A New Classification System for Outcome Measurements of Mid-Clavicular Fractures

Axel Jubel[1,*], Guido Weisshaar[2], Jonas Andermahr[3] and Christoph Faymonville[4]

[1]*Eduardus-Hospital Cologne, Custodisstr 3-17, D-50679 Cologne / Germany*

[2]*University Hospital of Cologne, Kerpener Str. 61, 50931 Cologne, Germany*

[3]*Orthopaedic Trauma-Department, Hospital of Mechernich, St. Elisabeth-Straße 2-6, 53894 Mechernich /Germany*

[4]*Trauma-Department, University Hospital of Cologne, Kerpener Str. 61, 50931 Cologne, Germany*

Abstract: *Purpose*: The current investigation was designed to evaluate and validate a simple assessment system focusing on outcomes on clavicle fractures.

Method: To examine the new scoring system focusing on outcomes post-midclavicular fracture and lateral clavicle fractures, 312 patients were studied on average 17 months post-injury. The cohort included 33 patients with lateral clavicle fractures, 46 non unions after midclavicular fracture and 233 patients with midclavicular fractures. As a control group, the same parameters in 45 healthy volunteers were examined. The Cologne Clavicle Score (CCS) is based on a system of three partnered objective/subjective items as well as radiographic assessment of fracture healing.

To validate the system, linear regression analysis was performed comparing the Cologne Clavicle Score to two established assessment systems (Score of Constant and Murley and the DASH Score).

Results: The correlation coefficients R=0.756 (Constant) and R=0.687 (DASH) post midclavicular fractures and R=0.780 (Constant and DASH) post lateral clavicle fractures indicated that the conclusions were comparable to two established assessment systems and therefore valid. The reliability coefficient Cronbach's Alpha was calculated at 0.8324, indicating high reliability.

Conclusion: The CCS is a simple, valid, and reliable instrument to assess outcomes post-midclavicular fracture and lateral clavicle fractures. It needs application in further studies to fully evaluate the quality of its conclusions.

Keywords: Clavicle score, clavicle fracture, outcome measurement, DASH score, Constant score.

1. INTRODUCTION

Clavicle fractures are one of the most common bony injuries. Epidemiologic studies estimate an incidence of 64 per 100,000 per year in the regular population, and 29 per 100,000 per year in populations over 13 years of age [39, 35].

Fractures of the middle third (Allman Group I) occur most frequently, in 67 to 81.3% of all clavicle fractures [3]. Standard therapy for these injuries is non-operative management [26, 38, 40, 10].

Despite the tendency for good healing, a number of studies have reported that non-operative therapy leads to unacceptable outcomes for a large proportion of patients with clavicle fractures [16]. This conclusion is still controversial, since prospectively randomized investigations have not yet been published [36, 13, 9].

Many authors, at the time of publication, have considered plate fixation the standard operative procedure [2, 46, 43, 8, 23, 27, 1]. Others consider intramedullary nailing, for which a number of technical variants exist [44, 34, 5, 33]. Current practice has established the use of a titanium nail [46].

In 2002, Jubel et al. first reported their intramedullary fixation technique for clavicles using a titanium nail [23, 21, 24, 20, 19, 22]. The principle of intramedullary fixation was initially described by A. Lambotte in 1907 [28]. Because of the positive results found in the treatment of acute fractures, the method of elastic intramedullary nailing (ESIN) has also been used for treatment of clavicular nonunion [25].

The criteria used to evaluate treatment outcomes are manifold, and inconsistent regarding the exact region of injury. The assessment is often based on the individual experience of the investigator [42, 15], or supplemented by an arrangement of patient-oriented questionnaires [16]. At times, the criteria used are not clearly defined [12, 1, 18, 11].

In fact, a consistent assessment and/or scoring system used by a majority of study designers for the evaluation of patient outcomes after clavicular fracture and treatment does not exist.

*Address correspondence to this author at the Eduardus-Hospital Cologne, Custodisstr 3-17; D-50679 Cologne/Germany; Tel: +49 221 8274 2243; Fax: +49 221 8274 2340; E-mail: axeljubek@t-online.de

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One system often used in published studies is the Constant and Murley Score [7, 6, 37, 41], which was primarily developed to assess global shoulder function. Another instrument used in various studies is the "Disabilities of the Arm, Shoulder, and Hand (DASH)" Score [17, 30, 31], which evaluates subjective everyday complaints of patients. This system assigns a numerical value between 0 and 100. The authors offered no evaluative cut-off values in their original publication [7, 17]. The consequence of this is that different studies use differing values to define good or poor results [32, 29, 4].

The range of values used is broad, so that a poor result score ranges from less than 60 to less than 25 points. This problem has already been discussed in a review study by Tingart et al. from 2001 [45].

The current investigation was designed to formulate a simple, efficient assessment system focusing on outcomes post-midclavicular fracture. The interpretation values were tightly defined to guarantee a high proportion of comparability.

2. MATERIALS AND METHODS

Raw data used to compile the score was collected during follow-up visits of patients with healed fractures of the middle third of the clavicle (at least six months post-injury). If bony healing was not present at six months, by definition the fracture was a non-union.

The Clavicle Score (CS) was based on two established score systems (Constant and Murley [7], DASH Score [17]) as well as original questions and measurements. The goal was to establish the data and then filter through the various elements to produce an optimal system for clinical practice.

Additionally, radiographs in two planes (anterior / posterior and angled 30° caudo-cranially) were obtained from each patient.

2.1. Patient Group

For the patient collective, inclusion criteria were defined as: type I Allman clavicle fractures, fracture age at least six months, and patient age greater than 15 years. Exclusion criteria were: patients with previous pathology of the shoulder girdle, pathologic fractures, and refractures.

172 patients were included in the study. From these, 133 (77.3%) were male and 39 (22.7%) were female. The median patient age was 36.5 (15-74) years. At the time of investigation, the median age of fracture was 14.84 (6-177) months. 99 (57.6%) patients had left-sided injuries, and 73 (42.4%) right. The dominant side was fractured in 74 (43%) patients.

64 patients (37.2%) were treated non-operatively with figure-of-eight bandages, 19 patients (11.1%) were fixed operatively with a plate, and 89 patients (51.7%) underwent elastic intramedullary nailing with a titanium nail (TEN®, Clinical House Bochum/Germany).

As controls, 45 volunteers over 15 years of age with healthy shoulders were selected. Of these, 22 (48.9%) were male and 23 (51.1%) were female. The median age of the controls was 27 (15–80) years.

2.2. Statistics

The raised data was compiled and processed using the SPSS for Windows Version 22.0 Copyright© SPSS Inc. The Mann-Whitney U Test, regression analysis, Cronbach's alpha, and discriminatory coefficient generators were used. A p-value of 0.05 was chosen as significant.

2.3. Development of Individual Score Items

The raised data were evaluated and the clavicle-specific items selected to generate the CS.

Three objective measurements were chosen. To determine evaluative cutoff points, the measured values were sub-classified into four categories corresponding to subjective patient observations (example see Figure **1**).

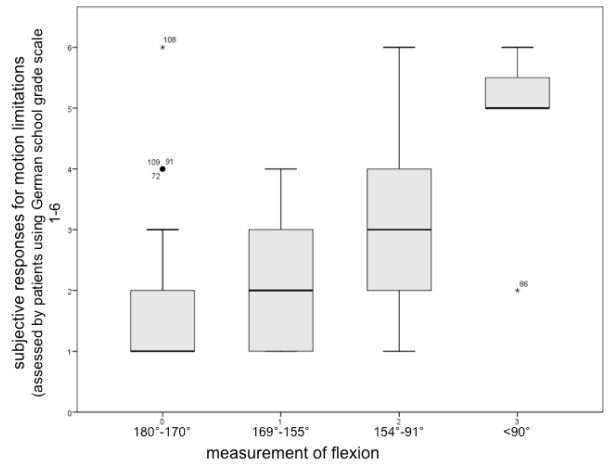

Figure 1: shows an example of a boxplot used to determine cutoff values (in this example with the classification 0 points for flexion ≥ 170°, 1 point for flexion < 170° and ≥ 155°, 2 points for flexion < 155° and > 90°, and 3 points for flexion ≤ 90°). This arrangement corresponds to that of the average subjective responses for motion limitations (assessed by patients using German school grade scale 1-6) and accorded point values (1-4). Other arrangements lead to incongruent value combinations.

An appropriate cutoff value for grade of shortening could not be resolved with our data, therefore we referred to results from a previously published study [14] that achieved significant differences in score results.

After the cutoff values for objective measurements were determined, they were compared with those subjective responses that were not direct results of the measurements. The subjective response with the lowest p-value and therefore most statistical relevance and strongest correlation to the objective measurement was chosen.

This yields six score categories: three objective and three corresponding subjective items. A final (seventh) category is the additional assessment of the radiograph. Fracture healing was classified according to the generally used criteria listed by Nordqvist [36] in his publication from 1998:

Satisfactory Healing (0 Points): Without displacement or with fragment displacement less than the width of the shaft and a fracture angle < 30°.

Poor Healing (4 Points): Fragment displacement equal or greater than one shaft width and / or a fracture angle > 30°.

Non-Union (6 Points): No fracture healing after six months.

The final score is determined by adding the individual point values of each item. The following cutoff values were used to evaluate final outcomes:

0-3 = very good.

4-8 = good.

9-14 = moderate.

15-24 = poor.

3. RESULTS

Figure **2** shows the final composition of the Clavicle Score (CS).

Clavicle Score

X-Ray finding	
good healing 0 points	→ displacement < width of the shaft and fracture angle <30°
bad healing 4 points	→ displacement > width of the shaft or fracture angle >30°
Non union 6 ponts	

measured elements	
Shortening	
< 0.5cm	0 points
0.5-1cm	1 points
>1-<2cm	2 points
>=2cm	3 points

questioned elements	
Asymmetry of shoulder girdle	
(using German school grade scale 1-6)	
excellent (1)	0 points
good (2)	1 points
moderate (3,4)	2 points
bad (5,6)	3 points

Shoulder flexion	
180°-170°	0 points
169°-154°	1 points
153°-90°	2 points
<90°	3 points

Problems with ADLs	
none	0 points
light	1 points
moderate	2 points
severe	3 points

Pain on VAS	
0	0 points
1-29	1 points
30-59	2 points
60-100	3 points

Problems at sports/heavy working	
none	0 points
light	1 points
moderate	2 points
severe	3 points

Result	
excellent	0- 3 points
good	4- 8 points
moderate	9-14 points
bad	15-24 points

Figure 2: Shows the Cologne Clavicle Score (CCS). The seven scoring categories were added; “Total Score” field shows the assessment of outcome.

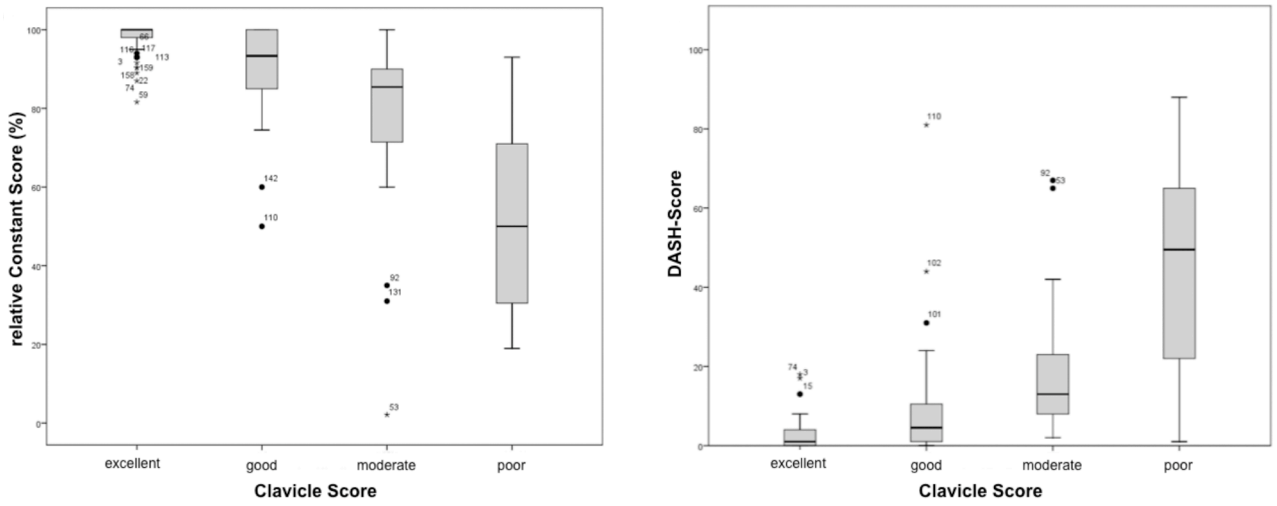

Figure 3: shows the point value distribution of the relevant Constant Scores and DASH scores corresponding to the CCS assessed outcome categories (very good, good, moderate, poor) as a boxplot. In the less successful outcome categories of the CCS, there are fewer score values. However, there are several cases in these categories where the "classical" scores assessed higher points. Circles highlight outliers, stars extreme values.

3.1. Validation of CS Against Established Scores

On average, relative values attained with the CS correlated well with the Constant and DASH scores (see Figure **3**). The calculated correlation coefficients (for Constant score 0.756, for DASH 0.687) show a significant linear correlation.

3.2. Reliability Analysis

To confirm the effectiveness of individual score items, the reliability coefficient Cronbach's Alpha, and the discriminatory coefficient of each item were generated. Cronbach's Alpha is a measure of accuracy for individual parameters within the test. Values register between 0 (no reliability) and 1 (maximal reliability). For the CS, Cronbach's Alpha measured 0.8241.

The discriminatory coefficient measures the correlation of individual items with the total score. Individual values between 0 (no correlation with total score) and 1 (high correlation with total score) were generated. Statistically, the value must be at least 0.2 for an item to be recognized as viable.

4. DISCUSSION

In principle, the goal of a score is to allocate a point value to each of a variety of measured elements, so that a total valuation can be compiled. In ideal cases, the score value is a reproducible characterization of the set of circumstances. The advantage is the consolidation of a complicated picture of specific parameters into an individual value that can be used to compare complex situations. However, there is a risk of oversimplification when individual items that don't reflect the entire clinical picture are selected for evaluation. A score generated with such elements might certainly produce values to compare, however the conclusions reached could be false for the investigated situation. For this reason it is especially important, during the development of a score system, that the specific situation be carefully analyzed and as many potential factors as necessary considered.

A further point is the distinction between objective and subjective items. Objective measures offer the advantages of reproducibility and relative autonomy from the transient psychological condition of the test subject. Disadvantages are that patient relevance cannot be exactly predicted. Thus, there is a risk that these objective items might negatively impact the total score but actually have no practical relevance for the test subject himself.

Subjective items have the advantage that the specific, individual relevance of each aspect can be registered. The disadvantage is the ostensibly worse reproducibility because responses are impacted by the current psychological state of the test subject.

Therefore, a combination of both subjective and objective items makes sense for the development of an effective score system.

Obviously, global shoulder function is evaluated in almost every investigation. However, exact cutoff values for outcomes are rarely specified. In a follow-up

study of 225 clavicle fractures in 1998, Nordqvist et al. used an extremely rough classification (reduction of shoulder abduction or flexion less than 25% was normal, 25-50% was average, and more than 50% was a poor outcome) [36]. In our patient collective, a flexion limitation of only 10% (5.6%) was considered a problem for shoulder function by patients. Patients with flexion limitations more than 25° assessed their outcome subjectively with "satisfactory" (i.e. a "C" using a school grading system).

Clavicular shortening is one of the less evident, but specific elements occurring during clinical follow-up. All other aspects of the examination (excluding the radiographs) are more or less contingent on the remaining components of the shoulder girdle. In our group of patients, Constant scores as well as CS became progressively worse as shortening increased.

One element that has been only sporadically investigated is aesthetics. Although this is extremely subjective, for large numbers of patients, it is very important. Scars, marked shortening of the jugular-acromial length, or pronounced callus bulge can make a severe negative impact on the symmetrical impression of the shoulder. In 2002, Jubel et al. concluded that correction of clavicular shortening is a requirement for a good aesthetic outcome [20].

The assessment of patient limitation in daily life is very important, since this clearly correlates with quality of life. One sub-goal of this study was to specify these limitations as well as possible, to identify whether certain aspects of daily life are particularly impacted after clavicle fracture. Therefore, individual questions from the DASH score were analyzed and added to our questionnaire in light of various common situations (i.e. sleep, exercise, work, backpack carrying, purse carrying). However, there was no one aspect of daily living that was significantly more affected than the others. The responses to the question, "Are you limited in your daily activities?" correlated very clearly with shoulder range of motion.

In the bulk of "healed" clavicle fractures, patients don't have significant complaints as long as no stress is loaded on the shoulder girdle. Our data shows that questions regarding problems with sports activities correlate closely with pain intensity.

Clearly, the goal of an effective assessment system remains to use elements that collect the maximal amount of detailed information possible. Items that are unsuitable for a subpopulation are therefore not desirable. We attempted to collect each item in the most nonarbitrary means possible. Further, we tried to balance the subjective and objective items. In the case where a supposed limitation is not relevant to the patient, for example, a poor objective measurement should be counterbalanced by the subjective response. Therefore, concordance between subjective patient responses and objective measurements was emphasized, as suggested by (among others) Tingart et al. in 2001 [45].

The six partnered items are equal in terms of information content, and are therefore evenly weighted. Giving "no limitation" a point value of zero offers the advantage of fast score calculations in uncomplicated cases. The radiographic result is the only factor weighted twice. This is because a non-union should not be evaluated as a "very good" result. A completely asymptomatic non-union can, however, be evaluated as a "good" result with the CS.

The system (very good, good, moderate, poor) is constructed so that one item (except the radiograph) can be evaluated as poor, but a "very good" result still attained. This should prevent outliers. In addition, in this way minimal measured or reported limitations can also receive a "very good" result. A "moderate" result should be attained for example when all objective measurements are "poor," but the patient reports no subjective limitation. Without subjective complaints from the patient, a "poor" result should not be assessed.

The CS correlates appropriately with both established scores (Constant and Murley, DASH score). This is an acceptable validation of the system. The average Constant Score values of the patients evaluated with the CS show similar results to those reached by Tingart et al. on the assessment of the Constant Score [45]. A large number of patients given a "very good" result by the Constant Score were accorded only "good" results by the CS.

The use of the CS for test subjects with healthy shoulders also resulted in "very good" results. This is desired and shows the specific nature of this assessment system.

CONCLUSIONS

The Clavicle Score is a functional, effective, reliable, and self-conclusive evaluative instrument. It has the potential to close certain gaps in clavicular fracture assessment that have been left by the currently used

score systems. Elements specific to the clavicle were kept, and extraneous information was eliminated.

The CS uses a balanced mixture of objective and subjective elements and correlates both with a completely subjective instrument (the DASH score) as well as the more objective-tending Constant and Murley Score.

The most marked problem with the current study is the small number of patients. Particularly in the “moderate“ and “poor” result categories, the patient numbers were too small to assess the practicality of the CS. Further studies of clavicle fractures should help clarify its application. As use of the Constant and Murley Score for clavicle fractures is clearly imperfect, there is still the question of the gold standard against which the CS should be validated.

Furthermore it has to stated, that the CS has been compiled and validated only for midclavicular fractures.

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