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# Validity and responsiveness of the Nottingham clavicle score in clavicle shaft fractures treated with titanium elastic nailing

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ABSTRACT

*Background:* The Nottingham Clavicle Score (NCS) has been recently described for functional outcome assessment after injuries to clavicle and the Acromioclavicular joint. However; validity and responsiveness are context specific psychometric terms and the NCS has not been previously described in surgically treated clavicle shaft fractures. Aim of the present study was to investigate validity and responsiveness of the NCS in clavicle fractures treated with titanium flexible nailing.

*Methods:* This prospective study was undertaken on consecutively operated clavicle shaft fractures treated with titanium elastic nail from November 2013 to August 2016. Functional assessment using NCS was done at two and six months postoperatively. Construct validity was also evaluated by formulating the null hypothesis that there would be no difference in NCS at six months after open and closed reduction and in 15B1 and 15B2 fracture sub-types. The above two hypotheses were formulated based on previous studies that used Constant score and DASH score. Pre-specified hypothesis and results in accordance with the hypotheses suggest satisfactory construct validity. Responsiveness was evaluated using standardized response mean (SRM) and Effect size (ES). ES and SRM values $\geq$0.80 suggest satisfactory responsiveness. The proportion of patients having the least possible score of 0 points (floor effect) and the highest possible score of 100 points (ceiling effect) was evaluated at two and six months postoperatively. Floor and ceiling effect of <15% suggests satisfactory internal validity.

*Results:* Thirty six consecutively operated patients were included in the study. The NCS at two months and six months was 69.6 $\pm$ 9.6 and 87.2 $\pm$ 7.1 respectively. The NCS at six months after fixation was 88.7 $\pm$ 4.8 in closed reduction cohort and 84.7 $\pm$ 9.4 in the open reduction cohort and this difference was not significant ($p = 0.1$). The NCS at six months after fixation was 85.3 $\pm$ 8.3 in 15B1 clavicular fractures and 89.7 $\pm$ 4.0 in 15B2 clavicular shaft fractures and this difference was also not significant ($p = 0.07$). All results pertaining to construct validity were in accordance with our hypothesis thereby suggesting that NCS demonstrates satisfactory construct validity. The ES and SRM were 1.8 and 2.6 respectively. NCS showed no ceiling (0%) or floor effect (0%) at two and six months postoperatively thereby suggesting adequate internal validity of the NCS.

*Conclusion:* NCS has satisfactory construct validity, internal validity and responsiveness in surgically treated clavicle shaft fractures with titanium elastic nailing.



## 1. Introduction

Outcome instruments that are used to evaluate functional outcome are broadly divided as condition specific, region specific and generic quality of life instruments. Outcome instruments can also be divided as clinician reported, patient reported and combination of clinician reported and patient reported instruments. In general, patient reported outcome instruments are considered as optimal indicators of functional improvement after an intervention. The Nottingham clavicle score (NCS) is a patient reported functional outcome instrument which has been described for injuries of the acromioclavicular joint, clavicle shaft and the sternoclavicular joint.[1–3] The Nottingham clavicle score has been described in studies evaluating results of surgical intervention for chronic acromioclavicular joint injuries [4–6] and non-surgical treatment of clavicle shaft fractures in adolescent patients.[7]

Construct validity of an outcome instrument is defined as the extent to which the results are in accordance with pre-specified hypothesis about expected differences or similarities in values of

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outcome instruments.[8] Responsiveness of an outcome instrument is defined as the sensitivity of the instrument to detect clinically relevant change over a period of time.[8] Floor and ceiling effect pertains to the proportion of patients achieving minimum possible score and the maximum possible score respectively.[8] Validity and responsiveness are context specific terms and the evidence is applicable to a particular condition and specific intervention only.[9,10] None of the studies so far have reported ceiling and floor effect of the NCS. Moreover, there has been no study which has evaluated psychometric properties like validity and responsiveness of the NCS in surgically treated clavicle shaft fractures in adult patients.

The aim of the present study was to investigate construct validity, responsiveness, ceiling and floor effect of the NCS in adults patients with clavicle shaft fractures treated with titanium elastic nails.

## 2. Materials and methods

### 2.1. IEC approval, inclusion and exclusion criteria

This prospective cohort study was undertaken after obtaining approval from the institutional ethics committee. Inclusion criteria were adult patients with clavicle shaft fractures having displacement or shortening of more than two centimetres or tenting of skin due to displacement of the fracture, Type 15B1 and type 15B2 clavicular shaft fracture as per Orthopaedic Trauma Association (OTA) classification. Patients who were unfit for anaesthesia, having psychiatric illness, neurovascular injury, pathological fracture and more than one month post-injury, type 15B3 clavicular shaft fracture as per OTA classification were excluded from the study. Included patients gave written informed consent to undergo the surgical procedure and participate in the study.

### 2.2. Surgical intervention

A small incision was made just lateral to the sternoclavicular joint and entry was taken using a pointed awl. A titanium elastic nail (TEN) was inserted and was advanced laterally under image intensification. TEN with diameter ranging from 2 mm to 3 mm were used depending upon the width of the bone. Closed reduction was successful in majority of the cases and in small proportion of patients, open reduction using small incision over the fracture site was needed.

### 2.3. Functional outcome assessment—Nottingham clavicle score

The Nottingham clavicle score is a patient reported 10-item questionnaire and it is scored from minimum score of 20 points to maximum score of 100 points.[2,3] Lower score suggests higher functional disability and higher score is suggestive of better functional ability. About 40% questions of the NCS pertain to pain sub-domain, 20% questions pertain to functional abilities, 10% questions pertain to cosmesis, 10% questions pertain to mechanical symptoms like clicking at the fracture site and 20% questions pertain to neurological symptoms comprising sensory symptoms (tingling and numbness in the upper limb) and motor symptoms (heaviness and dragging sensation in the upper limb).[2,3] Outcome based on NCS can be classified as excellent outcome ($\geq$ 80 points), good outcome (60–79 points), fair outcome (40–59 points) and poor outcome (20–39 points).[2,3] The NCS was evaluated at two months and six months postoperatively. Paired *t*-test was used to determine the significance of difference of NCS at two months and six months postoperatively. The level of significance was set at 5%.

### 2.4. Statistical analysis—validity and responsiveness

#### 2.4.1. Construct validity

For proving construct validity of an outcome instrument, one needs to demonstrate results as per pre-specified hypotheses that are not controversial.[11] If more than 75% of the results are in accordance with the hypothesis then it would be considered evidence of construct validity.[8,12] Two hypotheses were formulated based on previous studies that had used outcome instruments other than the NCS.

1 There would be no significant difference in the NCS of patients who underwent closed and open reduction of clavicle fracture and fixation with titanium elastic nails. NCS at final follow-up at six months postoperatively in both groups would be compared.
2 According to OTA classification[13] Type 15B1 is simple, non-comminuted two part fracture of the diaphysis of clavicle whereas Type 15B2 is a wedge fracture of the clavicular shaft. Type 15B3 fracture is complex type fracture with severe comminution or segmental fracture. Our hypothesis was there would be no significant difference in NCS at six months postoperatively of patients with type 15B1 and type 15B2 fractures.

For the two hypotheses unpaired *t*-test was performed and the level of significance was set at 5%.

#### 2.4.2. Internal validity

The proportion of patients acquiring lowest possible score of NCS of 20 points (floor effect) and those acquiring highest possible score of 100 points (ceiling effect) would be evaluated at two and six months postoperatively. Floor and ceiling effects are indicators of internal validity[14] and content validity[11] of an outcome instrument. The proportion of floor and ceiling effects must be less than 15% for an outcome instrument to remain valid in its measurement properties.[8]

#### 2.4.3. Responsiveness

Responsiveness was evaluated using effect size (ES; mean NCS at six months – mean NCS at two months/standard deviation of NCS at two months) and standardised response mean (SRM; mean NCS at six months – mean NCS at two months/standard deviation of the change score of NCS from two months to six months).[15] Both ES and SRM were interpreted as per Cohen's criteria wherein values of 0.2, 0.5 and 0.8 are considered as small, moderate and large effects respectively.[15] Moreover, SRM values more than 1.0 are usually seen after an effective surgical intervention.[15] ES and SRM value more than 0.80 is considered optimal evidence of responsiveness of an outcome instrument.[16]

#### 2.4.4. Statistical analysis

Numerical data such as age, NCS at two months postoperatively and six months postoperatively was presented as mean, standard deviation and range. Categorical data such as gender, side of injury, mechanism of injury, type of fracture (closed/open grade), affection of dominant upper extremity, associated injuries, co-morbidites, OTA classification, type of reduction (closed or open), diameter of titanium flexible nail used and grading of functional outcome was presented as proportion and percentage. Statistical analysis was performed using IBM SPSS version 19. Posthoc analysis was performed to evaluate any difference in functional outcome at two months and six months postoperatively using unpaired *t*-test in cohort of patients with associated injuries and those without any associated injury.

## 3. Results

This study included 37 consecutive patients who underwent flexible titanium nailing fixation from November 2013 to August 2016. One patient was lost to follow-up and NCS at two months and six months postoperatively was not available on this patient. Complete data of NCS at two and six months postoperatively was available on 36 patients.

### 3.1. Patient demographic data

The demographic detail of our cohort is presented in Table 1.

### 3.2. Functional outcome

The mean NCS at two months postoperatively was 69.6 ± 9.56 and the mean NCS at six months postoperatively was 87.2 ± 7.11. The mean difference in NCS between six months and two months postoperatively was 17.6 ± 6.81 (range: 6–40). Paired *t*-test showed that this improvement in NCS from two months to six months postoperatively was highly significant ($p < 0.0001$; 95% confidence interval: 15.3 to 19.9) (Fig. 1).

The grading of functional outcome showed that majority of patients had good outcome by two months and excellent outcome by six months after fixation using titanium elastic nailing (Table 2). None of the patients had poor outcome at two months and six months follow-up.

**Table 1**
Shows demographic features of the cohort. Age is presented as mean (SD){range} and rest of the other features are presented as frequency (percentage).

| Demographic character (n = 37) | |
|---|---|
| **Age** * | 36 years (12.3) {19 to 60 years} |
| **Gender** | |
| Male | 27 (73%) |
| Female | 10 (27%) |
| **Mechanism of injury** | |
| Road traffic injury | 36 (97.3%) |
| Fall | 1 (2.7%) |
| **Type of fracture** | |
| Closed | 34 (91.9%) |
| Open | 3 (8.1%) |
| OGI | 1 |
| OGII | 2 |
| **Side fractured** | |
| Right | 24 (64.9%) |
| Left | 13 (35.1%) |
| **Affected side** | |
| Dominant extremity | 26 (70.3%) |
| Non-dominant extremity | 11 (29.7%) |
| **Associated injuries** | |
| Rib fracture | 9 (24.3%) |
| Scapula fracture | 5 (13.5%) |
| Head injury | 4 (10.8%) |
| **Co-morbidities** | |
| Hypertension | 4 (10.8%) |
| Diabetes Mellitus | 1 (2.7%) |
| Ischemic heart disease | 1 (2.7%) |
| **OTA Classification** | |
| 15B1 | 21 (56.8%) |
| 15B2 | 16 (43.2%) |
| **Type of reduction** | |
| Closed reduction | 23 (62.2%) |
| Open reduction | 14 (37.8%) |
| **Diameter of TEN used** | |
| 2.0 mm | 11 (29.7%) |
| 2.5 mm | 24 (64.9%) |
| 3.0 mm | 2 (5.4%) |

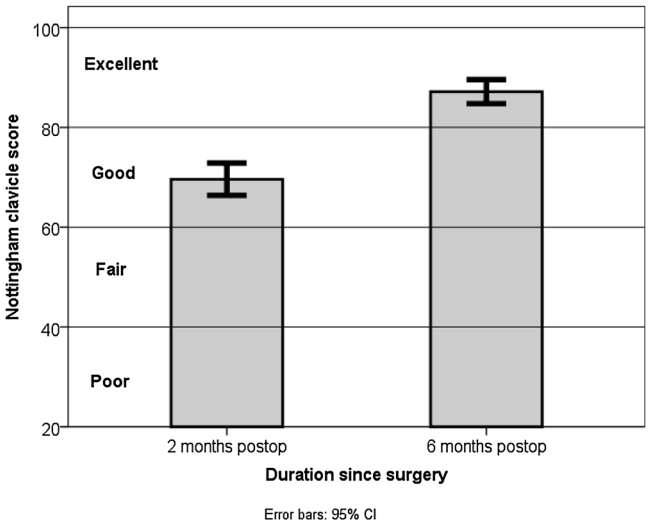


**Fig. 1.** Shows statistically significant improvement in NCS from two to six months as there is no overlapping of the 95% confidence intervals of mean NCS at two and six months.

### 3.3. Construct validity

In accordance with the first hypothesis, unpaired *t*-test showed no significant difference ($p = 0.07$; 95% confidence interval: −9.1 to 0.3) in the NCS at six months follow-up between 15B1 and 15B2 clavicular fractures (Fig. 2). The NCS at six months after fixation was 85.3 ± 8.3 in 15B1 clavicular fractures and 89.7 ± 4.0 in 15B2 clavicular shaft fractures. Excellent outcome was achieved in both 15B1 and 15B2 fracture subtypes.

In accordance with the second hypothesis, unpaired *t*-test showed that there was no significant difference ($p = 0.1$; 95% confidence interval: -0.8 to 8.8) in NCS at six months follow-up in cohorts of patients that underwent closed reduction and open reduction (Fig. 3). The NCS at six months after fixation was 88.7 ± 4.8 in closed reduction cohort and 84.7 ± 9.4 in the open reduction cohort.

Eighteen patients had associated injuries along with clavicle shaft fractures (Table 1). Posthoc testing showed that the mean NCS at two months postoperatively was 69 ± 10.2 in the cohort with associated injuries and 70 ± 9.2 in the cohort without associated injuries. Unpaired *t*-test showed no significant difference in the NCS at two months postoperatively ($p = 0.81$; 95% CI: −5.9 to 7.3). The mean NCS at six months postoperatively was 87 ± 6.5 in the cohort with associated injuries and 87 ± 7.9 in the cohort without associated injuries. Unpaired *t*-test showed no significant difference in the NCS at six months postoperatively ($p = 0.89$; 95% CI: -5.2 to 4.6).

### 3.4. Internal validity

The NCS at two months postoperatively ranged from 50 to 84 and the NCS at six months postoperatively ranged from 66 to 96. None of the patients achieved the lowest possible score or highest possible score at two months and six months follow-up. This suggests absence of floor and ceiling effect at two and six months after fixation with titanium flexible elastic nail.

### 3.5. Responsiveness

The Effect size (ES) and standardized response mean (SRM) were 1.8 and 2.6 respectively. Both were large effects as per Cohen's criteria and both measures suggested that NCS has adequate

**Table 2**
shows results of functional outcome based on stratification of the cohort.

| Grading of outcome based on NCS [2,3] | 2 months follow-up (N = 36) n (%) | 6 months follow-up (N = 36) n (%) |
|---|---|---|
| Excellent (NCS ≥ 80) | 5 (13.9%) | 32 (88.9%) |
| Good (NCS: 60 to 79) | 25 (69.4%) | 4 (11.1%) |
| Fair (NCS: 40 to 59) | 6 (16.7%) | 0 |
| Poor (NCS: 20 to 39) | 0 | 0 |

n = number of cases.

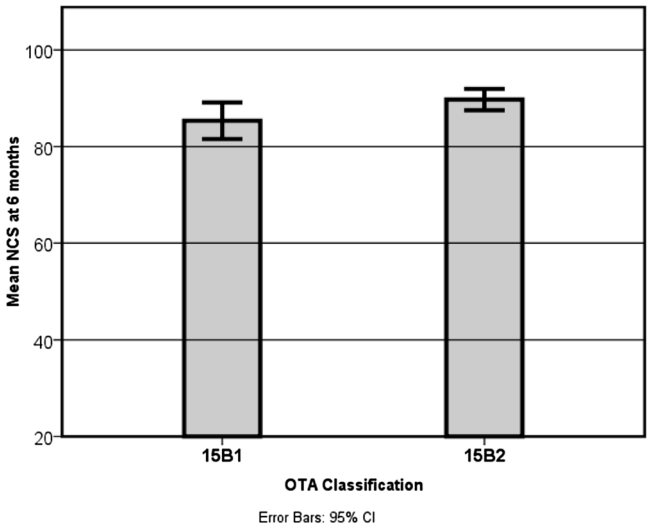


**Fig. 2.** Shows mean NCS at six months in both types of fracture configurations. There is overlapping of 95% confidence intervals of both groups suggesting no difference in functional outcome assessment using the NCS at six months.

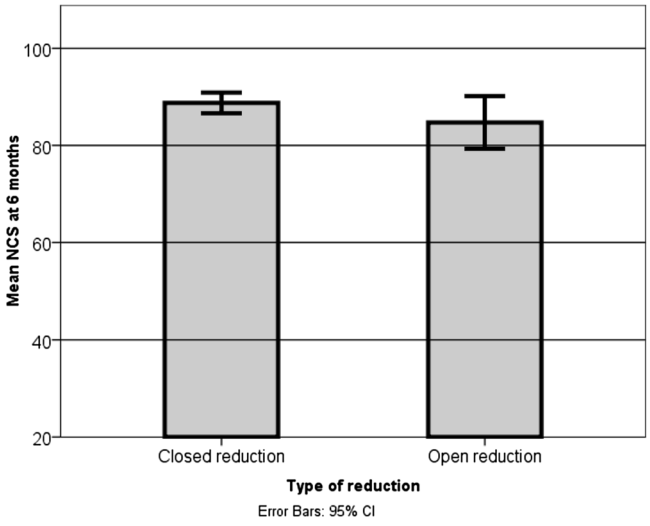


**Fig. 3.** Shows overlapping of 95% confidence interval of NCS at six months follow-up and thereby showing no difference in functional outcome after closed and open reduction.

responsiveness. SRM value of 2.6 is as per expected values seen after an effective surgical intervention.[15]

## 4. Discussion

### *4.1. Construct validity*

We observed that the results pertaining to NCS were 100% as per the hypothesis thereby showing that NCS has adequate construct validity. However, all the hypotheses in our study pertained to known groups or extreme groups' validity. Our study did not evaluate convergent and divergent validity of the NCS.

Our results were in accordance with two previous studies that showed no difference in functional outcome assessment using Constant score and DASH score in patients undergoing closed reduction and open reduction and internal fixation using titanium elastic flexible nails.[17,18] Just like the more popular outcome instruments like Constant score and DASH score, the NCS showed no difference in outcome between the two groups.

Our result showed no difference in the functional outcome after TEN fixations of 15B1 and 15B2 fractures. There was no 15B3 fracture in our study. In our institute, we prefer to treat 15B3 fracture types with open reduction and internal fixation using anatomic contoured locking plate. Our current practice is as per results published previously.[19] The union time of 15B1 and 15B2 fractures is not expected to be different as they were classed as a single cohort in a previous study.[20]

There are many studies that have described adequate convergent construct validity of the NCS however; most of these studies[4,5] have been on patients with acromioclavicular joint (ACJ) dislocations.

The NCS has demonstrated satisfactory convergent validity because studies have shown significant strong correlation between the NCS and the Oxford shoulder score,[3,4] significant strong correlation between the NCS and the DASH score,[3,5] significant strong correlation between the NCS and physical domain of SF-36[3] and significant strong correlation between the NCS and related domains (usual activity and pain/discomfort) of EQ-5D.[2] The NCS has demonstrated satisfactory divergent validity because one study has reported weak correlation between NCS and the mental domain of SF-36[3] and weak correlation between NCS and unrelated domains (mobility, self-care and anxiety/depression) of EQ-5D.[2]

Charles et al[2] reported significant correlation between postoperative NCS and postoperative Oxford shoulder score, postoperative Constant score and postoperative Imatani score. However; the study does not mention the value of the correlation coefficient which is necessary to draw conclusion about the strength of the correlation. Additionally the validation check was done in 65 out of 90 patients (72%). Moreover, the proportion of patients with clavicle shaft fractures in these 65 patients is not specified.

There was no difference in the NCS values at two months and six months postoperatively in the group with associated injuries and those without associated injuries. Functional outcome using NCS was similar in group with associated injuries and those without associated injuries. We do not anticipate any bias arising out of this.

### 4.2. Floor and ceiling effect

The NCS did not demonstrate any ceiling or floor effect at two or six months after the treatment of clavicle fracture. This psychometric property of the NCS is worth appreciation as it is expected that outcome instruments can demonstrate ceiling effect in clavicle fracture at six months.[21] However, as the functional outcome tends to plateau after one year after surgical intervention for clavicle shaft fractures,[22] future studies could evaluate the presence of ceiling effect at one year and two years after the surgical intervention.

### 4.3. Responsiveness

Distribution based methods demonstrated adequate responsiveness of the NCS in our study.

The Effect size (ES) in a recently published study[2] (ES: 1.92) was slightly higher than that observed in the present study (ES: 1.8). Possible explanation could be the heterogenous population consisting of surgically treated injures of the clavicle, SC joint and AC joint in the published study. Also, Charles et al[2] compared change from preoperative status to postoperative assessment at six months whereas in the present study, the responsiveness was measured from two months postoperative to six months postoperatively. However; Charles et al reported responsiveness only in 65 out of 90 patients (72%) and in 18 out of 65 patients (27.7%) the preoperative NCS value was obtained by asking the patients to retrospectively guess the level of preoperative functional disability. This method of retrospective assessment of preoperative score is valid but prone to recall bias.

Magetsari described responsiveness of QuickDASH and Constant score in a cohort of clavicle shaft fractures in adult patients. Like our study, there was no preoperative evaluation of the scores and the functional outcome was assessed at three months and six months after the commencement of treatment. The effect size and standardised response mean of QuickDASH score (ES: 0.71; SRM: 1.46) and Constant score (ES: 0.63; SRM: 1.45) were lower than the respective values of NCS that was observed in our study.[23] Probable explanation for this difference could be that the cohort in the study by Magetsari was not homogenous as 53% patients received operative intervention and the rest 47% patients were treated non-operatively. Recent meta-analysis has shown that operative intervention is better than non-operative intervention because it leads to better functional outcome, lesser non-union and early return to work.[24]

### 4.4. Justification for sample size and follow-up duration

In the absence of recommendation or guideline for optimal duration for assessment of responsiveness, six months duration follow-up after surgical intervention of clavicle fracture is a reasonable time period for assessment of functional outcome. Functional outcome tends to improve after healing of the clavicle fracture and long term studies have shown that the outcome tends to plateau after one year of surgical intervention. Two meta-analyses have described results of functional outcome at six months subsequent to surgical intervention for clavicle shaft fractures.[25,26] Clavicle shaft fractures that fails to unite by six months is deemed to be a non-union.[27] Studies have shown that the mean union time for clavicle fracture is from 2.2 months to 4 months.[28–31] Hence we feel that follow-up period of six months is sufficient to assess psychometric properties of outcome instrument in clavicle shaft fractures.

Our sample size of 36 patients was comparable to other published series on TEN for clavicle shaft fractures wherein the cohort size of patients ranged from 25 to 38 patients.[32–35]

There were only 9 patients with operatively treated clavicle shaft fractures in the study by Charles et al[2] and it was not specified as to what type of surgical intervention (intramedullary nail or plate and screw) was performed on those patients. The study by Charles et al[2] was on a heterogenous population consisting of patients who underwent surgical intervention for conditions of the acromioclavicular joint, sternoclavicular joint and the clavicle.

### 4.5. Strengths of the study

Our study was an independent evaluation of the NCS by a non-developer group. Our cohort was a homogenous group of adult patients treated with titanium elastic nail. Ours is the first study to report responsiveness of the NCS, report validity and responsiveness of the NCS in operatively treated clavicle shaft fractures and the absence of ceiling and floor effects of the NCS. Only one patient from the cohort of 37 patients had missing data due to loss to follow-up (2.7%) and could not be included in the analysis of NCS at two months and six months. This is much lower than the threshold value of 10% where loss to follow-up bias could begin to creep in.

### 4.6. Weaknesses of the study

The NCS was the sole functional outcome instrument used in the study and our study could be criticized for not having used other previously described instruments like the Oxford shoulder score or the Constant Murley score. We also would like to acknowledge that our sample size could have been bigger however; another study published recently had 36 patients with conservatively treated clavicle fractures and had reported satisfactory construct validity, internal consistency and high inter-rater agreement while using the Constant Murley score.[21]

The generalizability of results from the present study is limited only to clavicle shaft fractures that are treated with flexible titanium nail. The results are not generalizable to studies with injuries and conditions of the acromioclavicular joint, sternoclavicular joint and fractures of the lateral end of the clavicle.

### 4.7. Suggestions for future studies

Our study has described the results of NCS after intramedullary nail stabilization of the clavicular shaft fractures. It would be interesting to investigate any difference in improvement pattern in NCS after nail fixation and plate and screw fixation of clavicle shaft fracture. Attempts should also be made to determine the value of minimal clinically important difference (MCID) value of the NCS as it is crucial to discriminate between statistical significance and clinically relevant significance.

## 5. Conclusion

The Nottingham clavicle score is a functional outcome instrument with satisfactory construct validity, internal validity and responsiveness in surgically treated clavicle shaft fractures with titanium elastic nailing. Hence, we recommend the use of the Nottingham clavicle score to assess functional outcome after treatment of clavicle shaft fractures with titanium flexible nails.

## Conflict of interest

The authors declare absence of any conflict of interest.

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