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# SHOULDER & ELBOW What constitutes a clinically important change in Mayo Elbow Performance Index and range of movement after open elbow arthrolysis?

# Aims

This study aimed to determine the minimal detectable change (MDC), minimal clinically important difference (MCID), and substantial clinical benefit (SCB) under distribution- and anchor-based methods for the Mayo Elbow Performance Index (MEPI) and range of movement (ROM) after open elbow arthrolysis (OEA). We also assessed the proportion of patients who achieved MCID and SCB; and identified the factors associated with achieving MCID.

# **Methods**

A cohort of 265 patients treated by OEA were included. The MEPI and ROM were evaluated at baseline and at two-year follow-up. Distribution-based MDC was calculated with confidence intervals (CIs) reflecting 80% (MDC 80), 90% (MDC 90), and 95% (MDC 95) certainty, and MCID with changes from baseline to follow-up. Anchor-based MCID (anchored to somewhat satisfied) and SCB (very satisfied) were calculated using a five-level Likert satisfaction scale. Multivariate logistic regression of factors affecting MCID achievement was performed.

## Results

The MDC increased substantially based on selected Cls (MDC 80, MDC 90, and MDC 95), ranging from 5.0 to 7.6 points for the MEPI, and from 8.2° to 12.5° for ROM. The MCID of the MEPI were 8.3 points under distribution-based and 12.2 points under anchor-based methods; distribution- and anchor-based MCID of ROM were 14.1° and 25.0°. The SCB of the MEPI and ROM were 17.3 points and 43.4°, respectively. The proportion of the patients who attained anchor-based MCID for the MEPI and ROM were 74.0% and 94.7%, respectively; furthermore, 64.2% and 86.8% attained SCB. Non-dominant arm (p = 0.022), higher preoperative MEPI rating (p < 0.001), and postoperative visual analogue scale pain score (p < 0.001) were independent predictors of not achieving MCID for the MEPI, while atraumatic causes (p = 0.040) and higher preoperative ROM (p = 0.005) were independent risk factors for ROM.

## Conclusion

In patients undergoing OEA, the MCID for the increased MEPI is 12.2 points and 25° increased ROM. The SCB is 17.3 points and 43.3°, respectively. Future studies using the MEPI and ROM to assess OEA outcomes should report not only statistical significance but also clinical importance.

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## Introduction

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Bone Joint J 2021;103-B(2):366–372. Elbow function is important for basic life functions and more advanced activities.<sup>1</sup> Elbow stiffness leads to severe functional impairment in the upper limb and interferes with daily activities.<sup>2</sup> Generally, arthrolysis is indicated if the lost function does not improve with conservative therapy comprising physiotherapy and bracing.<sup>3,4</sup> In this respect, the elbow functional scores and mobility are the most important outcome measures before and after arthrolysis. The Mayo Elbow Performance Index (MEPI)<sup>5</sup> is the predominant functional score for evaluating elbow disorders, including elbow stiffness,<sup>6</sup> with

Table I. Comparison of study cohort and excluded patien	ts.
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Categorical variables	Study cohort (n = 265), n (%)	Patients with incomplete records (n = 155), n (%)	p-value*
Female	102 (38)	54 (34)	0.304
Overweight	98 (37)	46 (29)	0.075
Non-dominant arm	110 (42)	74 (48)	0.214
Aetiology (atraumatic vs traumatic)	27 (10)	9 (6)	0.098
Preoperative MEPI (excellent to good)†	95 (36)	70 (43)	0.117
Preoperative ROM (non-severe)‡	58 (22)	33 (20)	0.734
Continuous variables	Study cohort (n = 265), n (%)	Patients with incomplete records (n = 155), n (%)	p-value§
Age, years	37 (12)	33 (14)	0.258
Disease duration, months	27 (46)	28 (44)	0.641
Preoperative VAS for pain, points	2.2 (2.2)	1.5 (2.3)	0.066

\*Chi squared test or Fisher's exact test.

+Patients whose preoperative MEPI ratings were good or excellent (excellent, 90 to 100 points; good, 75 to 89 points; fair, 60 to 74 points; and poor, 0 to 59 points).

\*Patients whose preoperative ROM was not severe according to Mansat classification (mild, > 90°; moderate, 60° to 90°; severe, 30° to 60°; and very severe, < 30°).<sup>17</sup>

§Independent-samples t-test.

MEPI, Mayo Elbow Performance Index; ROM, range of movement; VAS, visual analogue scale.

Table II. Minimal detectable change, minimal clinically important change, and substantial clinical benefit.

Variables	MDC*			Minimal clinically important change		Substantial clinical benefit
	MDC 80	MDC 90	MDC 95	Distribution-based	Anchor-based	Anchor-based
MEPI, points	5.0	6.4	7.6	8.3	12.2	17.3
ROM, °	8.2	10.5	12.5	14.1	25.0	43.4
Extension, °	5.6	7.2	8.6	9.6	10.8	20.2
Flexion, °	6.9	8.8	10.5	11.0	14.5	23.1

\*Calculated with confidence intervals reflecting 80%, 90%, and 95% certainty reported, respectively, as MDC 80, MDC 90, and MDC 95

MDC, minimal detectable change; MEPI, Mayo Elbow Performance Index; ROM, range of movement.

range of movement (ROM, flexion-extension) being the most common obstacle for patients.

A challenge in using such outcome instruments is determining the clinical relevance of the changes in the scores during the course of treatment. Statistically significant changes do not necessarily imply clinical relevance; these changes may be clinically meaningless or even imperceptible to patients.<sup>7,8</sup> A clinically relevant change can be calculated by various methods, such as the minimal detectable change (MDC), minimal clinically important difference (MCID), and substantial clinical benefit (SCB). The MDC is defined as an indicator of the confidence that a change of the magnitude observed exceeds that of the measurement error. It is the smallest change that most likely reflects "true" change rather than simply variation as a result of measurement error.<sup>9</sup> The MCID, also sometimes referred to as the "minimal clinically important change" or "minimal clinically important improvement", is defined as the "smallest difference in the score in the domain of interest which patients perceive as beneficial".<sup>10,11</sup> The SCB is described as an alternative psychometric value that reflects the lower limit for defining optimal patient benefit.<sup>12</sup> These values carry the important clinical implications. Changes in the score that are less than the MDC imply a clinically irrelevant alteration, and score changes less than the MCID should be considered failures in treatment. Any change in a score falling between the MCID and SCB represents a result which is somewhere between perceptible and meaningful, but less than the substantial, but this depends on how the MCID is anchored in the surveys on which it is based. Only changes exceeding SCB should be looked upon as completely successful.

To the best of our knowledge, no study has evaluated the clinically relevant change in elbow-related outcome scores in a homogeneous patient population with elbow stiffness.<sup>13–16</sup> Therefore, this study aimed to calculate the MDC, MCID, and SCB under distribution- and anchor-based methods for the MEPI and ROM after open elbow arthrolysis (OEA); to assess the proportion of patients who achieved MCID and SCB; and to identify the factors associated with achieving MCID.

#### Methods

**Study participants.** Patients undergoing OEA in our institution (Shanghai Sixth People's Hospital East Campus) between January 2015 and June 2017 were included (n = 420). Our indications for OEA were lack of benefit from a six-month trial of nonoperative therapy; a restricted ROM defined as extension  $> 30^\circ$  or flexion  $< 130^\circ$ ; normal alkaline phosphatase, clear margins for any heterotopic ossification (HO) revealed on imaging; absence of complete destruction of the articular surface shown on imaging; absence of systemic or local signs of infection; absence of severe systemic disorders prohibiting operation; and psychologically normal and fully commited towards surgery, and able to cooperate with postoperative rehabilitation.

Among these, patients undergoing secondary operations in the same upper limb during the follow-up period, those without two-year satisfaction scores, and those with missing two-year follow-up MEPI or ROM were excluded (36.9%, n



The anchor-based MCID and SCB calculations of the MEPI, extension, flexion, and ROM for open elbow arthrolysis. For example, for MEPI: no significant difference (p = 0.685) was found among preoperative MEPI for the S (67.4 points), M (65.4 points), and N (66.5 points) groups. The mean changes ( $^{\triangle}$ ) of the MEPI from preoperative to two-year follow-up were 27.9 points, 22.8 points, and 10.6 points for S, M and N groups, respectively. Therefore, anchor-based MCID and SCB of the MEPI were 12.2 points (M minus N) and 17.3 points (S minus N). M, minimum improvement group; MCID, minimal clinically important difference; MEPI, Mayo Elbow Performance Index; N, no change group; ROM, range of movement; S, substantial improvement group.

= 155) from the analysis. A final cohort of 265 patients from 420 eligible patients (63.1%, n = 265) was assessed.

**Study population demographics.** The overall study population, included 163 males (61.5%) and 102 females (38.5%), with a mean age 37 years (SD 12; 8 to 67) at the time of release. The series had a wide spectrum of aetiologies for elbow stiffness, including trauma (n = 238, 89.8%) and atraumatic factors (n = 27, 10.2%). The mean time from index injury to arthrolysis in traumatic cases was 23 months (6 to 360), and the most common cause was distal humeral fracture (n = 82, 30.9%). Atraumatic causes mainly consisted of osteoarthritis and synovitis, but did not include neurogenic or congenital causes. The baseline variables between the included (n = 265) and excluded (n = 155) patients are compared in Table I. **MEPI and elbow range of movement**. Morrey and Adams<sup>5</sup> developed the MEPI in 1992 to evaluate outcomes after total elbow arthroplasty. It consists of four subscales, which are pain (45%), ROM (20%), stability (10%), and daily function (25%), with a score range from 0 to 100 points, and it is classified into four ranks: excellent, 90 to 100; good, 75 to 89; fair, 60 to 74; and poor, 0 to 59.

The ROM (including flexion and extension) was measured by using a goniometer, as described in previous studies,<sup>18</sup> with three landmarks: the lateral epicondyle (on which the goniometer was centred); the tip of the acromion process (at which the stationary arm was pointed); and the middle portion of the wrist (to which the mobile arm was pointed).

Variables	R-value	Standard error	T-value	p-value
MCID of MEPI score				p + 4.440
Non-dominant arm		0.042	2.296	0.022
Postoperative VAS for pain	0.659	0.016	-8.760	< 0.001
Preoperative MEPI (excellent to good)*		0.045	10.000	< 0.001
Preoperative ROM (non-severe)†		0.053	1.729	0.085
MCID of ROM				
Age, yrs	0.255	0.001	1.672	0.096
Preoperative VAS for pain		0.000	0.889	0.375
Aetiology (atraumatic)		0.036	2.063	0.040
Preoperative BOM (pop-severe)†		0.026	2 811	0.005

Table III. Results of multivariate linear regression for potential variables affecting the minimal clinically important difference (MCID) of the Mayo Elbow Performance Index (MEPI) and range of movement (ROM).

\*Patients whose preoperative MEPI ratings are good or excellent (excellent, 90 to 100 points; good, 75 to 89 points; fair, 60 to 74 points; and poor, 0 to 59 points).

<sup>†</sup>Patients whose preoperative ROM are not severe according to Mansat classification (mild, > 90°; moderate, 60 to 90°; severe, 30 to 60°; and very severe, < 30°).<sup>17</sup>

VAS, visual analogue scale.

In order to maximize the reliability and reproducibility, all MEPI and ROM measurements were performed by the corresponding author (CF) preoperatively, and at follow-up, who evaluated the four MEPI subscales (the second subscale was just ROM) together with the patients, and calculated the total scores.

In addition to the MEPI and ROM, patients also completed a five-level Likert satisfaction scale at follow-up: "Overall, how satisfied are you with the results of your elbow arthrolysis?" There were five answer options, namely, "very satisfied", "somewhat satisfied", "no change", "somewhat dissatisfied", and "very dissatisfied".

#### **Statistical analysis**

**Minimal detectable change.** The MDC calculations rely on a distribution-based method that reflects a correction factor applied to the standard error of measurement (SEM)<sup>19</sup> which was based on 80%, 90%, and 95% confidence intervals (CIs) (MDC 80, MDC 90, and MDC 95), corresponding to 5:1, 10:1, and 20:1 likelihood, respectively. The formula was: MDC = z x SEM x  $\sqrt{2}$ , in which the "z" equals 1.28 to MDC 80, 1.64 to MDC 90, and 1.96 to MDC 95, and the "SEM" was calculated as SEM = SD x  $\sqrt{(1 - intraclass correlation coefficient}$ (ICC)), with SD representing the SD of the baseline MEPI and ROM,<sup>20</sup> and ICC representing the reliability.<sup>15,21</sup> Previous studies showed the ICCs for the MEPI and ROM were 0.96 and 0.97, respectively.<sup>18,21</sup>

**Minimal clinically important difference**. At least nine methodologies have been reported in estimating MCID.<sup>22</sup> In this study, distribution- and anchor-based methods were both used. The distribution-based calculation most often used for MCID is MCID =  $0.5 \times SD$  of the  $\delta$  (MEPI and ROM changes from baseline to follow-up).<sup>23</sup> As for anchor-based MCID calculation, the five-level Likert satisfaction scale has often been used as an anchor in total shoulder arthroplasty (TSA)<sup>24</sup> and total hip arthroplasty (THA).<sup>25</sup> The anchor-based MCID is obtained by subtracting the mean change in the MEPI and ROM of the patients reporting "no change" or "somewhat dissatisfied" from that of those reporting "somewhat satisfied". The patients who reported that they were "very dissatisfied" were not included in the analysis, of whom there were six in this study, as they did not represent a minimal change or they showed no change/slight worsening.

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**Substantial clinical benefit.** The five-level Likert satisfaction scale was again used as anchor questions in this analysis. Indeed, patients who reported being "somewhat satisfied" were deemed to have minimal improvement, whereas patients who reported being "very satisfied" experienced substantial improvement. Therefore, to define optimal improvement for the anchor-based SCB, the difference in the MEPI and ROM between those who answered "no change" or "somewhat dissatisfied" and those who reported "very satisfied" was determined.

After calculating candidate MDCs, MCIDs, and SCBs for the MEPI and ROM, the proportion of patients in the cohort who achieved these values was determined. For validity, the scores for MDC should be lower than for MCID, which should be lower than the SCB.<sup>26</sup>

Univariate analysis of factors, including the demographic and clinical characteristics, was performed with the single risk factor of interest. Multivariate logistic regression of factors that influence the achievement of MCID was performed using forward stepwise selection of the risk factors with a probability < 0.10 in the univariate analysis. For regression analysis, a probability < 0.05 was considered statistically significant.

#### Results

**Minimal detectable change based on selected confidence intervals.** The MDCs calculated under the distribution-based method for the entire cohort increased substantially based on selected CIs (MDC 80, MDC 90 to MDC 95), ranging from 5.0 to 7.6 points for the MEPI, and from 8.2° to 12.5° for ROM, with approximately 1.5-times the value seen in MDC 95 than those in MDC 80. The MDC of extension and flexion are shown in Table II.

Validity of minimal clinically important difference estimates. The validity of MCID calculated using anchor- and distribution-based methods were determined whether the values were greater than MDC. The MCID of the MEPI were 8.3 points under distribution-based, and 12.2 points under anchor-based

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**Table IV.** Results by univariate analysis for the factors that influence the minimal clinically important difference (MCID) of the Mayo Elbow Performance Index (MEPI).

Categorical variables	OR (95% CI)	p-value*
Female	1.152 (0.650 to 2.042)	0.627
Overweight	1.037 (0.579 to 1.857)	0.903
Non-dominant arm	1.636 (0.929 to 2.881)	0.087
Aetiology (atraumatic vs traumatic)	0.488 (0.162 to 1.466)	0.193
Preoperative MEPI (excellent to good)†	12.063 (6.169 to 23.588)	< 0.001
Preoperative ROM (non-severe)‡	3.200 (1.693 to 6.048)	< 0.001
Postoperative nerve symptoms	1.208 (0.564 to 2.588)	0.627
Continuous variables	Mean difference (95% CI)	p-value§
Age, yrs	-2 (-5 to 2)	0.724
Disease duration, mths	-4 (-19 to 7)	0.107
Preoperative VAS for pain	-6 (-10 to 3)	0.131
Postoperative VAS for pain	11 (7 to 16)	< 0.001

\*Chi squared test or Fisher's exact test.

\*Patients whose preoperative MEPI ratings are good or excellent (excellent, 90 to 100 points; good, 75 to 89 points; fair, 60 to 74 points; and poor, 0 to 59 points).

\*Patients whose preoperative range of movement is not severe restricted according to Mansat classification (mild, > 90°; moderate, 60 to 90°; severe, 30 to 60°; and very severe, < 30°).<sup>17</sup>

§Independent-samples *t*-test.

CI, confidence interval; ROM, range of movement; VAS, visual analogue scale.

methods, which were greater than the corresponding MDC 95 (7.6 points). The distribution- and anchor-based MCID of ROM were 14.1° and 25.0°, respectively, and both were higher than the corresponding MDC 95 (12.5°). The MCID of extension and flexion are shown in Table II and Figure 1.

**Substantial clinical benefit thresholds.** The thresholds of SCB calculated using the anchor-based method were also determined. The SCB of the MEPI and ROM for the entire cohort were 17.3 points and 43.4°, respectively, which exceeded the corresponding anchor-based MCID (12.2 points and 25.0°). The SCB of extension and flexion are shown in Table II and Figure 1.

**Proportions of patients achieving MCID and SCB**. The proportion of patients who attained MCID of the MEPI, extension, flexion, and ROM was 84.2% (223/265), 88.7% (235/265), 95.5% (253/265), and 97.0% (257/265), respectively, under the distribution-based method, and for the anchor-based method was 74.0% (196/265), 83.8% (222/265), 95.5% (252/265), and 94.7% (251/265), respectively. Furthermore, 64.2% (170/265), 62.2% (165/265), 87.2% (231/265), and 86.8% (230/265), respectively, attained anchor-based SCB. As expected, the percentage attaining MCID was greater than for SCB.

Non-dominant arm (p = 0.022), higher preoperative MEPI rating (p < 0.001), and postoperative visual analogue scale (VAS) pain score (p < 0.001) remained independent predictors of not achieving a MCID for the MEPI score after elbow arthrolysis in the multivariate logistic regression analysis, while atraumatic causes (p = 0.040) and higher preoperative ROM (p = 0.005) were independent risk factors of not achieving MCID for the ROM (Table III). Preliminary univariate analysis also included age and preoperative VAS pain score as substantial

**Table V.** Results by univariate analysis for the factors that influence minimal clinically important difference (MCID) of range of movement (ROM).

Categorical variables	OR (95% CI)	p-value*
Female	2.691 (0.629 to 11.516)	0.268
Overweight	3.198 (0.746 to 13.699)	0.204
Non-dominant arm	1.413 (0.346 to 5.781)	0.723
Aetiology (atraumatic vs traumatic)	5.675 (1.277 to 25.228)	0.011
Preoperative MEPI (excellent to good)†	3.142 (0.733 to 13.458)	0.213
Preoperative ROM (non-severe)‡	6.871 (1.588 to 29.733)	0.012
Postoperative nerve symptoms	1.928 (0.375 to 9.918)	0.767
Continuous variables	Mean difference (95% CI)	p-value§
Age, yrs	8 (0 to 16)	0.073
Disease duration, mths	-5 (-38 to 27)	0.495
Preoperative VAS for pain	6 (-11 to 20)	0.052
Postoperative VAS for pain	6 (-3 to 15)	0.359

\*Chi squared test or Fisher's exact test.

†Patients whose preoperative MEPI ratings are good or excellent (excellent, 90 to 100 points; good, 75 to 89 points; fair, 60 to 74 points; and poor, 0 to 59 points).

\*Patients whose preoperative range of movement is not severely restricted according to Mansat classification (mild, > 90°; moderate, 60 to 90°; severe, 30 to 60°; and very severe, < 30°).</p>

§Independent-samples t-test.

CI, confidence interval; MEPI, Mayo Elbow Performance Index; VAS, visual analogue scale.

risk factors for not achieving the MCID, but these factors were non-significant in the multivariate analysis (Tables IV to V).

# Discussion

Scoring systems are increasingly used as functional measurement tools for orthopaedic patients. To the best of our knowledge, this is the first study which comprehensively evaluates the properties of the MDC, MCID, and SCB for the MEPI and ROM in a homogeneous patient population who underwent OEA for elbow stiffness. Ultimately, in a whole population of 265 patients with elbow stiffness, we found that the MCID for the MEPI and ROM (extension and flexion) were 12.2 points and 25.0° (10.8° and 14.5°), respectively, and the SCB were 17.3 points and 43.4° (20.2° and 23.1°), respectively.

Both distribution- and anchor-based methods are widely used to determine the important clinical changes. The advantage of distribution approaches is that they are easy to use because only a single timepoint is required, while the limitations are the differences in the estimates of variability between studies, and the absence of a clinical component which is insufficient for the interpretation of clinical results.<sup>13</sup> In principle, the anchorbased MCID may be considered superior to a distribution-based MCID because it relies on patient-reported improvements rather than an arbitrary sample distribution;<sup>27</sup> therefore, we use the anchor-based MCID for analysis of risk factors. A patient's retrospective rating of a change in status is used to determine the anchor-based MCID. Once the anchor has been chosen, several different methods can be used to derive the MCID. The easiest and most widely used method is specifying a range of anchor instrument results that correspond to the MCID and calculating the change in the outcome score that correlates with that range of values. We used this method in our analysis. The

other studies have used receiver operating curves to determine the MCID on the basis of the results of anchor instruments.<sup>28,29</sup>

A variety of instruments have been used to evaluate the outcomes of elbow disorders, however, very little is known about what constitutes a clinically relevant change.13,16,30-32 To the best of our knowledge, the SCB has not been reported previously for the MEPI, and the MCID was calculated in only one study. The researchers calculated MCID for the MEPI in 23 patients with rheumatoid arthritis using the patient global perceived effect as the external criterion for discrimination between improved and non-changed, with 15 MEPI points, which is slightly higher than our estimation (12 MEPI points).<sup>31</sup> Additionally, we also reported MCID and SCB which, to the best of our knowledge, have not been reported previously for ROM. Interestingly, O'Neill et al<sup>33</sup> indicated that flexion was more critical than extension in a ratio of approximately 2:1. The percentages of patients who attained MCID and SCB of extension and flexion in this study were higher in flexion than in extension.

Risk factors for the achievement of clinically important change after OEA have not been reported using the MEPI and ROM as an outcome measure or even elbow-related scoring systems but, in studies on other upper limb articulations (shoulder), a similar research question was investigated.<sup>24,34-36</sup> Researchers have found that higher preoperative American Shoulder and Elbow Surgeons-Shoulder (ASES)37 (odds ratio (OR) 0.96; p < 0.001) and history of a reverse shoulder arthroplasty (OR 0.36, p = 0.016) were associated with failure to achieve a MCID after TSA;24 and neurologic dysfunction (p = 0.006), age < 60 years (p = 0.020), and high preoperative Simple Shoulder Test score (p = 0.030) were independent risk factors after reverse total shoulder arthroplasty.<sup>34</sup> Using the MEPI and ROM as an endpoint, we noted similar results showing that higher preoperative scores and ROM predict a higher likelihood of not achieving MCID after OEA. This finding is important for surgical decision-making and for counselling patients before OEA, as patients with high levels of preoperative function or ROM may not experience marked benefits from the procedure compared with those with lower levels of preoperative function or ROM.

There are several limitations of our study. A major limitation is the substantial number of patients lost to follow-up. Patients who do not return for follow-up may have worse outcomes, which would affect the MCID and SCB, especially the anchorbased results. The incomplete follow-up rate in this study is 36.9% (155/420), but we have shown that the included patients and those lost to follow-up have similar baseline parameters. Secondy, the follow-up period is another potential limitation. We chose a minimum two-year follow-up period, which we believe is acceptable, as elsewhere studies have shown that the MEPI and ROM are likely comparable with five-year follow-up.38 However, they may not be generalizable to those calculated using a longer follow-up. Thirdly, this study is a retrospective review of a longitudinally maintained database, thus it is subject to selection, transfer, and assessment bias. The patients included are from one institution, which introduces selection bias and reduces the generalizability of the findings to other settings. Fourthly, in order to maximize the reliability

and reproducibility, all the MEPI and ROM measurements were performed by the corresponding author. Although this might introduce a measurement bias, previous studies showed the ICCs for the MEPI and ROM were 0.96 and 0.97,<sup>18,21</sup> which indicate high reliability. Therefore, we believe this would have little effect on the outcomes. Finally, the findings of this study may be applicable only to patients with surgical release of elbow stiffness, as we did not include patients who had undergone purely nonoperative treatment.

In patients undergoing OEA, the MCID in the MEPI is 12.2 and the SCB is 17.3 points. The MCID improvement in ROM is 25.0° and the SCD is 43.4°. These parameters are essential to interpret OEA outcomes and to ensure clinical studies are amply powered to detect meaningful differences. Future studies using the MEPI and ROM to assess OEA outcomes should report not only the statistical significance (p-values), but also the clinical importance (MCID and SCB).

### Take home message

- The minimal clinically important difference (MCID) of the Mayo Elbow Performance Index (MEPI) were 8.3 points disttribution-based and 12.2 points under anchor-based

methods; the distribution- and anchor-based MCID of range of movement (ROM) were 14.1° and 25.0°. The substantial clinical benefit (SCB) of MEPI and ROM were 17.3 points and 43.4°.

- The percentages of patients who attained anchor-based MCID of MEPI and ROM were 74.0% and 94.7%; furthermore, 64.2% and 86.8% attained SCB.

- Non-dominant arm, higher preoperative MEPI rating, and postoperative visual analogue scale pain score were independent predictors of not achieving MCID for MEPI, while atraumatic causes and higher preoperative ROM were independent risk factors for ROM.

#### Reference

- Morrey BF, Askew LJ, Chao EY. A biomechanical study of normal functional elbow motion. J Bone Joint Surg Am. 1981;63-A(6):872–877.
- Sun Z, Cui H, Ruan J, et al. What range of motion and functional results can be expected after open arthrolysis with hinged external fixation for severe posttraumatic elbow stiffness? *Clin Orthop Relat Res.* 2019;477(10):2319–2328.
- Jones V. Conservative management of the post-traumatic stiff elbow: a physiotherapist's perspective. Shoulder Elbow. 2016;8(2):134–141.
- 4. Veltman ES, Doornberg JN, Eygendaal D, van den Bekerom MPJ. Static progressive versus dynamic splinting for posttraumatic elbow stiffness: a systematic review of 232 patients. Arch Orthop Trauma Surg. 2015;135(5):613–617.
- Morrey BF, Adams RA. Semiconstrained arthroplasty for the treatment of rheumatoid arthritis of the elbow. J Bone Joint Surg Am. 1992;74-A(4):479–490.
- Evans JP, Smith CD, Fine NF, et al. Clinical rating systems in elbow research-a systematic review exploring trends and distributions of use. J Shoulder Elbow Surg. 2018;27(4):e98–e106.
- Crosby RD, Kolotkin RL, Williams GR. Defining clinically meaningful change in health-related quality of life. J Clin Epidemiol. 2003;56(5):395–407.
- Revicki D, Hays RD, Cella D, Sloan J. Recommended methods for determining responsiveness and minimally important differences for patient-reported outcomes. J Clin Epidemiol. 2008;61(2):102–109.
- de Vet HC, Terwee CB, Ostelo RW, et al. Minimal changes in health status questionnaires: distinction between minimally detectable change and minimally important change. *Health Qual Life Outcomes.* 2006;4(1):54.
- Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. *Control Clin Trials*. 1989;10(4):407–415.
- Leopold SS, Porcher R. Editorial: The minimum clinically important difference the least we can do. *Clin Orthop Relat Res.* 2017;475(4):929–932.
- Glassman SD, Copay AG, Berven SH, et al. Defining substantial clinical benefit following lumbar spine arthrodesis. J Bone Joint Surg Am. 2008;90-A(9):1839–1847.
- Copay AG, Chung AS, Eyberg B, et al. Minimum clinically important difference: current trends in the orthopaedic literature, part I: upper extremity: a systematic review. JBJS Rev. 2018;6(9):e1.

- Smith MV, Calfee RP, Baumgarten KM, Brophy RH, Wright RW. Upper extremity-specific measures of disability and outcomes in orthopaedic surgery. J Bone Joint Surg Am. 2012;94-A(3):277–285.
- Sun Z, Liu W, Wang W, Fan C. Development and validation of a new elbow-specific scoring system for patients with elbow stiffness: the Shanghai Elbow dysfunction score. J Shoulder Elbow Surg. 2019;28(2):296–303.
- The B, Reininga IHF, El Moumni M, Eygendaal D. Elbow-specific clinical rating systems: extent of established validity, reliability, and responsiveness. J Shoulder Elbow Surg. 2013;22(10):1380–1394.
- Mansat P, Morrey BF. The column procedure: a limited lateral approach for extrinsic contracture of the elbow. J Bone Joint Surg Am. 1998;80(11):1603–1618.
- Chapleau J, Canet F, Petit Y, Laflamme G-Y, Rouleau DM. Validity of goniometric elbow measurements: comparative study with a radiographic method. *Clin Orthop Relat Res.* 2011;469(11):3134–3140.
- Turner D, Schünemann HJ, Griffith LE, et al. The minimal detectable change cannot reliably replace the minimal important difference. J Clin Epidemiol. 2010;63(1):28–36.
- 20. Lyman S, Lee Y-Y, McLawhorn AS, Islam W, MacLean CH. What are the minimal and substantial improvements in the HOOS and KOOS and JR versions after total joint replacement? *Clin Orthop Relat Res.* 2018;476(12):2432–2441.
- de Boer YA, van den Ende CH, Eygendaal D, et al. Clinical reliability and validity of elbow functional assessment in rheumatoid arthritis. *J Rheumatol.* 1999;26(9):1909–1917.
- Wright A, Hannon J, Hegedus EJ, Kavchak AE. Clinimetrics corner: a closer look at the minimal clinically important difference (MCID). J Man Manip Ther. 2012;20(3):160–166.
- 23. Berliner JL, Brodke DJ, Chan V, SooHoo NF, Bozic KJ. Can preoperative patient-reported outcome measures be used to predict meaningful improvement in function after TKA? *Clin Orthop Relat Res.* 2017;475(1):149–157.
- 24. Werner BC, Chang B, Nguyen JT, Dines DM, Gulotta LV. What change in American shoulder and elbow surgeons score represents a clinically important change after shoulder arthroplasty? *Clin Orthop Relat Res.* 2016;474(12):2672–2681.
- 25. Paulsen A, Roos EM, Pedersen AB, Overgaard S. Minimal clinically important improvement (MCII) and patient-acceptable symptom state (pass) in total hip arthroplasty (THA) patients 1 year postoperatively. Acta Orthop. 2014;85(1):39–48.
- 26. Theodore BR. Methodological problems associated with the present conceptualization of the minimum clinically important difference and substantial clinical benefit. *Spine J.* 2010;10(6):507–509.
- McGlothlin AE, Lewis RJ. Minimal clinically important difference: defining what really matters to patients. JAMA. 2014;312(13):1342–1343.
- Nwachukwu BU, Fields K, Chang B, et al. Preoperative outcome scores are predictive of achieving the minimal clinically important difference after arthroscopic treatment of femoroacetabular impingement. Am J Sports Med. 2017;45(3):612–619.
- 29. Thigpen CA, Shanley E, Momaya AM, et al. Validity and responsiveness of the single alpha-numeric evaluation for shoulder patients. Am J Sports Med. 2018;46(14):3480–3485.
- Dawson J, Doll H, Boller I, et al. Comparative responsiveness and minimal change for the Oxford elbow score following surgery. *Qual Life Res.* 2008;17(10):1257–1267.
- de Boer YA, Hazes JM, Winia PC, Brand R, Rozing PM. Comparative responsiveness of four elbow scoring instruments in patients with rheumatoid arthritis. J Rheumatol. 2001;28(12):2616–2623.
- 32. Vishwanathan K, Alizadehkhaiyat O, Kemp GJ, Frostick SP. Minimal clinically important difference of Liverpool elbow score in elbow arthroplasty. JSES Open Access. 2017;1(3):144–148.
- O'Neill OR, Morrey BF, Tanaka S, An KN. Compensatory motion in the upper extremity after elbow arthrodesis. *Clin Orthop Relat Res.* 1992;281:89–96.
- Hartzler RU, Steen BM, Hussey MM, et al. Reverse shoulder arthroplasty for massive rotator cuff tear: risk factors for poor functional improvement. J Shoulder Elbow Surg. 2015;24(11):1698–1706.
- 35. Tashjian RZ, Deloach J, Green A, Porucznik CA, Powell AP. Minimal clinically important differences in ASES and simple shoulder test scores after nonoperative treatment of rotator cuff disease. J Bone Joint Surg Am. 2010;92-A(2):296–303.

- 36. Tashjian RZ, Hung M, Keener JD, et al. Determining the minimal clinically important difference for the American shoulder and elbow surgeons score, simple shoulder test, and visual analog scale (vas) measuring pain after shoulder arthroplasty. J Shoulder Elbow Surg. 2017;26(1):144–148.
- King GJ, Richards RR, Zuckerman JD, et al. A standardized method for assessment of elbow function. Research Committee, American shoulder and elbow surgeons. J Shoulder Elbow Surg. 1999;8(4):351–354.
- Sharma S, Rymaszewski LA. Open arthrolysis for post-traumatic stiffness of the elbow: results are durable over the medium term. J Bone Joint Surg Br. 2007;89(6):778–781.

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