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ARTICLE

The minimal clinically important difference of the Southampton Dupuytren's Scoring Scheme

Jens Jørgsholm and Rasmus Wejnold Jørgensen

Department of Orthopedic Surgery, Copenhagen University Hospital – Herlev and Gentofte, Gentofte, Denmark

ABSTRACT

The minimal clinically important difference (MCID) for patient-reported outcome questionnaires is important in the interpretation of outcome in clinical and research settings. MCID represents the smallest difference in score that the patient would identify as important. There is, to our knowledge, no reported MCID value for Southampton Dupuytren's scoring scheme (SDSS). The SDSS is a 5-item 20 points scale, where 0 is considered no discomfort or physical limitations and 20 is the worst possible discomfort and physical limitations. The aim of this study was to determine the MCID for the SDSS. The study population consisted of 192 patients, in a prospective period from 2018 to 2021. All patients completed baseline SDSS questionnaires and again at 6 months follow-up with an external anchor question added. We calculated the mean change in scores of SDSS and used the anchor-based approach as well as a distribution-based method to calculate the MCID. At 6 months 163/192 (85%) of the patients were satisfied with the treatment according to the anchor question. In conclusion, the MCID of the SDSS for patients receiving treatment for DD is 1.5 points when estimated by an anchor-based approach and 1.62 points when estimated by a distribution-based approach. These MCID values should be considered in the interpretation of SDSS scores in the future, as well as when planning future studies on DD.

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MCID; minimal clinically important difference; Southampton Dupuytren's Scoring Scheme; SDSS; PROM; Dupuytren's disease

Introduction

Patient-reported outcome measures (PROM) are useful for the evaluation of outcome following treatment. The minimal clinically important difference (MCID) is intended to clarify clinical significance or relevance in PROM score interpretation. MCID reflects the minimal difference in the score that is meaningful to the patient [1]. In other terms the change in scores after treatment may be statistically significant, but not considered worthwhile by the patient. There are two main approaches used to calculate the MCID. The anchor-based and the distribution-based method. The anchor-based method relies on an external criterion (anchor) to determine if a change in the outcome score is clinically important. The distribution-based method depends on statistical characteristics of a sample and describes the ability to detect changes in general.

Currently, multiple PROMs for Dupuytren's disease (DD) exists. Two recent reviews [2,3] evaluated different PROMs for patients with DD on both relevance and effectiveness. The most widely used is the disabilities of the arm shoulder and hand questionnaire (DASH) and the shortened version Quick-DASH [4,5]. The DASH and Quick-DASH are not disease specific for DD and are intended to assess the entire upper extremity. Presently, two disease specific PROMs exist for DD: The Unite Rhumatologique des affections de la Main (URAM) [6] and The Southampton Dupuytren's scoring scheme (SDSS) [7]. Both PROMs are self-administrated schemes that quantify the disability caused by the disease and both are sensitive to change in the disease [3]. The SDSS has been translated into Danish and validated [8]. Figure 1 shows the SDSS, published in 2014 by Mohan A et al. and is a 5-item 20 points scale, where 0 is considered no discomfort or physical limitations and 20 is the worst possible discomfort and physical limitations [7].

The validated Danish SDSS questionnaire was used in this study [8]. To our knowledge, and as reported by a recent review [3], there are no publications on MCID for SDSS. The aim of this prospective cohort study was to determine the MCID value of the SDSS through a distribution-based and an anchor-based approach in patients treated for DD.

Methods

Patients

The study population consisted of 192 patients receiving treatment for DD. A total of 249 patients were treated in a prospective period from 2018 to 2021 and 192 patients meet the inclusion criteria. All patients were treated in the same institute with four different techniques: Xiapex© injection, percutaneous needle fasciotomy, fasciectomy or dermo-fasciectomy. All surgeons who performed the treatments had more than 5 years of experience with the mentioned techniques. For study inclusion, we included all patients that meet the indication for treatment by the surgeon and was treated for DD. Patients were also required to prospectively answer the SDSS questionnaire at baseline and at 6 months follow-up. At 6 months follow-up the patients were also asked whether they were satisfied with the result (yes/no), and the answer was used as an anchor. As seen in Figure 2, 19 patients had less than 6 months follow-up and were not invited to answer the SDSS. After 6 months, 16.5% ($n = 38$) did not reply and were

CONTACT Jens Jørgsholm jens.bertel.joergsholm.01@regionh.dk Department of Orthopedic Surgery, Copenhagen University Hospital – Herlev and Gentofte, Gentofte, Denmark

Southampton dupuytren's scoring scheme

Name .....
Address.....
Hospital no .....
Hand dominance .....
Which fingers are affected .....

Please indicate how the condition affects you in each of the following areas:

How much trouble do you have with:	No problem	Minor inconvenience	Modest inconvenience	Definitely troublesome	Severe problem
Discomfort					
Personal activities, eg: washing face, dressing, washing hands, washing hair, putting on gloves.					
Domestic activities, eg; holding a glass/cup, opening jars, eating, cooking.					
Work / Social interaction, eg: using the computer, writing, shaking hands, cosmetic appearance.					
Hobbies, eg. driving/cycling, racket sports, DIY, playing musical instruments, gardening.					
Score (staff to complete)					

Total	

Figure 1. The Southampton Dupuytren's Scoring Scheme. Calculation of scores: No problem = 0; Minor inconvenience = 1; Modest inconvenience = 2; Definitely troublesome = 3; Severe problem = 4; Minimum score = 0; Maximum score = 20 [7].

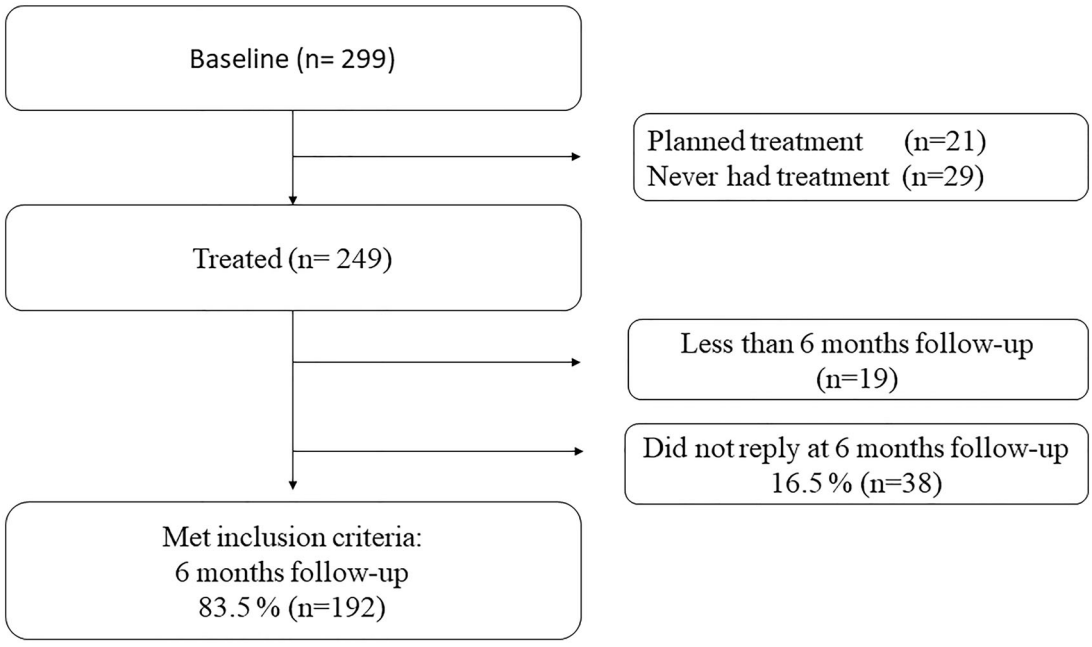

Figure 2. Inclusion criteria. n: number.

Table 1. Patient demographics ($n = 192$).

Demographic	*n*	Outcome
Age (years), mean (SD)	192	70 (8.4)
Gender		
Male	152	79.2%
Female	40	20.8%
Side		
Right	92	47.9%
Left	100	52.1%
Finger treated		
5th finger	83	44.9%
4th and 5thfinger	37	20.0%
4th finger	31	16.8%
3rd and 4th finger	11	6.0%
Other combinations	23	12.3%
No. of fingers treated		
1 Finger	125	67.6%
2 Fingers	53	28.6%
3 Fingers or more	7	3.8%
Treatment type		
Fasciectomy	131	68.2%
PNF	38	19.8%
Xiapex	22	11.5%
Dermofasciectomy	1	0.5%

SD: Standard deviation; PNF: percutaneous needle fasciotomy.

lost to follow-up. The baseline demographics of enrolled patients are presented in Table 1. In total, 83.5% ($n = 192$) of the patients had a complete dataset and were included in this study.

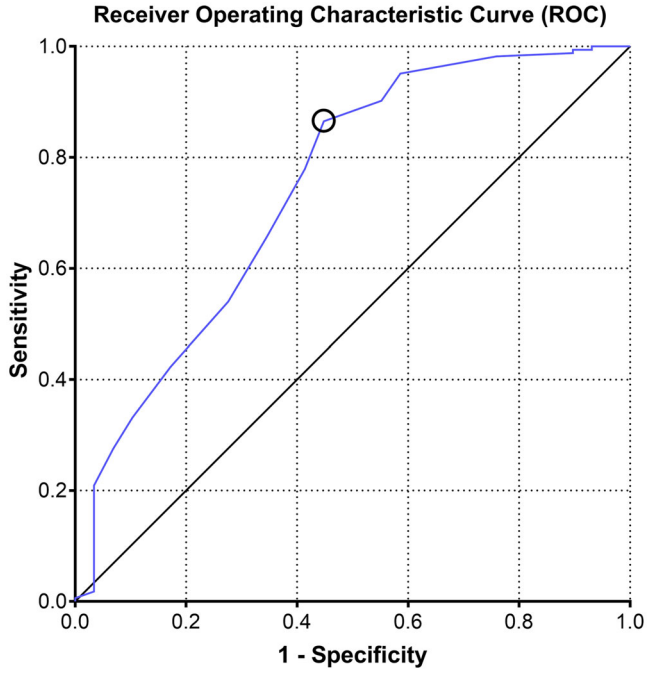

Figure 3. The receiver operating characteristic (ROC) curve for the SDSS at 6 months follow-up. The circle (0.448; 0.865) represents the MCID value of 1.5 points. The area under the ROC curve was 0.743.

Statistics

The MCID was calculated using an anchor-based method and a distribution-based method. The external criterion chosen in this study was the question: "Are you satisfied with the result following the treatment?" (Yes/No). The anchor was used to plot the receiver operating characteristic curve (ROC curve). This method is the most frequently used in hand surgery [4]. The ROC curve is obtained by plotting sensitivity against 1 – specificity at different cut-off points. Each plot on the ROC curve represents sensitivity and specificity for a given SDSS change. The optimal cut-off point is chosen, as the point that has the maximum values of sensibility and specificity combined. The Youden index was used to calculate the optimal cut-off point with the highest value of sensitivity + -specificity–1 [9].

The area under the ROC curve (AUC) is an overall summary of diagnostic accuracy. In this study, the AUC is a measure of how good the test distinguishes between the satisfied and not satisfied patient. AUC values 0.7–0.8 are considered acceptable, and values over 0.8 is considered a good to excellent discrimination [10].

Using a distribution-based method, we measured the change in scores that can be considered true and free from measurement

Table 2. SDSS scores before treatment and 6 months after treatment.

	n	Mean	SD	95% CI
Overall scores				
Baseline	192	7.62	3.85	7.10–8.20
6 months follow-up	192	2.95	3.34	2.48–3.43
Difference	192	4.67	4.05	4.09–5.24
Satisfied only				
Baseline	163	7.4	3.58	6.85–7.95
6 months follow-up	163	2.17	2.59	1.77–2.57
Difference	163	5.23	3.7	4.65–5.80
Not-satisfied only				
Baseline	29	8.86	5.02	6.95–10.77
6 months follow-up	29	7.35	3.73	5.93–8.76
Difference	29	1.51	4.56	−0.22–3.25
PNF				
Baseline	38	5.61	2.71	4.71–6.50
6 months follow-up	38	1.53	1.74	0.96–2.10
Difference	38	4.08	2.77	3.17–4.99
Xiapex©				
Baseline	22	7.96	3.63	6.34–9.57
6 months follow-up	22	2.82	3.83	1.12–4.51
Difference	22	5.14	3.47	3.60–6.67
Fasciectomy				
Baseline	131	8.20	3.96	7.51–8.88
6 months follow-up	131	3.40	3.52	2.80–4.01
Difference	131	4.79	4.43	4.03–5.56

Total, satisfied and not satisfied, Xiapex© injection, percutaneous needle fasciotomy (PNF), fasciectomy. One patient was treated with dermo-fasciectomy and had a low SDSS score both before and after surgery. SDSS: Southampton Dupuytren's Scoring Scheme; n: number; Min: minimum; Max: maximum; SD: standard deviation; CI: confidence interval.

error [11]. This measurement is referred to as the standard error of measurement (SEM): $SEM = SD \cdot \sqrt{1 - r}$.

The SEM is calculated by using the standard deviation at baseline (SD) and reliability of the measurement instrument. Reliability (r) is measured as Cronbach's Alpha.

All statistical analyses were performed using SPSS and the level of statistically significance was set at $p < 0.05$ and p-values were 2-tailed. Confidence intervals were expressed as 95% intervals.

Results

In total, 163/192 (85%) of the patients were satisfied with the result at 6 months according to the anchor question. The anchor-based MCID from the ROC curve analyse was 1.5 points as seen in Figure 3, and the AUC was 0.743 indicating an acceptable accuracy. The distribution-based method was calculated using the SEM and resulted in an MCID of 1.62 points. The SD of the mean baseline SDSS score was 3.85 and the Cronbach's Alfa was 0.822 indicating good reliability.

The total mean SDSS at baseline was 7.62 points and the mean SDSS 6 months following treatment was 2.95 points. This results in a mean improvement of 4.67 ($p < 0.001$), Table 2. The mean SDSS score improvement in the satisfied group was 5.23 ($p < 0.001$) and in the not satisfied group the improvement was not statistically significant 1.51 ($p = 0.084$). The mean difference between the satisfied and the not satisfied was 3.71 points (95%

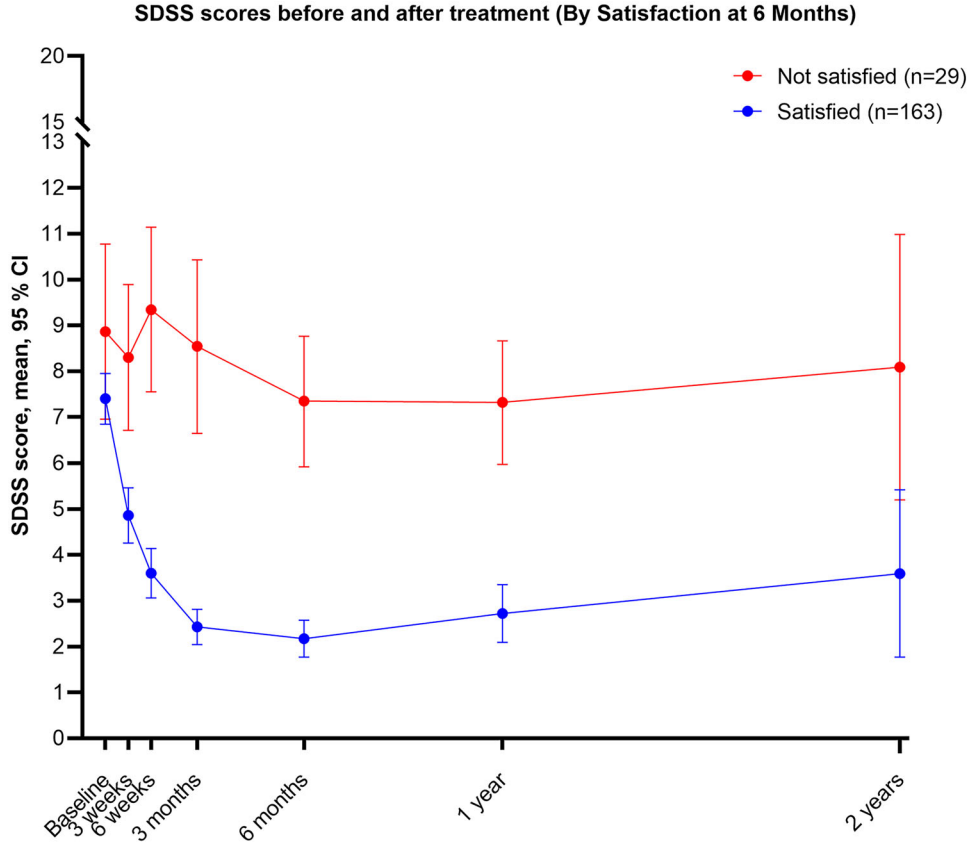

Figure 4. SDSS total and SDSS satisfied vs. not satisfied. Maximum of recovery after 6 months.

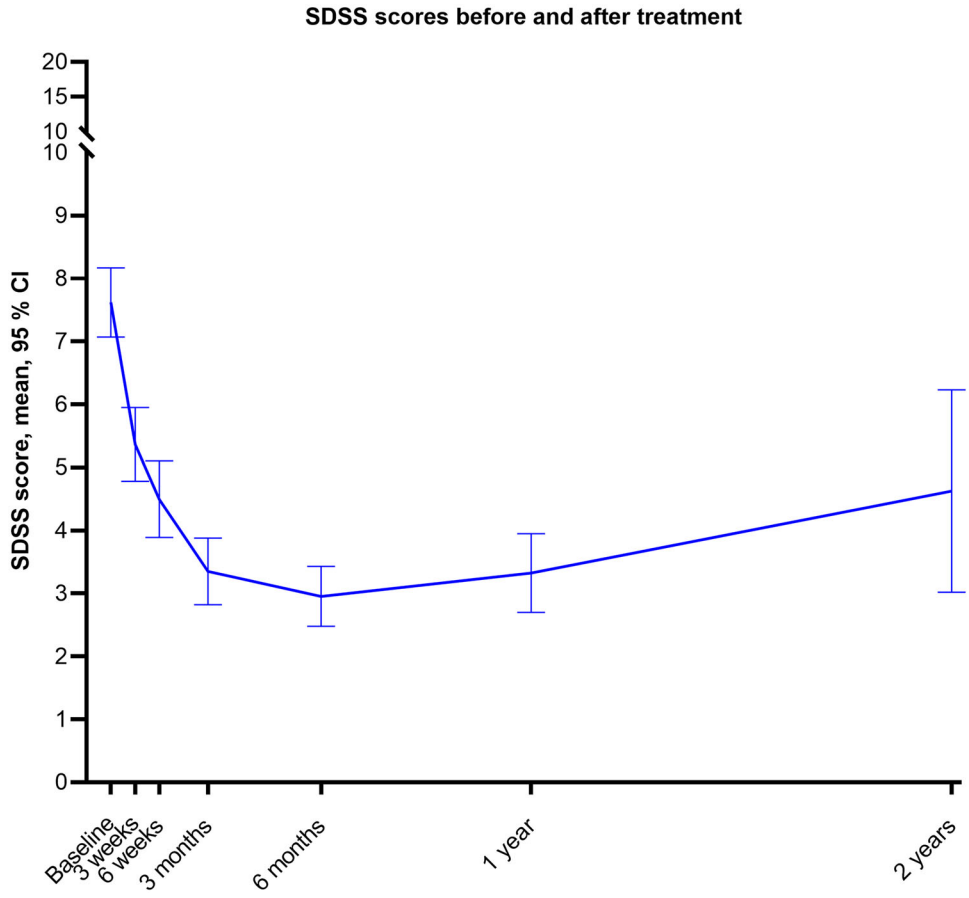

Figure 4. Continued.

CI 2.18–5.23, $p < 0.001$). In Table 2, the baseline scores and follow-up at 6 months are shown for each of the 4 treatment groups.

Discussion

In this methodological study of patients treated and followed prospectively for DD, we estimated the MCID using both an anchor-based and a distribution-based approach. Our estimated MCID for the SDSS score was 1.5 points using the anchor-based approach (ROC curve). This suggests that a change in score of more than 1.5 point can be considered clinically important to the patient. Our estimated MCID was 1.62 points using the distribution-based approach, and as such is very close to the anchor-based estimate. The distribution-based measure is considered supportive information to the MCID estimate from the anchor-based approach [12]. The satisfied group had a statistically significant improvement of 5.23 points and was well above our MCID estimate. A study by Fletcher et al. with an enrollment of 54 patients treated with Xiapex® reported a mean SDSS improvement at 12 months follow-up of 6.48 points on SDSS [13]. This finding was comparable to ours and was as expected well above our MCID estimate. This means that patients in the satisfied group experienced an important clinical change after the treatment. The not-satisfied group did not have a statistically significant improvement. In future studies, it would be interesting to investigate why the patients in the not-satisfied group are not improving in SDSS. MCID estimates for PROMs are important tools in research and clinical settings. The MCID estimates in this study contribute to the evaluation of clinical significance and can guide in clinical decision-making. In a sample size calculation, the MCID prevents the inclusion of more patients than necessary and ensures that enough patients are included to determine a true difference between groups, that is experienced as beneficial by the patients. To our knowledge, this is the first study to report an MCID estimate for SDSS, and consequently, there are no comparable MCID values (Figure 4).

Strengths and limitations

A strength of this study is the large study sample size of 192 patients. Furthermore, we have a high response rate of 84%. The study is heterogeneous as we included four different techniques for the treatment of DD and this strengthens the external validity of the study. The anchor used in our study was based on the external criterion with only one question yes/no. Other studies used the Global Rating of Change (GRC) scale as an anchor [14,15]. The GRC scale is using a 15-point scale that is divided into sub-groups and these are used as an anchor. However, it has been suggested in a study by Turner D et al. [16] that using the entire cohort for the ROC curve maximizes the precision and accuracy of the MCID estimate.

Conclusion

In conclusion, the MCID of the SDSS for patients receiving treatment for DD is 1.5 points when estimated by an anchor-based approach and 1.62 points when estimated by a distribution-based approach. These MCID values should be considered in the interpretation of SDSS scores in the future, as well as when planning future studies on DD.

Disclosure statement

No potential conflict of interest was reported by the author(s).

ORCID

Jens Jørgsholm http://orcid.org/0000-0003-3916-4443
Rasmus Wejnold Jørgensen http://orcid.org/0000-0001-5734-9244

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