



A validation of the Nottingham Clavicle Score: a clavicle, acromioclavicular joint and sternoclavicular joint–specific patient-reported outcome measure



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Background: Patients with acromioclavicular joint (ACJ) and sternoclavicular joint (SCJ) injuries and with clavicle fractures are typically younger and more active than those with other shoulder pathologies. We developed the Nottingham Clavicle Score (NCS) specifically for this group of patients to improve sensitivity for assessing the outcomes of treatment of these conditions compared with the more commonly used Constant Score (CS) and Oxford Shoulder Score (OSS).

Materials and methods: This was a cohort study in which the preoperative and 6-month postoperative NCS evaluations of outcome in 90 patients were compared with the CS, OSS, Imatani Score (IS), and the EQ-5D scores. Reliability was assessed using the Cronbach α . Reproducibility of the NCS was assessed using the test/retest method. Effect sizes were calculated for each score to assess sensitivity to change. Validity was examined by correlations between the NCS and the CS, OSS, IS, and EQ-5D scores obtained preoperatively and postoperatively.

Results: Significant correlations were demonstrated preoperatively with the OSS ($P = .025$) and all subcategories of the EQ-5D ($P < .05$) and postoperatively with the OSS ($P < .001$), CS ($P = .008$), IS ($P < .001$), and all subcategories of EQ-5D ($P < .02$). The NCS had the largest effect size (1.92) of the compared scores. Internal consistency was excellent (Cronbach $\alpha = 0.87$).

Conclusion: The NCS has been proven to be a valid, reliable and sensitive outcome measure that accurately measures the level of function and disability in the ACJ, SCJ and clavicle after traumatic injury and in degenerative disease.

Level of evidence: Basic Science Study; Development of Outcome Instrument

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Keywords: Clavicle; acromioclavicular joint; sternoclavicular joint; patient reported outcome measure; ACJ dislocation; SCJ dislocation

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Patient-reported outcome measures (PROMs) are useful, standardized instruments used in clinical practice to assess a patient's level of function and well-being as perceived by the patient.⁶ The ability to assess functional outcome after an intervention is essential to accurately measure whether the intervention has been successful and also to measure how successful that intervention was. PROMs can provide accurate and reliable assessments of outcome.⁹

Examples of shoulder-specific PROMs include the Oxford Shoulder Score⁸ (OSS), a 12-item questionnaire used to assess shoulder function after operations on the shoulder (not including stabilizations). The Oxford Instability Score⁷ (OIS), also a 12-item questionnaire, and the Western Ontario Shoulder Instability Index¹⁵ (WOSI), a 21-item instrument, have been developed to assess physical symptoms and changes in work, sport and recreation, lifestyle, and emotional function arising from shoulder instability. The Constant Score⁴ (CS) is a 100-point scale with different weightings for pain and activities of daily living, reported by the patient, and range of movement (ROM) and strength, measured by a clinical observer. The OSS was developed to assess overall shoulder function, the OIS and the WOSI were designed specifically for the assessment of shoulder instability, and the CS was originally intended to assess patients with rotator cuff pathologies. Several other PROMs have been put forward for use in shoulder assessment,^{1,11,13,16-18} although few have been properly validated.

Clavicle fractures, acromioclavicular joint (ACJ), and sternoclavicular joint (SCJ) dislocations are common injuries in young and often sporting people. These usually occur in the second and third decades of life while individuals are participating in high impact sports such as rugby, hockey, martial arts, mountain bike riding, motorcycling, and horse riding.¹⁰ The OSS and the CS are the scores currently used for the assessment of injuries to the clavicle, ACJ, and SCJ.

There are two disadvantages to using these scores: (1) the OSS and CS are not specific measures of injuries to the clavicle, ACJ, and SCJ and may not accurately measure the level of dysfunction after injury nor be sensitive to change after an intervention; and (2) the OSS does not give any weighting for sports or recreation, while the weighting in the CS is small (4 of 100) and has neither been rationalized nor properly validated. Considering that many of these patients will return to sport after recovery, it is fair to say that these earlier scores may be unable to accurately tell us whether shoulder function has actually returned to preinjury levels. To date no specific PROMS validated for the clavicle, ACJ, and SCJ are available for use. The Nottingham Clavicle Score (NCS) has been designed specifically for this group of patients.

Materials and methods

The NCS

The NCS (Fig. 1) is a 10-item PROM with a maximum score of 100 (fewest difficulties) and a minimum score of 20 (most

difficulties). Items 1 to 4 measure pain usually felt from the shoulder, pain in bed at night, pain during usual work, and pain during sport and recreation. We anticipated that including item 4, measuring "pain during sport and recreation," would make the NCS more appropriate for use than the OSS in sporting and active people. Items 5 and 6 measure the ability to lift heavy objects and overhead strength. Item 7 measures cosmetic satisfaction with the shoulder, item 8 assesses movements and clicking within the shoulder, and item 9 measures tingling and numbness in the arm and neck, and item 10 measures heavy or dragging sensations in the arm. The final score given by the NCS can be graded excellent (80-100), good (60-79), fair (40-59), or poor (<40).

Patient recruitment and data collection

Between June 2010 and February 2016, we recruited 90 patients (56 men and 34 women) into a partially prospective, partially retrospective cohort study in which data for patients were collected from the outpatient shoulder clinic and preoperative assessment clinic at our centers. Patients were a median age of 50 years (range, 19- 85 years).

We included patients who had received surgical intervention for injuries to or conditions of the ACJ, SCJ, and the clavicle. Exclusion criteria were patients aged younger than 18 and older than 85, patients who did not have clavicle, SCJ, or ACJ pathology, those whose first language was not English, and patients who had a history of mental health disorders (excluding mild to moderate depression), owing to the risk of unreliable assessment.

During the preoperative assessment, patients completed 1 of each of the NCS, OSS, CS, Imatani Score (IS), and EQ-5D and were also given another NCS to complete 24 hours later to be returned at follow-up. The patients then underwent the same assessments 6 months postoperatively. It was necessary to make retrospective assessments of 18 patients using only the self-reported outcome measures (NCS, OSS and EQ-5D), where patients were asked to complete the outcome measure based on their memory of their condition before surgery. This method of retrospective assessment has been validated by Wilson and Rangan.²¹ Patients who were assessed retrospectively completed the postoperative scores according to the protocol at the 6-month follow-up appointments.

Assessment of the patient's ROM was made by a physiotherapist or trained clinician using a goniometer for accuracy. Power was measured in pounds of resisted abduction at 90° in the scapular plane using a digital myometer.

Follow-up data were not obtained from 25 patients for the following reasons: 2 had died, 1 was in prison, 1 with mental health problems was excluded because he was not believed to be mentally competent at his outpatient clinic visit and any assessment would have been unreliable, 3 were excluded because they reinjured their clavicle/shoulder within 6 months after their operation, 15 were not at the 6-month stage after the operation, and 3 could not be contacted.

Reliability

To assess reliability we examined internal consistency and reproducibility. Internal consistency is a way of measuring the overall correlation of items within a scale and is expressed by the Cronbach α .⁵ We examined reproducibility using the test-retest method, in which we asked patients to complete another NCS 24 hours after completing the first one, to be returned by post or at their next outpatient

Nottingham Clavicle Score (for injuries to the collarbone, A/C & S/C Joint)

The following questions relate to the pain levels and difficulties you have experienced around your collarbone/shoulder area **during the last two months.**

1. How would you describe the pain you usually had from your shoulder/collarbone?		2. Have you been troubled by pain from your shoulder/collarbone in bed at night?	
<input type="checkbox"/> None	10	<input type="checkbox"/> No nights	10
<input type="checkbox"/> Very mild	8	<input type="checkbox"/> Only 1 or 2 nights	8
<input type="checkbox"/> Mild	6	<input type="checkbox"/> Some nights	6
<input type="checkbox"/> Moderate	4	<input type="checkbox"/> Most nights	4
<input type="checkbox"/> Severe	2	<input type="checkbox"/> Every night	2
3. How much has pain from your shoulder/collarbone interfered with your usual work (including housework or driving)?		4. How much has pain from your shoulder/collarbone interfered with your sporting activities or hobbies?	
<input type="checkbox"/> Not at all	10	<input type="checkbox"/> Not at all	10
<input type="checkbox"/> A little bit	8	<input type="checkbox"/> A little/occasionally	8
<input type="checkbox"/> Moderately	6	<input type="checkbox"/> Some of the time	6
<input type="checkbox"/> Greatly	4	<input type="checkbox"/> Most of the time	4
<input type="checkbox"/> Totally	2	<input type="checkbox"/> All of the time	2
5. How much has the problem with your shoulder/collarbone interfered with your ability or willingness to lift heavy objects?		6. Has your shoulder/collarbone easily tired or felt weak with overhead activity?	
<input type="checkbox"/> Not at all	10	<input type="checkbox"/> Not at all	10
<input type="checkbox"/> Occasionally	8	<input type="checkbox"/> A little/occasionally	8
<input type="checkbox"/> Some days	6	<input type="checkbox"/> Some of the time	6
<input type="checkbox"/> Most days	4	<input type="checkbox"/> Most of the time	4
<input type="checkbox"/> Every day	2	<input type="checkbox"/> All of the time	2
7. Have you been happy about the appearance of your collarbone area?		8. Have you felt any movements or clicking in the collarbone area that trouble or worry you?	
<input type="checkbox"/> Totally happy	10	<input type="checkbox"/> Not at all	10
<input type="checkbox"/> Very happy	8	<input type="checkbox"/> A little/occasionally	8
<input type="checkbox"/> Moderately happy	6	<input type="checkbox"/> Some of the time	6
<input type="checkbox"/> A little bit happy	4	<input type="checkbox"/> Most of the time	4
<input type="checkbox"/> Not at all happy	2	<input type="checkbox"/> All of the time	2
9. Do you experience tingling or numbness travelling up into your neck or down your arm?		10. Have you experienced any dragging sensation or feeling of heaviness of your arm?	
<input type="checkbox"/> Not at all	10	<input type="checkbox"/> Not at all	10
<input type="checkbox"/> A little/occasionally	8	<input type="checkbox"/> A little/occasionally	8
<input type="checkbox"/> Some of the time	6	<input type="checkbox"/> Some of the time	6
<input type="checkbox"/> Most of the time	4	<input type="checkbox"/> Most of the time	4
<input type="checkbox"/> All of the time	2	<input type="checkbox"/> All of the time	2

Figure 1 The Nottingham Clavicle Score. A/C, acromioclavicular; S/C, sternoclavicular; NHS, National Health Service.

appointment. We then used Bland-Altman plots to examine the agreement between the 2 returned scores.³

Validity

Construct validity was examined using Wilcoxon signed rank tests (matched-pairs) for the OSS, CS, and IS and Spearman correlations

for the EQ-5D. To allow comparative analysis of EQ-5D scores, we split the overall 5 number score into its 5 dimensions of “mobility,” “self-care,” “usual activities,” “pain/discomfort,” and “depression,” thus making possible analysis and comparison of EQ-5D’s individual categories with the NCS. The Spearman coefficient was interpreted as strong correlation for values >0.50, moderate correlation for values between 0.35 and 0.50, and weak correlation for values <0.35.¹²

Sensitivity to change

To measure sensitivity to change, we calculated the effect size for each score by dividing the difference between the mean preoperative and postoperative scores by the standard deviation of the preoperative scores. Sensitivity to change was also tested by asking each patient to indicate whether his or her symptoms had improved or deteriorated after surgery.

Results

Table I summarizes the various conditions of the clavicle, ACJ, and SCJ that we encountered during the study period. The patient with a SCJ hemiloosening previously underwent an extensive resection of the medial end of the clavicle for post-

Table I Injuries evaluated using the Nottingham Clavicle Score, Constant Score, Oxford Shoulder Score, Imatani Score, and the EQ-5D scores

Diagnosis	Patients No. (% of total)
ACJ dislocation	
Grade III	12 (13)
Grade IV	6 (6)
Grade V	9 (10)
Osteoarthritis	
ACJ	39 (43)
SCJ	4 (4)
SCJ	
Dislocation	2 (2)
Hemiloosening	1 (1)
Clavicle fracture	
Medial	1 (1)
Middle	9 (10)
Lateral	2 (4)
Middle clavicle fracture nonunion	1 (1)
Symptomatic os-acromiale	2 (2)
Acromion fracture	1 (1)
Acromion fracture nonunion	1 (1)
Total	90 (100)

ACJ, acromioclavicular joint; SCJ, sternoclavicular joint.

traumatic arthritis, leaving the SCJ unstable. This patient underwent a reconstruction of the SCJ using a Corin radial head prosthesis (Corin Group PLC, Cirencester, UK) inserted into the medial end of the clavicle as a spacer and joint stabilization with a LockDown device (Credit LockDown Medical Limited, Redditch, UK), which improved his symptoms.

Internal consistency

Analysis of preoperative data from 70 patients showed the overall Cronbach α was 0.71, which improved to 0.75 if item 7 (measuring cosmetic satisfaction) was removed. Item correlations were all acceptable (>0.3), except for item 7 (Table II). The Cronbach α postoperatively was 0.87, and the removal of item 7 improved the α to 0.90. Again, all interitem correlations were acceptable, except for item 7 (Table III).

Reproducibility

There were 90 scores completed 24 hours after completion of a first score and returned. Of these, 12 scores showed no difference from the first recorded score, 20 scores showed a 2-point difference, 25 scores showed a 4-point difference, 11 scores showed a 6-point difference, 13 scores showed an 8-point difference, 5 scores showed a 10-point difference, and the difference in 4 scores was >10 points (3 patients returned differences of 12 and 1 patient returned a difference of 14; Fig. 2).

Validity

Wilcoxon analysis of preoperative data ($n = 90$) showed significant correlations between the NCS and OSS ($P = .025$). There were no statistically significant preoperative correlations between the NCS and IS ($P = .988$) and CS ($P = .486$; Table IV). The postoperative Wilcoxon analysis ($n = 65$) demonstrated statistically significant correlations between the NCS and OSS ($P < .001$), IS ($P < .001$), and CS ($P = .008$; Table V).

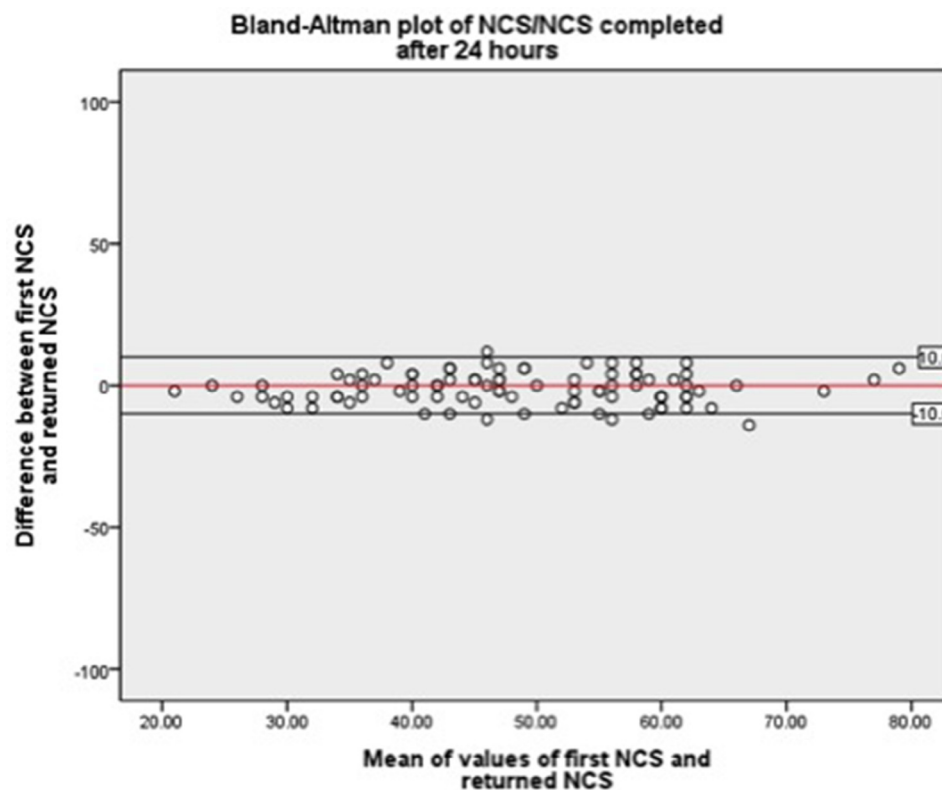
Spearman analysis of the preoperative EQ-5D data ($n = 90$) showed statistically significant correlations between the NCS

Table II Preoperative correlation of each question item with total correlation and the effect of item removal

Question item	Corrected item-total correlation	Cronbach α if item deleted
1. Usual pain from shoulder/collarbone	0.412	0.685
2. Pain in bed at night from shoulder/collarbone	0.459	0.676
3. Pain from shoulder/collarbone during usual activities	0.619	0.653
4. Pain from shoulder/collarbone during sports and hobbies	0.384	0.687
5. Interference with ability/willingness to lift heavy object	0.487	0.675
6. Does the shoulder/collarbone easily tire/feel weak with overhead activity	0.442	0.683
7. Cosmetic satisfaction	0.109	0.753
8. Clicking/movements in the collarbone	0.321	0.701
9. Tingling/numbness up into neck and down arm	0.420	0.680
10. Dragging sensations or feelings of heaviness	0.341	0.696

Table III Postoperative correlation of each question item with total correlation and the effect of item removal

Question item	Item-total correlation	Cronbach α if item deleted
1. Usual pain from shoulder/collarbone	0.697	0.854
2. Pain in bed at night from shoulder/collarbone	0.746	0.848
3. Pain from shoulder/collarbone during usual activities	0.742	0.851
4. Pain from shoulder/collarbone during sports and hobbies	0.821	0.842
5. Interference with ability/willingness to lift heavy object	0.761	0.848
6. Does the shoulder/collarbone easily tire/feel weak with overhead activity	0.757	0.848
7. Cosmetic satisfaction	0.102	0.895
8. Clicking/movements in the collarbone	0.374	0.880
9. Tingling/numbness up into neck and down arm	0.375	0.877
10. Dragging sensations or feelings of heaviness	0.619	0.861

**Figure 2** The Bland-Altman test of the Nottingham Clavicle Score (*NCS*) and retest evaluation after 24 hours.**Table IV** Wilcoxon analysis of preoperative data

Test statistics*	Imatani— NCS	OSS— NCS	CS— NCS
Z	-0.015	-2.238	-0.697
Asymptomatic significance (2 tailed)	.988	.025	.486

CS, Constant Score; *NCS*, Nottingham Clavicle Score; *OSS*, Oxford Shoulder Score.

* Wilcoxon signed ranks test.

Table V Wilcoxon analysis of postoperative data

Test statistics*	Imatani— NCS	OSS— NCS	CS— NCS
Z	-5.095	-4.169	-2.665
Asymptomatic significance (2 tailed)	<.001	<.001	.008

CS, Constant Score; *NCS*, Nottingham Clavicle Score; *OSS*, Oxford Shoulder Score.

* Wilcoxon signed ranks test.

Table VI Spearman analysis performed on the preoperative EQ-5D scores

Test Statistics	EQ-5D				
	Mobility	Self-care	Usual activity	Pain/discomfort	Anxiety/depression
Correlation coefficient	−0.268	−0.241	−0.409	−.0287	−0.275
Significance (2-tailed)	.011	.022	<.001	.006	.009
No.	90	90	90	90	90

Table VII Spearman analysis performed on the postoperative EQ-5D scores

Test Statistics	EQ-5D				
	Mobility	Self-care	Usual activity	Pain/discomfort	Anxiety/depression
Correlation coefficient	−0.300	−0.346	−0.708	−0.575	−0.333
Significance (2-tailed)	.015	.005	<.001	<.001	.007
No.	65	65	65	65	65

Table VIII The effect size for Nottingham Clavicle Score, Oxford Shoulder Score, Constant Score, and Imatani Score

Score	Pre-op mean	SD	Post-op mean	SD	Effect size
NCS	49.59	12.33	73.29	17.14	1.92
OSS	25.94	10.45	37.82	8.78	1.14
CS	50.94	21.67	69.94	19.39	0.88
IS	49.65	14.90	65.35	19.63	1.05

CS, Constant Score; IS, Imatani Score; NCS, Nottingham Clavicle Score; OSS, Oxford Shoulder Score; SD, standard deviation.

and “mobility” ($P = .011$), “self-care” ($P = .022$), “usual activities” ($P < .001$), “pain/discomfort” ($P = .006$), and “anxiety/depression” ($P = .009$). A moderate correlation coefficient was observed with “usual activity” (0.409) but not for any other domain (Table VI). Analysis of postoperative data ($n = 65$) showed statistically significant correlations between the NCS and “mobility” ($P = .015$), “self-care” ($P = .005$), “usual activities” ($P < .001$), “pain/discomfort” ($P < .001$), and “anxiety/depression” ($P = .007$). Strong correlation coefficients were observed with “usual activity” (0.709) and “pain/discomfort” (0.575), whereas weak correlations were found for “mobility” (0.3), “self care” (0.346), and “anxiety/depression” (0.333; Table VII).

Sensitivity to change

The calculated effect size was larger for the NCS (1.92) than for any of the other comparison scores (Table VIII).

At the 6-month follow-up, 91% of patients who reported an improvement in their symptoms postoperatively also demonstrated a higher postoperative value for the NCS. Of the 3 patients who reported deteriorated symptoms at 6 months, 2 also had lower NCS values.

Discussion

We have designed and tested an easy-to-use 10-item PROM for use in clavicle, ACJ, and SCJ injuries. The NCS does not require a clinician to be present, takes minutes to complete, and no patients reported difficulties or problems in answering the questions. We have tested the NCS in both traumatic injury and degenerative disease.

The content of the NCS was chosen by the team at the Nottingham Shoulder and Elbow Unit after monitoring patients with injuries to the clavicle, ACJ, and SCJ with input from patients, surgeons, and physiotherapists. The 10-items were carefully chosen after a thorough review of the relevant literature and years of experience treating ACJ, SCJ, and clavicle pathologies and after several peer-reviewed drafts of the score. All interitem correlations but one (item 7) were acceptable; however, it was interesting to observe considerable variance between most preoperative and postoperative interitem correlations, with items seeming to correlate more strongly when the NCS was used postoperatively—especially item 4 measuring “pain from shoulder during sport/activity,” the item that we predicted would make the NCS more useful for sporting and active people than current measuring tools.

Although statistical significance was observed preoperatively in all domains of the EQ-5D, the strength of the correlations was considered weak for all categories other than “usual activity” (moderate strength). Postoperatively, strong correlations were observed with the values obtained from “usual activity” and “pain/discomfort.” This is a good marker of the NCS’s validity in assessing 2 essential components of the patient’s condition, where a return to usual activity for a sporting individual is likely to represent a return to sport. Item 4 of the NCS would be able to better qualify this in order to give a fairer assessment of successful intervention in sporting individuals.

We observed a difference in a mean score of 6 or less in 75.6% of the scores returned after 24 hours (Fig. 2), suggesting good reproducibility. We observed a low number of

patients returning scores with a difference in means of more than 10, with 3 of the 4 patients reporting worse scores. How these changes in the scores occurred is difficult to understand, considering our score asks patients to report the “usual” symptoms they have from their shoulder rather than assessment from a single time. Although key words in each question have been emphasized in italics to aid patient understanding, it is possible that the questions were not fully understood in this small group and that the score was completed based on their condition at that point, rather than an average of the last 2 months, as stated on the NCS.

We expected an improvement in a patient’s symptoms to correlate with an improvement in his or her overall score and vice versa. The NCS correctly detected changes in symptoms in 89% of the follow-up patients.

The inclusion of an item measuring patients’ satisfaction with the appearance of their collarbone area tended to give misleading results in patients whose function was lower than average. It became apparent early on in the study that cosmetic satisfaction varied greatly from patient to patient and that patients who showed indifference to the appearance of their collarbone area scored highly in that item. This tended to cause some variance in the expected results for those patients. Although omitting this item may improve the internal consistency of the NCS, the literature suggests one of the main benefits to be had from operative management of Rockwood grade III ACJ dislocation is improved cosmetic satisfaction.^{2,19} This can be a useful tool in deciding whether a patient will receive conservative or operative treatment based on how the patient perceives the appearance of his or her shoulder; therefore, we have chosen to continue to include the cosmetic satisfaction question.

In 2015, Vascellari et al²⁰ conducted a translation, cross-cultural adaptation, and validation of the NCS. In this validation the OSS, Disability of the Arm, Shoulder and Hand (DASH), and 36-Item Short Form Health Survey (SF36) scores were used as comparison scores in 66 patients. The authors reported a similar internal consistency (Cronbach $\alpha = 0.86$), which was improved with the removal of item 7 measuring cosmetic appearance. The authors also reported similar reliability on test-retest, which was conducted 5 days after the first test. They did not test responsiveness in their validation, whereas we conducted tests to measure sensitivity to change over 6 months in our study.

A similar clavicle score has been designed and validated in Germany for the assessment of outcome in midclavicular fractures.¹⁴ This score contains subjective and objective elements as well as radiographic assessment for fracture healing. A trained clinician is therefore required to be present to complete the score. It would be interesting to compare these two scores to determine whether they measure similar properties.

A recognized limitation of this study is reliance on a relatively small sample size. When the OSS was validated, 111 patients were identified in testing internal consistency and reproducibility, and 56 were monitored in testing validity and sensitivity to change.⁸ We have included 90 patients to assess

reproducibility, 70 to assess internal consistency, and completed follow-up in 65 to measure validity and sensitivity to change.

Conclusion

The NCS can be used clinically to measure the outcomes of surgery and the progress of rehabilitation. Because of its subjective nature, it should not be used as the sole guide to a patient’s management but should be used to complement current practice. The ability to complete the NCS without clinician input makes the score suitable for long-term follow-up studies where data can be collected by post and will free up more clinic time. The NCS is now used routinely in our practice.

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