physiological solution and then sealed and secured in situ. Positioning was confirmed by fluoroscopy at each step of the procedure.

The remaining 6 studies used an arthroscopic technique with general anesthesia.<sup>16-18,20-22</sup> The irreparable nature of the cuff was confirmed during surgery, followed by debridement of the cuff margin and

**Table 1.** Publications Reporting Outcomes After Subacromial Spacer Implantation

Author	Year	Journal	Study Design (level of evidence)	Technique	MINORS Score	No. of Patients (shoulders)	Outcomes	Mean Follow-Up in Months (range)
Senekovic et al. <sup>17</sup>	2013	<i>Eur J Orthop Surg Traumatol</i>	Prospective cohort (IV)	Arthroscopic	11	20 (20)	CS	36
Gervasi et al. <sup>18</sup>	2016	<i>Musculoskelet Surg</i>	Prospective cohort (IV)	Fluoroscopic	11	15 (15)	CS, ASES	24
Deranlot et al. <sup>19</sup>	2017	<i>Arthroscopy</i>	Retrospective cohort (IV)	Arthroscopic	13	37 (39)	CS	32.8 (20.4-45.2)
Holschen et al. <sup>16</sup>	2017	<i>Obere Extremitat</i>	Retrospective case-control (III)	Arthroscopic	15	12 (12)	CS, ASES	22.3
Piekaar et al. <sup>20</sup>	2017	• <i>Musculoskelet Surg</i>	Prospective cohort (IV)	Arthroscopic	10	44 (46)	CS, OSS	12
Maman et al. <sup>21</sup>	2017	<i>Open Orthop J</i>	Prospective cohort (IV)	Arthroscopic	10	42 (42)	CS	12
Ricci et al. <sup>22</sup>	2017	• <i>Acta Biomed</i>	Retrospective cohort (IV)	Arthroscopic	11	30 (30)	CS	9.8 (3-24)

ASES, American Shoulder and Elbow Surgeons score; CS, Constant score; OSS, Oxford Shoulder Score.

**Table 2.** Total Constant Score (TCS) Outcomes

Study	No. of Patients	Preoperative TCS	Follow-Up TCS				
			3 Months	6 Months	12 Months	24 Months	36 Months
Senekovic et al. <sup>17</sup>	20	33.4	44.1	50.4	—	—	65.4
Gervasi et al. <sup>18</sup>	15	31.9	52.0	59.5	69.8	61.4	—
Deranlot et al. <sup>19</sup>	37	39.0	—	—	59.0	—	64.0
Holschen et al. <sup>16</sup>	12	36.8	—	—	61.6	69.5	—
Piekaar et al. <sup>20</sup>	44	37.1	49.3	60.6	60.2	—	—
Maman et al. <sup>21</sup>	42	36.7	54	61.0	65.8	—	—
Ricci et al. <sup>22</sup> (3 mo)	8	39.8	55.6	—	—	—	—
Ricci et al. <sup>22</sup> (6 mo)	9	39.9	—	62.3	—	—	—
Ricci et al. <sup>22</sup> (12 mo)	8	41.7	—	—	65.9	—	—
Ricci et al. <sup>22</sup> (24 mo)	5	41.8	—	—	—	66.8	—

subacromial bursa. Acromioplasty was performed in all 30 patients by Ricci et al.<sup>22</sup> Holschen et al.<sup>16</sup> performed partial repair of the cuff in 3 patients, whereas Piekaar et al.<sup>20</sup> performed partial repair in 11 patients.

Mean implantation time for the fluoroscopy-guided technique was 10 minutes (range, 5-10) according to the study by Gervasi et al.<sup>18</sup> Senekovic et al.<sup>17</sup> reported a range of implantation time from 2 to 20 minutes for the arthroscopic technique, with a decrease in implantation time with increased surgeon experience.

All 6 arthroscopic technique studies described the status of the long head of the biceps intraoperatively.<sup>16-22</sup> Of 189 shoulders, 132 (69.8%) had an intact biceps tendon, whereas 57 (30.2%) were found to already have a spontaneous rupture. Of the 132 shoulders with intact biceps tendons, 116 underwent biceps tenotomy, whereas 16 in the study by Maman et al.<sup>21</sup> did not. Biceps tenodesis was not performed in any patient. Deranlot et al.<sup>19</sup> found that the preoperative status of the long head of the biceps tendon did not affect the total Constant score (TCS) postoperatively. Additionally, Maman et al.<sup>21</sup> reported no significant difference in outcomes following subacromial spacer implantation with or without biceps tenotomy.<sup>26</sup>

Device placement and degradation were assessed by ultrasonography at 1 week, 3 months, and 6 months postoperatively in the study by Senekovic et al.,<sup>17</sup> and complete resorption of the device was confirmed by MRI at the 3-year follow-up. Longitudinal postoperative MRI description of the spacer was provided by Ricci et al.<sup>22</sup> This study reported that at 3 months, the implant was seen in the subacromial space with a mean width of 4 cm and thickness of 7 mm. At 12 months, the dimensions of the spacer decreased to a

width of 3 cm and thickness of 6.5 mm. At 24 months, the implant was not recognizable and was replaced by fibrosis.

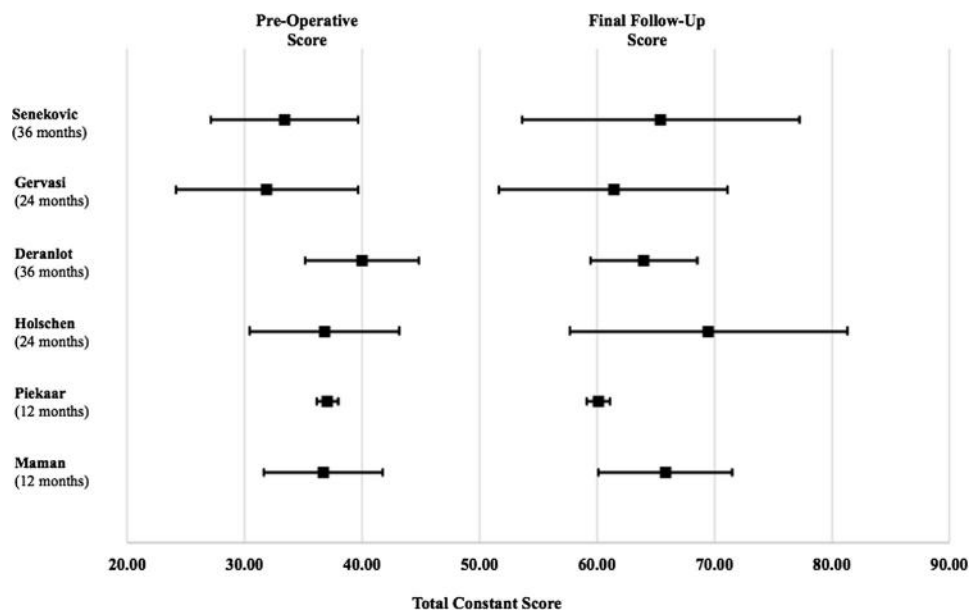
The most commonly used outcome measure was the TCS, reported in all 7 studies. American Shoulder and Elbow Surgeons (ASES) scores were reported in 2 studies.<sup>16,18</sup> A detailed breakdown of pre- and postoperative TCS and ASES scores for each of the included studies is outlined in Tables 2 and 3, respectively. A forest plot comparing Constant scores pre- and postoperatively at final follow-up for each individual study is provided in Figure 2. Piekaar et al.<sup>20</sup> additionally reported outcomes using the Oxford Shoulder Score and showed improvement from 21.8 preoperatively to 32.4 at the final 12-month follow-up.

Patient satisfaction was reported in 3 studies.<sup>16,18,20</sup> In the study by Holschen et al.,<sup>16</sup> one group underwent debridement with attempted partial repair, whereas the other group underwent debridement, attempted partial repair, and implantation of the subacromial spacer. Although both groups were satisfied with their clinical outcome, there were no differences in satisfaction between the 2 groups.<sup>16</sup> However, those with spacer implantation had better improvement in ASES and TCS scores. In the remaining 2 studies (59 patients, 61 shoulders), 81.4% (48/59) of patients were reportedly satisfied with their treatment.<sup>18,20</sup>

Other outcome measures included range of motion (ROM) testing and the visual analog scale score for pain. In the study by Deranlot et al.,<sup>19</sup> there was a statistically significant improvement in anterior elevation, abduction, and external rotation from preoperative measurements of  $124^{\circ}\pm 48^{\circ}$ ,  $113^{\circ}\pm 53^{\circ}$ , and  $32^{\circ}\pm 19^{\circ}$  to  $147^{\circ}\pm 35^{\circ}$ ,  $136^{\circ}\pm 43^{\circ}$ , and  $52^{\circ}\pm 25^{\circ}$ ,

**Table 3.** American Shoulder and Elbow Surgeons (ASES) Score Outcomes

Study	No. of Patients	Preoperative ASES Score	Follow-Up ASES Score			
			3 Months	6 Months	12 Months	24 Months
Gervasi et al. <sup>18</sup>	15	24.5	58.0	66.8	76.0	72.5
Holschen et al. <sup>16</sup>	12	31.5	—	—	66.7	85.7



**Fig 2.** Forest plot comparing total Constant score outcomes preoperatively and postoperatively at final follow-up. Six of the 7 studies reported a measure of variability (standard deviation or variance) and were eligible to be included in the forest plot.

respectively, at the 3-year follow-up ( $P < .05$ ). Three studies (92 shoulders) reported ROM subscores of the TCS, with improvement from 20.6, 32.4, and 21.2 preoperatively to 29.6, 45.6, and 32.3, respectively, at final follow-up.<sup>17,21,22</sup> The visual analog scale score was reported in 2 studies with 42 patients (42 shoulders) and improved from an average of 7.0 preoperatively to 2.2 at the 24-month follow-up.<sup>18,22</sup> Piekaar et al.<sup>20</sup> used the numeric rating scale for pain assessment and reported a mean reduction of 3.5 from 6.8 preoperatively.

Radiographic acromiohumeral interval (AHI) measurements were reported in 2 studies (67 patients, 69 shoulders).<sup>19,22</sup> In the study by Deranlot et al.,<sup>19</sup> mean AHI decreased from 8.2 mm preoperatively to 6.2 mm at the 3-year follow-up ( $P < .05$ ). In contrast, radiographic analysis in the study by Ricci et al.<sup>22</sup> showed that the AHI increased in each of the separate follow-up cohorts from 6.6 to 8.0 mm in the 3-month group, 6.6 to 8.2 mm in the 6-month group ( $P < .001$ ), 6.5 to 7.1 mm in the 12-month group ( $P < .001$ ), and 6.7 to 7.9 mm in the 24-month group ( $P < .001$ ).

Regarding conversion to shoulder arthroplasty, 1 patient in the study by Senekovic et al.<sup>17</sup> withdrew consent at 6 weeks because of an unsatisfactory outcome and was later converted to RTSA. Another patient in the study by Gervasi et al.<sup>18</sup> discontinued participation at 6 months because of insufficient improvement and was referred for shoulder arthroplasty. Similarly, 1 patient in the study by Holschen et al.<sup>16</sup> was excluded because the patient was converted to RTSA before follow-up.

In the study by Deranlot et al.,<sup>19</sup> 1 patient required revision surgery for spacer migration. In the study by Senekovic et al.,<sup>17</sup> 2 patients had no improvement in

TCS on follow-up and were found to have synovitis without cystic formation on MRI. Thus, the failure rate and overall complication rate was 3% (6/200) in our patients.

## Discussion

This systematic review synthesizes the currently available data on clinical outcomes and complications associated with subacromial spacer use in the treatment of MIRCT. Subacromial spacer implantation leads to improvement in outcome scores during short-term follow-up with a low rate of complications.

Although the subacromial spacer device has been approved for use in the European Union since 2010, it is currently not approved by the U.S. Food and Drug Administration and is not available for sale in the United States. There is an ongoing prospective, single-blinded multicenter controlled clinical trial in the United States comparing subacromial spacer implantation with partial repair for the treatment of MIRCT.<sup>27</sup> The results of this study may further elucidate the clinical safety and efficacy of subacromial spacer implantation.<sup>27</sup>

This systematic review shows improved outcome scores following subacromial spacer implantation in patients with MIRCT during a 2- to 3-year follow-up.<sup>16-19</sup> These results are comparable to early outcomes after existing treatment strategies for MIRCT, such as debridement,<sup>28</sup> biceps tenotomy or tenodesis,<sup>5</sup> partial repair,<sup>29-31</sup> superior capsule reconstruction,<sup>8</sup> and RTSA.<sup>32,33</sup> Because all patients, except in the study by Gervasi et al.,<sup>18</sup> underwent concomitant acromioplasty or biceps tenotomy, it is difficult to discern how much of the improvement in reported outcomes is simply

owing to debriding the rotator cuff and surgically addressing the biceps. Additional studies are needed to validate the use of subacromial spacer implantation in the setting of MIRCT.

Interestingly, improvement following subacromial spacer implantation is not limited by its biodegradable nature. Senekovic et al.,<sup>17</sup> Deranlot et al.,<sup>19</sup> and Holschen et al.<sup>16</sup> reported consistent improvement in the TCS over time, beyond the biodegradable period. A recent publication by Senekovic et al.<sup>34</sup> reported the 5-year follow-up results of the same patient cohort included in our review, which was excluded because of the high attrition rate (37.5%). Results of this longer follow-up were comparable to earlier results, with sustained significant improvement in outcomes; TCS improved from 34.2 to 67.4 at 5 years ( $P < .0001$ ). Considering the biodegradable nature of the spacer, there appears to be longevity in the treatment unrelated to the retention of the actual spacer. It is unclear as to whether this is related to other interventions, including debridement with biceps tenotomy or tenodesis, or if the temporary restoration of force coupling in the shoulder allows for improved rehabilitation.

ROM may also be improved by use of the spacer. Deranlot et al.<sup>19</sup> found significant improvement in anterior elevation, abduction, and external rotation at 3 years, which was supported by significant improvement in TCS ROM subscores in 3 of the other studies.<sup>17,21,22</sup> These results are comparable to those reported in the literature following other treatment options for MRCT. Regarding debridement and/or biceps tenotomy for MRCT, Scheibel et al.<sup>6</sup> reported similar results with active anterior elevation of 165° postoperatively and mean improvement in active external rotation of 35° after 40 months' follow-up. Di Benedetto et al.<sup>31</sup> reported ROM results for the 3-year follow-up after partial repair for MIRCT, showing improvement in active elevation and abduction to 151° and 135°, respectively. Mihata et al.<sup>8</sup> reported similar results after arthroscopic superior capsule reconstruction, with improved active elevation and external rotation to 148° and 40° postoperatively at 34.1 months. Leung et al.<sup>35</sup> reported improved active elevation and external rotation after RTSA, with 113° and 33° ROM, respectively, at the 2-year follow-up. Future studies with longer follow-up periods are needed to better understand ROM expectations and outcomes after subacromial spacer implantation.

Only 2 studies reported radiographic outcomes after subacromial spacer implantation.<sup>19,22</sup> Based on the principle of restoring force couples by pushing the humeral head down, it would be expected that the subacromial spacer would cause an increase in the AHI. However, Deranlot et al.<sup>19</sup> found a significant decrease in mean AHI of 2.1 mm at 36 months. This distance was found to decrease more than what has been reported in

the literature by Walch et al.<sup>36</sup> and Boileau et al.<sup>5</sup> after tenotomy or tenodesis of the biceps. In contrast, the study by Ricci et al.<sup>22</sup> found an increase in AHI measurements at 3, 6, 12, and 24 months. Chen et al.<sup>30</sup> published AHI results following arthroscopic partial repair after 29.6 months and found a mean increase in the AHI of 0.46 mm. This is smaller than the increase of 1.27 mm at 24 months in the cohort by Ricci et al.<sup>22</sup> It is unclear why the increase in the AHI would be maintained at 24 months given the biodegradable nature of the subacromial spacer. Further studies with longer follow-up times are needed to investigate the longitudinal effect of the subacromial spacer on the AHI.

There were a few complications associated with the use of subacromial spacers, which included 1 case of spacer migration and nonclinically significant synovitis in 2 cases. The polymer material used in this biodegradable spacer is not known to exhibit any toxic or tumorigenic properties.<sup>26</sup> Thus, based on early findings, subacromial spacer implantation appears to be a procedure with relatively minimal risk to the patients. Studies with larger cohorts, comparative interventions, and longer follow-up times are needed to further investigate the safety and efficacy of this treatment option.

### Limitations

A limitation of this present study, inherent to all systematic reviews, is a consequence of the low quality of the included studies. Six of the studies in our analysis were Level IV, and 1 was a case-control Level III study. All studies except that of Holschen et al.<sup>16</sup> had no control group. Furthermore, there was a fairly small number of patients in each study and a mean follow-up period of  $\leq 12$  months for more than half of these patients.

### Conclusions

Patients undergoing subacromial spacer implantation for the treatment of MIRCTs have satisfactory outcomes at the 2- to 3-year follow-up with a low rate of complications.

### References

1. Geary MB, Elfar JC. Rotator cuff tears in the elderly patients. *Geriatr Orthop Surg Rehabil* 2015;6:220-224.
2. Zingg PO, Jost B, Sukthankar A, Buhler M, Pfirrmann CWA, Gerber C. Clinical and structural outcomes of nonoperative management of massive rotator cuff tears. *J Bone Joint Surg Am* 2007;89:1928-1934.
3. Goldberg SS, Bell J-E, Kim HJ, Bak SF, Levine WN, Bigliani LU. Hemiarthroplasty for the rotator cuff-deficient shoulder. *J Bone Joint Surg Am* 2008;90:554-559.
4. Berth A, Neumann W, Awiszus F, Pap G. Massive rotator cuff tears: Functional outcome after debridement or arthroscopic partial repair. *J Orthop Traumatol* 2010;11:13-20.

5. Boileau P, Baque F, Valerio L, Ahrens P, Chuinard C, Trojani C. Isolated arthroscopic biceps tenotomy or tenodesis improves symptoms in patients with massive irreparable rotator cuff tears. *J Bone Joint Surg Am* 2007;89:747-757.
6. Scheibel M, Lichtenberg S, Habermeyer P. Reversed arthroscopic subacromial decompression for massive rotator cuff tears. *J Shoulder Elbow Surg* 2004;13:272-278.
7. Birmingham PM, Neviasser RJ. Outcome of latissimus dorsi transfer as a salvage procedure for failed rotator cuff repair with loss of elevation. *J Shoulder Elbow Surg* 2008;17:871-874.
8. Mihata T, Lee TQ, Watanabe C, et al. Clinical results of arthroscopic superior capsule reconstruction for irreparable rotator cuff tears. *Arthroscopy* 2013;29:459-470.
9. Moser M, Jablonski MV, Horodyski M, Wright TW. Functional outcome of surgically treated massive rotator cuff tears: A comparison of complete repair, partial repair, and debridement. *Orthopedics* 2007;30:479-482.
10. Aurora A, McCarron J, Iannotti JP, Derwin K. Commercially available extracellular matrix materials for rotator cuff repairs: State of the art and future trends. *J Shoulder Elbow Surg* 2007;16:S171-S178 (5 suppl).
11. Henry P, Wasserstein D, Park S, et al. Arthroscopic repair for chronic massive rotator cuff tears: a systematic review. *Arthroscopy* 2015;31:2472-2480.
12. Matthews TJW, Hand GC, Rees JL, Athanasou NA, Carr AJ. Pathology of the torn rotator cuff tendon. Reduction in potential for repair as tear size increases. *J Bone Joint Surg Br* 2006;88:489-495.
13. Savarese E, Romeo R. New solution for massive, irreparable rotator cuff tears: The subacromial "biodegradable spacer. *Arthrosc Tech* 2012;1:e69-e74.
14. Bozkurt M, Akkaya M, Gursoy S, Isik C. Augmented fixation with biodegradable subacromial spacer after repair of massive rotator cuff tear. *Arthrosc Tech* 2015;4:e471-e474.
15. Burks CA, Bundy K, Fotuhi P, Alt E. Characterization of 75:25 poly(l-lactide-co-epsilon-caprolactone) thin films for the endoluminal delivery of adipose-derived stem cells to abdominal aortic aneurysms. *Tissue Eng* 2006;12:2591-2600.
16. Holschen M, Brand F, Agneskirchner JD. Subacromial spacer implantation for massive rotator cuff tears: Clinical outcome of arthroscopically treated patients. *Obere Extremit* 2017;12:38-45.
17. Senekovic V, Poberaj B, Kovacic L, Mikek M, Adar E, Dekel A. Prospective clinical study of a novel biodegradable sub-acromial spacer in treatment of massive irreparable rotator cuff tears. *Eur J Orthop Surg Traumatol* 2013;23:311-316.
18. Gervasi E, Maman E, Dekel A, Cautero E. Fluoroscopy-guided biodegradable spacer implantation using local anesthesia: Safety and efficacy study in patients with massive rotator cuff tears. *Musculoskelet Surg* 2016;100:19-24 (suppl 1).
19. Deranlot J, Herisson O, Nourissat G, et al. Arthroscopic subacromial spacer implantation in patients with massive irreparable rotator cuff tears: Clinical and radiographic results of 39 retrospective cases. *Arthroscopy* 2017;33:1639-1644.
20. Piekaar RSM, Bouman ICE, van Kampen PM, van Eijk F, Huijsmans PE. Early promising outcome following arthroscopic implantation of the subacromial balloon spacer for treating massive rotator cuff tear [published online November 18, 2017]. *Musculoskelet Surg*.doi:10.1007/s12306-017-0525-5.
21. Maman E, Safran O, Beyth S, et al. Biceps tenotomy does not affect the functional outcomes of patients treated with spacer implantation due to massive irreparable rotator cuff tears. *Open Orthop J* 2017;11:1577-1584.
22. Ricci M, Vecchini E, Micheloni GM, et al. A clinical and radiological study of biodegradable subacromial spacer in the treatment of massive irreparable rotator cuff tears. *Acta Biomed* 2017;88:75-80 (4 suppl).
23. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred Reporting Items for Systematic reviews and Meta-Analyses: The PRISMA statement. *BMJ* 2009;339:b2535.
24. Slim K, Nini E, Forestier D, Kwiatkowski F, Panis Y, Chipponi J. Methodological Index for Non-Randomized Studies (MINORS): Development and validation of a new instrument. *ANZ J Surg* 2003;73:712-716.
25. Hamada K, Yamanaka K, Uchiyama Y, Mikasa T, Mikasa M. A radiographic classification of massive rotator cuff tear arthritis. *Clin Orthop Relat Res* 2011;469:2452-2460.
26. Ramot Y, Nyska A, Markovitz E, et al. Long-term local and systemic safety of poly(l-lactide-co-epsilon-caprolactone) after subcutaneous and intra-articular implantation in rats. *Toxicol Pathol* 2015;43:1127-1140.
27. U.S. National Library of Medicine. A pivotal study to assess the InSpace™ device for treatment of full thickness massive rotator cuff tears. *ClinicalTrials.gov*, <https://clinicaltrials.gov/ct2/show/NCT02493660>. Accessed August 31, 2018.
28. Konig MA, Braunstein VA. Tendon repair leads to better long-term clinical outcome than Debridement in massive rotator cuff tears. *Open Orthop J* 2017;11:546-553.
29. Kim S-H, Ha K-I, Park J-H, Kang J-S, Oh S-K, Oh I. Arthroscopic versus mini-open salvage repair of the rotator cuff tear: Outcome analysis at 2 to 6 years' follow-up. *Arthroscopy* 2003;19:746-754.
30. Chen K-H, Chiang E-R, Wang H-Y, Ma H-L. Arthroscopic partial repair of irreparable rotator cuff tears: Factors related to greater degree of clinical improvement at 2 years of follow-up. *Arthroscopy* 2017;33:1949-1955.
31. Di Benedetto ED, Di Benedetto P, Fiocchi A, Beltrame A, Causero A. Partial repair in irreparable rotator cuff tear: Our experience in long-term follow-up. *Acta Biomed* 2017;88:69-74 (4 suppl).
32. Ernstbrunner L, Suter A, Catanzaro S, Rahm S, Gerber C. Reverse total shoulder arthroplasty for massive, irreparable rotator cuff tears before the age of 60 years: Long-term results. *J Bone Joint Surg Am* 2017;99:1721-1729.
33. Mulieri P, Dunning P, Klein S, Pupello D, Frankle M. Reverse shoulder arthroplasty for the treatment of irreparable rotator cuff tear without glenohumeral arthritis. *J Bone Joint Surg Am* 2010;92:2544-2556.

34. Senekovic V, Poberaj B, Kovacic L, et al. The biodegradable spacer as a novel treatment modality for massive rotator cuff tears: A prospective study with 5-year follow-up. *Arch Orthop Trauma Surg* 2017;137:95-103.
35. Leung B, Horodyski M, Struk AM, Wright TW. Functional outcome of hemiarthroplasty compared with reverse total shoulder arthroplasty in the treatment of rotator cuff tear arthropathy. *J Shoulder Elbow Surg* 2012;21:319-323.
36. Walch G, Edwards TB, Boulahia A, Nove-Josserand L, Neyton L, Szabo I. Arthroscopic tenotomy of the long head of the biceps in the treatment of rotator cuff tears: Clinical and radiographic results of 307 cases. *J Shoulder Elbow Surg* 2005;14:238-246.