

No need to use both Disabilities of the Arm, Shoulder and Hand and Constant–Murley score in studies of midshaft clavicular fractures

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Background and purpose — Most newer randomized studies examining plate fixation and nonoperative treatment of midshaft clavicular fractures utilize both Disabilities of the Arm, Shoulder and Hand (DASH) and Constant–Murley score (CS) in the evaluation of patient outcomes. Compared with DASH, the use of CS requires on-site trained personnel and patient visits to obtain the score. The use of both DASH and CS should provide extra value compared with the use of a single functional outcome score; if this value is not provided, the combined use is not necessary. We evaluated the agreement between DASH and CS in patients with displaced midshaft clavicular fractures.

Patients and methods — We used prospectively collected data from 146 patients enrolled in a randomized study comparing operative and nonoperative treatment of midshaft clavicular fractures. We determined correlation between DASH and CS at all follow-up points and calculated mean bias in the Bland–Altman plot.

Results — We found moderate to high correlation (from 0.82 at 6 weeks' follow-up to 0.58 at 1-year follow-up) between DASH and CS score, and a small bias (2.21 [95% CI 0.22–4.20]) in the Bland–Altman plot.

Interpretation — In patients with displaced midshaft clavicular fractures DASH and CS measures the same degree of disability. Unless specifically studying strength and range of motion, we recommend the sole use of DASH as it would eliminate potential observer-induced bias along with removing the economic and logistic burden of obtaining CS without compromising the value of the collected data.

Almost all newer randomized studies (Canadian Orthopaedic Trauma Society 2007, Mirzatolooei 2011, Virtanen et al. 2012, Robinson et al. 2013, Ahrens et al. 2017, Woltz et al. 2017b, Qvist et al. 2018) examining plate fixation with nonoperative treatment of midshaft clavicular fractures utilize both Disabilities of the Arm, Shoulder and Hand (DASH) (Hudak et al. 1996) and Constant–Murley score (CS) (Constant and Murley 1987) in the evaluation of patient outcomes. DASH is a self-reported questionnaire, developed in 1996 to describe disability experienced by patients with a musculoskeletal condition of the upper extremity and to monitor change in symptoms and upper limb function over time. Developed in 1987, the CS evaluates shoulder function in general by combining subjective and objective measurements.

The use of CS requires on-site trained personnel and ambulatory patient visits to obtain the score and is more time consuming than obtaining DASH (Michener and Leggin 2001). The correlation between and measurement properties of DASH and CS have been examined in patients following nonoperatively treated clavicular fractures (Ban et al. 2016), rotator cuff repair (Skutek et al. 2000), and in patients with a humeral shaft fracture (Mahabier et al. 2017). These studies show a good correlation between DASH and CS, which indicates that either score alone may replace the use of both. In a research setting with finite resources the use of both DASH and CS should provide extra value compared with the use of a single functional outcome score. If this extra value is not provided, the combined use of DASH and CS is not necessary. Should the combined use of these instruments not be necessary DASH has the potential to be used as the sole instrument in register studies with large cohorts. This study evaluates the agreement between DASH and CS in patients receiving both nonoperative and operative treatment of displaced midshaft clavicular fractures.

Table 1. Demographic data 146 patients with midshaft clavicular fractures

Parameter	Demographic
Age (range)	40 (18–60)
Age groups, n	
18–30	38
31–45	59
46–60	49
Male:female ratio, n	119:27
Fracture type, n	
noncomminuted	46
comminuted fracture	94
missing data	6
Shortening, n	
< 1 cm	38
1–2 cm	64
> 2 cm	37
missing data	7

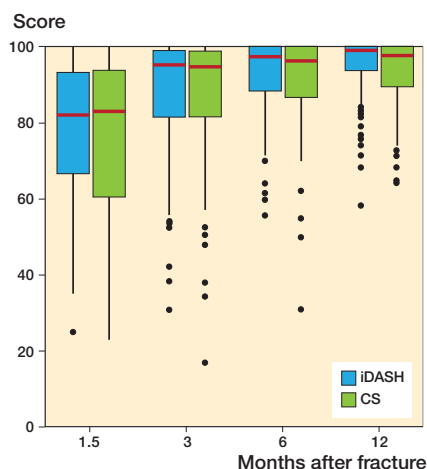


Figure 1. Boxplot of inverted Disabilities of the Arm, Shoulder and Hand (iDASH) and Constant–Murley score (CS) at each follow-up. Red line is the median. Top and bottom box borders indicate the interquartile range (IQR). Whiskers mark minimum and maximum value no further than $1.5 \times$ IQR from the hinge. Outliers beyond that are plotted individually.

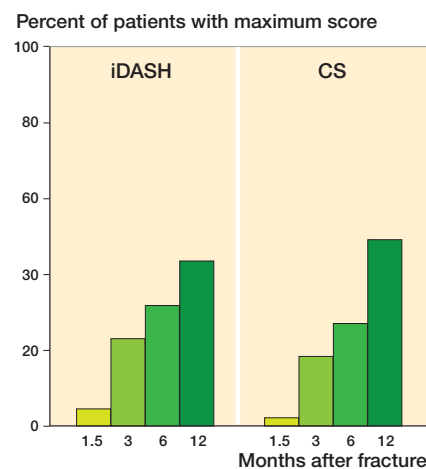


Figure 2. Ceiling effect for inverted Disabilities of the Arm, Shoulder and Hand (iDASH) and Constant–Murley score (CS) at each follow-up.

Patients and methods

We used prospectively collected data from 146 patients enrolled in a randomized study comparing operative and non-operative treatment of midshaft clavicular fractures (Qvist et al. 2018). DASH and CS were collected at 6 weeks, 3 months, 6 months, and 1-year follow-up. 146 patients were included in the study (Table 1). 71 patients were included in the nonoperative treatment group and 75 were included in the operative treatment group. 22 patients were lost to follow-up.

The DASH questionnaire consists of 30 items, each scored 1 to 5 on an ordinal scale (Hudak et al. 1996). The DASH score ranges from 0 to 100 points with 0 points representing normal function and increasing score representing increasing dysfunction. For analysis purposes only an inverted DASH (iDASH equal to $100 - \text{DASH}$) score was used.

CS evaluates shoulder function in general by combining subjective and objective measurements (Constant and Murley 1987). An observer measures range of motion (ROM) and power for a total of 35 points. In the original randomized trial this observer was blinded. The subjective measurement of CS is 2 patient-reported items for pain and activities of daily life (ADL) for a total of 65 points. CS ranges from 0 to 100 points with decreasing score representing dysfunction. A CS of 100 points equals a shoulder with full range of motion, no pain, no problems with performing activities of daily life, and an abduction force of 12 kg.

Statistics

We used R (R Core Team 2018) version 1.1.456 and the blandr package (Datta 2017). We did not impute missing

data. We used QQ plots and histograms to examine data for normality. Patient demographics were reported using descriptive statistics. Ceiling effect was calculated at each follow-up. Spearman's rank correlation coefficient (r) was calculated to describe correlation between iDASH and CS, as iDASH and Constant scores were not normally distributed at any follow-up point. Correlation was regarded as high if r was over 0.70, moderate if r was between 0.50 and 0.70, and low if r was lower than 0.50 (Mukaka 2012). We expected correlation to decrease with increasing follow-up, as some patients would be expected to reach the ceiling in iDASH before CS and vice versa. Spearman's rank correlation coefficient for operative and nonoperative groups was calculated to ensure that combining the 2 groups did not overestimate correlation (Hassler and Thadewald 2003). A Bland–Altman plot was used to describe the mean bias between iDASH and CS. The Bland–Altman plot requires that the difference between the 2 scores is normally distributed, which occurred only at 6 weeks' follow-up. 95% confidence intervals (CI) were calculated.

Ethics, registration, funding, and potential conflicts of interest

The original randomized study was approved by the Regional Ethical Committee Board in the North Denmark Region (N-20090054), and registered in the ClinicalTrials.gov database (Identifier: NCT01078480). This study received funding from Swemac Orthopaedics Aps. None of the authors received payments or services, either directly or indirectly in support of any aspect of this work.

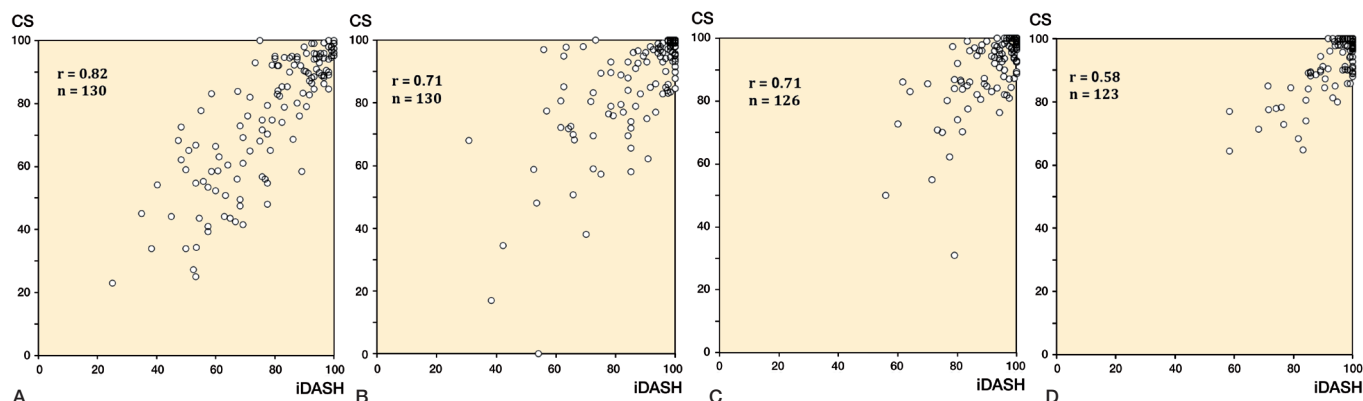


Figure 3. Scatterplots of inverted Disabilities of the Arm, Shoulder and Hand (iDASH) and Constant-Murley score (CS) at (A) 6 weeks' follow-up, (B) 3 months' follow-up, (C) 6 months' follow-up, and (D) 1-year follow-up. r = Spearman's rank correlations coefficient. n = number of subjects.

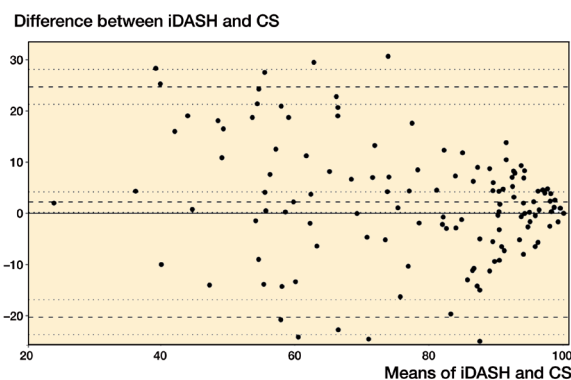


Figure 4. Bland–Altman plot of the means of inverted Disabilities of the Arm, Shoulder and Hand (iDASH) and Constant–Murley score (CS) versus the differences between iDASH and CS. Top dashed line indicates upper limits of agreement, while lower dashed line indicates lower limits of agreement. Middle dashed line indicates mean bias. Dotted lines show 95% confidence intervals around agreements and mean bias.

Table 2. Number of subjects (n) and correlation (r) between DASH and CS at each follow-up point

Treatment	6 weeks		3 months		6 months		1 year	
	n	r	n	r	n	r	n	r
Operative	67	0.77	65	0.64	63	0.71	63	0.65
Nonoperative	63	0.78	65	0.72	63	0.69	60	0.52
Combined	130	0.82	130	0.71	126	0.71	123	0.58

Results

Both iDASH and CS improved at each follow-up (Figure 1). Ceiling effect increased during follow-up and was present in 44% (CI 35–52) of all iDASH scores and in 49% (CI 41–58) of all CS after 1 year (Figure 2). Figure 3 shows scatterplots and Spearman's rank correlations coefficients of iDASH and CS at each follow-up point. We saw a decrease in correlation

coefficient from 0.82 at 6 weeks' follow-up to 0.58 at 1-year follow-up. Correlation between iDASH and CS at 6 weeks, 3 months, and 6 months' follow-up was high, while correlation at 1-year follow-up was moderate.

We found no severe overestimation of correlation coefficients when comparing groups (Table 2). The Bland–Altman plot (Figure 4) showed a mean bias towards iDASH of 2.2 (CI 0.2–4.2) with an upper limit of agreement of 25 (CI 21–28) and a lower limit of –20 (CI –17 to –24).

Discussion

We found moderate to high correlation between iDASH and CS score, and a small mean bias in the Bland–Altman plot. The correlation between iDASH and CS decreased with increasing follow-up and was moderate at 1-year follow-up. Scatterplots (Figure 1) of iDASH and CS show the impact of ceiling effect with increasing follow-up, which could explain the decrease in rank correlation, as some patients reach the ceiling in iDASH before CS and vice versa. The decrease in correlation may also be related to the loss of patients to follow-up, as the power of the correlation test decreases with the lower number of subjects late in the study. The combination of operative and nonoperative treatment groups increases sample heterogeneity and could overestimate the correlation coefficient (Hassler and Thadewald 2003); however, we found no severe overestimation of correlation coefficients when analyzing groups separately. The high correlation between iDASH and CS before the 1-year follow-up point is consistent with findings in previous studies. Ban et al. (2016) found a Pearson correlation coefficient between DASH and CS of –0.92 after 6 weeks of nonoperative treatment in 36 patients with a wide range of clavicular fracture types. Mahabier et al. (2017) found a Spearman rank correlation of –0.78 between DASH and CS at 6 months' follow-up in a large cohort of patients from a randomized controlled trial comparing operative and nonoperative treatment of humeral shaft fractures. In a large consecutive series of 372 patients

with rotator cuff disorders, a Lin's concordance correlation coefficient of 0.89 was found between DASH and CS at 24 months follow-up (Allom et al. 2009). None of the above studies investigated correlation when ceiling effect was present, and our finding of moderate correlation at 1-year follow-up is different from these previous findings.

Correlation coefficient alone does not provide enough information on agreement between methods of measurement (Bland and Altman 1995). To further compare the agreement between iDASH and CS, we constructed a Bland–Altman plot. We found a minimal mean bias between iDASH and CS of 2.2 (CI 0.2–4.2), meaning that on average iDASH would measure 2.2 points more than CS on a group level.

We consider the mean bias to be low, as it is lower than the 10-point clinically relevant difference in DASH. 95% of the differences between the iDASH and CS measurements lie between upper (25 points) and lower limits of agreement (-20 points), which is up to 2.5 times more than the clinically relevant difference in DASH. This may seem high, but the point of our Bland–Altman plot was not to investigate a possible direct translation from CS to DASH on an individual level, but to illustrate the mean bias between DASH and CS on a multi-subject scale when comparing groups in clinical studies. We do not consider the wide limits of agreement to be an issue in this regard. Supporting our finding of a low mean bias a recent meta-analysis found a similar absolute mean difference of 5.1 (CI 0.1–10.1) vs. 4.4 (CI 0.9–7.9) in DASH and CS score comparing operative and non-operative treatment of midshaft clavicular fractures at 1-year follow-up (Woltz et al. 2017a).

The overall high correlation and low mean bias shows similarity between the 2 scores and we believe that DASH and CS measures the same degree of disability. Support for this claim also comes from recent randomized trials (Canadian Orthopaedic Trauma Society 2007, Mirzatoolei 2011, Virtanen et al. 2012, Robinson et al. 2013, Ahrens et al. 2017, Woltz et al. 2017b, Qvist et al. 2018), where in all cases DASH and CS follows the same trends when comparing operative and nonoperative treatment.

DASH is a limb-specific instrument developed with the purpose of assessing symptoms and functional status in populations with upper extremity musculoskeletal conditions (Hudak et al. 1996) and CS was developed as a clinical method of shoulder function assessment (Constant and Murley 1987). The comparison of a limb-specific instrument with a shoulder-specific instrument may not be valid if the patient suffers from any other illness of the affected extremity. In our original randomized study these patients were excluded, and in this patient group of otherwise healthy patients we expect that any change in DASH would be related to disability following a midshaft clavicular fracture, making DASH comparable to CS.

The obtainment of CS requires on-site trained personnel and ambulatory patient visits, which can pose a logistic and economic challenge. This challenge has previously been recognized as a component in the difficulties of assessing long-

term outcome of shoulder disability (Dawson et al. 2001). The sole use of DASH does not require on-site trained personnel or ambulatory patient visits, as the DASH questionnaire could be completed at home and mailed in or submitted online via free tools such as REDCap (Harris et al. 2009). The sole use of DASH in the future evaluation of cuff disorders has been proposed in a study comparing DASH, CS, and Oxford score in patients with rotator cuff disorders (Allom et al. 2009). Furthermore, compared with CS, the DASH questionnaire was found to be the most reliable instrument in evaluating outcome in humeral shaft fractures (Mahabier et al. 2017). QuickDASH exists as a shortened version of the DASH questionnaire (Gummeson et al. 2006). QuickDASH contains only 11 questions and could potentially increase response rates compared with DASH. Although some detail is lost with the reduction of questions (Angst et al. 2009), QuickDASH has been shown to be a relevant substitute for DASH (Abramo et al. 2008, Macdermid et al. 2015, Tsang et al. 2017), and could potentially be used in future studies instead of DASH.

This study has some limitations. We did not perform a test–retest analysis, as no retest was performed. Lacking this analysis, we were not able to evaluate the test–retest reliability of CS and DASH. However, the scope of this study was not to validate CS and DASH in patients with midshaft clavicular fractures and we do not consider the lack of test–retest analysis to be a severe limitation. Ideally, the Bland–Altman plot should compare DASH or CS against a gold standard, but no such standard exists in the measurement of outcomes following midshaft clavicular fractures. Considering external validity our study population contains only patients with a displaced midshaft clavicular fracture and the results cannot be generalized to all types of clavicular fractures.

In conclusion, as DASH and CS in this study measure the same degree of disability in patients with midshaft clavicular fracture, we propose that DASH may be used as the only measurement instrument in future studies comparing outcomes following treatment of midshaft clavicular fractures, unless these studies have a specific aim of studying strength and range of motion, where CS could be used as the only instrument.

CMJ and SLJ designed the study. AHQ, MTV, CMJ, and SLJ acquired the data. AHQ, TJ, and SLJ did the statistical analysis. All authors discussed the results and contributed to the final manuscript.

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