



Development of the Utrecht Score for clavicle fractures: a short and complete clavicle score with patient-reported and objective measures

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Abstract

Purpose The purpose of this study was to develop a clavicle-specific questionnaire with patient-reported and objective measures.

Methods The present study used data of DASH and Constant scores from a previously performed randomized-controlled trial comparing plate and intramedullary pin fixation of clavicle fractures. Exploratory factor analysis was used to identify the most relevant items and the underlying structure of the questionnaires. To optimize the applicability to patients with a clavicle fracture, the selected items were reformulated. If relevant themes were underexposed, an additional question was added.

Results Based on the scree plot of eigenvalues and the parallel analysis, a seven-factor model with good factorability was constructed. Using exploratory factor analysis, 13 patient-reported and 2 objective measurements were identified. The internal consistency of the selected questions was excellent. An additional question was added to cover complaints relating to direct pressure on the clavicle and implants.

Conclusion The Utrecht Score for clavicle fractures is a compact yet complete tool that was developed to assess functional outcome specifically in patients with a clavicle fracture, consisting of patient-reported and objective measures. After external validation, the USC can be used for research purposes or clinical follow-up during rehabilitation in patients with a clavicle fracture.

Keywords Clavicle · Questionnaire · Patient-reported · Functional outcome

Introduction

In studies analyzing the outcome after treatment for fractures, the primary outcome measure is often functional. Several measurement tools are available to evaluate outcome of and recovery process after operative or conservative treatment in patients with a clavicle fracture [1]. The Disabilities of the Arm, Shoulder and Hand questionnaire (DASH) and Constant score (CS) are popular questionnaires often used concurrently [1–3]. The DASH is a 30-item patient-reported

questionnaire that quantifies physical function and symptoms. Although it is designed for upper limb disorders, it does not contain items that objectively assess range of motion (ROM) and strength [2]. The CS assesses pain, ROM, and the ability to work, sleep, and play sports. In contrast to the DASH, the CS was specifically designed for patients with shoulder injuries. However, it only contains a limited amount of patient-reported outcome items [3]. Combining the comprehensive functional outcome scores in the DASH with the objective ROM scores in the CS is the rationale behind using both questionnaires in many studies.

However, using both questionnaires can be problematic in terms of overlap and efficiency. They both assess pain, difficulty sleeping, and performing activities of daily living, and the combined length of the questionnaires most likely results in decreased response rates [4]. The main disadvantage of a questionnaire not specifically designed for a certain body region is the inability to detect region-specific changes. Limitations in wrist-related problems are obviously different

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from those with shoulder injuries. A functional outcome tool that assesses both patient-reported and objective (ROM) measurements specifically for patients with a clavicle fracture is lacking. Although we realize that, by developing a new questionnaire, we contribute to the increasing number of shoulder scores [1, 5, 6], we do believe that such a questionnaire could improve the accuracy of research regarding clavicle fractures, increase response rates, and decrease the administrative load. Therefore, the aim of this study was to combine and reduce two frequently used questionnaires, and develop a condition-specific questionnaire, with both patient-reported and objective measures, for the assessment of functional outcome during and after rehabilitation in patients with a clavicle fracture.

Methods

Patients and data

The present study used data from a RCT, which examined the outcome of intramedullary pin fixation versus plate fixation in 120 patients with a displaced midshaft clavicle fracture from January 2011 until August 2012 [7]. Post-operatively, patients were given a sling for comfort. They were encouraged to discard the sling as soon as possible. Weight-bearing was permitted after fracture consolidation (bridging bone or callus formation) was demonstrated radiographically. Functional recovery was assessed in all patients using the DASH and the CS at 6, 12 weeks, 6 months, and 1 year [2, 3, 7]. We chose to use outcome measurements at 6 weeks for both the DASH and CS in the present analysis. This specific point in time was chosen to ensure optimal discriminatory value of the questionnaires as the variability in outcome scores declines after this point [8].

Questionnaires

The DASH score is a 30-item questionnaire that evaluates physical function and symptoms in patients with upper extremity disorders. The score uses a five-point response scale from 1 to 5, representing no difficulty to severe difficulty. The DASH score is calculated by adding the response scores and dividing this sum by the number of completed responses. The result is then reduced by 1 and multiplied by 25 [2]. A higher score (maximum = 100) represents greater disability and a lower score good functioning.

The CS is a shoulder-specific questionnaire that determines functional capabilities. The patient-reported components are: pain (four-point scale, 15 points), ability to work, sleep, and play sports (dichotomous, 10 points), and arm positioning (five-point scale, 10 points). The objective components are: ROM without pain and strength (maximum of

65 points). The sum of all responses represents the CS [3]. A higher score indicates a better functioning (0–100 points).

Factor analysis and item selection

The purpose of our factor analysis was twofold: identification of the underlying dimensional structure and item reduction. To identify the dimensional structure among the 30 items of the DASH and 10 items of the CS, an exploratory factor analysis (EFA) was performed. Questions are termed items in the factor analysis. To assess the factorability, two measures of sampling adequacy were used: Bartlett's test of sphericity and the Kaiser–Meyer–Olkin. Bartlett's test of sphericity determines if there are correlations in the data set that are appropriate for factor analysis. If so, a significance below the set alpha level of 0.05 is found. The Kaiser–Meyer–Olkin value provides information about the degree of common variance among the items. Higher scores indicate a better factorability, as the factors extracted will account for a higher amount of variance. For item reduction analysis, both principal axis factoring and principal component analysis are considered equally adequate [9]. However, to identify an underlying dimensional structure, principal axis factoring is the preferred method, as it provides information about the shared variance in a set of items through a small set of factors [9, 10]. To clarify the factor matrix, the factors are rotated using the varimax method. This produces higher values for stronger items and lower values for weaker items, thus improving the interpretability of the model. To identify the optimal number of factors that should be retained during extraction, the break point in the scree plot of eigenvalues was analyzed and a parallel analysis (Eigenvalue Monte Carlo simulation, significant at 95%, not assuming normally distributed data) was performed [11–13]. The scree plot shows the eigenvalues of the retained factors against each single factor. Below the break point in the plot, when the plot starts to level off, the additional factors account for less variance than a single variable. The number of factors allowed to load was subsequently increased and decreased to assess if this led to a better interpretable model or a higher explained variance. This was done as a final verification of the adequacy of the number of retained factors [9]. Considering the sample size, a model with item loadings > 0.5 was considered sufficient and loaded into the rotated factor matrix for interpretation [9].

The dimensional structure stemming from the rotated factor matrix was evaluated and factors were labeled based on the items with highest loadings. To determine how many and which items should be selected per factor, several criteria were applied: (1) applicability of the item to patients with a clavicle fracture and (2) factor loading of the item. Inter-item correlation was determined if items appeared highly similar. The internal consistency of the selected items was assessed

with the Gutmann lambda 2 (> 0.7 was considered fair and > 0.9 excellent) [14].

To further optimize applicability, the ultimately selected items were reformulated and specified for patients with a clavicle fracture. As the items were selected from two non-clavicle-specific questionnaires, attention was paid to detect underexposed domains. If relevant themes were underexposed, an additional question was added. The final questionnaire was named the Utrecht Score for Clavicle fractures (USC).

Results

Exploratory factor analysis

Since eight patients had missing data, the EFA was performed in the 112 include patients. The baseline characteristics of the population and the DASH and CS 6 weeks after surgery are shown in Table 1 [7, 15].

Bartlett's test of sphericity ($p < 0.001$) and the KMO (0.81) indicated that the data were adequate for EFA. Analysis of the break point in the scree plot of eigenvalues and the parallel analysis (Eigenvalue Monte Carlo Simulation) revealed that extraction of seven factors was adequate. A model with six or eight factors did not increase the explained variance of the model, nor did it increase the interpretability of the model. The explained variance of the factor matrix was 59.8%. The variance per factor is displayed in Table 2.

Item selection and internal consistency reliability

Table 2 shows the factor matrix of the EFA, the selected items, and how the factors were labeled. Factor one loaded most items and explained 33% of the variance. Six items were selected from this factor. It was hypothesized that the item "Ability to carry a heavy object (5 kg)" was similar to "Ability to carry a shopping bag or briefcase". This hypothesis was confirmed by a high inter-item correlation of 0.85. The latter was selected, because it is formulated more specifically.

In factor two, "perceived functional capabilities", two out of three available items were selected. "Ability to perform sexual activities" was not selected due to its abstract formulation. In factor three, two items were selected. "Prepare a meal" was selected over "turn a key", because the latter is primarily concerned with small hand movement and, therefore, less applicable to patients with a clavicle fracture. Both items in factor four, "range of motion", were selected. The choice to include both items was based on their biomechanical properties. Lateral elevation of the arm produces compression in the clavicle, and forward flexion of the arm causes the clavicle to

Table 1 Baseline characteristics

Variables	Clavicle fractures (N= 112)
Age* (years)	39.0 ± 14.0
Sex [†]	
Male	105 (94%)
Female	7 (6%)
Caucasian [†]	110 (98%)
BMI* (kg/m ²)	24.5 (3.2)
Smoker [†]	
Yes	37 (33%)
No	75 (67%)
Alcohol/drug abuse [†]	
Yes	13 (12%)
No	99 (88%)
Hand dominance [†]	
Right	99 (88%)
Left	13 (12%)
Sports activities [†]	
No	32 (29%)
Yes	80 (71%)
Fracture side [†]	
Right	53 (47%)
Left	59 (52%)
Trauma mechanism [†]	
Traffic accident	45 (40%)
Sports	47 (42%)
Fall from stance/height/other	20 (18%)
Fracture classification ^{†‡}	
Simple	47 (42%)
Wedge	60 (53%)
Complex/comminuted	5 (5%)
Functional outcome	
DASH (SD, SEM)	14.0 (13.6, 1.3)
Constant (SD, SEM)	86.2 (15.2, 1.4)
Pain ^a	31 (28%)
Reduced ROM ^b	22 (20%)
Limited in daily activities ^c	90 (80%)

SD standard deviation, SEM standard error of mean

^aQuestion 24 + 25 of the DASH score regarding pain. On a five-point scale (1 = no pain, 5 = extreme pain) only patients with a score > 3 are counted for

^bAll patients who scored 6 points or less on the range of motion questions of the Constant score (0 = worst ROM, 10 = best ROM)

^cQuestion 22 + 23 of the DASH regarding daily activities. On a five-point scale (1 = not at all, 5 = extremely limited), only patients with a score > 3 are counted for. Question 2 + 3 + 4 of the Constant score regarding daily activities. On a two-point scale, only the patients with limitations were included

*The values are given as the mean and standard deviation

[†]The values are given as the number with the percentage in parentheses

[‡]Fractures classified according to the AO/OTA classification

Table 2 Factor matrix of the exploratory factor analysis, selected items, and factor labeling

Questions	Factor loading	Variable selection rationale	% of variance
1. Shoulder movement with moderate-to-high impact			33.8
Place an object on a shelf above your head	0.80	Selected	
Do heavy household chores (e.g., wash walls and wash floors)	0.74	Selected	
Recreational activities in which you move your arm freely	0.73	Selected	
Carry a heavy object (5 kg)	0.70	–	
Change a lightbulb overhead	0.70	Selected	
Push open a heavy door	0.69	–	
Carry a shopping bag or briefcase	0.68	Selected	
Open a tight or new jar	0.68	–	
Make a bed	0.59	Selected	
Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.)	0.56	–	
Gardening	0.54	–	
2. Perceived functional capabilities			7.1
Please rate the severity of the following symptoms in the last week: Weakness	0.69	Selected	
Sexual activities	0.60	–	
I feel less capable, less confident or less useful because of my arm, shoulder or hand problem	0.57	Selected	
3 Shoulder movement with low impact			5.5
Write	0.86	Selected	
Turn a key	0.80	–	
Prepare a meal	0.63	Selected	
Recreational activities which require little effort (e.g., card playing, knitting, etc.)	0.56	–	
4. Range of motion			4.1
Objective measurement of lateral elevation ^a	0.71	Selected	
Objective measurement of forward flexion ^a	0.71	Selected	
5. Patient-perceived range of motion			3.3
Ability to work at specific level: waist, chest, neck, head, above head ^a	0.71	Selected	
External rotation ^a	0.65	–	
Manage transportation needs (getting from one place to another)	0.53	–	
6. Pain			3.1
Please rate the severity of the following symptoms in the last week: Pain in arm shoulder or hand	0.81	Selected	
Pain in shoulder ^a	0.66	–	
Please rate the severity of the following symptoms in the last week: Arm, shoulder or hand pain when you performed any specific activity	0.58	–	
7. Direct pressure on the shoulder			2.8
During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand?	0.59	Selected	
Daily activity, limited in sleep ^a	0.59	–	

Factors with factor loadings of > 0.50 were included

Factors were labeled based on the items with highest loadings

^aConstant score question

rotate [16–18]. In factor five, only one item was selected. Factor six contained three items on “pain”, so the item with the highest loading was selected. Factor seven included items about the ability to sleep without problems and the corresponding question with the highest factor

loading was selected. This factor was labeled “direct pressure on the shoulder”. The internal consistency of the selected items was 0.907 (Gutmann Lambda 2) [14].

Item adjustment and questionnaire development

The final questionnaire with the adjusted items is shown in Table 3. To improve applicability to patients with a clavicle fracture all items referring to “arm, shoulder, or hand problems” were adjusted to shoulder problems. Item ten, “ability to position your arm to a specific level: waist, chest, neck, head, and above head”, derived from factor five, was reformulated to “please rate the following statement regarding your clavicle fracture: I am not satisfied with the range of motion of my shoulder, because it is insufficient to perform activities of daily living”. Finally, an additional question 14 was added: “please rate the severity of pain in your shoulder due to direct pressure on the shoulder/clavicle (carrying a bag on the shoulder, seatbelt, and pressure on skin due to implant or protruding bone)” (Table 3).

Patients completing the USC should be instructed that the items refer to the ability to perform activities on the affected side in the past week. A best estimate should be made when patients do not perform an assessed activity. The patient-reported measurements are on a five-point Likert scale for

items one to 14 (0 = best functional outcome, 4 = worst functional outcome). The ROM measurements for lateral and forward flexion are on a four-point Likert scale and performed by a physician (Table 3; 0 = 136°–180°, 12 = 0°–45°). The final score is calculated by summing the responses. The score range is 0–80. Lower scores indicate better outcome and higher scores worse outcome.

Discussion

The aim of the study was to combine and reduce the DASH and Constant score, and to develop a functional outcome tool specifically for the assessment of patients with a clavicle fracture. The USC contains both patient-reported as well as objective measures such as ROM. It covers several important domains of daily activities to adequately assess the function of the shoulder after a clavicle fracture. With 16 items, two of which are objectively assessed, we believe that it is a compact as well as a complete tool.

Table 3 Utrecht score for clavicle fractures

Please rate your ability to do the following activities in the last week as a result of your clavicle fracture:		No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
1	Place an object on a shelf above your head	0	1	2	3	4
1	Do heavy household chores (e.g., wash walls and wash floors)	0	1	2	3	4
2	Activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.)	0	1	2	3	4
3	Change a light bulb overhead	0	1	2	3	4
4	Carry a bag (e.g., shopping bag or briefcase)	0	1	2	3	4
6	Make a bed	0	1	2	3	4
7	Prepare a meal	0	1	2	3	4
8	To write	0	1	2	3	4
Please rate the following statement regarding your clavicle fracture in the last week		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
9	I feel less capable, less confident, or less useful because of my clavicle fracture	0	1	2	3	4
10	I am not satisfied with the range of motion of my shoulder, because it is insufficient to perform activities of daily living	0	1	2	3	4
Please rate the severity of the following symptoms in the last week		None	Mild	Moderate	Severe	Extreme
11	Pain in shoulder when performing activities	0	1	2	3	4
12	Weakness in shoulder when performing activities	0	1	2	3	4
13	Difficulty sleeping because of the pain in your shoulder	0	1	2	3	4
14	Pain in shoulder due to direct pressure on shoulder (carrying bag, seatbelt, pressure on skin due to implant or protruding bone)	0	1	2	3	4
Objective range of motion		180°–136°	135°–91°	90°–46°	45°–0°	
15	Forward flexion	0	4	8	12	
16	Lateral elevation	0	4	8	12	

The final score is calculated by summing the responses. The score range is 0–80. Lower scores indicate a better outcome and higher scores worse outcome

Although questionnaires evaluating functional outcome after upper extremity injuries are widely available, none of these questionnaires are specifically designed for use in patients with a clavicle fracture [1–3, 19–21]. In addition, many studies on functional outcome after treatment of a clavicle fracture use multiple questionnaires [1]. This increases the administrative burden and carries risk of decreased response rates due to their combined length [4]. Another argument for the use of a single condition-specific questionnaire is the demonstrated higher response rate compared to generic measures in patients with shoulder disorders [22, 23]. With the increasing quantity of research on clavicle fractures, a widespread adoption of a single responsive, reliable clavicle-specific outcome instrument would allow for a better comparison of treatment results [1].

To select the questions for the novel questionnaire, factor analysis was performed using patient data from the DASH and CS at 6 weeks [7]. In this analysis, most items loaded in factor one, “shoulder movement with moderate-to-high impact”. This is probably due to the high number of items in the DASH that assess activities of daily living, in contrast to the CS with only three dichotomous patient-reported outcome measures. The factor “shoulder movement with moderate-to-high impact” covered a somewhat similar domain as the factor “shoulder movement with low impact”. The main difference, however, relates to the level of kinetic impact that these activities induce (high versus low). Specific attention was given to the interpretation of factors four, “range of motion”, and five, “patient-perceived range of motion”. External rotation did not load in the “range of motion” factor. This could be due to the biomechanical properties of the clavicle in lateral and forward flexion as opposed to external rotation. Axial compression, measured across the intact clavicle, is greatest during lateral elevation compared to internal and external rotations. Forward flexion causes posterior rotation of the clavicle along the longitudinal axis [16–18]. The factor “range of motion” loaded only two items. A rule of thumb is one factor which must significantly load three or more items to aid in the identification and labeling of the factor [9, 10]. In other words, the more items per factor, the more likely it is that the covering domain is identified correctly. However, this phenomenon also depends on the design of the study [9, 10]. For instance, in the present study, the number of a priori available items that assess ROM was very limited (only four items from CS). We considered “range of motion” a reliable factor, because its items showed high factor loadings, and the ROM factor did not correlate highly with other factors. As ROM is a key element in the assessment of a patient’s progression after treatment of a clavicle fracture, both items were selected. The scale of the ROM items was adjusted and ranges from 0 to 12 ($0 = 136^\circ\text{--}180^\circ$, $12 = 0^\circ\text{--}45^\circ$) to increase the weight these items have for the overall USC score (Table 3). The

explained variance of the model was 60%, which is acceptable for studies that utilize patient data [9].

The final steps in the development of this questionnaire were the reformulation and adjustment of several questions and the inclusion of a new question. Patient satisfaction is an important outcome measure, as it reflects the balance between perceived capacity and intrinsic ability to perform activities. Thus, the first adjustment was to include an item to assess patient satisfaction with shoulder function by adjusting the CS question on perceived range of motion to satisfaction with range of motion during the last week. Only a few other shoulder scores address patient satisfaction [5, 6]. The UCLA Shoulder Score contains one item that gives the patient only two options: “satisfied and better” or “not satisfied and worse”. With this dichotomous outcome option, only a gross estimate of the patient’s level of satisfaction can be made. The USC question regarding patient satisfaction is on a five-point Likert scale, which allows for a better responsiveness when measuring a patient’s recovery over time. The second adjustment was to create an item addressing implant-related problems or complaints due to direct pressure on the clavicle. Any clinician will confirm that these problems are important to postoperative clavicle fracture patients and are often the topic of conversation during outpatient clinic visits. The third adjustment was to alter items of the DASH to improve applicability to clavicle fractures. As the DASH is an upper limb questionnaire, it contains several items with low applicability to patients with a clavicle fracture. Examples include “the ability to manage transportation needs (getting from one place to another)” and “the ability to turn a key”. In addition, the CS contains an item of strength measurement that has been criticized for its lack of objectivity, as the measurement is highly dependent on the patient’s demands [24, 25].

The present study analyzed the internal consistency with the Lambda 2 and found an excellent score of 0.907. Although Cronbach’s alpha is the most applied method to determine the internal consistency, some advocate against its use [14]. It is notable that the internal consistency in this study was obtained by assessing the initial selected items with all the original DASH and CS items. The internal consistency of the selected items, although in Lambda, appears to be equal or better than some of the existing shoulder scales (Cronbach alpha range, 0.83–0.97) [19, 21, 26]. In addition, we hypothesize that, by specifying the questions for clavicle fracture patients and adding questions that cover underexposed themes, the internal consistency of the final USC will be similar or even higher than 0.907.

This study has several limitations. Most importantly, the sample size of this study only meets the minimum of what is generally required for factor analysis [9]. Another drawback is that the data were derived from surgically treated patients with an isolated DMCF. However, the selected DASH and

CS questions are not specified for surgically or conservatively treated patients. Therefore, the USC is applicable to all patients with an isolated clavicle fracture, regardless of treatment. At last, the USC will require validation in future studies before it can be used reliably in a clinical setting. Ideally, this should include a confirmatory analysis, reliability testing, validity, and responsiveness assessments. In addition, the validation should involve patients with a clavicle fracture. They should advise on which activities are problematic for them but are not represented on the USC.

Conclusion

In the present study, the Utrecht Score for Clavicle fractures was developed, which is a compact and complete tool consisting of patient-reported as well as objective measures to assess functional outcome in patients with a clavicle fracture. The questions are specific for patients with a clavicle fracture, in contrast to most previous questionnaires, items related to malunion or implant-related complaints were also included. The internal consistency of the questionnaire was excellent. After external validation, the USC can be used for research purposes or clinical follow-up of functional outcome during rehabilitation in patients with a clavicle fracture.

Compliance with ethical standards

Conflict of interest M. Hulsmans, S. Ferree, R Houwert, M Dijkgraaf, E.J. Verleisdonk, and M. van Heijl declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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