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 CIs (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.

Introduction
Elbow function is important for basic life functions and more advanced activities. Elbow stiffness leads to severe functional impairment in the upper limb and interferes with daily activities. Generally, arthrolysis is indicated if the lost function does not improve with conservative therapy comprising physiotherapy and bracing. 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) is the predominant functional score for evaluating elbow disorders, including elbow stiffness.
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.1,5 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.9 The smallest change that most likely reflects “true” change rather than simply variation as a result of measurement error. It is the smallest change that most likely reflects “true” change rather than simply variation as a result of measurement error.

Table I. Comparison of study cohort and excluded patients.

| 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°).

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.

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° or flexion < 130°; 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 committed 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 (Δ) 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.

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.

MEPI and elbow range of movement. Morrey and Adams5 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,18 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).
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)\(^9\) 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 = \( z \times \text{SEM} \times \sqrt{2} \), 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 \( \text{SEM} = \text{SD} \times \sqrt{1 - \text{ICC}} \), with SD representing the SD of the baseline MEPI and ROM,\(^19\) and ICC representing the reliability.\(^15,21\) Previous studies showed the ICCs for the MEPI and ROM were 0.96 and 0.97, respectively.\(^18,21\)

**Minimal clinically important difference.** At least nine methodologies have been reported in estimating MCID.\(^22\) In this study, distribution- and anchor-based methods were both used. The distribution-based calculation most often used for MCID is MCID = 0.5 x SD of the \( \delta \) (MEPI and ROM changes from baseline to follow-up).\(^23\) As for anchor-based MCID calculation, the five-level Likert satisfaction scale has often been used as an anchor in total shoulder arthroplasty (TSA)\(^24\) and total hip arthroplasty (THA).\(^25\) 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.

**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.\(^26\)

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
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 atrophic 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 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 14.1° and 25.0° (10.8° and 14.5°), 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.

**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 (traumatic 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 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°).§Independent-samples t-test.
CI, confidence interval; ROM, range of movement; VAS, visual analogue scale.

**Table V.** Results by univariate analysis for the factors that influence the 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 (traumatic 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°).
§Independent-samples t-test.
CI, confidence interval; MEPI, Mayo Elbow Performance Index; VAS, visual analogue scale.
other studies have used receiver operating curves to determine the MCID on the basis of the results of anchor instruments.28,29

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.3,13,16,20–32 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).31 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 al33 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.24,25,26 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.34 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 anchor-based 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. Secondly, 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.28 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 0.97,19,21 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 distribution-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 lower preoperative ROM as an outcome measure or even elbow-related scoring systems but, in studies on other upper limb articulations, have not been reported using the MEPI and ROM.

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Ethical review statement:
The Ethics Committee of Shanghai Sixth People’s Hospital East Campus concluded that no approval was necessary for this study based on its retrospective design. Data were analyzed anonymously, all patients approved the publication of the results of this study by oral consent. All clinical investigations were conducted in accordance with the guidelines of the Declaration of Helsinki.

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