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SHOULDER

Time required to achieve clinically significant outcomes after arthroscopic superior capsular reconstruction

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Abstract

Purpose To investigate the time-dependent nature of clinically significant outcomes, including the minimal clinically important difference (MCID), substantial clinical benefit, and Patient Acceptable Symptomatic State (PASS) after arthroscopic superior capsular reconstruction, and the factors contributing to the achievement of early clinically significant outcomes.

Methods Patients who underwent ASCR between March 2015 and September 2020 with complete preoperative and postoperative 6-month, 1-year, and 2-year patient-reported outcome measures (PROMs) were retrospectively analysed. Threshold values for MCID, substantial clinical benefit, and PASS were obtained from the previous literature for the PROMs. The time required to achieve clinically significant outcomes was calculated using Kaplan–Meier analysis. Multivariate Cox regression was performed to evaluate the variables predictive of an earlier or delayed achievement of MCID.

Results Fifty-nine patients with a mean age of 64.5 ± 8.7 years old were included. The time of mean achievement of MCID, substantial clinical benefit, and PASS for VAS was 11.2 ± 0.9, 16.3 ± 1.1, and 16.6 ± 0.9 months, respectively. The time of mean achievement of MCID, substantial clinical benefit, and PASS for ASES was 13.2 ± 1.0, 16.8 ± 1.0, and 18.3 ± 0.9 months, respectively. The time of mean achievement of MCID, substantial clinical benefit, and PASS for the Constant score was 11.6 ± 0.9, 15.1 ± 1.0, and 14.7 ± 0.9 months, respectively. The time of mean achievement of MCID, substantial clinical benefit, and PASS for SANE was 14.4 ± 1.0, 16.1 ± 1.0, and 15.5 ± 0.8 months, respectively. Patients with a higher preoperative VAS score achieved an earlier MCID for VAS ($P = 0.014$). However, patients with a higher preoperative ASES and SANE scores achieved delayed MCID for ASES and SANE ($P = 0.026$, and $P < 0.001$, respectively).

Conclusion Most patients achieved MCIDs around 1 year after arthroscopic superior capsular reconstruction. A higher preoperative VAS score favours faster MCID achievement, while higher preoperative ASES and SANE scores contribute to delayed MCID achievement.

Study design Cohort study

Level of evidence Level IV.

Keywords Superior capsular reconstruction · Minimal clinically important difference · Substantial clinical benefit · Patient Acceptable Symptomatic State · Time to achieve clinical significance

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Introduction

Arthroscopic superior capsular reconstruction has been introduced for the treatment of irreparable massive rotator cuff tears with promising biomechanical [21, 23] and clinical outcomes [17, 18, 28]. Patient-reported outcome measures (PROMs) are commonly used to evaluate surgical outcomes after rotator cuff surgeries [1, 9, 11]. Although statistically significant differences between pre- and postoperative PROMs are proposed to be associated with clinically significant outcomes, statistical significance may not necessarily correlate with clinical relevance [12, 15]. Thus, it is of great importance to understand the clinical benefit of a procedure in the era of value-based systems of care [10, 26].

Currently used clinically significant outcome (CSO) measures consist of the minimal clinically important difference (MCID), substantial clinical benefit, and Patient Acceptable Symptomatic State (PASS) [22, 28]. MCID is defined as the minimum degree of quantifiable outcome improvement that a patient perceives after treatment. Substantial clinical benefit is defined as the minimum amount of quantifiable outcome improvement that makes a patient feel ''sufficiently better'' after treatment. PASS refers to the degree of symptoms that distinguish satisfaction and dissatisfaction with the patient's current condition according to the patient's pain and function [28].

Recently, Manderle et al. investigated the timeline of the achievement of clinically significant outcomes and their contributing factors after arthroscopic rotator cuff repair [22]. Although MCID, substantial clinical benefit, and PASS values for PROMs after ASCR have been previously investigated [8, 28], knowledge about the time-dependent nature of clinically significant outcomes after arthroscopic superior capsular reconstruction is lacking. Therefore, the purposes of this study were (1) to investigate the time required to achieve MCID, substantial clinical benefit, and PASS after arthroscopic superior capsular reconstruction for four shoulder PROMs: the American Shoulder and Elbow Surgeons (ASES), Single Assessment Numeric Evaluation (SANE), visual analogue scale (VAS), and Constant scores; and (2) to identify factors associated with the time required for the achievement. It was hypothesised that (1) most patients would achieve MCID, substantial clinical benefit, and PASS within postoperative 6 months–1 year; and (2) lower preoperative PROMs would contribute to earlier achievements of CSOs.

Materials and methods

Approval from the Institutional Review Board of Asan Medical Center (No. 2023-0408) was acquired before this retrospective study was conducted. A total of 106 patients who underwent arthroscopic superior capsular reconstruction by a single senior orthopaedic surgeon (IHJ) between March 2015 and September 2020 were reviewed. A fascia lata autograft was used for patients between March 2013 and September 2016, and a fascia lata autograft with mesh augmentation was used for patients between October 2016 and September 2020. The change in the technique for graft preparation was based on the operating surgeon's investigation of the preliminary outcomes of the earlier technique [18]. Four PROMs, including the VAS, ASES, Constant score, and SANE questionnaire, were routinely collected preoperatively and at postoperative 6 months, 1 year, and 2 years.

Patient selection

The inclusion criteria were: (1) diagnosis of an irreparable rotator cuff with (a) the biggest dimension of the tear > 5 cm, (b) complete tear of > two tendons, or (c) medial retraction of ≥ Patte grade 3 on preoperative magnetic resonance imaging; (2) surgical confirmation of irreparability under arthroscopy as being irreducible to its anatomic footprint; and (3) using autograft (tensor fascia lata). The exclusion criteria were: (1) previous ipsilateral shoulder surgery; (2) irreparable subscapularis tendon tear; or (3) incomplete pre- and postoperative PROMs.

Of the initial 106 patients, 11 patients underwent revision arthroscopic superior capsular reconstruction. Eight patients were excluded because of using an allograft, and 28 patients were excluded because of no follow-up data at any of the three time points. Finally, 59 patients were included in the study (Fig. 1). Their mean age was 64.5 ± 8.7 years. Thirty-nine (66.10%) patients were female. Their mean BMI was 25.9 ± 3.7 kg/m^2.

Surgical technique and postoperative protocol

The surgical procedure consisted of several routine steps. First, acromioplasty and tenotomy of the biceps, if present, were performed. The defect size was carefully measured, and the graft was prepared. The graft was obtained from the ipsilateral fascial lata and meticulously prepared by the assisting surgeon at a designated table. To augment the graft, a single-layer polypropylene mesh (Prolene Mesh; Ethicon) was utilised and fashioned within the folded fascia lata. The graft margin was sealed with a running stitch using No. 2-0 polyester suture (Ethibond; Ethicon). For fixation, three suture anchors (JuggerKnot, 2.5 mm; Zimmer Biomet or Helicoil, 4.5 mm; Smith & Nephew) were employed at the glenoid site, while two polyetheretherketone (PEEK) threaded anchors (Helicoil, 4.5 mm; Smith & Nephew) were used at the humeral site for medial row fixation, following a double-row suture bridge construct. The remaining bursal

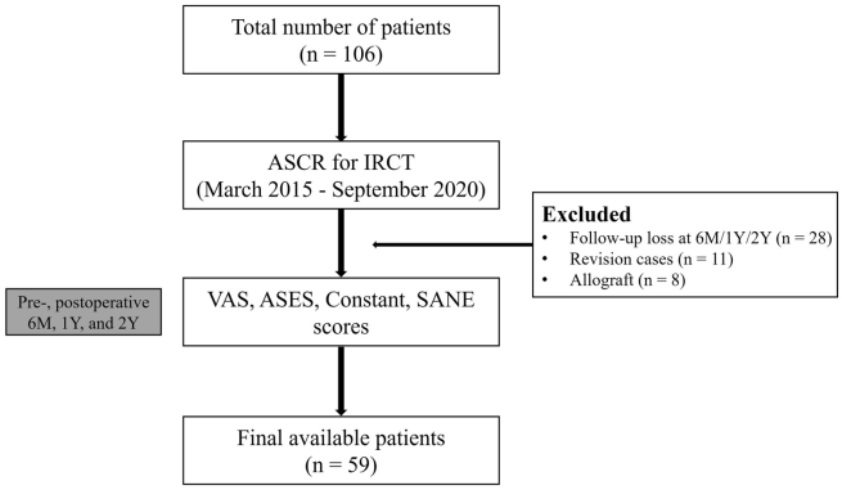

Fig. 1 Flow diagram of the study. *ASCR* arthroscopic superior capsular reconstruction, *IRCT* irreparable rotator cuff tear, *VAS* visual analogue scale, *ASES* American Shoulder and Elbow Surgeons, *SANE* Single Assessment Numeric Evaluation, *M* month, *Y* year

tissue was fixed on top of the graft [18]. Finally, two knotless anchors (Footprint Ultra 4.5 mm; Smith & Nephew) were used to fix the suture limbs. After surgery, all patients were provided with a shoulder abduction brace and instructed to initiate strengthening exercises after a six-week recovery period [4].

Outcome measures

Patient demographics, including age, gender, body mass index (BMI), and comorbidities, including hypertension and diabetes mellites, were collected. Pain was evaluated using a visual analogue scale (VAS), with 0 being no pain and 10 being the maximum possible pain. The functional outcomes were evaluated using the ASES score, Constant score, and SANE questionnaire [3]. A dynamometer (Mecmesin BFG 200N) was used to measure isometric strength for the calculation of the Constant score.

The acromiohumeral distance (AHD) was calculated on anteroposterior plain radiographs. A shoulder MRI was performed with a 3T machine (Achieva; Philips Healthcare) before SCR. On MRI, the Goutallier classification was used to assess fatty infiltration of the RC muscles [20], and the Patte classification was used to assess RC retraction [28]. All imaging evaluation was performed by a fellowship-trained shoulder surgeon (H.B.) who was not involved in the surgery and was blinded to the patients' information and clinical outcomes.

Clinically significant outcome measures

The PASS, MCID, and substantial clinical benefit benchmarks were utilised from a previous study that established these values utilising an anchor-based method: VAS (PASS, 1.5; MCID, 2.5; substantial clinical benefit, 4.5), ASES (PASS, 81.0; MCID, 19.0; substantial clinical benefit, 27.5), SANE (PASS, 60.5; MCID, −0.5; substantial clinical benefit, 5.5), and Constant score (PASS, 75.0; MCID, 27.5; substantial clinical benefit, 32.5) [28].

Statistical analysis

Continuous data are presented as mean ± SD and the Shapiro–Wilk test was used to investigate the data normality distribution. Baseline data were compared using the independent Student *t* test or Mann–Whitney *U* test for continuous data and the chi-square test or Fisher exact test for categorical data. A time-to-event analysis was performed using a Kaplan–Meier survivorship curve to determine the time to the achievement of MCID, SCB, and PASS. Multivariate Cox regression was performed to evaluate the independent variables predictive of earlier or delayed achievement of MCID. Variables in the multivariate Cox regression analysis included age, gender, BMI, hypertension, DM, mesh, and preoperative functional scores. Statistical analysis was performed using SPSS 27.0 software (IBM, NY, USA) with the statistical significance level set at $P < 0.05$.

Results

Patient selection and baseline data

Patient-reported outcome measures

The preoperative scores of the current cohort were: VAS, 5.7 ± 1.9; ASES, 50.4 ± 17.0; Constant, 53.5 ± 11.9; and SANE, 43.8 ± 19.3 (Table 1). The percentage of the patients

Table 1 Demographics and preoperative findings

	Value
Age, years	64.5 ± 8.7
BMI, kg/m^2	25.9 ± 3.7
Sex, male:female, *n*	20:39
Diabetes mellitus, yes:no, *n*	25:34
Hypertension, yes:no, *n*	25:34
Graft, FL:FL/M, *n*	18:41
ASES score	50.4 ± 17.0
Constant score	53.5 ± 11.9
SANE score	43.8 ± 19.3
VAS score	5.7 ± 1.9
Goutallier classification, grades 0:1:2:3:4, *n*	
Supraspinatus	1:11:19:14:14
Infraspinatus	4:16:13:7:19
Subscapularis	15:19:15:6:4
Teres minor	54:4:1:0:0
Acromiohumeral distance, mm	5.5 ± 2.9

Data are presented as mean ± SD unless otherwise specified

BMI body mass index, *FL* fascia lata, *FL/M* fascia lata with mesh interposed, *ASES* American Shoulder and Elbow Surgeons, *SANE* Single Assessment Numeric Evaluation, *VAS* visual analogue scale, *mm* millimetre

who achieved MCID, substantial clinical benefit, and PASS for VAS, ASES, Constant, and SANE are detailed in Table 2. The time required to achieve these values varied across different outcome measures (Table 3).

Characteristics associated with MCID achievement

As shown in Table 4, earlier achievement of MCID for VAS was significantly correlated with the preoperative VAS score (hazard ratio [HR], 1.425; 95% confidence interval [CI], 1.164–1.745; $P = 0.001$). Delayed achievement of MCID for ASES was significantly correlated with the preoperative ASES score (HR, 0.962; 95% CI, 0.930–0.995; $P = 0.026$). No variables were found to be correlated with the achievement of MCID for the Constant score. Delayed achievement of MCID for SANE was significantly correlated with the preoperative SANE score (HR, 0.948; 95% CI, 0.923–0.973; $P \leq 0.001$).

Discussion

The most important finding of the current study was that most patients achieved MCID (74.58%), SCB (56.78%), and PASS (65.68%) after arthroscopic superior capsular

Table 2 Patients achieving MCID, SCB, and PASS for VAS, ASES, Constant, and SANE

	MCID			SCB			PASS		
	6 M	1 Y	2 Y	6 M	1 Y	2 Y	6 M	1 Y	2 Y
VAS	59.3	78.0	81.4	30.5	47.5	55.9	13.6	50.8	64.4
ASES	37.3	71.2	66.1	22.0	47.5	50.8	10.2	45.8	61.0
Constant	54.2	74.6	81.4	23.7	61.0	62.7	18.6	64.4	69.5
SANE	27.1	62.7	69.5	23.7	50.8	57.6	10.2	62.7	67.8

Data are presented as %

VAS visual analogue scale, *ASES* American Shoulder and Elbow Surgeons, *SANE* Single Assessment Numeric Evaluation, *MCID* minimal clinically important difference, *SCB* substantial clinical benefit, *PASS* Patient Acceptable Symptomatic State, *M* month, *Y* year

Table 3 Mean time required (in months) to achieve MCID, SCB, and PASS for VAS, ASES, Constant, and SANE score

	MCID	SCB	PASS
VAS	11.2 ± 0.9 (5.8 ± 1.8[a])	16.3 ± 1.1 (6.2 ± 2.9[a])	16.6 ± 0.9 (7.2 ± 3.8[a])
ASES	13.2 ± 1.0 (6.3 ± 2.4[a])	16.8 ± 1.0 (7.1 ± 4.1[a])	18.3 ± 0.9 (9.3 ± 5.9[a])
Constant	11.6 ± 0.9 (6.9 ± 3.9[a])	15.1 ± 1.0 (7.1 ± 4.1[a])	14.7 ± 0.9 (8.7 ± 5.5[a])
SANE	14.4 ± 1.0 (–)	16.1 ± 1.0 (–)	15.5 ± 0.8 (–)

Data are presented as mean ± standard deviation

VAS visual analogue scale, *ASES* American Shoulder and Elbow Surgeons, *SANE* Single Assessment Numeric Evaluation, *MCID* minimal clinically important difference, *PASS* Patient Acceptable Symptomatic State, *SCB* substantial clinical benefit

[a]Data in the brackets were derived from a published paper on rotator cuff repair [22]

Table 4 Multivariate Cox regression of variables associated with MCID achievement

	VAS		ASES		Constant		SANE	
	Hazard ratio (95% CI)	*P*	Hazard ratio (95% CI)	*P*	Hazard ratio (95% CI)	*P*	Hazard ratio (95% CI)	*P*
Age	1.001 (0.961–1.043)	n.s.	1.010 (0.970–1.051)	n.s.	1.030 (0.989–1.073)	n.s.	0.977 (0.936–1.021)	n.s.
BMI	0.999 (0.929–1.075)	n.s.	1.046 (0.966–1.132)	n.s.	0.994 (0.911–1.083)	n.s.	1.039 (0.949–1.137)	n.s.
Hypertension	0.860 (0.463–1.598)	n.s.	1.050 (0.543–2.029)	n.s.	1.017 (0.549–1.882)	n.s.	1.539 (0.771–3.069)	n.s.
DM	1.039 (0.418–2.582)	n.s.	1.142 (0.478–2.731)	n.s.	1.461 (0.574–3.721)	n.s.	0.802 (0.319–2.014)	n.s.
Gender	0.966 (0.509–1.834)	n.s.	1.065 (0.481–2.358)	n.s.	1.147 (0.549–2.396)	n.s.	0.740 (0.344–1.592)	n.s.
Mesh	1.216 (0.619–2.389)	n.s.	1.027 (0.477–2.213)	n.s.	0.642 (0.322–1.281)	n.s.	1.193 (0.567–2.510)	n.s.
PreOP VAS	1.425 (1.164–1.745)	**0.001**	1.048 (0.851–1.292)	n.s.	1.018 (0.843–1.230)	n.s.	0.992 (0.813–1.211)	n.s.
PreOP ASES	1.006 (0.978–1.034)	n.s.	0.962 (0.930–0.995)	**0.026**	0.989 (0.957–1.022)	n.s.	1.005 (0.972–1.038)	n.s.
PreOP Constant	1.008 (0.972–1.045)	n.s.	0.994 (0.954–1.035)	n.s.	0.964 (0.928–1.001)	n.s.	1.011 (0.973–1.050)	n.s.
PreOP SANE	1.005 (0.986–1.025)	n.s.	1.004 (0.982–1.027)	n.s.	1.021 (0.997–1.046)	n.s.	0.948 (0.923–0.973)	**<0.001**

Bold indicates statistical significance ($P < 0.05$)

MCID minimal clinically important difference, *CI* confidence interval, *BMI* body mass index, *DM* diabetes mellitus, *PreOP* preoperative, *VAS* visual analogue scale, *ASES* American Shoulder and Elbow Surgeons, *SANE* Single Assessment Numeric Evaluation, *n.s.* not significant

reconstruction for the four measured PROMs 2 years after surgery. The current study established the timeline of MCID achievement and identified important variables that affected this time to achievement of MCID for the VAS, ASES, Constant, and SANE scores. The mean time after the surgery to achieve MCID was 11.2 ± 0.9 months for VAS, 13.2 ± 1.0 months for ASES, 11.6 ± 0.9 months for the Constant score, and 14.4 ± 1.0 months for SANE. The higher preoperative VAS score was found to contribute to earlier MCID achievement, while higher preoperative ASES and SANE scores were found to lead to delayed MCID achievement. These results are beneficial for patient selection, patient education, and clarification of the changes in PROMs to evaluate the achievement of clinical significance after arthroscopic superior capsular reconstruction.

These results revealed that the time required to achieve MCID for the VAS, ASES, Constant, and SANE scores occurred 11–15 months after arthroscopic superior capsular reconstruction. Furthermore, these patients achieved substantial clinical benefit and PASS as soon at 14–19 months after surgery. In previous studies, pain and functional outcomes significantly improved from 1 year [7, 19, 27] to 2 years[14, 25] after arthroscopic superior capsular reconstruction, potentially explaining why most patients achieved clinically significant outcomes at 1 year and the number continued to increase until 2 years postoperatively. Furthermore, most patients had persistent improvements for clinically significant outcomes from postoperative 1–2 years, indicating that patients could achieve stable clinically significant benefits during this period. Evuarherhe et al. found that patients undergoing arthroscopic superior capsular reconstruction using a dermal allograft achieved MCID, substantial clinical benefit, PASS for ASES (64.4%, 52.2%, 40.0%), SANE (60.9%, 43.5%, 41.3%), and the Constant score (75.8%, 42.4%, 51.5%) during an average follow-up of 23 months [8]. In this study, patients using a fascia lata autograft achieved MCID, substantial clinical benefit, PASS for ASES (66.1%, 50.8%, 61.0%), SANE (69.5%, 57.6%, 67.8%), and the Constant score (81.4%, 62.7%, 69.5%) at 2 years postoperatively, which seemed to be superior using a dermal allograft. Establishing the 2-year follow-up timeline to achieve clinically significant outcomes is helpful for better patient education by informing them about the estimated time to reach satisfactory recovery. Still, it is of great importance to investigate an evidence-based path to recovery because patients' expectations can affect perceived outcomes after surgery [5, 16]. When the timeline to achieve clinically significant outcomes is better understood, limited resources, such as clinic follow-up and physical therapy sessions, can be utilised more efficiently to facilitate patient recovery after surgery. In addition, this timeline is useful for setting patient expectations of postoperative improvement. Specifically, the results of this study may be beneficial for alleviating patients' frustration and improving overall satisfaction after arthroscopic superior capsular reconstruction because the patients can expect (1) satisfactory recovery within the first year and (2) continued improvement of treatment outcomes until 2 years.

Furthermore, the time of mean achievement of clinically significant outcomes after arthroscopic superior capsular reconstruction was compared with that after arthroscopic rotator cuff repair [22]. As shown in Table 3, patients undergoing arthroscopic superior capsular reconstruction require a much longer time to achieve MCID, substantial clinical benefit, and PASS compared to those undergoing rotator cuff repair.

Several PROMs, including VAS, ASES, Constant, and SANE scores, were used to evaluate clinically significant outcome improvement in this study. MCID, substantial clinical benefit, and PASS were shown to be mostly achieved for the Constant score for the entire timeline. Prior studies have demonstrated the Constant score to be a reliable and responsive instrument for assessing postoperative improvement in shoulder function [6]. Also, the Constant score possesses good reproducibility and construct validity [13]. The high sensitivity for clinically significant outcomes improvement shown by the Constant score in the current study may reflect its well-rounded and unbiased characteristics as the Constant score emphasises both subjective and objective changes after the operation [2]. MCID obtained from the ASES score was found to decrease from postoperative 1–2 years, which was consistent with previous work [8, 11]. However, to our knowledge, the results at 1 year after arthroscopic superior capsular reconstruction are insufficiently studied.

The current cohort revealed that a higher preoperative VAS score favoured earlier MCID achievement but higher preoperative ASES and SANE scores contributed to delayed MCID achievement, demonstrating the previously reported important roles of preoperative functional conditions in MCID achievement [8, 28]. Yeom et al. found lower preoperative scores to generate significantly higher odds ratios in the postoperative MCID and substantial clinical benefit, suggesting a higher possibility of achieving MCID and substantial clinical benefit after arthroscopic superior capsular reconstruction [28]. Similarly, Evuarherhe et al. found a lower preoperative ASES score to be predictive of the achievement of MCID and substantial clinical benefit [8].

In the present study, patients with poor preoperative functional scores were demonstrated to achieve earlier MCID after surgery. Manderle et al. also found that lower preoperative scores were associated with earlier MCID achievements because a patient with worse function preoperatively is likely to gain more after arthroscopic rotator cuff repair than someone experiencing less of a preoperative deficit [22]. Furthermore, Nwachukwu et al. found that patients with higher preoperative scores took a longer time to achieve MCID and substantial clinical benefit after arthroscopic treatment of femoroacetabular impingement [24].

There are some limitations to this study. First, since the patient condition was assessed at only three time points, the exact timing of clinically significant outcomes achievement was unclear. More frequent follow-ups could further delineate outcome achievement. Second, since only patients followed up at all three time points were included, selection bias may not be avoided. Third, arthroscopic superior capsular reconstruction has only been recently introduced with narrow indications, which makes the small sample size inevitable. Fourth, mesh was used for graft augmentation in some patients, which may have an influence on the generalisation of the data from the current study.

The findings of this study offer some knowledge on counselling patients about expected outcome time frames and predictors for expedited recovery after arthroscopic superior capsular reconstruction. This study demonstrated that the time required for the average patient to achieve MCID for VAS, ASES, SANE, and the Constant score occurred at 11–15 months after ASCR. The patients could achieve substantial clinical benefit and PASS at 15–19 months postoperatively. Furthermore, our data demonstrated that patients continued to achieve subjective clinical benefits until 1 year, and a few patients continued to do so until 2 years postoperatively. As patient expectations are associated with perceived outcomes after surgery [5], this study was proposed to generate clinical benefits for recovery after arthroscopic superior capsular reconstruction.

Conclusion

Overall, most patients can achieve MCID 1 year after arthroscopic superior capsular reconstruction. A higher preoperative VAS score favours faster MCID achievement, while higher preoperative ASES and SANE scores contribute to delayed MCID achievement.

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Data availability The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Conflict of interest We have no conflict of interest to disclose.

IRB approval Institutional Review Board (IRB) approval number: 2023-0408.

Ethical approval This retrospective chart review study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The Human Investigation Committee (IRB) of Asan Medical Center approved this study.

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