

博 士 論 文

**Evaluation of the therapeutic effectiveness of EMG
bio-feedback therapy after elbow surgery using
minimal detectable change as performance indicators
: an observational case series study**

肘関節術後における筋電図バイオフィードバック療法に
対する治療効果判定に用いる最小可検変化量
: 症例観察研究

埼玉県立大学大学院
保健医療福祉学研究科
博士論文

2020年3月

高 橋 里 奈

Evaluation of the therapeutic effectiveness of EMG
bio-feedback therapy after elbow surgery using
minimal detectable change as performance indicators
: an observational case series study

肘関節術後における筋電図バイオフィードバック療法に
対する治療効果判定に用いる最小可検変化量
: 症例観察研究

埼玉県立大学大学院
保健医療福祉学研究科
博士論文

2020年3月

1891003

高橋 里奈

Contents

Abstract	3
Abbreviations	5
1. Introduction	6
2. Methods	11
2.1. Statement of ethics	11
2.2. Post-operative rehabilitation program	12
2.3. Biofeedback therapy.....	12
2.4. Measured outcomes	14
2.5. Signal processing and analysis	15
2.6. Data analysis	16
3. Results	19
4. Discussion	22
5. Conclusion	27
Acknowledgments	28
References	29
Figure Legends	41
Figure	47
Appendix 1. DASH	54
Appendix 2. DASH-JSSH	58
Appendix 3. PREE	63
Appendix 4. PREE – J	66

Abstract

Introduction: Electromyographic biofeedback (EMG-BF) therapy provides information on the state of contraction of targeted muscles and relaxation of their antagonists, which can facilitate early active range of motion (RoM) after elbow surgery. Our aim in this study was to calculate the minimum detectable change (MDC) in EMG-BF therapy, initiated in the early postoperative period after elbow surgery.

Methods: This study is an observational case series study. Thirty-six patients, 53 ± 16 years old, who underwent surgery were enrolled. EMG-BF of muscle contraction and relaxation was provided during active elbow flexion and extension exercises. Patients completed 3 sets of 10 trials each of flexion and extension, for 4 weeks. Total range of flexion-extension motion and scores on the Japanese Society for Surgery of the Hand version of the Disability of the Arm, Shoulder, and Hand questionnaire (DASH-JSSH) and the Japanese version of the Patient-Rated Elbow Evaluation (PREE-J) were obtained at baseline and weekly during the 4-week period of intervention. A prediction formula was created from the time series data obtained during the intervention period, using the least-squares method. The estimated value was calculated by removing the slope from the prediction formula and adding initial scores to residuals between measured scores and predicted scores individually.

Systematic error, MDC at the 95th percentile cutoff (MDC₉₅), repeatability of measures, and the change from baseline to each time point of intervention were assessed.

Results: There was no evidence of systematic bias between the baseline and 4-week data on the Bland-Altman analysis. Repeatability of measurement was excellent for range of motion and the DASH-JSSH score, and good-to-excellent for the PREE-J score. Improvement in total elbow RoM and the DASH-JSSH and PREE-J scores exceeded the MDC₉₅, indicative of a clinically meaningful change from baseline to week 4 of EMG-BF therapy.

Conclusions: The MDC₉₅, which is an indicator of the efficacy of EMG-BF therapy after surgery around the elbow, was determined using the data for the early postoperative initiation of the elbow ROM and ADL. The calculated MDC values could be used as reference values to assess the therapeutic effects in individuals.

Abbreviations

BA analysis= Bland-Altman analysis, BA plots= Bland-Altman plots, DASH = Disability of the Arm, Shoulder, and Hand questionnaire, DASH-DS = DASH subscale: disability and symptoms, DASH-JSSH = Japanese version of DASH, EMG-BF = Electromyographic biofeedback, ICC = intraclass correlation coefficient, MDC = minimum detectable change, MCID = Minimal Clinically Important Difference, MDC_{90} = minimum detectable change at the 90th percentile cutoff, MDC_{95} = minimum detectable change at the 95th percentile cutoff, PREE = Patient-Rated Elbow Evaluation, PREE-F = PREE subscales: function, PREE-J = Japanese version of PREE, PREE-P = PREE subscales: pain, PREE-SF = PREE subscales: specific activities, PREE-UF = PREE subscales: usual activities, PRO = patient-reported outcomes, RoM = range of motion, SEM = standard error of the measurement.

1. Introduction

The elbow joint is particularly prone to the development of contractures after surgery due to shortening of peri-articular soft tissues during prolonged immobilization ^[1]. Early mobilization of the elbow joint after surgery is, therefore, recommended to avoid this complication ^[2], and patients are advised to perform active elbow flexion and extension within a non-painful range. Fear of moving the elbow immediately after surgery is, thus, a risk factor for post-operative contracture ^[3]. Electromyographic biofeedback (EMG-BF) therapy provides information on the state of contraction of targeted muscles and relaxation of their antagonists, which can facilitate early active range of motion (RoM) after elbow surgery, as well as reduce pain and, therefore, anxiety around moving the elbow ^[4, 5]. The ability to “self-regulate” the contraction and relaxation of muscles during active elbow movement, based on visual feedback via the BF system, shows promise as an effective intervention to minimize joint immobility after surgery ^[6, 7].

In Japan, the therapeutic effectiveness of interventions to improve elbow function after surgery is generally evaluated using both joint-specific metrics, such as RoM, and patient-reported outcomes (PRO), such as the Japanese Society for Surgery of the Hand version of the

Disability of the Arm, Shoulder, and Hand questionnaire (DASH-JSSH) [8] and the Japanese version of the Patient-Rated Elbow Evaluation (PREE-J) [9, 10]. However, clinical judgement of therapeutic effectiveness using these measures is based only on the relative reliability of the measurement, which has principally been expressed as correlation coefficients [9, 11]. In reality, however, this measured change will include some measurement error and/or systematic bias which would affect the interpretation of the score in clinical practice [12]. Relative reliability captures the random error of measurement without providing information on the presence or absence of systematic bias of the measure, nor its magnitude when present. Considering that systematic bias can limit the responsiveness of a measure to change and, thus, the judgement of therapeutic effectiveness, it would be clinically relevant to consider the systemic bias of the measure when evaluating the therapeutic effectiveness of an intervention, including EMG-BF therapy. In addition, the use of PRO measures, such as the DASH, to evaluate change in patient status or the therapeutic effectiveness of an intervention requires an understanding of how different outcome measures relate to each other [13]. It can be determined by using “Minimal Clinically Important Difference ” MCID [14].

There are two methods for MCID: anchor-based and

distribution-based. Anchor-based methods are calculated the MCID to measure by PRO using external reference “anchors” such as patients self-assessment ^[15, 16] and clinician perspectives ^[17], clinical parameters ^[18]. Distribution-based methods rely on expressing change scores in terms of an underlying sampling distribution, whether in between-person standard deviation units, within-person standard deviation units, or some variation of SEM ^[19]. Distribution-based methods rely on the statistical characteristics of a group’s baseline PRO measurement scores to determine—given the spread of a group’s baseline PRO measurement scores—how much of a change may be clinically important ^[20]. One of the distribution-based change indexes is the minimal detectable change (MDC) ^[21, 22] that provides the minimal amount of change that is not likely to be due to chance variation in measurement and is thus clinically meaningful ^[19]. In addition, reporting of any systematic bias in the measure, estimated using the standard error of the measurement (SEM), ^[23-25] in combination with the MDC would provide a transparent interpretation of the clinical significance of the measured change ^[19]. Using the concept of MDC, it is possible to determine the proportion of intervention effects that have achieved at least a minimal amount of reliable change. Reporting the proportion of patients achieving a degree of improvement that is beyond

measurement error is a more informative method for describing the effects of the intervention than overall mean change [19]. According to a rehabilitation study, the minimum level of detectable change in Roland–Morris Disability Questionnaire as PRO for disturbances of daily living due to low back pain was reported [12]. On the other hand, MDC of Fugl-Meyer assessment [26, 27] and Berg Balance Scale [28] were also estimated in rehabilitation studies. With regard to PRO for upper limb function, the MDC has previously been reported for the DASH but not the PREE. The MDC has also been reported for RoM [29], using measurement error, with indications that RoM might not provide a reliable marker of therapeutic efficacy. If we are to use the MDC, and associated SEM, confirmation of the reproducibility of the measured value, with an intra-class correlation coefficient ($ICC_{1,1} \geq 0.8$) is necessary [30]. Generally, the ICC is calculated during steady state of a measure [31], with the MDC during the acute phase and intervention periods not having been appropriately addressed, despite the clinical relevance.

The time-series data is generally used to evaluate therapeutic effectiveness during periods of change, such as the acute phase and intervention periods, and interpreted using trend analysis of change [32–34]. This trend in the data must be removed to create a regression model of recovery [35].

Removal of this trend requires calculation of an estimated value, using a prediction formula created by flexible discriminant analysis (FDA), unit root test, or least-square method, which is subtracted from each data point to detrend the data set ^[36]. This study aimed to determine the MDC in EMG-BF therapy, initiated in the early postoperative period after elbow surgery, for three outcome measures (elbow RoM, DASH-JSSH score, and PREE-J score) typically used in practice. The calculated MDC can be used to assess the individual treatment effect of EMG-BF therapy after elbow surgery by comparing the changes in the three outcome measures.

2. Methods

2.1. *Statement of ethics*

Our study protocol was approved by the Ethics Committee of Saitama Prefectural University, on August 23, 2013 (approval no. 25513), and the Bioethics Committee of Dokkyo Medical University Saitama Medical Center, on September 4, 2013 (reference number: 25015). Informed written consent was obtained from the participants.

Study design and participants

This was an observational case series study. Included were patients who underwent elbow surgery at one of our two affiliated centers (Saitama Medical Center, Dokkyo Medical University; and Department of Orthopedics, Koshigaya Seiwa Hospital), between July 2013 and January 2017. Eligible patients were diagnosed by trauma surgeons and physicians, using the AO/OTA fracture and dislocation classification of bone fractures. Exclusion criteria included non-closure of the epiphysis, involvement of both upper limbs, and inability to follow the instructions for EMG-BF therapy.

The sample size was determined to be sufficient through calculations using the G*Power 3.1.1 computer program software ^[37]. Power analysis indicated that a total of 21 participants were needed when $\alpha = 0.05$ for a power of 0.95, using a change score of -0.15, as previously reported for the DASH to be indicative of a clinically meaningful

change ^[38].

2.2. Post-operative rehabilitation program

All patients received standard care after elbow surgery at our medical centers and hospital, including physical therapy (with passive RoM, avoiding varus/valgus stress) and a home program of active RoM within a pain-free range. Patients whose surgery included ligament repair used a functional brace, except during RoM exercises, for the first six post-operative weeks. The brace included an external strut to prevent excessive valgus stress. Dynamic splinting was used after post-operative week 6 in patients who developed a severe contracture. Patients were permitted to perform minor tasks related to activities of daily living after post-operative week 6, with lifting activities being permitted after post-operative week 12 (Fig. 1).

2.3. Biofeedback therapy

EMG-BF therapy was provided during physical therapy sessions. All EMG-BF-assisted RoM exercises were performed with patients seated in a chair with their feet on the ground. Surface EMG electrodes were secured on the skin overlying the muscle of the biceps and triceps, with the EMG signal recorded using the Telemetry DTS system (Noraxon U.S.A., Arizona) and provided as visual feedback on a monitor placed in front of patients ^[5, 6]. Patients completed 10 repetitions each of elbow flexion (A) and extension (B), with each repetition consisting of a 10 s

contraction of the agonist (and relaxation of the antagonist), followed by a 10 s relaxation of the agonist (Figure 2). Flexion (A) was first performed with the elbow in flexion, and patients were asked to contract their biceps as intensely as possible (with relaxation of the triceps), followed by a 10 s relaxation of the biceps. All patients were asked to relax tension of biceps by decreasing myoelectric potential close to 10 μ V as soon as possible. For progression, the cycle of biceps contraction and relaxation was incorporated into active elbow flexion, encouraging patients to move to the greatest range of elbow flexion possible. In the same way, for extension (B), patients first started with a 10 s contraction of the triceps, with the elbow in extension and relaxation of the biceps, followed by 10 s of triceps relaxation. For progression, the cycle of triceps contraction and relaxation was incorporated into active elbow extension, encouraging patients to move to the greatest range of elbow extension possible. All patients began with simple contraction/relaxation under EMB-BF guidance and progressed to incorporate the BF into active elbow flexion and extension once they were able to self-regulate the contraction/relaxation cycle. Of note, although all patients started the flexion exercise after surgery, extension was delayed until 3 weeks post-surgery, with the exact timing of extension RoM exercise being dependent on the surgical

approach, type of ligament injury, and other variables.

Patients completed three sets of 10 repetitions each of flexion (A) and extension (B), performed 3-5 times per week, for 4 weeks.

2.4. Measured outcomes

The following outcomes were measured: total elbow RoM (sum of the range in flexion and extension), the DASH-JSSH total score, and the PREE-J total score. Baseline measurements were obtained at the first BF therapy session and were also obtained at the end of each of the 4 weeks of the EMG-BF therapy program (Figure 1). RoM was measured using a standard universal goniometer, with 1 axis and 2 arms, one stationary and movement arm, covering a range of 180° (Sakai Medical, Tokyo, Japan). All RoM measures were obtained by a same evaluator. Each measurement was performed three times, with the average used for analysis. The DASH-JSSH is the Japanese version of the DASH, a self-reported questionnaire developed by the American Academy of Orthopaedic Surgeons to specifically assess upper limb disability in individuals with musculoskeletal conditions [8]. The DASH-JSSH consists of 30 items regarding functional impairment (disability subscale) and symptoms (symptoms subscale), as well as two other subscales, of 4 items each, regarding sports/leisure activities and work. In this study, as we focus on the early post-operative period, we included

only the disability and symptoms subscales (DASH-DS). Each item is rated on a scale of 1-5, with higher scores indicative of greater disability and symptoms. The PREE-J is also a patient-reported measure developed to quantify upper limb disability and elbow-related pain ^[9]. The reliability, validity, and responsiveness of the Japanese version (PREE-J) has previously been confirmed ^[10]. The PREE included two subscales: pain (PREE-P) and function (PREE-F). The PREE-P subscale included 5 items, rated on a 10-point scale, from 0 (no pain) to 10 (worst possible pain). The PREE-F includes 11 items to measure specific activities (PREE-SF) and 4 items regarding usual activities (PREE-UF), with each item rated on a 10-point scale, from 0 (no difficulty) to 10 (completely impossible). The total score is calculated as the sum of the PREE-P and PREE-F subscores and can range from 0 to 100 points. All measurements were performed by one registered hand-therapist. In addition to the three measurements, baseline information of the study group (sex, age, affected side: dominant hand, days after surgery, diagnosis, social/work profile, clinical profile, and details of the surgery) was recorded.

2.5. Signal processing and analysis

We constructed a state-changing model, which includes a detrending process (using the initial y-intercept and slope of the RoM and DASH-DS and PREE-J scores) and a steady-

state process (with random variation for decomposing the slope of the RoM and DASH-DS and PREE-J scores) as follows:

$$f(t) = \alpha + \beta t + \varepsilon_t \quad (\text{Eq. 1}),$$

where α is the initial RoM and DASH-DS and PREE-J scores, β the slope of the RoM and DASH-DS and PREE-J scores, ε_t the steady process (with random variation of the RoM and DASH-DS and PREE-J scores), and t the number of assessments. Data from each patient were fitted to the model using the least-squares method, thus eliminating the slope of RoM and DASH-DS and PREE-J scores. The calculated α and ε_t values were used to evaluate the inherent random error in the RoM and DASH-DS and PREE-J scores.

2.6. Data analysis

Reproducibility was assessed by comparing the RoM, and the DASH-DS and PREE-J scores across the time points of the assessment: first (baseline) and second time point (week 1), first and third time point (week 2), first and fourth time point (week 3), and first and fifth time point (week 5). The ICC values was used to estimate the variance in score between time points, with ICC values of 0.8-1.0 indicative of excellent repeatability, values of 0.6-0.8 indicative of good reliability, and values of <0.6 indicative of poor repeatability [30]. Values are presented as the ICC, with the associated 95% confidence interval (Table 3).

The Bland-Altman (BA) analysis was used to identify systematic error in measurements ^[39], with the difference between pairs of scores (d , x-axis) plotted against their mean (y-axis) for each outcome measure. In this way, the BA analysis identifies the relationship between the measurement error and true value.

Absolute reliability was evaluated using the MDC at the 95th percentile cutoff (MDC_{95}), which indicates the smallest change in measurement required to exceed the measurement error and thus demonstrate a true change that can be attributed to the intervention, which was EMG-BF therapy in our study ^[40]. The MDC_{95} and SEM were calculated as follows ^[19]:

$$MDC_{95} = SEM \times 1.96 \sqrt{2} \quad (\text{Eq. 2}),$$

$$SEM = SD \times \sqrt{(1 - ICC)} \quad (\text{Eq. 3}),$$

where SEM is the standard error of measurement ^[23] and 1.96 is the z-score at the 95% confidence interval for normal distribution. In this formula, the square root of 2 takes into account errors made in repeat measurements.

The change in score between the first (baseline) and second time point (week 1), first and third time point (week 2), first and fourth time point (week 3), and first and fifth time point (week 5) was then compared to the MDC_{95} value to determine if the change in RoM, the DASH-DS and the PREE-J scores exceeded the measurement error. We defined

all statistical significance as $P < 0.05$. Participants with missing data were excluded from the analysis without compensation. All statistical analyses were performed using R 3.4.2 software (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

Thirty-six (cases) in 65 patients were included in the study after screening individuals with missing data (Figure 3). The baseline characteristics of these 36 patients are shown in Table 1. The mean (\pm standard deviation, SD) age of our study group was 53 ± 16 years, with a male-to-female ratio of roughly 4:6 (44% males, 56% females). Among these 36 patients, 8 (22.0%) were involved in manual work, including manufacturing, construction, equipment maintenance, garbage collection, nursing, beautician, and hairdresser. The main occupation of the remaining patients was as follows: housewife, 14 (39.0%); office clerk, 7 (19.0%); driver, 3 (8.0%); student, 2 (6.0%); and musician, 1 (3.0%); with the final patient being unemployed (3.0%). The most common mechanism of injury was a fall, (72.0%), with other causes as follows: traffic accident (14.0%), sport injuries (8.0%); and elbow joint disease (6.0%). The indications for surgery are detailed included: acute fractures of the distal humerus (28%); elbow fracture and dislocation (28%); elbow dislocation and medial/lateral collateral ligament injury (19%); olecranon fracture (3%); chronic distal humerus fracture (8%); and synovial osteochondromatosis (6%). The dominant arm-to-non-dominant ratio was roughly 6:4 (injury to the dominant arm in 58% of patients and the non-dominant arm in 42%).

BA analysis results are shown in Figures 4 through 6. The mean difference in scores were as follows: RoM, -6.1° to -0.3° (SD, 8.8° to 20.3°); DASH-DS score, 2.2 to 4.2 points (SD, 14.4 to 22.6 points); and PREE-J score, 3.0 to 7.4 points (SD, 16.5 to 28.4 points). The BA plot confirms the absence of any systematic bias for all three outcome measures at each time point of measurement: baseline and week 1, baseline and week 2, baseline and week 3, and baseline and week 4. The MDC_{95} values for all three outcome measures are reported in Table 2, with the range of values, as follows: RoM, 8.3° to 22.5° ; PREE-J score, 17.6 to 30.6 points; and DASH-DS score, 14.2 to 22.9 points.

The change in RoM from baseline was as follows: 14.3° (SD, 11.0°) at week 1; 25.1° (SD, 15.3°) at week 2; 32.8° (SD, 16.7°) at week 3; and 38.3° (SD, 17.7°) at week 4. The change in PREE-J score from baseline was as follows: 12.8 points (SD, 15.0 points) at week 1; 13.5 points (SD, 17.6 points) at week 2; 18.0 points (SD, 15.2 points) at week 3; and 23.6 points (SD, 16.4 points) at week 4. The change in the DASH-DS score from baseline was as follows: 8.0 points (SD, 8.7 points) at week 1; 12.3 points (SD, 11.7 points) at week 2; 14.6 points (SD, 12.9 points) at week 3; and 18.7 points (SD, 12.9 points) at week 4.

The time-series plots for RoM, and the PREE-J and the DASH-DS scores for all 36 patients are shown in Figure 7.

The DASH-DS and PREE-J scores decreased from baseline to the fifth time point of measurement (week 4), with the total RoM at the elbow increasing from baseline to the fifth time point of measurement (week 4). The values obtained after detrending are plotted in Figure 7. Compared to the estimated MDC_{95} , the change in RoM improved over the MDC_{95} cutoff in 8 of the 36 patients (22%) from baseline to week 1, in 20 patients (56%) from baseline to week 2, in 34 patients (94%) from baseline to week 3, and 35 (97%) patients from baseline to week 4. Changes in the PREE-J above the estimated MDC_{95} was achieved in 5 patients (14%) from baseline to week 1, in 8 (22%) patients from baseline to week 2, in 20 (56%) patients from baseline to week 3, and in 22 (61%) patients from baseline to week 4. With regard to the DASH-JSSH, a change above the MDC_{95} was achieved in 6 patients (17%) from baseline to week 1, in 5 (14%) from baseline to week 2, and 19 (53%) patients from baseline to week 3, and in 22 (61%) patients from baseline to week 4.

ICC values between pairs of time points of measurement for the detrended data (Eq. 1) were excellent for RoM (0.80 to 0.97), good-to-excellent for the PREE-J score (0.75 to 0.92), and excellent for the DASH-DS score (0.86 to 0.95), as shown in Table 3.

4. Discussion

The use of validated indicators of performance improves the reliability of the assessment of the therapeutic effectiveness of interventions [41, 42]. Our results demonstrate that elbow RoM, as well as the PREE-J and DASH-DS scores, measured after elbow surgery, are reproducible, providing a reliable measure of the change elbow and upper limb function to evaluate the effectiveness of an intervention, EMG-BF in our study. We evaluated the MDC_{95} values during the acute phase after surgery and early rehabilitation phase (4 weeks after surgery) by applying a detrending method. To our knowledge, this is the first study to have estimated the MDC_{95} by using the time-series data from the time of surgery to the recovery period, correcting the trend of change. All three indices demonstrated good-to-excellent reliability, with the change in score from baseline to the endpoint of the interventions (4 weeks) exceeding the MDC_{95} threshold for clinical relevance for elbow extension RoM and for the DASH-DS and PREE-J scores. Therefore, EMG-BF therapy is effective for increasing elbow extension and elbow joint function, as well as ameliorating symptoms after surgery.

The MDC_{95} of the DASH-DS score calculated in this study was equivalent to previously reported [38, 43]. In their case series of 104 patients evaluated using the DASH score

after surgery, Dawson et al. calculated the 90th percentile MDC₉₀ value of 9.3 points for the pain and function subcomponents of the DASH [44]. Franchignoni et al. evaluated the test-retest reliability of the DASH score in a group of 255 patients with upper limb musculoskeletal disorders (including 13 elbow fractures), before and after physical therapy, and reported an ICC (2, 1) value of 0.93 and an MDC₉₀ value of 10.8 points [45]. The interval between DASH measurements in these studies ranged between 1 and 14 days and, therefore, the MDC values did not reflect the recovery process, including therapeutic interventions. In our study, we include values related to both the natural recovery after elbow surgery, as well as recovery related to EMG-BF. We controlled for the effects of early recovery and EMG-BF intervention on MDC₉₅ values by applying a detrending analysis.

The MDC₉₅ values have not previously been reported for the PREE-J scores. In their systematic review, Vincent et al. did report an ICC value for inter-rater reliability of the PREE-J ≥ 0.90 , but without calculating the MDC value [46]. It is possible that the MDC value for the PREE might reflect the extent to which this PRO is used; specifically, the DASH has been translated in 47 languages, while the PREE has been translated in only 3 languages. PREE is a specific index for elbow joint disorders, being widely used in Japan, the

United States, and Germany [9, 10, 47]. The MDC_{95} value that we calculated for the PREE in our study will serve as a clinical reference to evaluate therapeutic effectiveness of an intervention, such as EMG-BF.

With regard to RoM, Armstrong et al. reported a measurement error for hand-held goniometry of 5.9° for elbow flexion and 6.6° for elbow extension, based on measurements obtained in 38 patients after injury and surgery for various injuries to the elbow, forearm, or hand [29]. When measured with a goniometer, the elbow ROM showed The MDC for elbow flexion were approximately $7.0 - 9.6^\circ$ [48, 49]. Our MDC_{95} value for elbow RoM was equivalent to previously reported, ranging between 8.3° and 22.5° . These data suggested that a change of less than 10° may be considered clinically insignificant in elbow RoM.

Reporting the proportion of patients who achieve a degree of improvement that is beyond the measurement error is more informative for describing the effects of the intervention than the overall mean change^[19]. In our study, we confirmed that changes in the RoM, PREE-J score, and DASH-DS score after the 4-week program of EMG-BF therapy exceeded the respective MDC_{95} estimates for each of the three outcome measures. The MDC can be used to determine the therapeutic effects on individuals. Further, our valid method of calculating the MDC by eliminating the

slope from the state change model may be applied to calculate the MDC in the acute phase or the early recovery phase. This method for calculating MDC under these conditions is a first attempt and, thus, the validity of this analysis method is not guaranteed, requiring further confirmation.

However, the limitations of our study need to be acknowledged when evaluating the application of our findings in clinical practice. Firstly, in this study, since the control of disease severity, sex differences, and age differences is not sufficient, further stratification analysis is required in future studies to clarify these effects on measured outcomes. Second, we measured RoM using a hand-held goniometer that does not have the same inter-rater reliability of measurement as a smartphone or electronic goniometer [29, 50]. High reliability and validity of electric devices were reported in measuring the active movements of elbow joint [50]. Third, this study investigated data during the early treatment phase after elbow surgery. There data has a trend during this period, and interpreted using trend analysis of change. Our data were obtained with an interval of maximum 4 weeks, which was anticipated that the estimated value would not change and that the effects of training effects could be eliminated. However, there was considerable difference in the test-retest interval, as well as

in the underlying conditions between our study and previously published studies on this topic. Although the sample size was small, it was equivalent to the number of cases in the study by Schmit et al. ^[43]. Lastly, all measures were obtained by one examiner, and all patients were from the same institution. Therefore, inherent selection bias cannot be denied and multi-center studies are needed to evaluate the reproducibility of our findings.

5. Conclusion

The MDC_{95} values, which are indicators of the efficacy of EMG-BF therapy after surgery around the elbow, were determined using the data recorded for the early postoperative initiation of the elbow ROM and ADL. Our study findings suggest that the calculated MDC could be used as a reference value to assess the therapeutic effects in individuals.

Acknowledgments

I would like to thank Professor Toyohiro Hamaguchi, Professor Kenichi Tanaka, Professor Naoki Nakaya and Associate professor Toshiyuki Ishioka, Graduate School of Health Sciences, Saitama Prefectural University; Dr. Kazuhumi Sano, Department of Plastic and Reconstructive Surgery, Juntendo University Hospital; Dr. Kazumasa Kimura, Department of Orthopaedic Surgery, Koshigaya Seiwa Hospital, Professor Makoto Suzuki, Department of Rehabilitation, Tokyo Kasei University; Professor Satoru Ozeki, Department of Orthopaedic Surgery, Dokkyo Medical University for their help to accomplish this study.

I would like to thank the Saitama Medical Center, Dokkyo Medical University staff at the Department of Rehabilitation and Koshigaya Seiwa Hospital staff at the Department of Rehabilitation for their contributions the operational approval to conduct the study. This study was supported by Grant-Aid for Japan Hand therapy society (JHTS) in 2017-2019.

References

- [1] Muraki T, Domire ZJ, McCullough MB, Chen Q, An KN. Measurement of stiffness changes in immobilized muscle using magnetic resonance elastography. *Clin Biomech (Bristol, Avon)* 2010;25(5):499-503.
- [2] Lee MJ, LaStayo PC, vonKersburg AE. A supination splint worn distal to the elbow: a radiographic, electromyographic, and retrospective report. *J Hand Ther* 2003;16(3):190-198.
- [3] Chinchalkar SJ, Szekeres M. Rehabilitation of elbow trauma. *Hand Clin* 2004;20(4):363-374.
- [4] Sime WE, DeGood DE. Effect of EMG biofeedback and progressive muscle relaxation training on awareness of frontalis muscle tension. *Psychophysiology* 1977;14(6):522-530.
- [5] Tsushima WT, Hawk AB. The clinical application of EMG biofeedback therapy for muscle contraction headaches. *Hawaii Med J* 1978;37(9):270-271.
- [6] Holtermann A, Mork PJ, Andersen LL, Olsen HB,

- Sogaard K. The use of EMG biofeedback for learning of selective activation of intra-muscular parts within the serratus anterior muscle: a novel approach for rehabilitation of scapular muscle imbalance. *J Electromyogr Kinesiol* 2010;20(2):359-365.
- [7] Huang HY, Lin JJ, Guo YL, Wang WT, Chen YJ. EMG biofeedback effectiveness to alter muscle activity pattern and scapular kinematics in subjects with and without shoulder impingement. *J Electromyogr Kinesiol* 2013;23(1):267-274.
- [8] Imaeda T, Toh S, Nakao Y, et al. Validation of the Japanese Society for Surgery of the Hand version of the Disability of the Arm, Shoulder, and Hand questionnaire. *J Orthop Sci* 2005;10(4):353-359.
- [9] MacDermid JC. Outcome evaluation in patients with elbow pathology: issues in instrument development and evaluation. *J Hand Ther* 2001;14(2):105-114.
- [10] Hanyu T, Watanabe M, Masatomi T, et al. Reliability, validity, and responsiveness of the Japanese version of

- the patient-rated elbow evaluation. *J Orthop Sci* 2013;18(5):712-719.
- [11] Farazdaghi MR, Mansoori A, Vosoughi O, Kordi Yoosefinejad A. Evaluation of the reliability and validity of the Persian version of Patient-Rated Elbow Evaluation questionnaire. *Rheumatol Int* 2017;37(5):743-750.
- [12] Stratford PW, Binkley J, Solomon P, Finch E, Gill C, Moreland J. Defining the minimum level of detectable change for the Roland-Morris questionnaire. *Phys Ther* 1996;76(4):359-365; discussion 366-358.
- [13] Wright HH, O'Brien V, Valdes K, et al. Relationship of the Patient-Specific Functional Scale to commonly used clinical measures in hand osteoarthritis. *J Hand Ther* 2017;30(4):538-545.
- [14] King MT. A point of minimal important difference (MID): a critique of terminology and methods. *Expert Rev Pharmacoecon Outcomes Res* 2011;11(2):171-184.
- [15] Jaeschke R, Singer J, Guyatt GH. Measurement of health

- status. Ascertaining the minimal clinically important difference. *Control Clin Trials* 1989;10(4):407-415.
- [16] Deyo RA, Centor RM. Assessing the responsiveness of functional scales to clinical change: an analogy to diagnostic test performance. *J Chronic Dis* 1986;39(11):897-906.
- [17] Wyrwich KW, Metz SM, Kroenke K, Tierney WM, Babu AN, Wolinsky FD. Measuring patient and clinician perspectives to evaluate change in health-related quality of life among patients with chronic obstructive pulmonary disease. *J Gen Intern Med* 2007;22(2):161-170.
- [18] Cella D, Eton DT, Lai JS, Peterman AH, Merkel DE. Combining anchor and distribution-based methods to derive minimal clinically important differences on the Functional Assessment of Cancer Therapy (FACT) anemia and fatigue scales. *J Pain Symptom Manage* 2002;24(6):547-561.
- [19] Haley SM, Fragala-Pinkham MA. Interpreting change

scores of tests and measures used in physical therapy.

Phys Ther 2006;86(5):735-743.

- [20] Sedaghat AR. Understanding the Minimal Clinically Important Difference (MCID) of Patient-Reported Outcome Measures. *Otolaryngol Head Neck Surg* 2019;161(4):551-560.
- [21] Lu WS, Wang CH, Lin JH, Sheu CF, Hsieh CL. The minimal detectable change of the simplified stroke rehabilitation assessment of movement measure. *J Rehabil Med* 2008;40(8):615-619.
- [22] Wu CY, Chuang LL, Lin KC, Lee SD, Hong WH. Responsiveness, minimal detectable change, and minimal clinically important difference of the Nottingham Extended Activities of Daily Living Scale in patients with improved performance after stroke rehabilitation. *Arch Phys Med Rehabil* 2011;92(8):1281-1287.
- [23] de Vet HC, Terwee CB, Knol DL, Bouter LM. When to use agreement versus reliability measures. *J Clin Epidemiol*

2006;59(10):1033-1039.

- [24] Cunningham Amundson SJ, Crowe TK. Clinical Applications of the Standard Error of Measurement for Occupational and Physical Therapists. *Phys Occup Ther Pediatr* 1993;12(4):57-71.
- [25] Wyrwich KW. Minimal important difference thresholds and the standard error of measurement: is there a connection? *J Biopharm Stat* 2004;14(1):97-110.
- [26] Hiengkaew V, Jitaree K, Chaiyawat P. Minimal detectable changes of the Berg Balance Scale, Fugl-Meyer Assessment Scale, Timed "Up & Go" Test, gait speeds, and 2-minute walk test in individuals with chronic stroke with different degrees of ankle plantarflexor tone. *Arch Phys Med Rehabil* 2012;93(7):1201-1208.
- [27] See J, Dodakian L, Chou C, et al. A standardized approach to the Fugl-Meyer assessment and its implications for clinical trials. *Neurorehabil Neural Repair* 2013;27(8):732-741.

- [28] Godi M, Franchignoni F, Caligari M, Giordano A, Turcato AM, Nardone A. Comparison of reliability, validity, and responsiveness of the mini-BESTest and Berg Balance Scale in patients with balance disorders. *Phys Ther* 2013;93(2):158-167.
- [29] Armstrong AD, MacDermid JC, Chinchalkar S, Stevens RS, King GJ. Reliability of range-of-motion measurement in the elbow and forearm. *J Shoulder Elbow Surg* 1998;7(6):573-580.
- [30] Bartko JJ. The intraclass correlation coefficient as a measure of reliability. *Psychol Rep* 1966;19(1):3-11.
- [31] Weir JP. Quantifying test-retest reliability using the intraclass correlation coefficient and the SEM. *J Strength Cond Res* 2005;19(1):231-240.
- [32] Cardamone-Breen MC, Jorm AF, Lawrence KA, Rapee RM, Mackinnon AJ, Yap MBH. A Single-Session, Web-Based Parenting Intervention to Prevent Adolescent Depression and Anxiety Disorders: Randomized Controlled Trial. *J Med Internet Res* 2018;20(4):e148.

- [33] Coulibaly NF, Moustapha NM, Djoumoi HH, Lamine S, Badara GA, Daniel SA. Management Of Recent Elbow Dislocations: Functional Treatment Versus Immobilization; A Prospective Study About 60 Cases. *Open Orthop J* 2017;11:452-459.
- [34] Cortes JC, Goldsmith J, Harran MD, et al. A Short and Distinct Time Window for Recovery of Arm Motor Control Early After Stroke Revealed With a Global Measure of Trajectory Kinematics. *Neurorehabil Neural Repair* 2017;31(6):552-560.
- [35] Poikolainen K, Alanko T. Population Alcohol Consumption as a Predictor of Alcohol-Specific Deaths: A Time-Series Analysis of Aggregate Data. *Alcohol Alcohol* 2017;52(6):685-691.
- [36] Tu YK, Chien KL, Burley V, Gilthorpe MS. Unravelling the effects of age, period and cohort on metabolic syndrome components in a Taiwanese population using partial least squares regression. *BMC Med Res Methodol* 2011;11:82.

- [37] Faul F, Erdfelder E, Lang AG, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods* 2007;39(2):175-191.
- [38] Beaton DE, Katz JN, Fossel AH, Wright JG, Tarasuk V, Bombardier C. Measuring the whole or the parts? Validity, reliability, and responsiveness of the Disabilities of the Arm, Shoulder and Hand outcome measure in different regions of the upper extremity. *J Hand Ther* 2001;14(2):128-146.
- [39] Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986;1(8476):307-310.
- [40] Chan WLS, Pin TW. Reliability, validity and minimal detectable change of 2-minute walk test, 6-minute walk test and 10-meter walk test in frail older adults with dementia. *Exp Gerontol* 2019;115:9-18.
- [41] Beninato M, Gill-Body KM, Salles S, Stark PC, Black-Schaffer RM, Stein J. Determination of the minimal

clinically important difference in the FIM instrument in patients with stroke. *Arch Phys Med Rehabil* 2006;87(1):32-39.

- [42] Chen RE, Papuga MO, Nicandri GT, Miller RJ, Voloshin I. Preoperative Patient-Reported Outcomes Measurement Information System (PROMIS) scores predict postoperative outcome in total shoulder arthroplasty patients. *J Shoulder Elbow Surg* 2018.
- [43] Schmitt JS, Di Fabio RP. Reliable change and minimum important difference (MID) proportions facilitated group responsiveness comparisons using individual threshold criteria. *J Clin Epidemiol* 2004;57(10):1008-1018.
- [44] 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.
- [45] Franchignoni F, Vercelli S, Giordano A, Sartorio F, Bravini E, Ferriero G. Minimal clinically important difference of the disabilities of the arm, shoulder and

- hand outcome measure (DASH) and its shortened version (QuickDASH). *J Orthop Sports Phys Ther* 2014;44(1):30-39.
- [46] Vincent JI, MacDermid JC, King GJW, Grewal R, Lalone E. Establishing the psychometric properties of 2 self-reported outcome measures of elbow pain and function: A systematic review. *J Hand Ther* 2019;32(2):222-232.
- [47] John M, Angst F, Pap G, Junge A, Mannion AF. Cross-cultural adaptation, reliability and validity of the Patient Rated Elbow Evaluation (PREE) for German-speaking patients. *Clin Exp Rheumatol* 2007;25(2):195-205.
- [48] Chapleau J, Canet F, Petit Y, Laflamme GY, Rouleau DM. Validity of goniometric elbow measurements: comparative study with a radiographic method. *Clin Orthop Relat Res* 2011;469(11):3134-3140.
- [49] Geertzen JH, Dijkstra PU, Stewart RE, Groothoff JW, Ten Duis HJ, Eisma WH. Variation in measurements of range of motion: a study in reflex sympathetic dystrophy

patients. *Clin Rehabil* 1998;12(3):254-264.

- [50] Behnoush B, Tavakoli N, Bazmi E, et al. Smartphone and Universal Goniometer for Measurement of Elbow Joint Motions: A Comparative Study. *Asian J Sports Med* 2016;7(2):e30668.

Figure Legends

Figure 1 Study protocol.

Outcome measures of therapeutic effectiveness were the active elbow range of motion, expressed as the total sum of flexion and extension, the Japanese Society for Surgery of the Hand version of the Disability of the Arm, Shoulder, and Hand questionnaire (DASH-JSSH) disability/symptom score, and the Japanese version of the Patient-Rated Elbow Evaluation (PREE-J) score. Baseline measurements were obtained at the first biofeedback (EMG-BF) therapy session and were subsequently obtained at weekly intervals over the 4-week period of EMG-BF intervention. In addition to EMG-BF, post-operative management included physical therapy and a home program of active range of motion. All restrictions in activities of daily living were lifted by 12 weeks after surgery.

Figure 2 Example of the use of electromyography-based (EMG) biofeedback therapy for elbow flexion exercises.

EMG waveforms recorded from electrodes placed over biceps and triceps muscles indicate the activation state of the biceps and triceps (upper and lower left panels, respectively). Patients were instructed to complete sets of 10 cycles of contraction and relaxation of the biceps at a cycle frequency of 10 s (timed using an audio cue, upper right

panel).

Figure 3 Patient selection and inclusion criteria. Procedure of data acquisition and selection for analysis.

Figure 4 Bland-Altman-plots of the range of motion (RoM) measures between baseline and (A) week 1, (B) week 2, (C) week 3, and (D) week 4 of treatment. The dotted line denotes the mean difference in scores between pairs of assessments, with the ± 2 standard deviations of the mean boundaries identified.

Figure 5 Bland-Altman-plots of the Japanese version of the Patient-Rated Elbow Evaluation (PREE-J) scores between baseline and (A) week 1, (B) week 2, (C) week 3, and (D) week 4 of treatment. The dotted line denotes the mean difference in scores between pairs of assessments, with the ± 2 standard deviations of the mean boundaries identified.

Figure 6 Bland-Altman-plots of the Japanese Society for Surgery of the Hand version of the Disability of the Arm, Shoulder, and Hand questionnaire disability/symptom (DASH-DS) scores between baseline and (A) week 1, (B) week 2, (C) week 3, and (D) week 4 of treatment. The dotted line denotes the mean difference in scores between pairs of

assessments, with the ± 2 standard deviations of the mean boundaries identified.

Figure 7 Time course of change in (A) range of motion (RoM), (B) the Japanese version of the Patient-Rated Elbow Evaluation (PREE-J) score, and (C) the Japanese Society for Surgery of the Hand version of the Disability of the Arm, Shoulder, and Hand questionnaire disability/symptom (DASH-DS) score. The black squares are represented MDCs. The circle symbols shows scores of treatment periods subtracted the patient's initial scores respectively. The gray line shows their transitions. RoM increased beyond the MDC_{95} , from baseline, at all time points of assessment (from week 1 through week 4), with a concomitant decrease in the DASH-DS and PREE-J scores beyond the MDC_{95} .

Tables

Table 1 Patients' characteristics at baseline

Descriptor	Data
Number of patients (Female)	36 (20)
Age (years, mean \pm standard error)	53 \pm 16
Affected side (Dominant : Non-dominant)	21:15
Days after surgery	17 \pm 8
Diagnosis (n)	
Distal Humeral fracture (acute) ^a	10
Elbow dislocation fracture ^b	10
Elbow dislocation (MCL and LCL rapture)	7
Olecranon fracture (B1)	4
Distal Humeral fracture (chronic)	3
Synovial osteochondromatosis	2

AO Classification A3=1 patient, B1=2 patients, B2=1 patient, C1=1 patient, C2=1 patient, and C3=4 patients

^b Posterior dislocation and radial head fracture=4 patients, posterior dislocation and coronoid fractures=2 patients, posterior dislocation and olecranon fracture=1 patient, posterior dislocation and radial head and coronoid fractures=3 patients. Values are presented as mean \pm SD. MCL: medial collateral ligament, LCL: lateral collateral ligament.

Table 2MDC₉₅ of measured outcomes during biofeedback therapy

Evaluation/Interval	MDC ₉₅			
	0-1 week	0-2 weeks	0-3 weeks	0-4 weeks
Elbow RoM	20.4	22.5	14.0	8.3
PREE-J	30.6	26.7	17.9	17.6
DASH-JSSH	17.2	22.9	15.0	14.2

MDC₉₅: minimum detectable change at the 95th percentile

cutoff; RoM: range of motion; PREE-J: Japanese version of

the Patient-Rated Elbow Evaluation; DASH-JSSH: Japanese

Society for Surgery of the Hand version of the Disability of

the Arm, Shoulder, and Hand questionnaire

Table 3

Reliability coefficient of measurements during EMG-BF therapy

Evaluation/ Interval	Intra-Class Correlation coefficient : $ICC_{(1, 1)}$ and 95% confidence interval			
	0-1 week	0-2 weeks	0-3 weeks	0-4 weeks
	Elbow RoM	0.80 (0.59- 0.90)	0.81 (0.56- 0.91)	0.91 (0.71- 0.96)
PREE-J	0.75 (0.50- 0.88)	0.81 (0.66- 0.90)	0.92 (0.83- 0.96)	0.92 (0.84- 0.96)
DASH- JSSH	0.91 (0.79- 0.96)	0.86 (0.73- 0.93)	0.94 (0.89- 0.97)	0.95 (0.90- 0.97)

BF, biofeedback; RoM: range of motion; PREE-J: Japanese version of the Patient-Rated Elbow Evaluation; DASH-JSSH: Japanese Society for Surgery of the Hand version of the Disability of the Arm, Shoulder, and Hand questionnaire

Figure

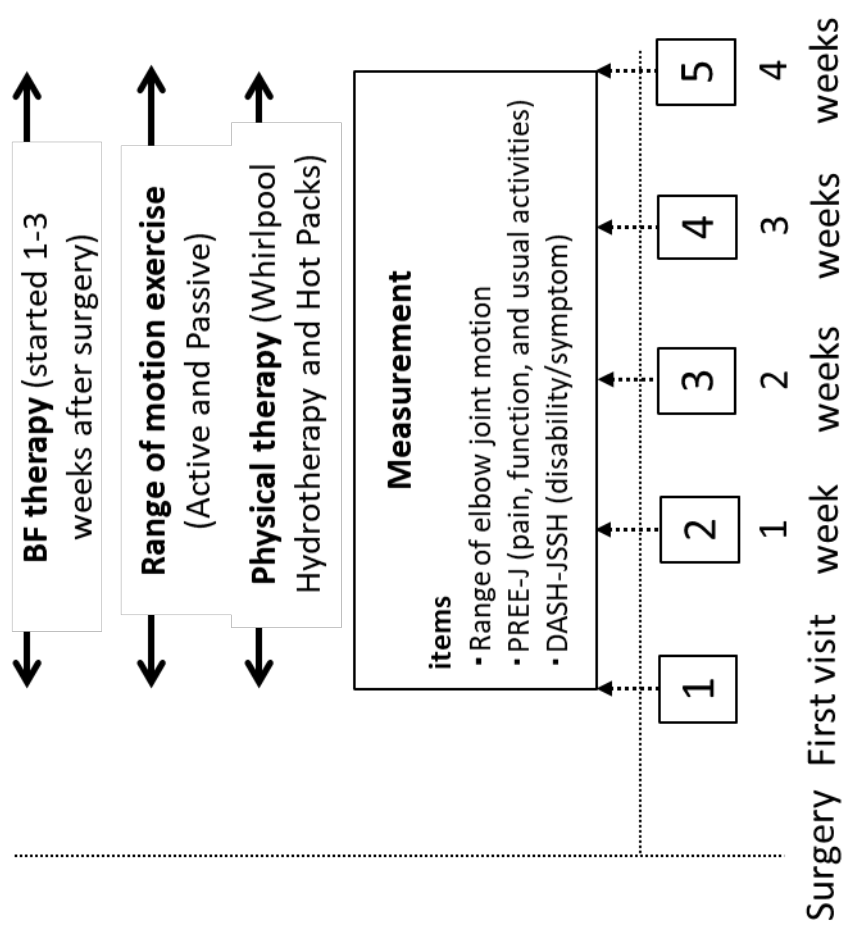


Figure 1

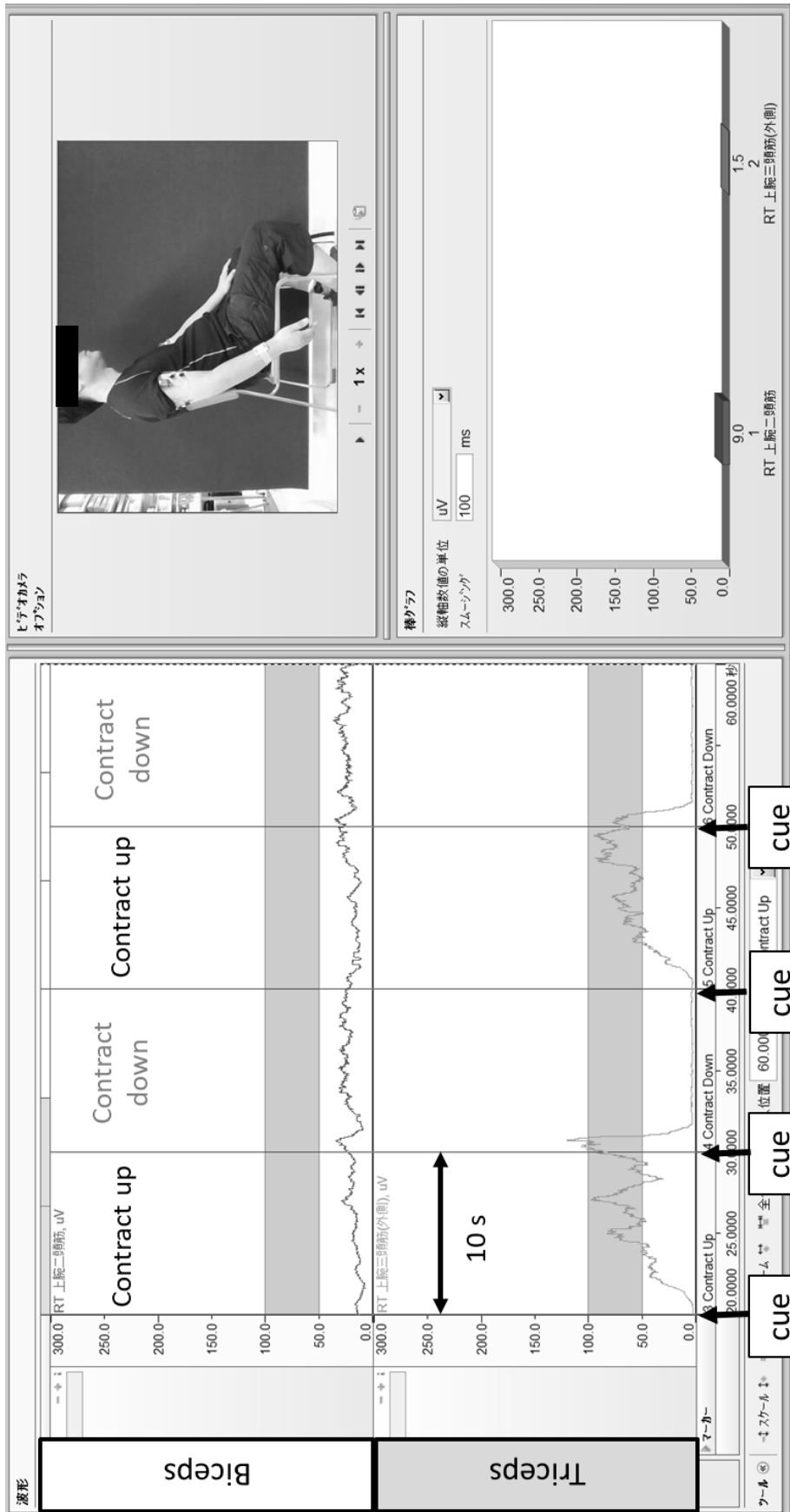


Figure 2

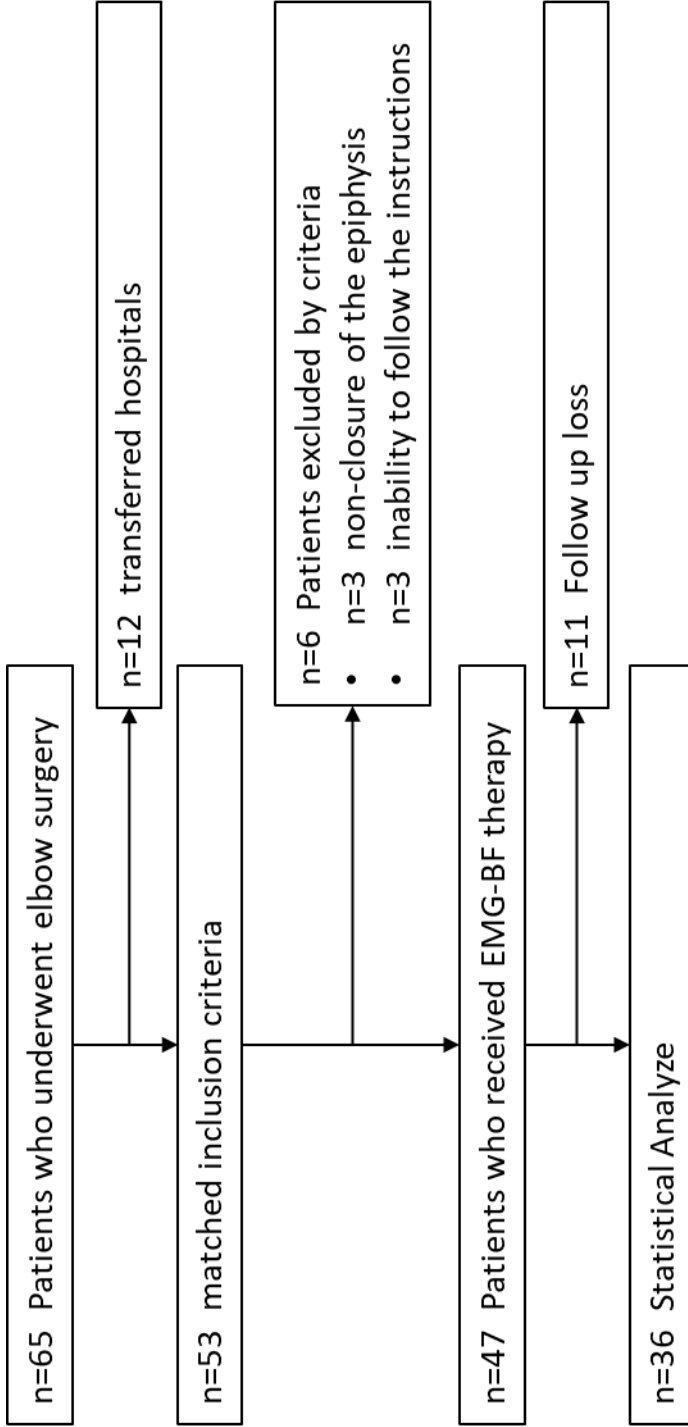


Figure 3

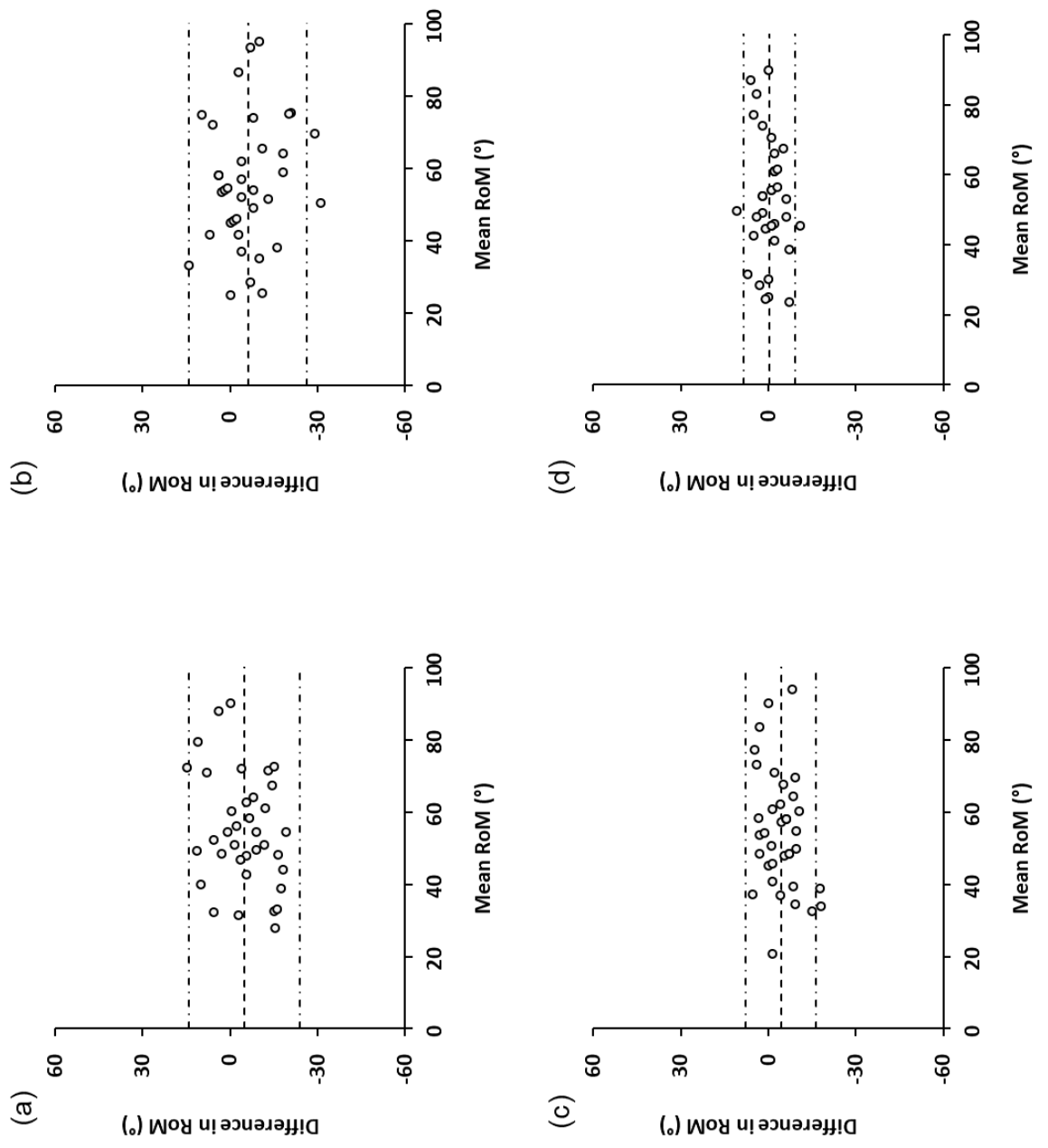


Figure 4

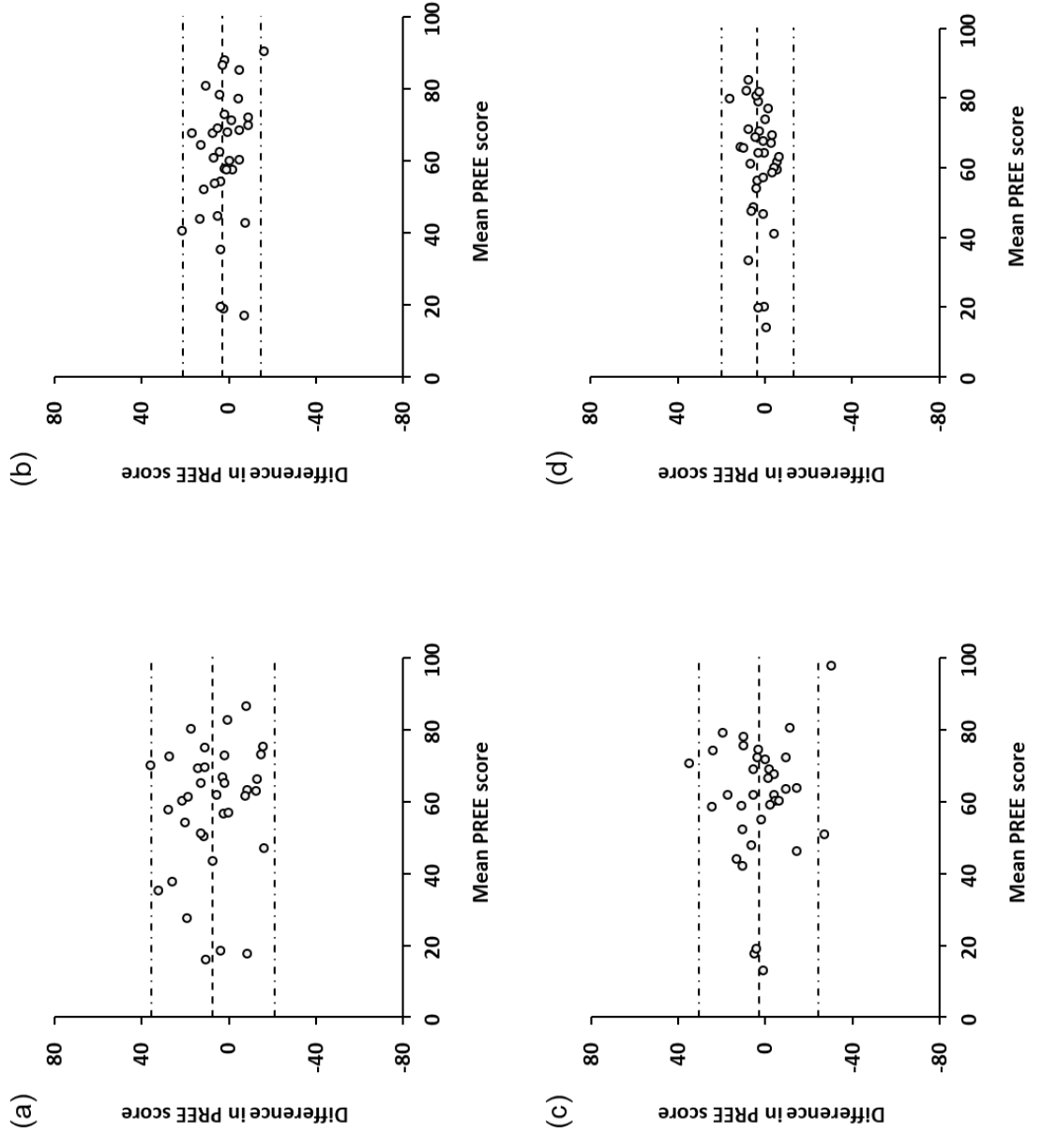


Figure 5

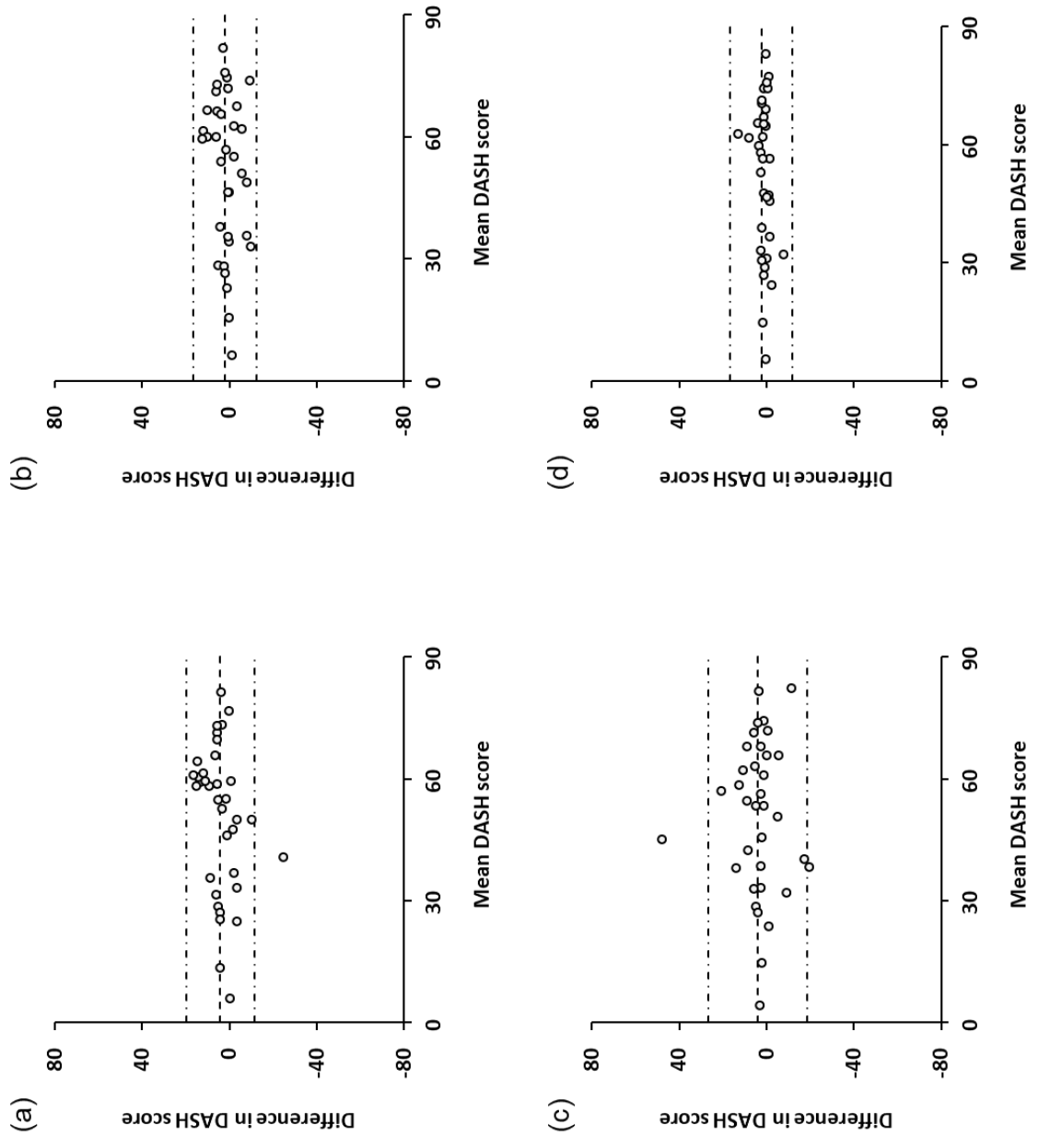


Figure 6

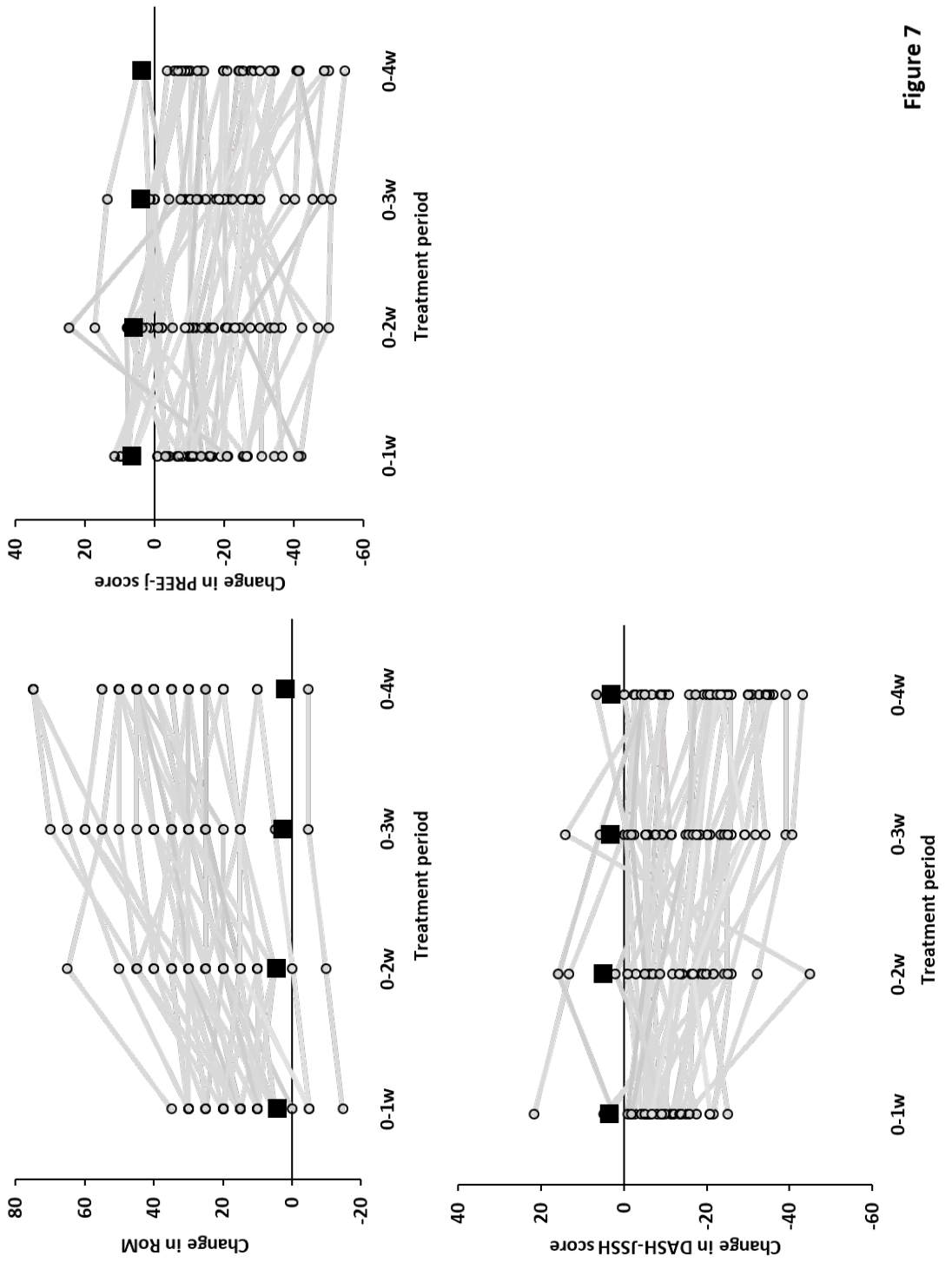


Figure 7

DISABILITIES OF THE ARM, SHOULDER AND HAND

THE **DASH**

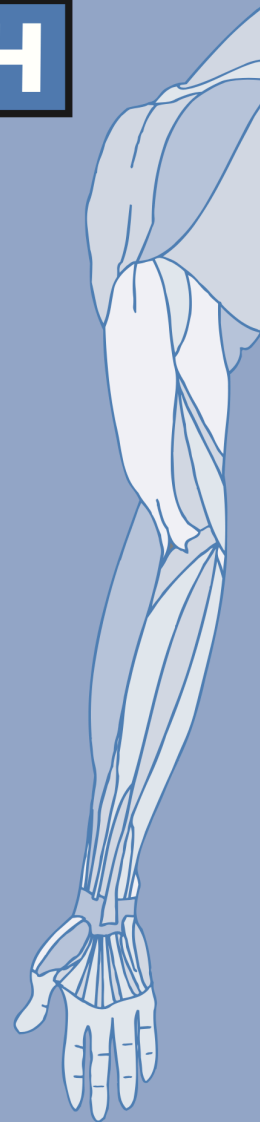
INSTRUCTIONS

This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer *every question*, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* on which response would be the most accurate.

It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.



DISABILITIES OF THE ARM, SHOULDER AND HAND

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5
5. Push open a heavy door.	1	2	3	4	5
6. Place an object on a shelf above your head.	1	2	3	4	5
7. Do heavy household chores (e.g., wash walls, wash floors).	1	2	3	4	5
8. Garden or do yard work.	1	2	3	4	5
9. Make a bed.	1	2	3	4	5
10. Carry a shopping bag or briefcase.	1	2	3	4	5
11. Carry a heavy object (over 10 lbs).	1	2	3	4	5
12. Change a lightbulb overhead.	1	2	3	4	5
13. Wash or blow dry your hair.	1	2	3	4	5
14. Wash your back.	1	2	3	4	5
15. Put on a pullover sweater.	1	2	3	4	5
16. Use a knife to cut food.	1	2	3	4	5
17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.).	1	2	3	4	5
18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5
19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.).	1	2	3	4	5
20. Manage transportation needs (getting from one place to another).	1	2	3	4	5
21. Sexual activities.	1	2	3	4	5

DISABILITIES OF THE ARM, SHOULDER AND HAND

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
22. During the past week, <i>to what extent</i> has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? <i>(circle number)</i>	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? <i>(circle number)</i>	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*

	NONE	MILD	MODERATE	SEVERE	EXTREME
24. Arm, shoulder or hand pain.	1	2	3	4	5
25. Arm, shoulder or hand pain when you performed any specific activity.	1	2	3	4	5
26. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5
27. Weakness in your arm, shoulder or hand.	1	2	3	4	5
28. Stiffness in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
29. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? <i>(circle number)</i>	1	2	3	4	5

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem. <i>(circle number)</i>	1	2	3	4	5

DASH DISABILITY/SYMPTOM SCORE = $\frac{(\text{sum of } n \text{ responses})}{n} - 1$ x 25, where n is equal to the number of completed responses.

A DASH score may not be calculated if there are greater than 3 missing items.

DISABILITIES OF THE ARM, SHOULDER AND HAND

WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including home-making if that is your main work role).

Please indicate what your job/work is: _____

I do not work. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for your work?	1	2	3	4	5
2. doing your usual work because of arm, shoulder or hand pain?	1	2	3	4	5
3. doing your work as well as you would like?	1	2	3	4	5
4. spending your usual amount of time doing your work?	1	2	3	4	5

SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

The following questions relate to the impact of your arm, shoulder or hand problem on playing *your musical instrument or sport or both*. If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you: _____

I do not play a sport or an instrument. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for playing your instrument or sport?	1	2	3	4	5
2. playing your musical instrument or sport because of arm, shoulder or hand pain?	1	2	3	4	5
3. playing your musical instrument or sport as well as you would like?	1	2	3	4	5
4. spending your usual amount of time practising or playing your instrument or sport?	1	2	3	4	5

SCORING THE OPTIONAL MODULES: Add up assigned values for each response; divide by 4 (number of items); subtract 1; multiply by 25.

An optional module score may not be calculated if there are any missing items.

DISABILITIES OF THE ARM, SHOULDER AND HAND

THE **DASH**
The JSSH Version

上肢障害評価表 (DASH) の記入について

この質問表は、あなたの手の症状や能力 (どの程度できたか?) についてお聞きするものです。

それぞれの質問に対して、先週 1 週間の状態を、該当するものに○をつけて答えて下さい。

その中にあなたが先週 1 週間で実際に行っていないものがあった場合は、どの程度にできたかを想像して、できるだけすべての質問にお答え下さい。

各動作を行うにあたって、左右どちらかの手あるいは両手を使ったかは関係ありません。あなたがどの程度できたのかに○をして下さい。(あなたが普通は右手で字を書いている、先週は何かのトラブルで左手で書いていたなら、左手で字を書く動作について最も当てはまる項目に○をつけて下さい。)

お名前 _____ 年齢 _____

男 / 女 利き腕 右 / 左

記入日 年 月 日

以下は当方で記入します。

診断 _____

手術日 年 月 日

手術方法 _____

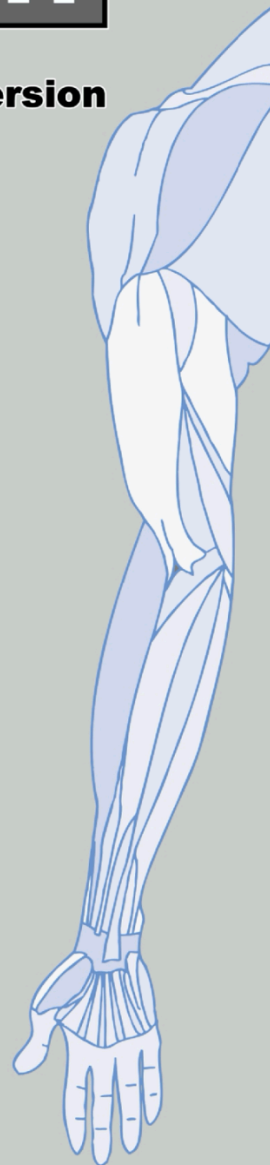
カルテ番号 _____

DASH score _____

Disability/symptom _____

Sports/music _____

Work _____



© Institute for Work & Health 2006. All rights reserved

Japanese translation courtesy of Functional Evaluation Committee, JSSH, I

DISABILITIES OF THE ARM, SHOULDER AND HAND

先週1週間に次にあげる動作ができたかどうか、該当する状態の番号を○で囲んで下さい。

- | | | | | | |
|---|-----------|---------|----------|----------|-----------|
| 1. きつめのまたは新しいビンのフタを開ける | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 2. 書く | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 3. カギを回す | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 4. 食事の支度をやる | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 5. 重いドアを開ける | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 6. 頭上の棚に物を置く | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 7. 重労働の家事をする(壁ふきや床掃除など) | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 8. 庭仕事をする | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 9. ベッドメイキングまたは布団を敷く | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 10. 買い物バックや書類かばんを持ち運ぶ | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 11. 重い物を運ぶ(5kg 以上) | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 12. 頭上の電球を交換する | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 13. 洗髪やヘアードライヤーを使用する | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 14. 背中を洗う | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 15. 頭からかぶるセーターを着る | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 16. 食事でナイフを使う | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 17. 軽いレクリエーションをする(例: トランプ、編み物、碁、将棋など) | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 18. 肩、腕や手に筋力を必要とするか、それらに衝撃のかかるレクリエーション活動をする(ゴルフ・テニス・キャッチボールをする、ハンマーを使うなど) | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 19. 腕を自由に動かすレクリエーション活動をする(フリスビー、バドミントンなど) | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 20. 交通機関の利用が自由にできる(移動の際に) | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |
| 21. 性生活をする | 1: 全く困難なし | 2: やや困難 | 3: 中等度困難 | 4: かなり困難 | 5: できなかった |

DISABILITIES OF THE ARM, SHOULDER AND HAND

22. 腕・肩・手の障害が、家族、友人、隣人、あるいは仲間との正常な社会生活をどの程度妨げましたか

1：まったくなかった 2：ややあった 3：中等度あった 4：かなりあった 5：極度にあった

23. 腕・肩・手の障害によって先週の仕事・日常生活に制限がありましたか

1：制限なし 2：やや制限 3：中等度制限 4：かなり制限 5：極度に制限

先週1週間の症状について、該当する番号を○で囲んで下さい。

24. 腕・肩・手に痛みがある

1：まったくなかった 2：ややあった 3：中等度あった 4：かなりあった 5：何もできないほど

25. 特定の運動をしたときに腕・肩・手に痛みがある

1：まったくなかった 2：ややあった 3：中等度あった 4：かなりあった 5：何もできないほど

26. 腕・肩・手がチクチク痛む(ピンや針を刺したような痛み)

1：まったくなかった 2：ややあった 3：中等度あった 4：かなりあった 5：何もできないほど

27. 腕・肩・手に力がいらない

1：まったくなかった 2：ややあった 3：中等度あった 4：かなりあった 5：何もできないほど

28. 腕・肩・手にこわばり感がある

1：まったくなかった 2：ややあった 3：中等度あった 4：かなりあった 5：何もできないほど

29. 腕・肩・手の痛みによって眠れないときがありましたか

1：まったくなかった 2：ややあった 3：中等度あった 4：かなりあった 5：眠れないほど

30. 腕・肩・手の障害のために、自分の能力に自信がないとか、使いづらいと思っていますか

1：まったく思わない 2：あまり思わない 3：何とも言えない 4：そう思う 5：非常に思う

DISABILITIES OF THE ARM, SHOULDER AND HAND

スポーツ / 芸術活動（選択項目）

楽器の演奏やスポーツをするにあたって、あなたの肩・腕・手の障害がどの程度影響しているか以下の質問に答えて下さい。もしあなたがひとつ以上のスポーツもしくは楽器演奏などを行っている場合は、あなたが最も重要だと考えている活動について答えて下さい。

その活動は： _____

私は楽器の演奏やスポーツをしません。（以下の1から4の質問には答える必要はありません）

先週1週間で、あなたの状態を最も示している番号を○で囲んで下さい。

なにか困難がありましたか？

1. スポーツ、もしくは楽器演奏においていつもの活動ができましたか

1：全く困難なし 2：やや困難 3：中等度困難 4：かなり困難 5：できなかった

2. 腕、肩、手の痛みのために活動がどの程度制限されましたか

1：全く困難なし 2：やや困難 3：中等度困難 4：かなり困難 5：できなかった

3. 自分の思うように活動ができましたか

1：全く困難なし 2：やや困難 3：中等度困難 4：かなり困難 5：できなかった

4. いつもと同じ時間でできましたか

1：全く困難なし 2：やや困難 3：中等度困難 4：かなり困難 5：できなかった

仕事（選択項目）

あなたの仕事（家事を含む）をするにあたって、あなたの腕・肩・手の障害がどの程度影響しているか以下の質問に答えて下さい。

あなたの仕事は： _____

私は働いていません。（以下の1から4の質問には答える必要はありません）

先週1週間で、あなたの状態を最も示している番号を○で囲んで下さい。

なにか困難がありましたか？

1. 仕事において、いつもの活動ができましたか

1：全く困難なし 2：やや困難 3：中等度困難 4：かなり困難 5：できなかった

2. 腕・肩・手の痛みのために仕事が制限されましたか

1：全く困難なし 2：やや困難 3：中等度困難 4：かなり困難 5：できなかった

3. 自分の思うように仕事ができましたか

1：全く困難なし 2：やや困難 3：中等度困難 4：かなり困難 5：できなかった

4. いつもと同じ時間仕事ができましたか

1：全く困難なし 2：やや困難 3：中等度困難 4：かなり困難 5：できなかった

DASH

DASH の採点法

2002 年の春に、the DASH Outcome Measure の採点法を改訂し導入しました。この新しい方法は代数的には元の方法と同じですが、欠損値を扱う際にもっと簡単に効率よくわかりやすく使えるようになりました。以上の理由で改訂された方法を採用してくださるようお勧めします。しかし、結果的にスコアは同じになるので、どちらの方法を使っても大丈夫です。

DASH は二部構成です。機能障害 / 症状に関する質問（30 項目の質問があり、それぞれ 1-5 点が当てられます）とスポーツ / 芸術活動、仕事に関する選択項目（それぞれ 4 項目の質問があり、各項目に 1-5 点が当てられています）です。

機能障害 / 症状 スコア

点数を計算するためには、30 項目中少なくとも 27 項目に回答してもらう必要があります。答えを得られた回答の点数を単純に合計し平均して、5 点満点の点数を出します。その値から 1 を引き 25 を掛けて、100 点満点に換算します。この換算をすると 0-100 点で評価された他の尺度と比較しやすくなります。点数が高ければ高いほどより障害が大きいことを示しています。

$$\text{DASH機能障害/症状のスコア} = \left[\frac{(\text{n個の加算点数})}{n} - 1 \right] \times 25$$

n は回答があった項目数

選択項目（スポーツ / 芸術活動、仕事）スコア

それぞれ 4 項目からなりますが、質問の性質上、回答する人もいれば回答しない人もいます。この選択項目の目的は、プロのスポーツ選手、プロの演奏家、仕事をする人達が、日常生活上では影響がなく、先の DASH 機能障害 / 症状スコアではあらわれないが、専門的な活動においてはどの程度の障害があるかを明確にすることです。

上で述べた手順に従い選択の 4 項目の点数を計算します。点数を計算するためには、4 つの質問すべてに回答してもらう必要があります。各回答の点数を単純に合計し 4（項目の数）で割ります。それから 1 を引き 25 を掛けて、100 点満点の点数を計算します。

$$\text{DASH選択項目スコア} = \left[\frac{(\text{4個の加算点数})}{4} - 1 \right] \times 25$$

回答がない項目の取り扱い

もし 10%を超える項目（つまり 4 項目以上）で回答が無記入の場合、DASH 機能障害 / 症状 スコアは計算できません。このルール（無回答の項目が 10%を超えてはいけない）に従い、スポーツ / 芸術活動、仕事のセクションではたった 4 項目しかないので、一つの欠損値も許されません。この欠損値のルールは、オリジナルの採点法にも改定の採点法にも適応されます。

Appendix 3. PREE

Appendix 3. PREE

PATIENT-RATED ELBOW EVALUATION

Name _____ Date _____

*The questions below will help us understand the amount of difficulty you have had with your elbow in the past week. You will be describing your **average** elbow symptoms **over the past week** on a scale 0-10.*

1. PAIN

*Rate the average amount of pain in your elbow **over the past week** by circling the number that best describes your pain on a scale from 0-10. A **zero (0)** means that you **did not have any pain** and a **ten (10)** means that you had **the worst pain you have ever experienced**.*

RATE YOUR PAIN:

When it is at its worst	0 1 2 3 4 5 6 7 8 9 10
At rest	0 1 2 3 4 5 6 7 8 9 10
When lifting a heavy object	0 1 2 3 4 5 6 7 8 9 10
When doing a task with repeated elbow movement	0 1 2 3 4 5 6 7 8 9 10

How often do you have pain?	0 1 2 3 4 5 6 7 8 9 10
	Never Always

Please turn the page.....

2. FUNCTION											
A. SPECIFIC ACTIVITIES											
<p><i>Rate the amount of difficulty you experienced performing each of the items listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. A zero (0) means you did not experience any difficulty and a ten (10) means it was so difficult you were unable to do it at all.</i></p>											
	No Difficulty									Unable To Do	
Comb my hair	0	1	2	3	4	5	6	7	8	9	10
Eat with a fork or spoon	0	1	2	3	4	5	6	7	8	9	10
Pull a heavy object	0	1	2	3	4	5	6	7	8	9	10
Use my arm to rise from a chair	0	1	2	3	4	5	6	7	8	9	10
Carry a 10lb object with my arm at my side	0	1	2	3	4	5	6	7	8	9	10
Throw a small object, such as a tennis ball	0	1	2	3	4	5	6	7	8	9	10
Use a telephone	0	1	2	3	4	5	6	7	8	9	10
Do up buttons on the front of my shirt	0	1	2	3	4	5	6	7	8	9	10
Wash my opposite armpit	0	1	2	3	4	5	6	7	8	9	10
Tie my shoe	0	1	2	3	4	5	6	7	8	9	10
Turn the doorknob and open a door	0	1	2	3	4	5	6	7	8	9	10
B. USUAL ACTIVITIES											
<p><i>Rate the amount of difficulty you experienced performing your usual activities in each of the areas listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. By "usual activities", we mean the activities that you performed before you started having a problem with your elbow. A zero (0) means you did not experience any difficulty and a ten (10) means it was so difficult you were unable to do any of your usual activities.</i></p>											
1. Personal activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
2. Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
3. Work (your job or everyday work)	0	1	2	3	4	5	6	7	8	9	10

4. Recreational activities	0 1 2 3 4 5 6 7 8 9 10
----------------------------	------------------------

Comments:

PREE日本語版 (PREE-J)

Patient-Rated Elbow Evaluation (PREE) The Japanese Version

お名前 _____ 年齢 _____

男/ 女 _____ 利き腕 右/ 左 _____

記入日 _____ 年 _____ 月 _____ 日 _____

以下は当方で記入します。

診断 _____

手術日 _____ 年 _____ 月 _____ 日 _____

手術方法 (右・左) _____

カルテ番号 _____

PREE スコア _____

痛み (PREE-P) _____

機能 (PREE-F) _____

特定の動作 _____

(PREE-SF) _____

通常の動作 _____

(PREE-UF) _____

© Joy MacDermid 2009, all right reserved.
Japan Elbow Society, Japan

ID: _____

記入日: 年 月 日

肘 の 評 価

下記の質問は、調査(手術)対象となっている側の肘について、お答えください。あなたが、この1週間にどの程度、肘に不具合を感じているかを理解するためのものです。この1週間の平均的な肘の症状について、0から10の数字の中から選んで表してください。全ての質問に対して、回答をお願いします。もしその動作をしていなければ、痛みや困難さを予想して判断してください。その動作を一度もしたことがなければ、無記入で結構です。

1. 痛み	
<p style="text-align: center;">この1週間の平均的な肘の痛みの程度について、最もよく表している数字を0から10の中から選んで、○で囲んで評価してください。ゼロ(0)は何の痛みもなかったという意味で、10は今まで経験したうちで最悪の痛みだった、または痛みのためにその動作が全くできなかったという意味です。</p> <p style="text-align: center;"> 目盛りの見本 0 1 2 3 4 5 6 7 8 9 10 全く痛くない これまでで最悪の痛み </p> <p style="text-align: center;">み</p>	
痛みを評価してください:	
肘が最悪の状態の時	0 1 2 3 4 5 6 7 8 9 10
休んでいる時	0 1 2 3 4 5 6 7 8 9 10
重い物を持ち上げる時	0 1 2 3 4 5 6 7 8 9 10
繰り返して肘を動かす仕事をしている時	0 1 2 3 4 5 6 7 8 9 10
<p style="text-align: center;">どの位の頻度で痛みますか？</p> <p style="text-align: center;"> 0 1 2 3 4 5 6 7 8 9 10 一度もない 常 </p> <p style="text-align: center;">に</p>	

2. 機能											
A. 特定の動作											
この1週間に下記の各項目を行う時に感じた 困難さの程度 について、最もよく表している数字を 0 から 10 の中から選んで、○で囲んで評価してください。 0 は何の困難も感じなかったという意味で、 10 はとて も困難 なので 全くできなかった という意味です。											
目盛りの見本	0	1	2	3	4	5	6	7	8	9	10
	全く困難がなかった					全くできなかった					
髪をとかす	0	1	2	3	4	5	6	7	8	9	10
ナイフまたはスプーンで食べる	0	1	2	3	4	5	6	7	8	9	10
重いものを引っ張る	0	1	2	3	4	5	6	7	8	9	10
腕を使って椅子から立ち上がる	0	1	2	3	4	5	6	7	8	9	10
自分の腕にさげて5 kgの物を運ぶ	0	1	2	3	4	5	6	7	8	9	10
電話器を使う	0	1	2	3	4	5	6	7	8	9	10
テニスボールのような小さなものを投げる	0	1	2	3	4	5	6	7	8	9	10
シャツの前ボタンをかける	0	1	2	3	4	5	6	7	8	9	10
反対側の脇の下を洗う	0	1	2	3	4	5	6	7	8	9	10
靴ひもを結ぶ	0	1	2	3	4	5	6	7	8	9	10
ドアの取っ手を回してドアを開ける	0	1	2	3	4	5	6	7	8	9	10
B. 通常の動作											
この1週間に下記の分野で 通常 の動作を行う時に感じた 困難さの程度 について、最もよく表している数字を 0 から 10 の中から選んで、○で囲んで評価してください。「 通常の動作 」とは あなたの肘 に 問題 が起こる 以前 に行っていた動作という意味です。 0 は何の困難も感じなかったという意味で、 10 はとて も困難 なので 全くできなかった という意味です。											
身の回りの動作 (服を着る, 体を洗う)	0	1	2	3	4	5	6	7	8	9	10
家事 (掃除, 補修)	0	1	2	3	4	5	6	7	8	9	10

Appendix 4. PREE-J

仕事（職業としての仕事 または普段する 事になっている日常的な事）	0	1	2	3	4	5	6	7	8	9	10
レクリエーション	0	1	2	3	4	5	6	7	8	9	10