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# When do patients truly reach maximal medical improvement after undergoing reverse shoulder arthroplasty? The incidence and clinical significance of pain and patient-reported outcome measure improvement



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#### ARTICLE INFO

Keywords: Shoulder arthroplasty reverse total shoulder arthroplasty maximum medical improvement sports medicine pain patient-reported outcome measures

*Level of evidence:* Level IV; Case Series; Treatment Study **Hypothesis:** Patients receiving reverse total shoulder arthroplasty (RTSA) may reach MMI prior to 12 months postoperatively.

**Background:** With the growth of RTSA indications, there is a paucity of information regarding maximum medical improvement (MMI) after these procedures. Systems of evaluating recovery, such as patient-reported outcome measures and minimal clinically important differences (MCIDs) will allow for measurement of when patients reach maximum medical improvement (MMI) after these procedures. **Purpose:** To evaluate when patients have reached MMI after RTSA.

**Methods:** Patients were prospectively enrolled in the institution's RTSA registry. All patients undergoing RTSA who agreed to be enrolled were included. Patient-specific factors, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) score, and pain data were collected preoperatively and at 6 and 12 months postoperatively. Subgroup analysis was performed on preoperative diagnosis before analyzing MCID and MMI. MMI was calculated by using the last time point interval that an MCID did not occur.

**Results:** Of 182 patients, 92 had complete 12-month postoperative data, including visual analog scale (VAS) pain and ASES scores. Subgroup analysis showed preoperative diagnosis of rotator cuff arthropathy, revision surgery, glenohumeral arthritis, proximal humerus fracture, and chronic dislocation. All 5 groups had improvement that exceeded MCID thresholds at 6 months and variable improvement from 6-12 months. Analysis of variance compared the different groups, showing that VAS pain scores and ASES scores were different at all time points except for preoperative VAS pain scores.

**Conclusions:** Patients undergoing RTSA may reach MMI at 6 months instead of the previously reported 1-year time point. Data from this study can allow providers to deliver value care and potentially limit visits after 6 months postoperatively.

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Shoulder arthroplasty is a commonly performed procedure for patients with shoulder pain and dysfunction. Although anatomic total shoulder arthroplasty (TSA) provides treatment for a number of preoperative diagnoses, the development of reverse total shoulder arthroplasty (RTSA) has expanded the surgical indications for the treating surgeon.<sup>3,4,7,10,23–26,28,33,41,42,44,45</sup> Since its approval by the Food and Drug Administration, its use and our understanding of the topic is increasing.<sup>11,19,20</sup>

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The growth of the RTSA market has occurred while health care expenditure in the United States has been increasing considerably. This comes at a time of transition between a quantity-based model to a quality-based model of reimbursement.<sup>6</sup> Consequently, patient-reported outcome measures (PROMs) increasingly have been used in the literature to capture some of the subjective experiences patients have on various aspects of their care.<sup>21</sup> This also had an effect on reimbursement, as a recent study used PROMs to determine the effectiveness of bundled payments.<sup>39</sup> These PROMs are helping physicians in the orthopedic community to improve clinical decision making by converting patient perspectives into analyzable data.<sup>1</sup> One tool that can help measure the changes in clinical outcomes is the minimal clinically important difference (MCID). The MCID helps to determine the threshold change in score

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#### Table I

Patient PROM data	Preoperative	6 mo postoperative	12 mo postoperative
ASES			
Pain score	16	35.8	36.8
Functional score	16	29.8	30.6
Total score	32	65.6	67.3
VAS pain score	6.2	3	2.7

PROM, patient-reported outcome measure; ASES, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; VAS, visual analog scale.

on PROMs that is considered clinically significant.<sup>18</sup> In essence, it connects statistically significant PROM scores to clinical improvements according to the patient. This can be tailored to groups with different preoperative pathologies, allowing for more specific analysis. One of the advantages of using the MCID metric is that it may help identify when a patient may have reached their maximal clinical benefit, also known as maximal medical improvement (MMI).<sup>47</sup>

Evaluation of postoperative milestones is underway. For example, clinical outcomes and long-term survivorship after TSA or RTSA have been performed.<sup>12,13,17,27,29,36,38,41</sup> Additionally, preliminary studies have begun to investigate the rate of improvement.<sup>35</sup> However, the literature evaluating when patients reach MMI after an RTSA has yet to be thoroughly examined. Uncovering the change in pain and functional outcomes in the early postoperative period is important to map out when patients and surgeons can expect to see functional improvement and reduction in pain. The information gathered by the MMI may help physicians improve the timing of follow-up visits so that certain milestones can be recognized earlier. Inconsequential visits can then be avoided, especially with use of remote examination measures (eg, mailed questionnaires). The purpose of this study is to track the change in pain and functional outcome measures preoperatively to postoperatively and identify when patients reach MMI.

### Methods

Patients were prospectively enrolled in an academic medical center's RTSA registry. All patients who agreed to participate and underwent an RTSA at the institution between 2016 and 2019 were considered eligible for inclusion. The cases were performed by a single surgeon (B.M.G.). Patient-specific factors, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) score, and pain data were collected preoperatively as well as at 6 and 12 months postoperatively. Descriptive statistics (eg, mean and range) were used on continuous variables. Frequencies and percentages were calculated for categorical variables. A subgroup analysis was performed on preoperative diagnosis prior to analyzing MCID and MMI. Previously validated MCID of ASES and visual analog scale (VAS) pain scores in patients undergoing reverse shoulder arthroplasty was used for analysis. Specifically, 2 studies

#### Table II

Preoperative diagnosis data

	n
Rotator cuff arthropathy	94
Revision arthroplasty	34
Glenohumeral arthritis	19
Proximal humerus fracture	12
Dislocation	10
Humeral head osteonecrosis	5
Other*	8

\* Other humeral fractures, osteonecrosis, rheumatoid arthritis, or cancer.

#### Table III VAS pain data per diagnosis

	Preoperative	6 mo postoperative	12 mo postoperative
Rotator cuff arthropathy	5.86 (2.64)	2.5 (2.47)	1.84 (2.47)
Revision arthroplasty	6.88 (1.91)	4.94 (2.68)	4.43 (2.90)
Glenohumeral arthritis	6.56 (2.82)	2.8 (2.49)	2.89 (2.03)
Proximal humerus fracture	6.0 (2.19)	1.5 (0.71)	3.5 (3.73)
Chronic dislocation	8.33 (1.51)	4.33 (3.51)	6.0 (4.08)

VAS, visual analog scale.

Values are mean VAS pain scores (standard deviations)

have published MCID for RTSA patients using a similar anchorbased methodology.<sup>34,37</sup> The threshold for an MCID in ASES in this study was calculated by a weight-based average between the 2 referenced studies and defined as a change of at least 10.9. Similarly, a threshold of 1.3 was used for the VAS pain score after completing a weight-based average.<sup>34,37</sup> Afterward, MMI was calculated by using the last time point interval that an MCID did not occur.47

#### Results

A total of 182 patients were included in the study. The mean patient age was 66.7  $\pm$  9.8 years (range, 38-96). In total, 44% (n = 80) were male patients and 56% (n = 102) were female (Table I). There were 152 patients who had complete preoperative data, 107 patients with complete 6-month postoperative data, and 92 patients with complete 12-month postoperative data. The mean VAS pain and ASES total scores are illustrated in Table I.

A subgroup analysis on preoperative diagnosis revealed that 94 patients had rotator cuff arthropathy, 34 were undergoing a revision surgery, 19 had glenohumeral arthritis, 12 had a proximal humerus fracture, and 10 had chronic dislocation. All diagnostic groups are illustrated in Table II. Mean VAS pain and ASES scores for each diagnostic group is illustrated in Tables III and IV.

Transitioning from preoperative to 6-month postoperative time points, patients from all 5 diagnostic groups had improvements that exceeded the ASES and VAS pain score MCID thresholds (10.9 and 1.3 points, respectively). However, transitioning from 6- to 12month postoperative time points, there was variable improvement between diagnostic groups, but none to a degree that it exceeded the ASES and VAS pain score MCID thresholds. Conversely, there were some diagnostic groups that did not improve their ASES and VAS pain scores between the 6- and 12-month postoperative time points, for example, the VAS pain score for those with glenohumeral arthritis, proximal humerus fractures, and chronic dislocation and the ASES score for proximal humerus fractures and chronic dislocation (Tables III-V). In considering only changes in scores that fulfill the MCID threshold in a positive direction, all

Table IV
ASES data per diagnosis

	Preoperative	6 mo postoperative	12 mo postoperative
Rotator cuff arthropathy	36.38 (20.42)	69.94 (21.76)	75.52 (20.65)
Revision arthroplasty	28.12 (15.25)	49.21 (25.29)	54.72 (27.38)
Glenohumeral arthritis	29.24 (19.95)	68.77 (17.02)	70.93 (17.78)
Proximal humerus fracture	22.5 (9.31)	66.66 (11.79)	54.17 (22.03)
Chronic dislocation	14.5 (0.01)	37.78 (18.36)	25.0 (24.73)

ASES, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form.

Values are mean ASES scores (standard deviations).

 Table V

 MCID of ASES and VAS pain scores

	Preoperative to 6 mo postoperative	6 mo postoperative to 1 yr postoperative
Rotator cuff arthropathy		
$\triangle$ VAS pain score; ASES score	-3.36; 33.56	-0.66; 5.58
Met MCID threshold	Yes; yes	No; No
Revision arthroplasty		
riangle VAS pain score; ASES score	-1.94; 21.09	-0.51; 5.51
Met MCID threshold	Yes; Yes	No; No
Glenohumeral arthritis		
riangle VAS pain score; ASES score	-3.76; 39.53	0.09; 2.16
Met MCID threshold	Yes; Yes	No; No
Proximal humerus fracture		
riangle VAS pain score; ASES score	-4.5; 44.16	2.0; -12.49
Met MCID threshold	Yes; Yes	Yes*; Yes*
Chronic dislocation		
riangle VAS pain score; ASES score	-4.0; 23.38	1.67; -12.78
Met MCID threshold	Yes; Yes	Yes <sup>*</sup> ; Yes <sup>*</sup>

*MCID*, mimimal clinically important difference; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; *VAS*, visual analog scale;  $\triangle$ , change.

Values met in reverse direction.

diagnostic groups reached the MMI for both VAS pain and ASES scores at 6 months postoperatively (Figs. 1 and 2). Diagnostic groups that met MCID thresholds in the reverse direction are marked with an asterisk (Table V).

A 1-way analysis of variance was performed to evaluate any differences in scores based on diagnoses at various time points. There was a statistically significant difference in mean scores for VAS pain and ASES scores at all time points except for VAS pain score preoperatively. Results are shown in Table VI.

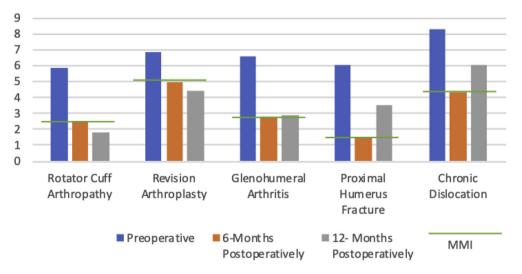
#### Discussion

RTSA serves as a reliable option for the treatment of shoulder pain and dysfunction. PROMs provide a valuable tool in evaluating patient satisfaction and functional outcomes in orthopedic clinics, and have shown promising results.<sup>14,17</sup> As patients are typically followed postoperatively for recovery in the short term and later for complications, determining the MMI is relevant for the both the patient and the provider. MMI-related data provide the potential for clinical follow-up visits between 6 months and 1 year to be reappropriated until later time points when it is prudent to monitor for glenoid loosening while knowing the patient has reached MMI.<sup>31</sup> Recent studies suggest glenoid loosening to occur on average around 19 months and suggest a minimum 2-year follow-up.<sup>2</sup> In addition, the postoperative course for a patient undergoing RTSA may vary depending on the preoperative diagnosis.<sup>41</sup>

Prior literature has sought to determine the MCID for a number of orthopedic procedures.<sup>8,9,16,22,30,34,37,40,43,46</sup> Similarly, MMI is a contemporary concept that has sparsely evaluated RTSA. A study by Cabarcas et al<sup>5</sup> concluded that MMI was reached at 12 months for those undergoing shoulder arthroplasty. However, there is no literature to date that has evaluated MCID or MMI of only RTSA with a subgroup analysis based on preoperative diagnosis. This is the first study to do so. Furthermore, the authors of this study suspected that patients may reach MMI earlier than the previously reported 12 months. As a result, the authors evaluated the change in functional outcome measures and pain preoperatively to postoperatively based on preoperative diagnosis and re-evaluated the concept that MMI is reached at 12 months for each of these groups.

The data in this study suggest that the MCID for ASES and VAS pain scores for patients undergoing RTSA were met for the period between preoperative and 6-month postoperative time points but were not for the period between the 6-month and 1-year time points. Considering these results, it is believed that patients reach MMI at 6 months, which corresponds to half the time that is reported in prior literature.<sup>5</sup> This indicates that patients may be undergoing a rapid improvement in pain and function during the 6-month postoperative period, then a gradual, tapered improvement afterward.

Transitioning from 6- to 12-month postoperative time points, the glenohumeral arthritis, proximal humerus fracture, and chronic dislocation groups had an increase in VAS pain. In addition, the proximal humerus fracture and chronic dislocation groups had a reduction in ASES score during the same time period. The authors believe that the reversal in improvements after fulfilling MCID at 6 months represents a sample of patients who continued to be seen



### VAS Pain Score

Figure 1 VAS pain score. VAS, visual analog scale.

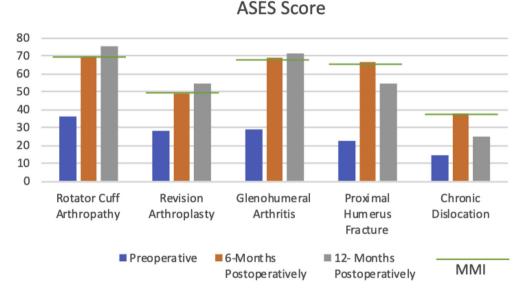


Figure 2 ASES score. ASES, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form.

for less than satisfactory results, whereas those who reached MMI were following up less frequently. This supports the notion that many patients are reaching MMI at 6 months postoperatively.

Analysis of variance illustrates that there is significant variability in the mean VAS pain and ASES scores between diagnostic groups. In spite of this variability, all diagnostic groups reached MMI at 6 months postoperatively. This suggests that the preoperative diagnosis may not play a large role in determining when patients reach MMI. It is unclear at this point which component of the surgical or rehabilitation protocol provides the greatest benefit toward reaching MMI. Future studies will need to identify the variables that are most important so that an emphasis can be placed at particular times and could possibly help patients reach MMI sooner.

The findings in this study suggest it may be possible to focus resources during periods that patients experience the greatest progress. For example, more frequent clinical visits and physical therapy sessions may be scheduled during the immediate 6-month postoperative window. Although the data suggest providers can consider a reduction in the number of clinical visits after 6 months, it is still prudent to monitor for complications, as the majority occur at more than 1 year after surgery.<sup>5</sup>

#### Strengths and limitations

There are a number of strengths and limitations in this study. One strength is that all the RTSA procedures were performed by a single surgeon, which controls for a number of confounding variables. The prospective design reduces the documentation errors and inconsistency in the data that is often seen in retrospective

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VAS pain and ASES score analysis of variance

	Preoperative		6 mo postoperatively		12 mo postoperatively	
	VAS pain	ASES	VAS pain	ASES	VAS pain	ASES
P value	.09	.02	.01	<.01	<.01	<.01

VAS, visual analog scale; ASES, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form.

studies. In addition, the use of MMI helps to mitigate the ceiling effect of MCID described in previous studies.<sup>15,32</sup>

There are also a number of limitations in this study. Question fatigue is a common occurrence in PROMs, and patients may feel rushed and provide inaccurate answers. Also, although our study had close to 200 participants, it may not be generalizable to the wider population. Albeit ASES and VAS pain scores are validated measures for pain and function, they may not be entirely representative of the metrics that are important for the patient. In addition, although the data suggest patients may be reaching MMI earlier, we do not have an understanding of the magnitude of the effect each factor during the rehabilitation process has on progress postoperatively. Future studies may consider adding more frequent PROMs during the initial 6-month period to better capture exactly when patients make the most improvement and correlate with components of the rehabilitation protocol at the same time point.

#### Conclusion

Patients undergoing RTSA may reach MMI at 6 months instead of the previously reported 1-year time point. The data drawn from this study can help providers deliver value care and limit potentially unnecessary visits after 6 months postoperatively.

#### Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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