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PART I

INTRODUCTION

CHAPTER 1

Introduction and outline of this thesis

INTRODUCTION

Epidemiology

With an overall incidence of 29 to 80 per 100 000 people a year,[1-4] clavicular fractures are among the most common fractures of the shoulder, and account for 2.6% to 4% of all fractures in adults.[1,3] Anatomically the clavicle can be divided into three equal parts.[5] In adults about 70% of the clavicular fractures involve the middle third or midshaft, whereas about 30% involve the lateral third and less than 5% the medial third.[4] Midshaft clavicular fractures are mostly seen in young male adults and the lateral clavicular fractures mostly in elderly women.[1-4,6] The vast majority of these fractures result from a direct blow on the shoulder, caused for example by a fall from height, bike, or other traffic accidents, and in some cases from a fall on the outstretched hand.[3,4,7] In the latest published results on sports injuries in the Netherlands in 2012, about 5 400 people were treated in the hospital for shoulder or clavicular fractures caused by sports accidents.[8] Since these numbers do not include the number of clavicular injuries at home, traffic injuries or injuries related to work, the total annual number of clavicular fractures is presumably much higher. Since clavicular fractures affect mostly the young and active, and involve long recovery and sickness leave, especially for construction workers, these fractures lead to a considerable burden to society in terms of productivity and costs.

Function of the clavicle

The clavicle connects the arm to the thorax in an osseous way and has several functions; it protects the underlying neurovascular structures, it serves as a suspension for the shoulder, thorax and neck muscles and it supports the respiratory system. Together with the scapula and thorax it forms the osseous shoulder girdle, a so-called closed-chain-mechanism.[9] Changes in the shoulder anatomy, for example after mal-union and shortening of a clavicular fracture, may result in altered function of the arm.[10,11] In vivo studies suggested that shortening of the clavicle of at least 15 mm after a midshaft clavicular fracture can also lead to impaired arm function.[12-14] Other studies did not find any association between shortening and impairment.[11,15,16] None of these studies addressed the active motion kinematics of the shoulder after a clavicular fracture.

Diagnosis and classification

Whereas the diagnosis of a clavicular fracture can be made by physical examination, the amount of angulation, shortening, dislocation or displacement ad latum and comminution of the fracture can only be evaluated on radiodiagnostic images.[17,18] These aspects are considered of importance for treatment decisions. According to the standard medical protocol an anteroposterior (AP) radiograph is taken when a clavicular fracture is suspected. Shortening of the fracture may be measured on the AP radiograph, but it is questionable whether a one plane view adequately displays the clavicle for measuring length and displacement, accurately, i.e. without magnification and projection errors.

Classification systems are useful as a basis for treatment decisions and may help to predict treatment outcome. For use in clinical practice, a classification system has to be reliable and easy to apply. Robinson developed a classification system for clavicular fractures that takes into account the extent of displacement and comminution of the fracture (Figure 1).[4] He showed substantial to excellent inter- and intra-observer agreement on scoring medial, lateral and midshaft clavicular fractures according to his classification system.[4] Although commonly used in scientific research, the reliability of the Robinson classification has not been studied for subtypes of midshaft clavicular fractures.

Treatment

The first to describe the treatment of clavicular fractures were the Ancient Egyptians in the Edwin Smith Papyrus in 1600 BC, which was a copy of an older document that originated around 3000 BC. In this writing a construction similar to the now-called "figure-of-eight" bandage is explained.[19] In 400 BC, Hippocrates recognized that the treatment of clavicular fractures may pose a challenge. He suggested to use compresses and bandages, even though he knew that these materials would not keep the fracture in place and the fracture would finally heal itself.

"When, then, a [clavicle] fracture has recently taken place, the patients attach much importance to it, as supposing the mischief greater than it really is, and the physicians bestow great pains in order that it may be properly bandaged; but in a little time the patients, having no pain, nor finding any impediment to their walking or eating, become negligent; and the physicians finding they cannot make the parts

Undisplaced Fractures (Type 1A)

Extra-articular (Type 1A1)

Intra-articular (Type 1A2)

Displaced Fractures (Type 1B)

Extra-articular (Type 1B1)

Intra-articular (Type 1B2)

Fig. 1a

Cortical Alignment Fractures (Type 2A)

Undisplaced (Type 2A1)

Angulated (Type 2A2)

Displaced Fractures (Type 2B)

Simple or wedge comminuted (Type 2B1)

Isolated or comminuted segmental (Type 2B2)

Fig. 1b

Cortical Alignment Fractures (Type 3A)

Extra-articular (Type 3A1)

Intra-articular (Type 3A2)

Displaced Fractures (Type 3B)

Extra-articular (Type 3B1)

Intra-articular (Type 3B2)

Fig. 1c

Figure 1   Robinson classification: diagrams of type-1 (fig. 1a), type-2 (fig. 1b) and type-3 (fig. 1c) clavicular fractures.

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look well, take themselves off, and are not sorry at the neglect of the patient, and in the meantime the callus is quickly formed".[20]

Until the 1990s treatment of clavicular fractures remained primarily non-operative. Non-union rates after non-operative treatment were considered to be low (<1%) as shown by Neer and Rowe in the 1960s.[21,22] Operative treatment was restricted to open fractures, neurovascular injury, and floating shoulders.[23,24] More recent research in the 1990s showed higher non-union rates (5-15%) than previously assumed.[4,12] Based on those and similar publications, the opinion on how to treat midshaft clavicular fractures gradually shifted from primarily non-operative treatment to invasive methods, such as intramedullary nailing and plate fixation. Improved surgical techniques and materials resulted in a growing believe in the uncomplicated fracture consolidation after operative treatment of clavicular fractures, and especially in a lower risk of non-union compared to conservative treatment. The supposed decrease in healing time to full recovery of arm function after operation also promoted the popularity of operative treatment. No solid evidence existed to substantiate the 'gut-feeling' preference for operative treatment of surgeons world-wide until 2005, when a systematic review on this topic was published showing that good results had been achieved with operative treatment.[25]

A randomised controlled trial (RCT) published in 2007 further strengthened surgeons' preference for treatment with plate fixation for displaced midshaft clavicular fractures, as the RCT showed less non-unions and better functional scores in the operative treatment group.[26] However, some weaknesses in the enactment of this trial, such as a large, and possibly selective, drop-out in the non-operatively treated group which may have led to bias, caused scientists to question the interpretation of the results of this RCT. In 2009, two other randomised studies were published comparing the Hagie pin and elastic stable intramedullary nailing (ESIN) with non-operative treatment.[27,28] Though the functional outcome after short-term follow-up was better for the Hagie pin, functional scores were similar after 6 months and the complication rate was higher after operative treatment.[27] The ESIN resulted in lower non-union rates compared to non-operative treatment and a better functional outcome, but complications such as medial nail protrusion and revision surgery were substantial.[28] At the start of the studies described in this thesis, more studies were needed to determine optimal treatment for displaced midshaft clavicular fractures. Apart from

the functional outcome, it is also important to study whether operative treatment leads to faster recovery compared to conservative treatment. Since most clavicular fractures involve the young and active, a faster return to work and reduction of sick days might also reduce loss of productivity and societal costs. From the hospital perspective, operative treatment is in general more expensive than non-operative treatment due to the costs for in-patient stay and the operation itself. However, other costs, such as costs for physical therapy and non-medical costs due to absence of work for non-operative and operative treatment are unknown, but expected to be higher after non-operative treatment. In one study based on the data of the Canadian RCT,[26] the cost-effectiveness of operative treatment versus non-operative treatment of midshaft clavicular fractures was evaluated. In this study, operative treatment was considered cost-effective only if the functional benefits compared to non-operative treatment would persist for at least nine years,[29] which is doubtful from a clinical point of view. Long-term results from this study are not available yet. To what extent these cost-effectiveness calculations would apply to the Dutch system is not investigated. More research is needed in diagnostics and treatment decisions to establish a more definite ground to base treatment decisions on for economical as well as patient-centred reasons. In economical and surgical ways the patient, the surgeon and the society will benefit from evidence based optimization of clavicular fracture care. In this light, the themes of this thesis are opted.

OUTLINE OF THIS THESIS

Although clavicular fractures are seemingly simple fractures, many questions on optimal diagnostic strategies and treatment are still unanswered. The goal of the studies described in this thesis was to optimise management of clavicular fractures by providing answers to unsolved diagnostic and treatment issues. The three parts of this thesis address *diagnostic aspects*, *treatment* and *biomechanics,* all of which relate to clinical decision making. Most studies presented in this thesis are on the subject of midshaft clavicular fractures, whereas in one chapter the treatment of lateral clavicular fractures is discussed. The results of the studies are summarised and commented on in the general discussion.

Diagnostic aspects

The first part of this thesis relates to challenges in the diagnostic work-up of clavicular fractures. In Chapter 2 the reliability of the Robinson classification for midshaft clavicular fractures is studied amongst experienced trauma surgeons and radiologists. Clavicular length measurements performed on radiographs are compared with three-dimensional length measurements in Chapter 3. The value of the additional 30-degree caudocephalad radiograph for determining treatment strategy is evaluated in Chapter 4. The following research questions were addressed:

- What is the inter- and intra-observer agreement of the Robinson classification for displaced and comminuted midshaft fractures amongst trauma surgeons and radiologists? **Chapter 2**
- Is the Robinson classification reliable in clinical practice? **Chapter 2**
- Do measurements of clavicular length and shortening on AP panorama radiographs reflect reality? **Chapter 3**
- What type of measure should be used to adequately determine clavicular shortening after fracture? **Chapter 3**
- What is the influence of the 30-degree caudocephalad radiograph in treatment decisions for midshaft clavicular fractures? **Chapter 4**

Treatment

In the second part of this thesis several factors influencing treatment and treatment decisions for clavicular fractures are discussed. The outcomes of the most commonly used surgical techniques for operative management of lateral clavicular fractures are compared in a meta-analysis described in Chapter 5. Union rates, time to union, functional outcome and complications reported in the available literature are summarised and compared to provide the best available evidence for optimal treatment. In Chapter 6 the results of an online survey on treatment of midshaft clavicular fractures are presented. Dutch trauma surgeons judged AP-radiographs of midshaft clavicular fractures and expressed which treatment they preferred for the displayed fractures. The influence of the surgeons' background on treatment decisions was also assessed. In Chapter 7 a retrospective cohort of patients with clavicular fractures in two hospitals were studied to find potential relations between the chosen treatment and patient and fracture characteristics. In Chapter 8 the study protocol of

the Sleutel-TRIAL is presented. The Sleutel-TRIAL is a multi-center randomised controlled trial on the treatment of displaced midshaft clavicular fractures, in which patients are randomised between operative treatment with plate fixation and non-operative treatment with a sling. Union rates, complications, functional outcome and quality of life will be compared between the treatment arms. The following research questions were addressed in the chapters on treatment of clavicular fractures:

- Which surgical technique for fixation of lateral clavicular fractures is preferred in terms of complications, union rate, and functional outcome? **Chapter 5**
- What is the current practice of the Dutch trauma surgeons on how to treat displaced midshaft clavicular fractures and is there consensus? **Chapter 6**
- Are treatment and trauma mechanism associated with the fracture type for midshaft clavicular fractures? **Chapter 7**
- How to develop a scientifically sound and clinically feasible study protocol that will provide the highest level of evidence for determining the optimal treatment for midshaft clavicular fractures? **Chapter 8**

Biomechanics

Severe shortening of the clavicle with associated dysfunction of the shoulder/arm is considered to be the main reason for operative treatment of displaced clavicular fractures. To evaluate whether this assumption holds true, a study on the kinematics of the shoulder after consolidation of a midshaft clavicular fracture was conducted, which is described in the third part of this thesis in Chapter 9. In this study the relation between scapula rotations and humeral motion was assessed in 32 subjects with a shortened non-operatively treated consolidated midshaft clavicular fracture. The following research questions were addressed:

- Does the extent of shortening of the consolidated clavicle influence scapular kinematics in rest and during motion? **Chapter 9**
- Is Range of Motion and shoulder strength impaired after clavicular shortening? **Chapter 9**

In **Chapter 10** the results of the presented studies on clavicular fractures are discussed and conclusions and recommendations following from the results and discussion are presented. **Chapters 11** and **12** include summaries in English and Dutch.

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PART II

DIAGNOSTIC TOOLS

CHAPTER 2

Reliability of the Robinson classification for displaced comminuted midshaft clavicular fractures

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ABSTRACT

This study aimed to assess the reliability of the Robinson classification for displaced comminuted midshaft fractures. 102 surgeons and 52 radiologists classified 15 displaced comminuted midshaft clavicular fractures on anteroposterior and 30-degree caudocephalad radiographs twice. For both surgeons and radiologists inter-observer and intra-observer agreement significantly improved after showing the 30-degree caudocephalad view in addition to the anteroposterior view. Radiologists had significantly higher inter- and intra-observer agreement than surgeons after judging both radiographs ($\kappa_{multirater}$ 0.81 vs. 0.56; $\kappa_{intra-observer}$ 0.73 vs. 0.44). We advise to use two-plane radiography and to routinely incorporate the Robinson classification in the radiology reports.

INTRODUCTION

Classification systems for fractures serve as a basis for treatment choice and outcome prediction. Classification systems for clavicular fractures have been developed by Allman[1] for the anatomical site, by Neer[2] for the lateral third fractures, and by Craig[3] for the lateral and medial third fractures. The Robinson classification[4] has been established as the most appropriate classification method for the midshaft clavicular fractures[5] with the highest prognostic value for treatment outcome in terms of union and non-union. The Robinson classification differentiates between two main types of midshaft clavicular fractures i.e., undisplaced (type A) fractures and displaced (type B) fractures (Figure 1). In daily practice, the differentiation between displaced simple comminuted fractures (type 2B1) and segmental comminuted fractures (type 2B2) is the most challenging. To our knowledge the reliability of the Robinson classification system for this distinction has not been analyzed. The aim of our study was to assess the inter-observer and intra-observer agreement on the Robinson classification for type B midshaft clavicular fractures among surgeons with an interest in fracture surgery and radiologists with an interest in skeletal imaging.
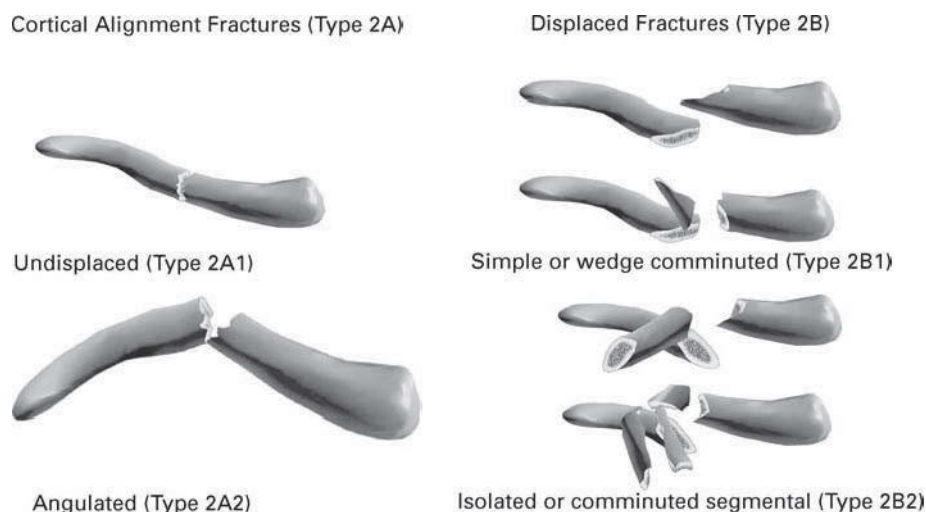
Figure 1   Robinson classification for midshaft clavicular fractures.
Reprinted with permission of C.M. Robinson.[4]

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MATERIAL AND METHODS

Radiographs

Fifteen displaced and comminuted midshaft clavicular fractures of adult patients were selected randomly from the electronic hospital registry. These fractures had been classified according to the Robinson clavicle fracture classification (Figure 1)[4] by an expert panel consisting of 2 trauma surgeons and a radiologist. Both the anteroposterior (AP) trauma radiograph and the 30 degree caudocephalad radiograph of the fractures were retrieved from the medical records. For examples see Figure 2.
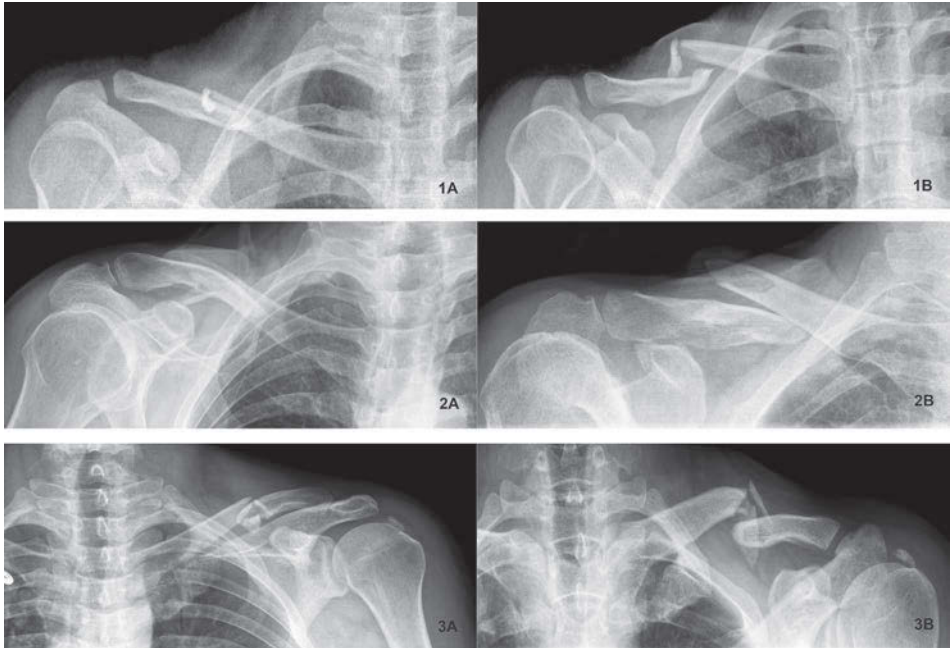
Figure 2 Three series of anteroposterior (A) and 30-degree caudocephalad (B) radiographs of midshaft clavicular fractures.

Survey

The 30 radiographs of the 15 displaced and comminuted midshaft clavicular fractures were presented in an online survey developed with LimeSurvey 1.91+ software. For each fracture, the radiographs were presented on separate pages, starting with the AP radiograph and followed by the corresponding 30-degree caudocephalad radiograph. The respondents had to classify each midshaft clavicular fracture presented on the radiographs and were not able to revise previously given answers. Eight weeks after the initial assessment, the survey was presented again in a different case order to determine the intra-observer reliability.

Respondents

The online survey was performed in the Netherlands and Belgium amongst the clinical members of the Dutch Trauma Society, members of the Dutch Society of Radiology, and members of the muscular and skeletal imaging division of the Royal Belgian Society of Radiology in August 2011. Members of these societies with an active e-mail address were invited to participate in the survey. A reminder e-mail was sent if the respondent had not filled out the survey.

Statistical analysis

The inter-observer agreement on the Robinson classification for the AP radiographs and 30-degree caudocephalad radiographs was calculated using the free-marginal multirater kappa ($\kappa_{multirater}$) for categorical data[6] for the respondent group as a whole and separately for surgeons and radiologists. The strength of the inter-observer agreement was determined using the table of Landis and Koch, that indicates kappa ≤ 0 as poor agreement, 0.01 to 0.20 as slight agreement, 0.21 to 0.40 as fair agreement, 0.41 to 0.60 as moderate agreement, 0.61 to 0.80 as substantial agreement and 0.81 to 1.00 as almost perfect agreement.[7] For each $\kappa_{multirater}$ the 95% confidence interval (95%-CI:) was calculated. If the 95%-CI:'s for the $\kappa_{multirater}$ estimates of the surgeons and radiologists did not overlap, the inter-observer agreement between the respondent groups was considered statistically different.

The intra-observer agreement was calculated using Cohen's kappa ($\kappa_{intra-observer}$) for each respondent. The mean intra-observer agreement was calculated for the group of respondents as a whole, and separately for surgeons and radiologists.

This was calculated for the AP radiographs and 30-degree caudocephalad radiographs. Differences between estimates of the intra-observer agreement for the two respondent groups (surgeons and radiologists) and for both types of radiographs (AP and 30-degree caudocephalad) were considered statistically significant if the 95%-CI:'s did not overlap. All statistical analyses were performed using IBM SPSS version 20 (Statistical Package for the Social Sciences Inc., Chicago Il, USA).

RESULTS

Of the 242 invited members of the Dutch Trauma Society 112 filled out the first survey (response rate 46.3%), of which 102 surveys were complete. Those 102 surgeons received the second survey after eight weeks, of which 66 were returned (response rate 64.7%). Of the second survey, nine were incomplete and therefore excluded, leaving 57 surveys for analysis (Figure 3). Of the 132 invited radiologists 53 returned the first survey (response rate 40.1%), of which 52 were complete. In the second round 35 of the 52 radiologists returned the survey (response rate 67.3%; Figure 3). The expert panel adjudicated the 15 midshaft clavicular fractures as 6 type 2B1 and 8 type 2B2 fractures.

Inter-observer agreement on the Robinson classification

The $\kappa_{multirater}$ values for agreement on the classification of displaced comminuted fractures in the total observer group ranged between 0.42 (moderate agreement) and 0.81 (almost perfect agreement) (Table 1). When more information was given by means of the 30-degree radiographs, the inter-observer agreement on classification was significantly higher than for the AP radiographs alone (Table 1). The inter-observer agreement between the radiologists tended to be better than between the surgeons, but the difference between the respondent groups was statistically significant only after reviewing the 30-degree radiographs.
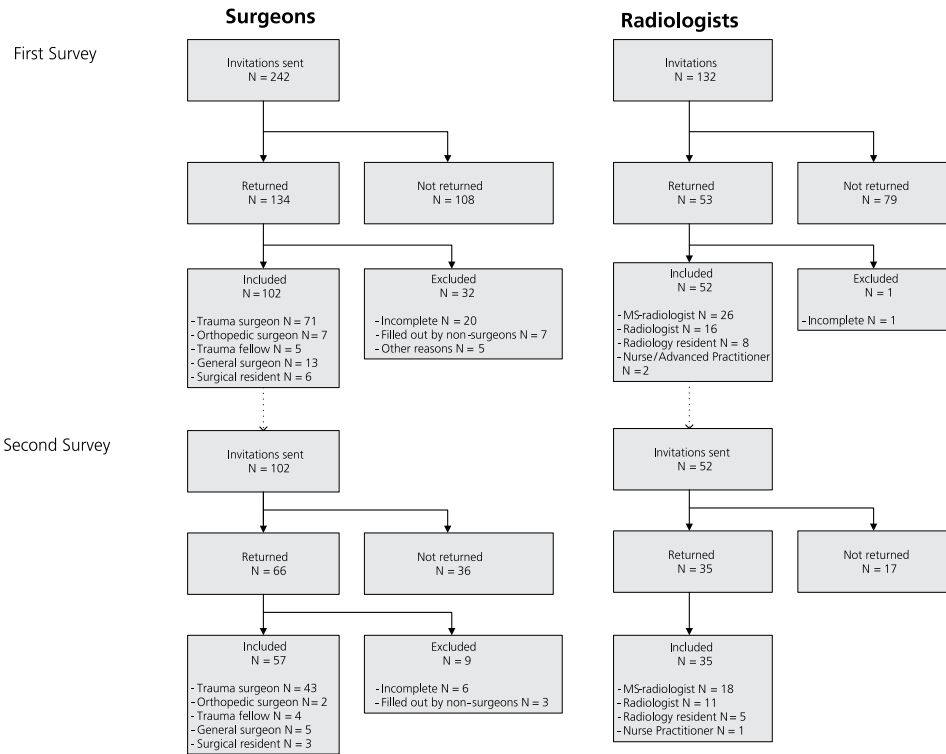
Figure 3   Flowchart of invitations sent and responses received.

Table 1   Multi-rater free-marginal kappa coefficients for inter-observer agreement on the Robinson classification in survey 1 and the intra-observer agreement between survey 1 and 2.

	Inter-observer agreement			Intra-observer agreement		
	N	Kappa	95%-CI	N	Kappa	95%-CI
Surgeons + Radiologists	154			92		
AP radiograph		0.45	0.40 – 0.50		0.31	0.26 – 0.36
30 degree radiograph		0.63	0.58 – 0.67		0.55	0.49 – 0.62
Surgeons	102			57		
AP radiograph		0.42	0.36 – 0.48		0.29	0.23 – 0.35
30 degree radiograph		0.56	0.51 – 0.62		0.44	0.37 – 0.52
Radiologists	52			35		
AP radiograph		0.52	0.45 – 0.61		0.34	0.26 – 0.42
30 degree radiograph		0.81	0.71 – 0.90		0.73	0.64 – 0.82
N=number of respondents						

Intra-observer agreement on the Robinson classification

The overall intra-observer agreement was fair to moderate for the combined respondent groups on classification of the AP and 30-degree radiographs respectively ($\kappa_{intra-observer}$ for AP: 0.31, for 30-degree: 0.55; Table 1). For both surgeons and radiologists, the intra-observer agreement on classification of the 30-degree caudocephalad radiographs was significantly higher compared to that of the AP radiographs. The reliability within observers seemed higher for the radiologists, but this difference was statistically significant only for the 30-degree radiographs (Table 1).

DISCUSSION

In this study we found that the inter-observer and intra-observer agreement on the Robinson classification of displaced and comminuted midshaft clavicular fractures was moderate. Additional 30-degree caudocephalad radiographs improved both the inter-observer and intra-observer agreement. Radiologists were found to classify these fractures more reliably than surgeons. Their intra-observer and inter-observer agreement was substantial after viewing the fractures on two-plane radiography.

Robinson validated his classification system in a group of five orthopaedic surgeons who reviewed 20 series of lateral, midshaft and medial clavicular fractures.[4] He found substantial inter-observer agreement, with an overall mean kappa of 0.77. The intra-observer agreement was excellent with a mean kappa coefficient of 0.84 (range 0.69 to 0.88).[4] In the present study, the estimated kappa coefficients were lower than those found by Robinson. This may be explained by the fact that the current study only focused on the distinction between type 2B1 and 2B2 fractures, whereas Robinson included all types of clavicular fractures. In our study, we deliberately did not include undisplaced or angulated midshaft clavicular fractures (type 2A1 and 2A2), because these types of fractures are uncommon in adults[4,5,8] and have good union results without surgical intervention.

In our survey, the fractures were first classified based on an AP radiograph. Subsequently additional insight into the fracture characteristics were provided on a 30-degree radiograph. We therefore expected that observers would classify the fractures on the 30-degree radiograph more reliably. This assumption was confirmed

for the intra-observer and inter-observer agreement of both the surgeons and specialized musculoskeletal radiologists in our study.

The decision whether or not to operate midshaft clavicular fractures may depend on the physical abilities and wishes of the patient; nevertheless it is also based on the amount of shortening, displacement and comminution as judged on the radiograph. Displacement and comminution of the clavicle are the most important factors for determining the fracture type according to the Robinson classification. In the study of Jones et al.[9] it was found that these fracture characteristics could reliably be assessed on AP and 30-degree caudocephalad radiographs, but shortening could not. Two other studies showed that the extent of shortening and dislocation ad latum might be underestimated if displayed on AP radiographs alone.[10,11] The current study shows that the extent of comminution, as displayed in simple or wedge comminuted (2B1) and isolated or segmental comminuted fractures (2B2), is difficult to classify on both AP and 30-degree caudocephalad radiographs. The prognostic value of the Robinson classification as described by O'Neill et al.[5] may therefore be overrated, because there is a possibility that the clavicular fracture is wrongly classified. In contrast to our study, Jones et al.[9] found a moderate to strong inter- and intra-observer agreement for displacement and comminution on similar radiographs. However, in the study of Jones et al.[9] only the presence of comminution was documented and not the degree of comminution as is necessary to differentiate between wedged and segmented comminuted clavicular fractures.

The Robinson classification has been stated to provide the most reliable prognostic information compared to the other classification methods for midshaft clavicular fractures.[5,12] We found no other studies on the reliability of classification systems for clavicular fractures to compare our data with. Based on the results of our current study, we advise to use the Robinson classification. To optimize the inter-observer and intra-observer agreement, we recommend using two-plane imaging, as our results showed significantly higher overall inter- and intra-observer agreement after displaying the 30-degree radiograph. Furthermore, the reliability of the classification may be optimized by including the Robinson classification in the radiology reports on midshaft clavicular fractures, because our study suggests that radiologists may classify displaced comminuted midshaft clavicular fractures more reliably than surgeons. Implementing the Robinson classification in this manner may

improve treatment decisions and optimize the prognosis and treatment outcome. The relatively low response rates (46% for the first survey and 65% for the second survey among the responders to the first survey) pose a limitation to this study. All participating respondents have judged radiographs of clavicular fractures before, because of their interest in trauma surgery or musculoskeletal radiology. The results of this study are therefore generalizable for those who treat midshaft clavicular fractures on daily basis. Response rates were sufficient to calculate inter- and intra-observer agreements.

In conclusion, midshaft clavicular fractures should be classified according to the Robinson classification on two-plane radiography to optimize treatment decisions. Furthermore, we advise to include the Robinson classification in the radiology reports on midshaft clavicular fractures to improve the fracture classification of displaced comminuted fractures.

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CHAPTER 3

Measurement of clavicular
length and shortening after a
midshaft clavicular fracture:
*Spatial digitization versus planar
roentgen photogrammetry*

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ABSTRACT

Purpose

Clavicular shortening after fracture is deemed prognostic for clinical outcome and is therefore generally assessed on radiographs for clinical decision making, although the reliability and accuracy of these measurements are unclear. This study aimed to assess the reliability of measurements of clavicular length and shortening on radiographs, and to compare these with three-dimensional (3D) measurements obtained with a spatial electromagnetic recording system.

Patients and Methods

Thirty-two participants with a consolidated non-operatively treated midshaft clavicular fracture were analysed. Two observers measured clavicular lengths and absolute and proportional clavicular shortening before and after fracture consolidation. The clavicular lengths were also measured in 3D with the electromagnetic Flock of Birds system. Inter-observer agreement on the radiographic measurements was assessed using the Intraclass Correlation Coefficient (ICC). Agreement between the radiographic and spatial digitization measurements was assessed using a Bland-Altman plot.

Results

The inter-observer agreement on clavicular length, and absolute and proportional shortening on trauma radiographs was almost perfect (ICC>0.90), but moderate for absolute shortening after consolidation (ICC=0.45). The Bland-Altman plot comparing measurements of length on AP panorama radiographs with spatial digitization showed substantial differences.

Conclusion

Measurements of clavicular length on radiographs are highly reliable between observers, but may not reflect the actual length, since 2D measurements (radiographs) differed from 3D measurements (Flock of Birds). We recommend to use proportional shortening when measuring clavicular length or shortening on radiographs for clinical decision making.

INTRODUCTION

Non-operative treatment of displaced midshaft clavicular fractures may lead to mal-union and subsequent shortening of the clavicle.[1-4] Several studies suggested that conservative treatment of fractured clavicles with more than 15 mm shortening on the trauma radiograph may lead to poor functional outcome[2,5,6] or non-union.[7,8] For these cases, surgical fixation in the first weeks after trauma is generally advocated.[7,9] However, if applied in clinical decision making, clavicular length and shortening must be measured in a reliable and valid manner.

In current clinical practice, clavicular length and shortening are measured on (two-dimensional) digital radiographs, with the fracture projected in one or two planes. Two notes of criticism about these clinically relevant measurements are in place: the accuracy of these measurements is questionable, because the use of different types of radiographs, different directions of the x-ray beam, and the conversion of three-dimensional (3D) to two-dimensional (2D) information, may lead to magnification and projection errors. The reliability and validity of clavicular length and shortening measurements on radiographs have been scarcely investigated. The other point of discussion is whether clavicular shortening should be expressed as an absolute measure (in mm). Since clavicular length varies between individuals, a certain amount of shortening may not have the same effect on the shoulder function in every patient.[10] For this reason, it may be more appropriate to express clavicular shortening as a proportional measure.

The 3D positions of predefined bony landmarks can be determined accurate and reliable with an electromagnetic tracking device (spatially digitized observations),[11] from which bone lengths can be calculated. It may also be assumed that the 3D spatial digitization measurements reflect anatomic clavicular length more closely than 2D planar photogrammetry. However, this method is only feasible in a research setting. Currently, the agreement between measurements on radiographs and spatial digitization is not known.

This study aimed to determine the inter-observer reliability of measurements of clavicular length and absolute and proportional shortening on radiographs and to compare these 2D photogrammetry measurements of clavicular length with spatially digitized 3D measurements. Furthermore, we evaluated an alternative

method for calculating proportional shortening of consolidated clavicles on radiographs which accounts for inter-individual variation of clavicular length.

PATIENTS AND METHODS

This exploratory study was approved by the institutional Medical Ethics Review Committee and registered in the Dutch Trial Registry (NTR3167). The study was performed between December 2011 and April 2012.

Participants

For this exploratory study no sample size calculation was performed. Patients with a non-operatively treated displaced midshaft clavicular fracture that had consolidated within four months after trauma were selected from the medical databases 2006-2010 of the Leiden University Medical Centre and the Rijnland Hospital in the Netherlands. Patients were eligible for inclusion in the study if they were aged 18 to 60 years at time of fracture and had no associated injuries, pathological fracture, neurovascular injury, or previous acromioclavicular injury of either shoulder. Patients with non-union of the fractured clavicle were excluded. Candidates with a cardiovascular pacemaker were also excluded, since an electromagnetic field was used for the spatial digitization measurements. All 74 eligible patients were subsequently contacted by phone after having received written information. Of those, 32 patients were willing to participate in the study and visited the outpatient clinic for radiography and spatial digitization. Informed consent was obtained from each participant.

Roentgen photogrammetry

The anteroposterior (AP) trauma radiographs of all participants were retrieved from the hospital records. During the study visit, an additional AP panorama radiograph comprising both clavicles was acquired of each participant. For this AP panorama radiograph, it was ensured that the candidates were standing straight and that the spinous processes of the thoracic vertebrae were projected in the midline, to eliminate thoracic rotation and clavicular protraction.
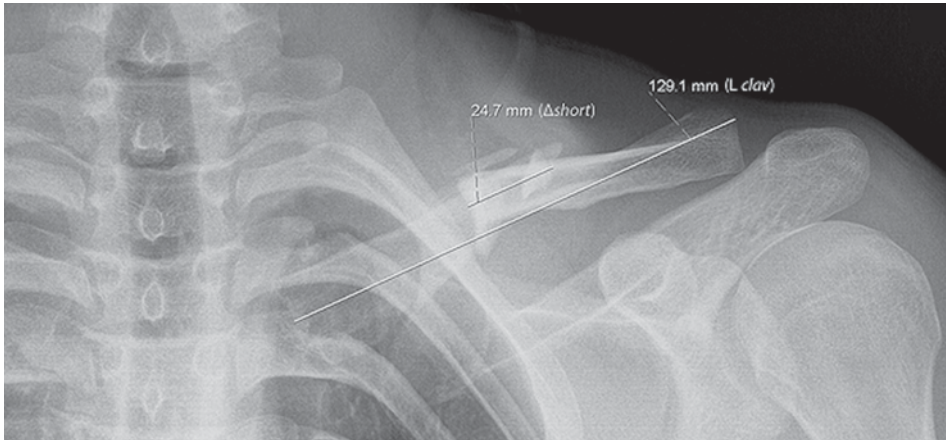
(A) Anteroposterior trauma radiograph*

Clavicular length (L *clav*) is defined by the line connecting the middle of the medial border with the most lateral edge. Absolute shortening (Δ *short*) was calculated by connecting the cortical fragments along the axial line of the clavicle.
The Clavicular Shortening Index (CSI) is defined as the absolute shortening divided by the length of the affected clavicle plus absolute shortening. For this case, the relative shortening is 24.7/(129.1+24.7) x 100= 16.1%.
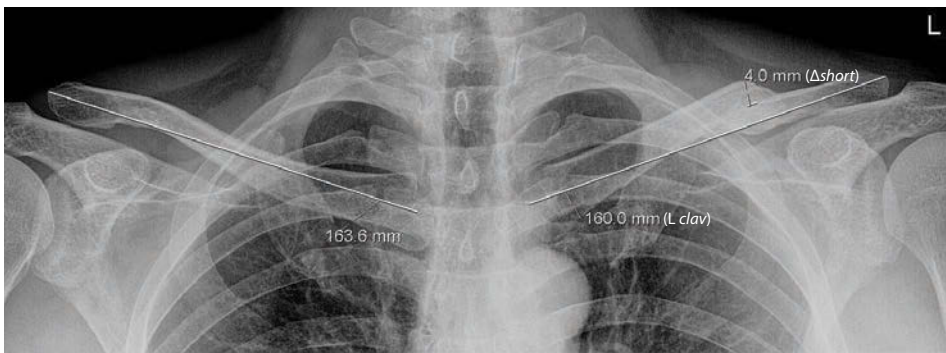
(B) Anteroposterior panorama radiograph taken after consolidation*

Clavicular length (L *clav*) is defined by the line connecting the middle of the medial border with the most lateral edge. The length of the consolidated clavicle (L) in this example is 160.6 mm and the length of the contralateral clavicle (R) is 163.4 mm. Absolute shortening (Δ *short*) is defined as the axial distance between the cortical fragment ends. In this case, the absolute shortening is 4.0 mm.
* Figures 1A and 1B are from different patients.

Figure 1 Measurement of clavicular length and shortening after a midshaft fracture, on the anteroposterior trauma radiograph (A) and anteroposterior panorama radiograph (B).

Roentgen photogrammetry was performed on the initial AP trauma radiograph of each fractured clavicle and on AP panorama radiographs that had been taken after consolidation for study purposes. Two researchers independently measured the length of the affected clavicle on the primary AP trauma radiograph, by connecting the middle of the medial border with the most lateral edge in a straight line (L *clav*) (Sectra Imtec 2009, Janköping, Sweden) (Figure 1). The lengths of the consolidated and the contralateral clavicle on the AP panorama radiographs were measured in the same way.

The extent of shortening of the affected clavicle was measured in two ways. First, absolute shortening was measured as the axial distance in mm between the cortical fracture fragments ends (Δ *short*) on the AP trauma radiograph and the AP panorama radiograph after consolidation (Figure 1). Second, as a measure for proportional shortening (i.e., percentage of the initial clavicular length lost after fracture), the "Clavicular Shortening Index" (*CSI*) was calculated from these measurements, by dividing the absolute shortening by the initial length. The initial length is obtained by adding the absolute shortening to the measured clavicular length. The calculation of the *CSI* is based on the formula for proportional shortening proposed by Smekal et al.[10]:

$$CSI = \frac{(\Delta\ short)}{(\Delta\ short + L\ clav)} \times 100\%$$
(Eq. 1)

Spatial digitization

The "Flock of Birds" 3D Electromagnetic Motion Tracking Device (FoB, Ascension Technology Corp, Burlington, VT, USA) and custom made computer software (FoBVis, Clinical Graphics, Delft, The Netherlands) were used to measure the spatial length of the participants' affected and contralateral clavicles.[11-13] The spatial length of both clavicles was determined by locating the three-dimensional coordinates of two pre-defined bony landmarks: the sternoclavicular joint (SC) and the acromioclavicular joint (AC), using an electromagnetic stylus/digitizer.[13] The three dimensional position of the SC- and AC-joint was determined relative to a sensor that was placed on the sternum, in order to reduce movement artefacts and to

account for the participant's individual anatomy.[14] The clavicular lengths were calculated in a 3-dimensional plane as the (Euclidian) distance between AC- and SC-joint, by applying the Pythagorean Theorem.

Statistical analysis

Inter-observer agreement on roentgen photogrammetry measurements (for affected and the contralateral clavicle) and *CSI* was assessed by evaluating systematic differences between the observers with paired Student's t-tests and by calculating Intraclass Correlation Coefficients (ICCs). The strength of agreement was interpreted according to Landis and Koch,[15] who indicated ICC≤0 as poor agreement, 0.01 to 0.20 as slight agreement, 0.21 to 0.40 as fair agreement, 0.41 to 0.60 as moderate agreement, 0.61 to 0.80 as substantial agreement and 0.81 to 1.00 as almost perfect agreement.

   A Bland-Altman plot was constructed to graphically compare the results of roentgen photogrammetry and spatial digitization. In such a plot, the difference between the measurements is plotted against the mean of the measurements for each study subject.[16,17] Horizontal lines are drawn in the plot at the mean difference and at the 95% limits of agreement, which are calculated as the mean difference ± 1.96 times the standard deviation of the differences.[16,17] If the mean difference between both methods is close to 0, no systematic difference (bias) exists. If the differences between the measurements within the limits of agreement are considered not clinically meaningful, the methods may be used interchangeably. For this purpose we used the AP roentgen photogrammetry results of only one of the observers, since the inter-observer agreement between the two observers was high.

   Statistical analyses were performed with SPSS version 20.0 (Statistical Package for Social Sciences Inc, Chicago, IL). P-values <0.05 were considered statistically significant.

Results

The study group consisted of 32 participants: 27 men with a mean age of 31 years (range: 21-62 years) and 5 women with a mean age of 27 years (range: 25-31 years). In one case, the AP trauma radiograph was not calibrated and could not be used in the study. For another participant, the length of the non-fractured clavicle could not be measured due to incomplete imaging of the clavicle on the AP panorama radiograph. The other data of these two patients were adequate and were used for analysis.

Inter-observer agreement on roentgen photogrammetry

There were no systematic differences in measurements of the clavicular length between the observers (Table 1). The inter-observer agreement on clavicular length was almost perfect for both fractured and contralateral clavicles (ICCs>0.90; Table 1). The inter-observer agreement on absolute shortening of the fractured clavicle on the AP trauma radiograph was also almost perfect (ICC=0.97, 95%-confidence

Table 1   Inter-observer agreement on clavicular length and shortening after non-operatively treated midshaft fractures as measured on the AP trauma radiograph and on the AP panorama radiograph taken after consolidation.

	Observer 1	Observer 2	Difference	P-value	Intraclass Correlation
	mean (SD)	mean (SD)	mean (SD)		Coefficient (95%-CI)
AP trauma radiograph					
Length [mm] of fractured clavicle (n=31)*	164.7 (20.5)	164.2 (21.2)	0.5 (3.5)	0.46	0.99 (0.97 – 1.00)
Absolute clavicular shortening, [mm] (n=31)*	16.9 (8.4)	17.2 (8.4)	-0.3 (1.9)	0.42	0.97 (0.95 – 0.99)
AP panorama radiograph after consolidation					
Length [mm] of consolidated clavicle (n=32)	156.7 (13.2)	157.8 (14.2)	-1.1 (5.6)	0.28	0.92 (0.84 – 0.96)
Length [mm] of non-fractured clavicle(n=31)*	170.2 (12.7)	168.9 (13.2)	1.3 (3.4)	0.05	0.97 (0.93 – 0.98)
Absolute clavicular shortening, [mm] (n=32)	15.1 (8.1)	17.6 (7.3)	-2.5 (8.1)	0.10	0.45 (0.12 – 0.69)

* The AP trauma radiograph was in one case not calibrated and could not be used in the study. For another participant, the length of the non-fractured clavicle could not be measured due to incomplete imaging of the clavicle on the AP panorama radiograph.

interval [CI]: 0.95 – 0.99) when measured on the AP trauma radiograph, but only moderate (ICC=0.45, 95%-CI: 0.12 – 0.69) when measured on the AP panorama radiographs acquired after consolidation (Table 1). There were no systematic differences in measurements of absolute shortening on the trauma and AP panorama radiographs between the two observers (Table 1).

For each observer the *CSI* was calculated from the absolute measurements on the trauma radiographs. The overall mean *CSI* was 9.2% (range: 1.4 – 22.5%). In the 13 participants who had an absolute shortening of more than 15 mm, the mean CSI was 5.6% (range: 1.4 – 9.1%). Almost perfect agreement was found for *CSI* between both observers (ICC=0.97; 95%-CI: 0.94 – 0.99). No systematic difference for *CSI* was found between the observers (p=0.42). The agreement for *CSI* after consolidation between the observers was fair (ICC=0.40; 95%-CI: 0.07 – 0.66) with no systematic difference for *CSI* (p=0.11).

Agreement between roentgen photogrammetry and spatial digitization

There was no statistically significant systematic difference between the clavicular length measurements obtained with roentgen photogrammetry vs. spatial digitization (Table 2). The mean difference between planar roentgen photogrammetry and spatial digitization for all clavicles was 1.38 mm (95%-CI: -3.21 – 5.98). In the Bland-Altman plot (Figure 2), the differences between the methods were evenly spread over the range of clavicular lengths with wide limits of agreement, indicating that the clavicular length measured on the radiographs may be up to 37 mm longer or 34 mm shorter than measured with spatial digitization.

Table 2 Agreement between measurements of clavicular length and of clavicular shortening with panorama AP roentgen photogrammetry and spatial digitization, in consolidated non-operatively treated midshaft fractures.

	Roentgen photogrammetry	Spatial digitization	Difference (bias)	
	Mean (SD)	Mean (SD)	Mean (95%-CI)	P-value
Length [mm] of consolidated clavicle(N=32)	156.7 (13.2)	158.2 (22.2)	-1.52 (-9.12 – 6.08)	0.69
Length [mm] of non-fractured clavicle(N=31)	170.2 (12.7)	165.9 (17.4)	4.37 (-0.95 – 9.70)	0.10

Figure 2 Bland-Altman plot for agreement between measurements of clavicular length with panorama AP roentgen photogrammetry and spatial digitization (FoB). The continuous black line indicates the average difference between the measurements with planar radiography and spatial digitization, and the dashed lines indicate the limits of agreement.

○ Fractured side
□ Non-fractured side
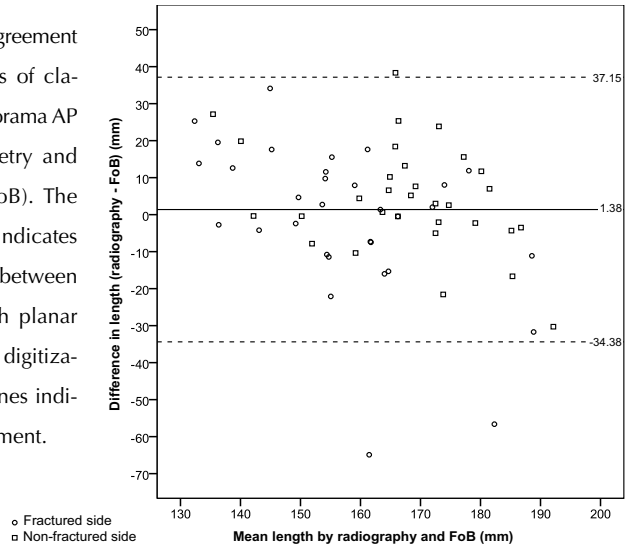
Discussion

Shortening of the clavicle after consolidation is generally believed to have a relevant influence on patients' daily functioning. Therefore, it is important to determine the length and shortening of the fractured clavicle in a valid and reliable manner. This study showed that the inter-observer agreement on measurements of clavicle length and shortening performed on trauma radiographs was almost perfect. The measurements of shortening after consolidation on the other hand were less reliable, which may be explained because callus formation obscures the outer edges of the fracture on the radiograph. To determine if length measurements on radiographs (2D) concur with actual 3D clavicle length, the results of planar roentgen photogrammetry were compared to measurements obtained with spatial digitization. The Bland-Altman plot showed clinically relevant differences between the measurements with planar roentgen photogrammetry and spatial digitization, which indicates that these methods cannot be used interchangeably for measuring clavicular length.

The discrepancies between the measurements with planar roentgen photogrammetry and spatial digitization might partially be explained by the movement of the skin during palpation for determination of the bony landmarks for

the spatial digitization, although this palpation error is small and not systematic.[18] Furthermore, the bony landmarks used for spatial digitization are slightly different from the ones used for roentgen photogrammetry, because the mid-medial border and the most lateral edge as used in roentgen photogrammetry cannot be reached with the electromagnetic stylus. This might induce a difference in length measurement between both methods. Another explanation for the length measurement differences relates to the discrepancies between two- and three-dimensional visualisation. The horizontal axis of the anatomically normal non-fractured clavicle is positioned at a backward angle of 10-15 degrees relative to the sternum.[19] Due to this sternoclavicular joint angle, the clavicles are projected out of plane on roentgen photogrammetry, which causes projection errors that do

Figure 3 Schematic cranial view of two clavicles, to illustrate the length measurement differences between spatial digitization (FoB) and roentgen photogrammetry due to projection errors on the radiograph.
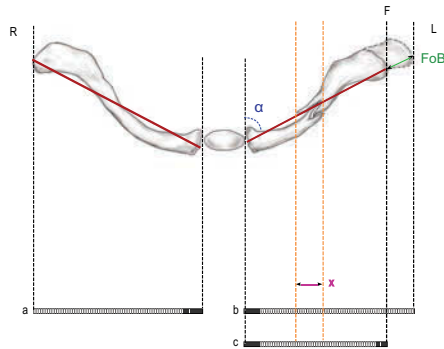
In this illustration, the fracture resulted in shortening of the left clavicle (**L**) as indicated by the line marked **F**. For roentgen photogrammetry the length of the non-fractured right clavicle (**R**) is indicated by ruler marked **a**. The original length of the left clavicle is indicated by **b**. After the fracture the length of the left clavicle is indicated by **c**. The purple line (**x**) between the two orange lines indicates in this theoretical case the absolute shortening as measured on roentgen photogrammetry.

When using spatial digitization the length of the clavicles is indicated by the two red lines. The reduction in length, after fracture, for the left clavicle is indicated by the green line (red line **R** – red line **L**). As depicted the green and purple line are at an angle (α). The sternoclavicular joint angle (α) between the lines, depicted with the blue dashed line, is depending on the degree of retraction of the clavicle. The larger the degree of retraction and amount of shortening, the smaller the angle (α) and the larger the difference in length between the purple (**x**) and green line (**FoB**) will be (Pythagorean Theorem).

not occur with spatial digitization. This error can be even worse in case of overlapping consolidated fracture fragments. The anatomical changes in the closed-chain mechanism of the shoulder after a clavicular fracture causes the sternoclavicular joint angle to increase, which results in more retraction of the lateral end of the affected clavicle after healing. Consequently, the fractured clavicle will be projected more out of plane compared to the contralateral side on roentgen photogrammetry. This 2D projection error will cause a deduction of 1-2 cm on the total length of the affected side as measured on the radiograph compared to spatial digitization. The 2D projection error phenomenon is schematically illustrated in Figure 3.

To account for these projection errors we advocate to use the Clavicle Shortening Index (*CSI*) on AP trauma radiographs, when using shortening in clinical decision making. A similar proportional measure was also advocated by Smekal et al., who measured proportional shortening on PA thorax radiographs using the contralateral side as a reference.[10] On theoretical grounds, the *CSI* is to be preferred to the absolute measurement of clavicular shortening, or to the use of the contralateral side as reference for several reasons. First, projection errors are of less influence when using a proportional measure. Second, the *CSI* is more comparable between patients than the absolute measured shortening, because variation in clavicular length between individuals is accounted for. For example, a certain amount of shortening may have a larger impact on the shoulder kinematics in patients with a short clavicle than in patients with a long clavicle. Third, clavicles within individuals are asymmetrical in length,[20,21] and therefore it is best not to use the contralateral side as reference. However, further research is needed to determine e.g. a CSI cut-off point that can be used in clinical decision making.

A limitation of this study is that AP (panorama) radiographs were used instead of PA radiographs, as AP radiographs are standard protocol for clavicular fractures in our hospital. This could introduce a small but consistent amplification error due to the larger distance to the projection surface.[10,22] Another limitation is that not all eligible former patients were willing to participate in this study, which could have led to selection bias. However, we do think that the participant group is a good representation of the total field of non-operatively treated midshaft clavicular fracture patients at our hospitals.

Conclusion

Shortening of the fractured clavicle is often mentioned as an important factor in clinical decision making for fracture treatment. This study describes the potential problems of measurements of the clavicle, when acquired on standard radiographs. From the results we conclude that (2D) clavicular length and shortening can be measured reliably on radiographs acquired shortly after trauma, but the measurements may not reflect the actual length and shortening. Furthermore, the inter-observer agreement of shortening for measurements on radiographs taken after consolidation is poor. These issues should be taken into account of radiograph based clinical decision making. To overcome measurement errors due to two-dimensional projection, clavicular asymmetry and individual clavicular length differences, we recommend using a proportional measure for clavicular shortening (*CSI*) based on the AP trauma radiographs for treatment decisions.

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CHAPTER 4

Value of the additional 30-degree caudocephalad radiograph in treatment decisions for midshaft clavicular fractures: *an online survey among 102 surgeons*

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Pieta Krijnen, Inger B. Schipper

ABSTRACT

Background

Midshaft clavicular fractures are usually diagnosed by anteroposterior radiography. An additional cephalic or caudal tilt radiograph is often not part of the standard diagnostic protocol because of cost considerations. We studied whether an additional 30-degree caudocephalad view affects the choice of treatment for complicated midshaft clavicular fractures.

Methods

In an online survey performed in August-September 2011, the members of the Dutch Society of Trauma Surgery were invited to indicate the preferred treatment for 15 randomly selected displaced or comminuted midshaft clavicular fractures presented on anteroposterior radiography. After presenting them with the additional 30-degree caudocephalad view radiograph, they were asked to indicate whether they would change their choice of treatment. Data were analysed using a repeated measures logistic regression model.

Results

The response rate was 46.3% and 102 returned surveys were eligible for analysis. After displaying the 30-degree caudocephalad radiograph, choice of treatment was changed in 24% of cases (95%-CI: 20.5 – 27.8) (p<0.001), mostly from non-operative to operative treatment.

Conclusions

Our results show that the additional 30-degree caudocephalad radiograph often results in a different choice of treatment than based on anteroposterior radiography alone. The standard protocol for diagnostic work-up of clavicular fractures should include radiological assessment in at least two planes.

INTRODUCTION

Midshaft clavicular fractures account for 3% to 10% of all adult fractures.[1,2] In the early literature low non-union rates were reported after non-operative treatment (<1%),[3,4] but more recent studies showed higher percentages (11-20%).[5-9] The incidences of delayed and non-union after operative treatment is considerably lower (1-3.9%).[5,7,8] Since non-union is assumed to be associated with clavicular shortening and displacement ad latum after trauma,[2,5,6,10,11] these aspects need to be assessed when deciding whether or not to operate. The extent of shortening and displacement ad latum can be evaluated using radiography. Both an anteroposterior (AP) view and a cephalic or caudal tilt radiograph have been suggested for evaluation of suspected clavicular fractures, because the extent of shortening[12] and especially the displacement ad latum may be underestimated if evaluated on the AP view alone.[11,13] In many hospitals, however, the cephalic or caudal tilt radiographs are not standard procedure after trauma. They may be omitted because of cost considerations and lacking evidence for its additional value.

In an online survey among the clinical members of the Dutch Society of Trauma Surgery we evaluated the effect of the 30-degree caudocephalad radiograph additional to the AP view, on treatment choice for midshaft clavicular fractures.

MATERIALS AND METHODS

Patients and Radiographs

Fifteen patients were randomly selected from patients who had been treated in the Leiden University Medical Centre in Leiden, The Netherlands for a displaced or comminuted midshaft clavicular fracture in 2010. Their primary AP view and 30-degree caudocephalad tilt view radiographs, which had been routinely made, were retrieved from the hospital records. Figure 1 shows the radiographs of one of the included patients as an example. The 15 fractures were classified according to Robinson as 13 type 2B1 and 2 type 2B2 fractures.[2]
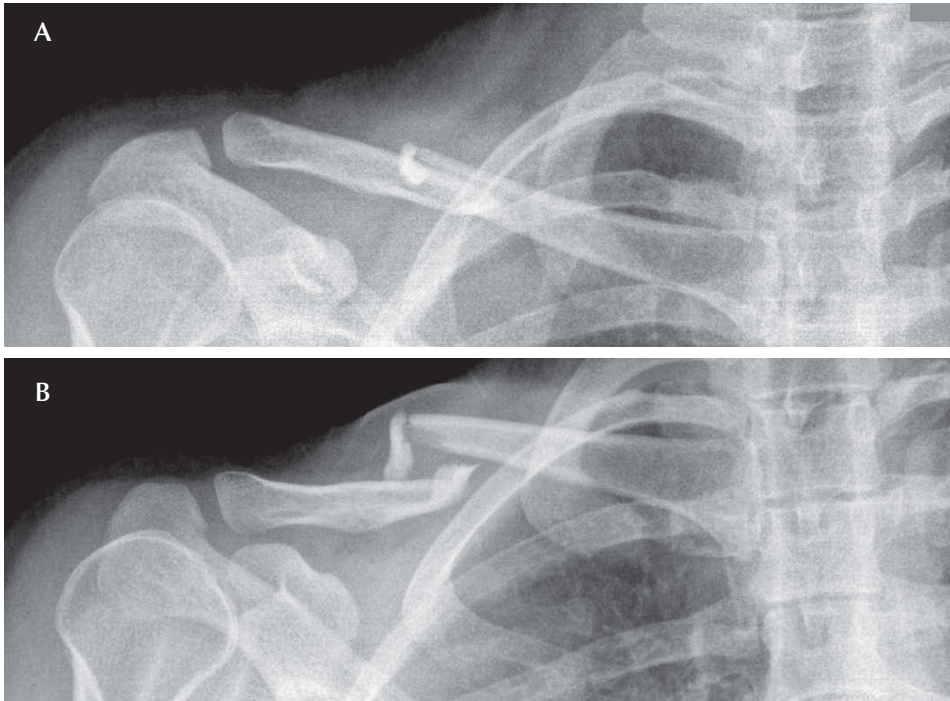
Figure 1. AP view (A) and 30-degree caudocephalad view (B) radiographs of one of the 15 midshaft clavicular fractures presented in the survey.

Survey

The 30 radiographs of the 15 fractures were presented to the 242 clinical members of the Dutch Trauma Society in an online survey in August 2011. In the survey the radiographs were shown one by one on separate pages for each patient. The respondents were first presented with the AP view, then with the 30-degree view. For each radiograph the respondents had to state which treatment he/she preferred for that particular fracture, considering it an isolated injury in a 50-year-old healthy male. Predefined treatment options were non-operative treatment with a sling, non-locking plate fixation, locking plate fixation, intramedullary fixation, and other. If opting for 'other treatment', the respondents were asked to specify the preferred treatment. Only after they had filled out their preferred treatment for the clavicular fracture in AP view, they were presented with the 30-degree view and asked for their choice of treatment again. The respondents could not to scroll back to the previous pages nor revise their answers once given. The survey was developed using LimeSurvey 1.91+ software.

Statistical analysis

For analysis, the responses were dichotomized into non-operative and operative treatment. (Change in) treatment choice was expressed as percentage and its 95% confidence interval (CI). Since the analysis involved repeated binary observations within patients by the same group of surgeons, a repeated measures logistic regression was performed using Generalized Estimating Equation (GEE) analysis in order to adjust the precision of the estimated (changes in) treatment choice. Resulting odds-statistics and their 95%-confidence limits were transformed into probabilities. Statistical analyses were performed using SPSS version 20 (Statistical Package for the Social Sciences Inc., Chicago Il, USA).

Results

Of the 242 invited members, 112 filled out the online survey (response rate 46.3%). Ten surveys were incomplete and excluded from analysis. The remaining 102 surveys rendered 3060 evaluations of the 15 fractures (AP view: 1530 evaluations, 30-degree view: 1530 evaluations). The vast majority of the respondents were trauma surgeons (n=71), the other respondents were orthopaedic surgeons (n=7), general surgeons (n=13), trauma fellows (i.e., surgeons subspecialising in trauma surgery after their general surgical training; n=5) and surgical residents (n=6).

Overall evaluation (n=1530 cases)

Based on the information of only the AP radiograph, conservative treatment was chosen in 803 of the 1530 (52.5%) evaluations of the 15 fractures. After the additional 30-degree radiograph was displayed, this number decreased to 468 evaluations (30.6%) (Table 1; Figure 2). Overall, the respondents changed their primary choice for either conservative or operative treatment in 24.0% of the cases (95%-CI: 20.5 – 27.8).

Table 1   Preferred treatment for 15 midshaft clavicular fractures by 102 surgeons (1530 fracture evaluations), based on only the AP view and on the combined AP and 30-degree radiographs.

			Treatment choice based on AP and 30-degree view				
		Total	Non-operative treatment	Non-locking plate fixation	Locking plate fixation	Intramedullary fixation	Other
Treatment choice based on AP view							
AP view	Non-operative treatment	803 (100%)	452 (56.3%)	65 (8.1%)	248 (30.9%)	31 (3.9%)	7 (0.9%)
	Non-locking plate fixation	168 (100%)	3 (2.1%)	141 (83.9%)	21 (14.9%)	3 (2.1%)	0 (0.0%)
	Locking plate fixation	432 (100%)	12 (2.8%)	4 (0.9%)	405 (93.8%)	11 (2.5%)	0 (0.0%)
	Intramedullary fixation	91 (100%)	0 (0.0%)	3 (3.3%)	21 (23.1%)	66 (72.5%)	1 (1.1%)
	Other	36 (100%)	1 (2.8%)	1 (2.8%)	4 (11.1%)	1 (2.8%)	29 (80.6%)
	Total	1530 (100%)	468 (30.6%)	214 (14.0%)	699 (45.7%)	112 (7.3%)	37 (2.4%)
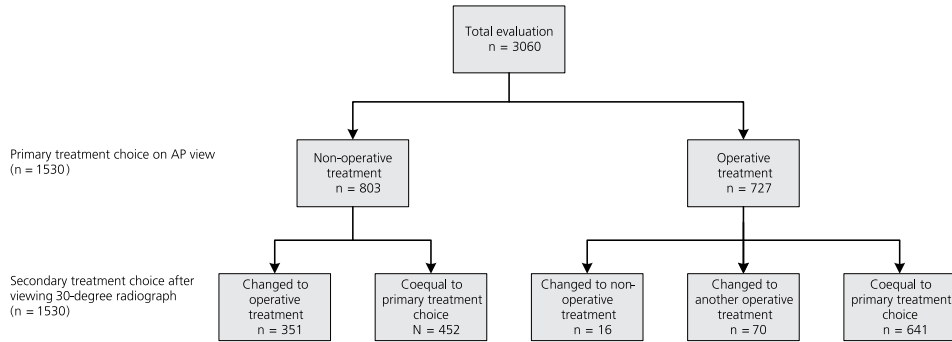
Figure 2. Flowchart of the 3060 evaluations of 102 surgeons based on only the AP view and on the combined AP and 30-degree radiographs.

Changes in treatment choice

For the 803 cases in which non-operative treatment was chosen based on the AP view, the respondents changed their treatment choice to operative treatment in 48.2% of cases after viewing the additional 30-degree radiograph (95%-CI: 42.5 – 53.9) (Figure 2). On the contrary, for the 727 cases in which operative treatment was chosen based on the AP view, the respondents changed their treatment choice to conservative treatment in only 2.3% of cases after viewing the additional 30-degree radiograph (95%-CI: 1.4 – 3.8). In addition, the respondents changed the preferred type of operative treatment in 8.4% of these 727 cases (95%-CI: 5.8 – 12.0) after viewing the corresponding 30-degree radiograph (Figure 2). These changes involved a switch from intramedullary fixation or non-locking plate fixation to locking plate fixation in 60% of the cases, and from locking plate fixation to intramedullary fixation in 15.7% of the cases (Table 1).

Discussion

The results of our survey showed that the 30-degree radiograph had a considerable effect on treatment decisions for complex midshaft clavicular fractures, in addition to the AP view radiograph. Overall, 24.0% of the treatment decisions were changed after viewing the additional radiograph, mostly from non-operative to operative treatment. We may conclude that adding an extra view to the conventional AP radiograph leads to more support for operative treatment, and may also lead to a different choice in surgical technique in some cases.

A standard AP view with an additional 30-degree caudocephalad tilt radiograph provides more insight into the degree of comminution and displacement as illustrated in Figure 1. The current study confirms that an AP view radiograph alone is not sufficient to decide on the type of treatment in about 25% of the cases. It is even questioned in the literature whether radiographs in two directions are sufficient for clinical decision making. Austin et al. assessed the additional value of the 4-view radiograph (AP, 20-degree cephalad, and additional orthogonal views: 45-degree cephalad, and 45-degree caudad) compared to the 2-view radiograph for treatment decisions.[14] Surgeons were likely to operate 12% more cases after reviewing 4-view radiography than after reviewing 2-view radiography. From our study it would seem that more is gained from adding one additional view to the AP radiograph than from adding two additional views to two-way radiography. Jones et al. found that AP and 30-degree caudocephalad radiographs are not sufficient to determine the need for surgical intervention,[12] however surgical intervention is not only determined on fracture characteristics. Patients' and surgeons' specific wishes and conditions, such as co-morbidities, occupation, daily activities and sports, also play a role in clinical decision making.[15-17] This may even be more important than the number of views. The question remains which number of views is optimal when balancing the additional clinical benefit and additional cost. In this trade-off, potential adverse outcomes of operative treatment such as complications and need for reoperation and the risk of non-union after non-operative treatment should also be taken into account.[7,15,18]

Despite the relatively low response to the survey, the answers of the respondents are likely to represent the opinion of Dutch surgeons with an interest

in upper extremity fractures. All clinical members of the Dutch Society of Trauma Surgery received an invitation to participate in the survey, thus including surgeons with different backgrounds and working in different types of hospitals throughout the country. We demonstrated a clear tendency to operate on displaced and comminuted fractures after adjudicating the additional 30-degree view. This tendency may have been triggered by the largest randomised controlled trial on midshaft clavicular fractures[5] published at that time which operative treatment showed overall better results than non-operative treatment. This Canadian study has had a considerable impact on the treatment of clavicular fractures in clinical practice.[19] Another limitation of our survey was that the surgeons were not aware of patient-specific characteristics when they evaluated the radiographs online, which may have influenced their choice of treatment. Some respondents pointed out in the survey, that they would have treated the patient differently if he was active in sports. These considerations where not taken into account for analysis.

Conclusion

Our results show that 2-view radiography leads to a more deliberate decision for treatment of midshaft clavicular fractures than only the standard AP view. In clinical practice it is advisable to perform an AP view and an additional 30-degree angulated view of the clavicle in all cases of suspicion of a fracture, for determination of the treatment strategy.

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PART III

TREATMENT

CHAPTER 5

Surgical treatment of Neer type-II fractures of the distal clavicle: a meta-analysis

Sylvia A. Stegeman, Hakan Nacak, Koen H.J. Huvenaars, Theo Stijnen, Pieta Krijnen, Inger B. Schipper

Abstract

Background and purpose

Type-II distal clavicle fractures according to the Neer classification are generally operated because of the high non-union rate after non-operative treatment. Several surgical techniques have been developed in order to reduce the non-union rate and improve functional outcome. This meta-analysis overviews the available surgical techniques for type-II distal clavicular fractures.

Methods

We searched the literature systematically. No comparative studies were found. 21 studies (8 prospective and 13 retrospective cohort studies) were selected for the meta-analysis. Data were pooled for 5 surgical outcome measures: function, time to union, time to implant removal, major complications, and minor complications.

Results

The 21 selected studies included 350 patients with a distal clavicular fracture. Union was achieved in 98% of the patients. Functional outcome was similar between the treatment modalities. Hook-plate fixation was associated with an 11-fold increased risk for major complications compared to intramedullary fixation and a 24-fold increased risk compared to suture anchoring.

Interpretation

If surgical treatment of a distal clavicle fracture is considered, a fixation procedure with a low risk of complications and a high union rate such as plate fixation or intramedullary fixation should be used. The hook-plate fixation had an increased risk for implant-related complications.

INTRODUCTION

Neer type-II fractures of the distal clavicle are unstable fractures in which the clavicle becomes separated from the underlying coracoclavicular (CC) ligament complex without damage to the most distal end of the clavicle and the acromioclavicular joint (AC joint).[1] These fractures are known to have a high percentage of non-union and malunion after non-operative treatment (>20%).[2,3] Neer has already recommended that these types of fractures should be treated operatively in order to reduce the non-union rate.[1] The distal clavicle may be osteosynthesised by a hook-plate or locking-plate fixation, double-plate fixation, transacromial fixation using Kirschner wires, cerclage wiring of the fragments, tension-band wiring, or stabilization of the medial fragment with coracoclavicular screws or slings. Hardware is usually removed after 8–12 weeks when the fracture is radiographically and clinically healed to prevent acromial osteolysis or other plate-induced complications.[4] None of the fixation techniques described has been nominated the 'gold standard'; each of these treatment modalities has its advantages and disadvantages.

This study was a meta-analysis to compare functional outcome, union rates and complications between the surgical treatment strategies for Neer type-II clavicular fractures.

Materials and Methods

The meta-analysis was performed following the guidelines set by the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA).[5]

Search strategy

A systematic literature search was performed in PubMed, EMBASE, and Web of Science. The search included keywords for fracture, clavicle or collar bone, and lateral or distal (Table 1). The selection was not restricted regarding treatment modality, study design, publication language, or year of publication. Duplicate articles were removed.

Table 1. Search terms in each search engine.

Search engine	Search
Pubmed	("Fractures, Bone"[Mesh] OR fracture[all fields] OR fractures[all fields] OR "Fracture Fixation"[Mesh] OR "Fracture Healing"[Mesh]) AND ("Clavicle"[Mesh] OR clavicle[all fields] OR clavicles[all fields] OR clavicular[all fields] OR clavicula[all fields] OR claviculas[all fields] OR "collar bone"[All Fields] OR "collar bones"[All Fields]) AND ("lateral"[all fields] OR "distal"[all fields])
EMBASE	(clavicle fracture/ OR ((clavicle*.mp. OR clavicula*.mp. OR clavicle/ OR collar bone*.mp.) AND (fracture*.mp. OR exp fracture/ OR exp fracture fixation/ OR exp fracture healing/))) AND (lateral.mp. OR distal.mp.)
Web of Science	TS= (fracture OR fractures) AND TS= (clavicle* OR clavicula* OR "collar bone*" OR midclavicular) AND TS=(lateral OR distal)

Eligibility criteria and study selection

The title and abstract of all articles were screened to select articles on surgical treatment of distal clavicle fractures in human subjects. Subsequently, the full-text articles of the selected abstracts were retrieved for detailed evaluation. All studies that assessed surgical treatment of adult patients with acute Neer type-II distal

clavicle fractures and that provided quantitative data on patient characteristics, surgical intervention, outcomes, and complications were included in the final selection. We excluded studies including only minors (< 16 years), studies including only patients with delayed union or non-union, studies including acromioclavicular joint injuries (type-III Neer classification), studies dealing with midshaft or medial clavicle fractures, studies without any data on surgical intervention, and/or treatment outcomes, reviews, case series with less than 5 patients, technical reports, and expert opinions (level of evidence V). If selected studies included both eligible and non-eligible patients, these studies were only included if the data of the eligible patients could be extracted from the article. The reference lists of the articles were screened for potentially relevant studies that had not been found by the initial literature search. Study selection and data extraction were carried out by 2 independent reviewers (SAS and HN). Disagreement was resolved by consensus.

Type of outcome measures

We compared 4 types of surgical treatment (hook-plate fixation, other types of plate fixation, intramedullary fixation with pins/screws, and suture anchoring/tension bands) with respect to 5 outcome variables: function as measured by the Constant score, time to union in weeks, time to implant removal in weeks, and complications (major and minor complications separately). Union was assessed on the radiograph at the last follow-up visit.

Assessment of study quality

2 reviewers (SAS, HN) independently assessed the methodological quality of each selected study by classifying the study design, and the level of evidence using the scale introduced by Wright et al. (2003).

Data extraction

Data were extracted from each study using a data-extraction form. The following data were documented from each study: study characteristics (country, period), patient numbers (inclusion, follow-up), patient characteristics (age, sex, and fracture type), duration of follow-up, type of surgical intervention and outcome measures (number of unions, time to achieve union, time to implant removal, major complications, and

minor complications). For continuous outcome parameters, means and standard deviations were extracted. In cases where mean outcome measures were reported without any standard deviation, the standard deviation was estimated as range (maximum – minimum) / 4. For dichotomous outcome parameters, proportions and sample size were extracted.

Data pooling across studies

Separate meta-analyses were performed for the 5 outcome measures: functional outcome (measured with the Constant Score), time to union in weeks, time to implant removal in weeks, and major and minor complications. Complications were classified as major (reoperation, implant failure, refracture, acromial osteolysis, pseudarthrosis and signs of impingement) or minor (wound infection and skin irritation).

Data analysis

For continuous outcome data (the Constant Score, time to union, time to implant removal), the standard random-effects meta-regression model,[6] with the surgical treatment as a categorical covariate represented by 3 dummy variables, was used to estimate the mean differences in outcome between the surgical treatments with the corresponding 95% confidence intervals (CIs). Heterogeneity between studies was modeled by a random study effect. For dichotomous outcomes (major and minor complications) the ORs and corresponding CIs were calculated using a logistic regression model with a random intercept to account for heterogeneity between studies.[7] Heterogeneity between studies was tested by comparing a model with and without the random study effect using the likelihood ratio test. To test differences between treatments, first an overall test was performed. If the overall test resulted in a small p-value (< 0.1), differences were tested pairwise. All analyses were performed using SAS/STAT statistical software. Any p-values < 0.05 were considered to be statistically significant.

Results

Study selection

In the initial search, we identified 943 abstracts (Figure 1). After removing duplicates, 504 articles remained. We selected 130 articles for detailed evaluation based on content after reading the titles and abstracts. Of these 130 articles, 21 remained after applying the in- and exclusion criteria.[8-28] No randomised or non-randomised controlled trials comparing surgical modalities for distal clavicle fractures were found. Of the 21 studies finally selected, only 1 was a retrospective case-control (level III) study comparing non-operative treatment to open reduction with coracoclavicular stabilization with suture bands, whereas all other 20 articles were prospective or retrospective case series (level-IV).
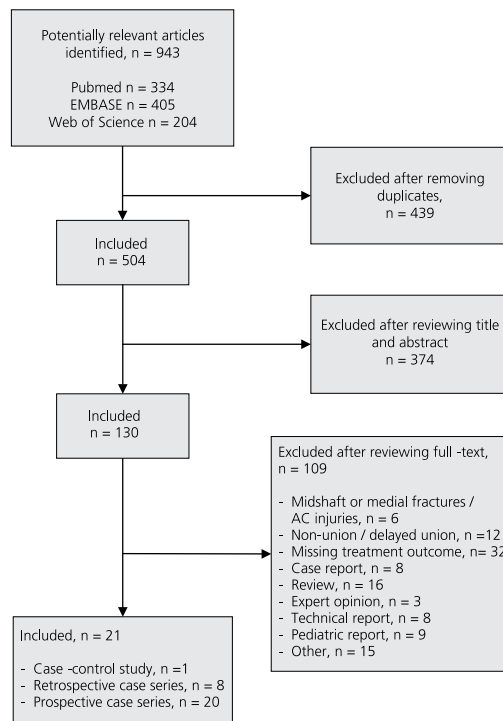
Figure 1   Flow chart of selection of papers for into the meta-analysis.

Study characteristics

All articles included were published in English. 8 studies were conducted in Asia, 11 studies in Europe, 1 study in North-America, and 1 study in Australia (Table 2).

Table 2A   Characteristics of the included studies using hook-plate fixation.

References	Level of Evidence Study design	Inclusion period and country	Treatment modalities	Number of included patients (Number in last follow up)	Gender male:female age range	Neer type
Bhangal et al. 2006	IV RS	2002-2005 UK	AO HP	13 (FU 11)	NR 41.6 (24-65)	II
Kashii et al. 2006	IV RS	Sept 1999- Sept 2003 Japan	Acromio-clavicular titanium HP	34 (FU 34)	28:6 40 (21-74)	II
Meda et al. 2006	IV PS	1998-2002 UK	Clavicular HP	16 (FU 16)	13:4 51.5 (25-86)	II
Muramatsu et al. 2007	IV PS	June 2003- Oct 2004 Japan	AO clavicle HP + K-wire	15 (FU 15)	13:2 47 (20-71)	II
Renger et al. 2009	IV RS	Jan 2003- Dec 2006 Spain/ The Netherlands	Clavicle HP	51 (FU 44)	29:15 38.4 (18-66)	II
Lee et al. 2010	IV PS	Jan 2008-Apr 2009 Korea	Arthroscopic-assisted LCP Clavicular HP	23 (FU 23)	19:4 43 (21-74)	II

NR=Not Reported; N/A= Not Applicable; RS=Retrospective case series; PS=prospective case series; UCLA= University of California Los Angeles score; ASES= American Shoulder and Elbow Surgeons self-report; JOA= Japanese Orthopaedic Association; UK= United Kingdom; USA = United States of America

The surgical procedures described in the studies were performed between 1989 and 2007. In total, 405 patients with a distal clavicle fracture were included in the 21 selected studies. Excluded from the analysis were 13 patients with non-union at

Table 2A Follow up

Duration of follow-up in weeks (mean)	Weeks to union (range)	Weeks to implant removal (range)	Constant score (unless indicated otherwise)	Complications
64 (20-108)	NR (10 – 12) Union: 12/13	NR (12-104) Removed:11/11	91.8 (83-95)	8% implant failure/ asymptomatic non-union
50 (48-60)	16.4 (12-26) Union: 34/34	21.2 (14-60) Removed:34/34	JOA 98.3 (90-100)	3% plate displacement 3% acromion # and hook cut out 56% hook hole widening 38% upward migration 3% rotator cuff tear
171 (72-272)	7 (6-9) Union: 16/16	23.7 (16-36) Removed:13/16	97 (86-100)	6% superficial infection 19% impingement signs 16% Radiolucent hook tips/plate removal
62 (32-96)	<16 Union: 15/15	18 (12-32) Removed:12/15	89 (75-95)	87% hook migration into acromion
110 (56-192)	NR (16-56) Union: 42/44	33.6 (8-132) Removed:44/44	92.4 (74-100)	4.5% Hypertrophic scar tissue 4.5% superficial wound infection 6.8% acromial osteolysis 4.5% pseudarthrosis 68% irritation by hook plate
52 (24-84)	16.8 (13.6-28) Union: 23/23	20.4 (14.4-28) Removed:23/23	91 (81-98)	17% acromial osteolysis 13% arthrosis of AC-joint 1 refracture

inclusion in the study,[15,16,19] 16 patients with non-operative treatment, 7 patients with a type Neer-III fracture,[19] 17 patients who were lost to follow-up, and 2 minors,[14,16] leaving the data on 350 patients for analysis. The mean number of patients with a complete follow-up was 17 (6–44) per study. Fracture fixation was performed using hook plates in 143 patients[10,17-20,22] (Table 2A). In the group using different types of plate fixation, distal radial locking plates were used in 20 patients[13,16,28] and double plates in 9 patients[15] (Table 2B). As intramedullary fixation, Knowles pins were used in 68 patients,[11,14,26] coracoclavicular screws in 30 patients,[12] and malleolar screws

Table 2B Characteristics of the included studies using some type of plate fixation.

References	Level of Evidence Study design	Inclusion period and country	Treatment modalities	Number of included patients (Number in last follow up)	Gender male:female age range	Neer type
Kalamaras et al. 2008	IV RS	July 2004-May 2005 Australia	Distal radius locking plate. T-plates, L-plates and if necessary sutures.	8 (FU 7)	6:1 28.9 (16-41)	II
Herrmann et al. 2009	IV RS	Oct 2006-Dec 2007 Germany	Locking T-plates and suture anchors	8 (FU 7)	6:1 39.1 (26-55)	IIB
Yu et al. 2009	IV PS	NR China	Distal radius volar locking compression plate	6 (FU 6)	4:2 36.5 (23-52)	II
Kaipel et al. 2010	IV PS	Jan 2006-June 2008 Switzerland	Double-plate fixation	11 (FU 9)	5:4 48.4 (32-61)	II

NR=Not Reported; N/A= Not Applicable; RS=Retrospective case series; PS=prospective case series;

in 10 patients[24] (Table 2C). For the group with suture anchoring or tension bands, K-wires with suture anchoring were used in 10 patients,[9] tension-band suturing in 43 patients,[8,23,25] vicryl tape in 6 patients[21] and a Dacron arterial graft in 11 patients[27] (Table 2D, see Supplementary data). The studies included 238 men and 101 women and mean age was 38 (17 – 86) years at the time of trauma. In 1 study, sex ratio was not reported (n = 11).[10]

Table 2B   Follow up

Duration of follow-up in weeks (mean)	Weeks to union (range)	Weeks to implant removal (range)	Constant score (unless indicated otherwise)	Complications
54 (40-76)	10.3 (6-18) Union: 7/7	None removed	96 (96-100)	13% Wound infection
33 (16-64)	<6 (NR) Union: 7/7	2 (24 and 40 weeks)	93.3 (82-99)	14% Mild pain during strenuous activity 14% Limited internal rotation
17 (10-25)	8 (6-10) Union: 6/6	None removed	97.5 (95-100)	None
63 (6–20)	12 (10-16) Union: 9/9	NR (9 – 112) Removed: 3/11	90 (68-100)	22% screw migration 11% meteo rosensitivity and local dysesthesia

Table 2C Characteristics of the included studies using some type of pin fixation.

References	Level of Evidence Study design	Inclusion period and country	Treatment modalities	Number of included patients (Number in last follow up)	Gender male:female age range	Neer type
Fann et al. 2004	IV PS	1991-2001 Taiwan	Trans-acromial Knowles-pin	34 (FU 32)	18:14 41.2 (18-83)	II
Scadden et al. 2005	IV RS	1996-2002 UK	AO/ASIF Malleolar screw	10 (FU 10)	8:2 29.3 (18-84)	II
Fazal et al. 2007	IV RS	Jan 1995-dec 2003 UK	Temporary coraco-clavicular screw	30 (FU 30)	22:8 29 (21-53)	II
Wang et al. 2008	IV RS	1993-2005 Taiwan	Trans-acromial extra-articular Knowles pin	25 (FU 25)	15:10 33.5 (17-84)	IIA/IIB V Craig Class.
Jou et al. 2011	IV RS	August 2005-July 2009 Taiwan	Knowles pin	11 (FU 11)	5:6 41.5 (25-61)	II

NR=Not Reported; N/A= Not Applicable; RS=Retrospective case series; PS=prospective case series;

UCLA= University of California Los Angeles score; UK= United Kingdom;

Study quality

None of the 21 articles included pertained to a randomised controlled trial (RCT). One retrospective case-control study[23] was identified, comparing suture bands with non-operative treatment, and only the surgically treated patients were included in the present meta-analysis. All other studies were prospective (n = 8) or retrospective

Table 2C Follow up

Duration of Follow-up in weeks (mean)	Weeks to union (range)	Weeks to implant removal (range)	Constant score (unless indicated otherwise)	Complications
320 (48-528)	6.8 (4-12) Union: 32/32	12 (4-24) Removed:32/32	UCLA 24.5 (23-25)	3% acromioclavicular arthrosis
6-12 Review/ telephone (104-208)	6.3 (6-12) Union: 10/10	8-14 Removed:10/10	Oxford 21.4/60 (17-32)	None
68 (56-96)	NR (6 – 10) Union: 30/30	NR Removed:30/30	Simple shoulder test questionnaire 11 (9-12) 28/30	7% backing out of the CC-screw 3% superficial wound infection
204 (96-424)	NR (8-12) Union: 23/25	37.6 (20-84) Removed:25/25	93.9 (85-100)	4% infection 12% heterotrophic ossification 32% lateral pin-migration 9% delayed or non-union with pin loosening
61 (24-96)	12.5 (10-16) Union: 11/11	14.4 (12-18) Removed:11/11	UCLA 33.8 (30-35)	27% Skin irritation due to pin prominence

case series (n = 12).[8-22,24-28] The primary outcome in all studies was the incidence of union and non-union, as determined on radiographs or by clinical evaluation (withstanding pressure on fracture side without pain). Evaluation of the outcome was not done blind in any of the studies.

Table 2D Characteristics of the included studies using some type of suture anchoring.

References	Level of Evidence Study design	Inclusion period and country	Treatment modalities	Number of included patients (Number in last follow up)	Gender male:female age range	Neer type
Webber et al. 2000	IV RS	Nov 1988- March 1995 UK	Dacron arterial graft	11 (FU 11)	8:3 29.8 (17-46)	II
Othman et al. 2002	IV PS	NR UK	internal fixation with vicryl tape	6 (FU 6)	4:2 29.8 (24-33)	II
Rokito et al. 2002	III RS	1989-1997 USA	open reduction and coraco-clavicular stabilization with suture bands	14 (FU 14)	8:6 35.5 (22-47)	II
Bezer et al. 2005	IV RS	Feb 2001- Jan 2003 Turkey	K-wire fixation with suture anchoring	12 (FU 10)	6:4 33 (20-45)	IIB
Badhe et al. 2007	IV RS	May 2003 – May 2005 UK	Tension band suturing	10 (FU 10)	8:2 41 (15-72)	II
Shin et al. 2009	IV PS	NR Korea	Two suture anchors and suture tension bands	19 (FU 19)	14:5 43.4 (17-70)	IIB

NR=Not Reported; N/A= Not Applicable; RS=Retrospective case series; PS=prospective case series; UK= United Kingdom; USA = United States of America

Table 2D Follow up

Duration of follow-up in weeks (mean)	Weeks to union (range)	Weeks to implant removal (range)	Constant score (unless indicated otherwise)	Complications
221 (96-432)	6.2 (3-8) Union: 11/11	NR Removed:2/15	98.9 (90-100)	7% superficial irritation due to plate fixation in revision surgery 7% low grade infection 7% sterile sinus
(6-8) and (36-48)	NR (6-8) Union: 6/6	N/A	91.2 (85-100)	None
239 (48-428)	NR (6-10) Union: 14/14	N/A	88.1 (NR)	None
96 (48-144)	7.5 (6-9) Union: 10/10	(6-9) Removed:10/10	96.6 (90-100)	10% Mild pain with strenuous work 10% pin tract infection and loosening
70 (36-120)	9.2 (6-16) Union: 10/10	N/A	93.9 (85-100)	None
104 (96-160)	19.2 (12-48) Union: 16/19	N/A	94 (88-100)	11% Clavicular erosion 11% Limitation in forward flexion and internal rotation 11% Mild discomfort with heavy labor 1 patient non-union with subsequent distal clavicle resection 2 patients delayed union

Assessment of study quality

The studies included differed regarding the timing of radiography, type of surgical treatment, duration and follow-up occasions. Loss to follow-up occurred in 7 studies.[9-11,13,15,16,22] None of the researchers were blinded regarding evaluation of the radiograph, or regarding functional outcome. No inconsistency was found in percentage union and functional outcome across the surgical methods. No differences in the directness were expected in effect sizes across the studies, and the study population, interventions and outcome measures in each study were comparable. Functional outcome was measured using the Constant score in 16 of the studies, the UCLA score in 2 studies, the Oxford Shoulder Score in 1 study, the simple shoulder test questionnaire in 1 study, and the Japanese Orthopaedic Association score in 1 study. Since the results of these instruments could not be compared directly, only the studies using the Constant score or those that could be converted to a percentage score were included in the analysis of functional outcome. There appeared to be a relationship between age and risk of major complications. However no confounders were identified to influence the outcomes of each study, because the data did not allow it.

Treatment outcome

Function. Function according to the Constant score was similar after hook-plate fixation and after the other surgical approaches in general (p=0.9; Figure 2). All patients had good to excellent scores in the tests for functional outcome at final follow-up. Heterogeneity between studies was highly significant (p<0.001).

Union. Overall union was achieved in 342 of 350 patients (98%). Of the 21 studies, 16 reported a union rate of 100%. The average time to union ranged from less than 6 weeks till more than 33 weeks (Table 2). 8 of 350 (2%) patients developed non-union (n = 6) or delayed union (n = 2). Of those, 3 patients had been treated with a hook plate, 2 with intramedullary fixation and 3 with sutures. The 2 delayed unions achieved union after 9 and 10 months. No non-unions were found in the plate-fixation group. There was a tendency to significant differences in time to fracture union between treatments (overall p = 0.08). After hook-plate fixation, it took on average 10 weeks longer to obtain fracture union than with pin fixation (p = 0.02) (Figure 2). Time to union after hook-plate fixation was not statistically significantly

different to that after plate fixation and suture fixation, although there was a longer consolidation periods after hook-plate fixation (p=0.07; p=0.1). The heterogeneity between studies was highly significant (p<0.001).

Implant removal. The occurrence of implant removal after hook-plate fixation was compared to that after plate fixation and intramedullary fixation. In some studies, implant removal was standard practice for prevention of skin irritation or pin/screw protrusion after bony union had been achieved.[9-12,14,17,18,22,24,26] In 5 other studies the implant was only removed if major complications occurred.[13,15,19,20,27] In the studies reporting on sutures and tension bands, patients did not require a second operation for removal of the implants.[8,16,21,23,25,28] No statistically significant difference was found when comparing treatment for weeks to implant removal (p = 0.7). On average, intramedullary fixation was removed earlier (-2 weeks) than hook-plate fixation, whereas plate fixation was left in situ longer (8.6 weeks; Figure 2). Heterogeneity between studies was highly significant (p<0.001).

Constant score

Treatment	Estimate	95% CI	P-value
Plate fixation	0.01	(-0.03 – 0.05)	0.7
Pins	0.01	(-0.02 – 0.05)	0.5
Sutures	0.01	(-0.02 – 0.05)	0.5

Heterogeneity: Chi^2 = 52.4, Df = 13 (p<0.0001)
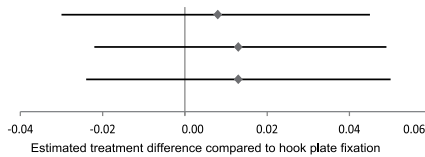
Weeks to union

Treatment	Estimate	95% CI	P-value
Plate fixation	-8	(-18 – 1)	0.1
Pins	-10	(-19 – -2)	0.0
Sutures	-7	(-16 – 2)	0.1

Heterogeneity: Chi^2 = 203, Df = 10 (p<0.0001)
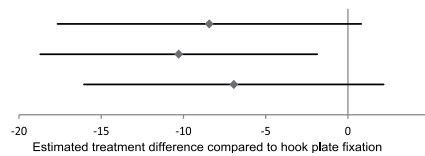
Weeks to implant removal

Treatment	Estimate	95% CI	P-value
Plate fixation	9	(-15 – 32)	0.5
Pins	-2	(-14 – 10)	0.7

Heterogeneity: Chi^2 = 27, Df = 6 (p=0.0007)

Df= Degrees of freedom.
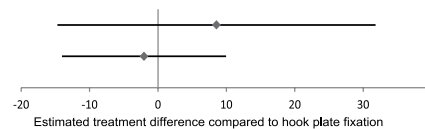
Figure 2 Mean differences in Constant scores, weeks to union and weeks to implant removal for plate fixation, pins and sutures compared to hook plate fixation.

Complications

In all but 4 studies, complications of treatment were observed.[8,21,24,28] Some complications, such as pin or screw migration, led to a second operation. Regarding minor complications, no differences were found between the treatment modalities (p=0.9) (Figure 3). In contrast, the overall test for differences in the incidence of major complications was statistically significant (p = 0.01). Acromial osteolysis, refracture and implant failure occurred 11 times more frequently after hook-plate fixation than after intramedullary fixation (p = 0.02) and 24 times more frequently after suturing (p=0.01) (Figure 3). The number of major complications after plate fixation was not significantly different from that after hook-plate fixation (p = 0.08). For both complication variables, significant heterogeneity between studies was found.

Minor complications

Treatment	Estimate	95% CI	P-value
Plate fixation	5.4	(0.2 – 172.4)	0.3
Pins	1.5	(0.1 – 27.2)	0.8
Sutures	1.1	(0.0 – 24.7)	1.0

Heterogeneity: Df = 19 (p=0.005)

Major complications

Treatment	Estimate	95% CI	P-value
Plate fixation	0.08	(0.0 – 1.4)	0.1
Pins	0.09	(0.0 – 0.7)	0.02
Sutures	0.04	(0.0 – 0.5)	0.01

Heterogeneity: Df =19 (p=0.4)
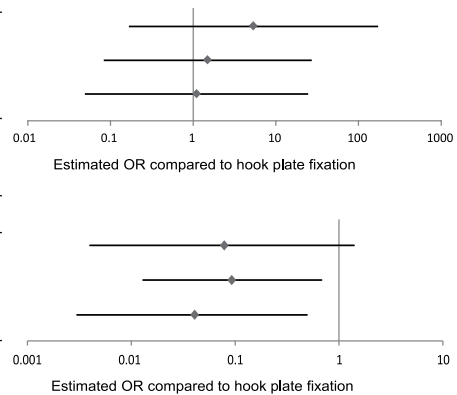
Df= Degrees of freedom; OR= Odds Ratio.

Figure 3   The Odds Ratio for percentage minor and major complications for plate fixation, pins and sutures compared to hook plate fixation.

DISCUSSION

There is little evidence available for the preferred operative treatment of distal clavicle fractures regarding radiographic union, function, and complications associated with the treatment. In general and independent of the type of fixation, in our meta-analysis we found union rates of over 90% after operative treatment of the distal clavicular fractures. The function outcomes ranged from good to excellent; all patients regained full functional range of motion. Both union rate and functional outcome were not significantly different with hook-plate fixation, plate fixation, pins, or sutures. Time to union, however, was shortest after fixation with pins and longest after hook-plate fixation, with only pins showing a statistically significantly shorter time to union than with hook-plate fixation. Weeks to implant removal were not significantly different between the surgical treatment modalities. Hook-plate fixation was associated with a higher risk of major complications such as reoperation and implant failure, compared to intramedullary fixation and sutures.

One systematic review of type-II distal clavicle fractures, identifying union and complication rates according to the different treatment methods, has been published previously.[29] These authors found a non-union rate of 33% for non-operatively treatment, but with similar functional scores as for the surgically treated groups in most of the studies. The authors noted that the functional outcome after non-operative treatment remained controversial, and that a well-designed RCT was therefore needed. We did not include non-operative treatment in our analysis, because only a very small number of non-operatively treated patients were analyzed in one of the comparative studies[23] and no other eligible studies with non-operatively treated patients were identified. In accordance with our results, Oh et al. (2011) found similar satisfactory functional outcome results for all surgical modalities. The decision for surgical treatment should not be based on functional outcomes, because despite the percentages of high non-union, no similar function was found for non-operative or surgical treatment.[29] The complication rate, however, for the non-operatively treated patients was low compared to the surgical group, again despite the high non-union rate.[23,29] Non-operative treatment has been considered by some authors as treatment for Neer type-II fractures,[3,30,31] but these data were not compared to an operative method.

The data we present in this meta-analysis are clinically relevant. Hook-plate fixation is the most frequently used method for fixating type-II clavicular fractures. However, although the performance of the hook plate is comparable to that for other surgical types of fixation, its complication rate is higher and the fracture healing takes longer than for intramedullary fixation. When choosing which method to use for fixation of a type II-clavicular fracture, the benefit to the patient is the first priority. This is mostly associated with optimal functional outcome and a low complication risk. Merely due to the relatively high complication risk, hook-plate fixation is therefore not the method of choice and its use should be reserved for very specific indications, e.g. when no alternative adequate methods are available and the operation can be performed by a surgeon who has extensive experience with hook-plate fixation.

Limitations

Several studies[9-11,13,15,16,22] suffered from loss to follow-up for different reasons, which led to incomplete data on functional outcome and union and possibly gave rise to bias in cases of selective dropout. The sample sizes in these studies became relatively small, thus contributing to a relatively small total sample size in this meta-analysis and possibly leading to a lack of power.

The level of evidence of the studies was low and heterogeneity for the outcome parameters was high. Heterogeneity was accounted for by using random-effects modeling. The definition, by which non-union was confirmed, was not uniform across studies, which may affect union-rates to a lesser extent. Functional outcomes were defined using different methods, and they were therefore difficult to compare. This was solved by selecting only the studies that provided Constant Scores – or those convertible to percentages comparable with the Constant score – for data analysis. Heterogeneity between the studies was high. In this meta-analysis, we applied correction for heterogeneity. A well-designed RCT comparing operative treatment and non-operative treatment or another operative method should bypass these kinds of flaws.

In conclusion, if surgical treatment of a distal clavicle fracture is indicated, a fixation procedure with a low risk of complications and a high union rate should be used. The number and severity of hook-plate related complications seem to disqualify this implant. However, due to the limited quality of the studies included

and the relatively small number of patients involved, no definite conclusion can be stated regarding the most preferred treatment. Evidence from RCTs is lacking.

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CHAPTER 6

Online radiographic survey of midshaft clavicular fractures:
no consensus on treatment for displaced fractures

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ABSTRACT

The choice of treatment for midshaft clavicular fractures is not straightforward, but depends on fracture characteristics such as comminution, angulation and displacement. An online survey was conducted amongst trauma and orthopaedic surgeons to determine the preferred treatment for midshaft clavicular fractures, based on anteroposterior radiographs, for 17 randomly selected displaced or comminuted midshaft clavicular fractures. The background and experience of the respondents were documented. Data were analyzed using a Generalized Estimating Equations (GEE) model. The 102 respondents preferred non-operative treatment more frequently for displaced fractures than for comminuted fractures (OR 3.24, 95%-CI: 2.55 – 4.12). Locking plate fixation was more often preferred over other surgical modalities for comminuted than for displaced fractures (OR 1.50, 95%-CI: 1.17 – 1.91). In clinical practice, there is no consensus between surgeons on the choice of treatment for displaced or comminuted midshaft clavicular fractures. This lack of agreement calls for evidence-based treatment guidelines for these fractures.

INTRODUCTION

A clavicular fracture can readily be diagnosed with physical examination and radiography.[1] The decision whether and how to operate a clavicular fracture, however, is not straightforward and is influenced by factors such as neurovascular compromise, soft tissue compromise, tenting of the skin over the displaced fracture or accompanying injury as a scapular neck fracture.[2] Fracture characteristics like displacement, shortening and comminution seem to predispose for unfavourable results after non-operative treatment,[3-8] but treatment guidelines have not been published. In clinical practice, undisplaced fractures are generally treated non-operatively, but for displaced fractures the choice of treatment seems to be based on the position of the fracture fragments on the anteroposterior (AP) radiography and the clinical condition of the patient.

Based on two large retrospective studies in the late 1960s[9,10] it was believed that operative treatment of clavicular fractures increased the risk of non-union. The rate of non-union after non-operative treatment was considered to be less than one per cent.[3,9-13] The complication rates in these surgical studies were high, probably due to less optimal fixation techniques.[1] Since the last decade the negative attitude towards operative treatment has changed. Several large studies suggested that operative treatment results in better functional outcome and lower non-union and mal-union rates than previously assumed.[1,6,14-16] On the basis of these studies, the preference for operative treatment seems to have increased. We conducted an online survey amongst the members of the Dutch Trauma Society to determine the preferred treatment for displaced and comminuted midshaft fractures, based on evaluation of AP trauma radiographs. Secondarily, we analysed whether treatment choice was related to the surgeon's background or experience.

MATERIALS AND METHODS

In the Netherlands, about 80% of fracture care is performed by trauma surgeons and 20% by orthopaedic surgeons. The membership of the Dutch Trauma Society therefore consists mainly of trauma surgeons. In August 2011, all physician-members

of the Dutch Trauma Society were invited by email to participate in an online survey. In September, a reminder was sent to the members who had not responded. In the survey, each participant was asked to give his or her preferred treatment for 20 angulated, displaced or comminuted midshaft clavicular fractures, based on radiographs and standardized clinical information. The 3 angulated fractures were left out of the analyses, leaving 17 displaced or comminuted fractures.

Radiographs

The 17 fractures were randomly selected from the electronic registry of our hospital. The anteroposterior (AP) view radiograph of these fractures, taken on the day of trauma, were classified by an expert panel of 2 experienced trauma surgeons and 1 radiologist as fourteen displaced (type 2B1 according to the Robinson classification[17]) and three comminuted (type 2B2) fractures (Figure 1). This ratio reflects the distribution of displaced and comminuted clavicular fractures that is normally seen in the emergency department.

Cortical Alignement Fractures (Type 2A)   **Displaced Fractures (Type 2B)**
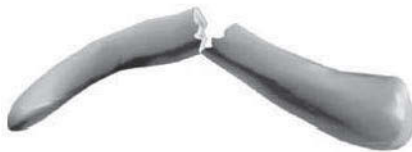
Undisplaced (Type 2A1)   Simple or wedge comminuted (Type 2B1)

Angulated (Type 2A2)   Isolated or comminuted segmental(Type 2B2)

Fig 1   Robinson classification of midshaft clavicular fractures.

Reprinted with permission of C.M. Robinson.[17]

Survey

The 17 anonymous radiographs were presented one by one in random order in an online questionnaire, which was developed using LimeSurvey 1.91+ software. The respondents were asked to state the preferred treatment for each fracture. No additional clinical data of the patients was presented to the respondents in order to prevent that this information would influence the choice of treatment. Instead, the respondents were asked to consider each radiograph as that of an isolated injury in a 50 year old, otherwise healthy male. Predefined treatment options in the survey were non-operative treatment with a sling, non-locking plate fixation, locking plate fixation, intramedullary fixation, and other. If opting for 'other treatment', the respondent was asked to specify the preferred treatment. When filling out the questionnaire, it was not possible to scroll back in order to view or revise previously given answers.

Respondents

The 242 physician-members of the Dutch Trauma Society with an active email address received an invitation to fill out the questionnaire. Six respondent groups were distinguished according to background and experience: orthopaedic surgeons, trauma surgeons, trauma fellows (general surgeons subspecialising in trauma surgery), general surgeons, and surgical residents.

Statistical analysis

Treatment choice was analysed for the total fracture group and by 2B fracture type. Analyses were performed for the total group of respondents and by background. Results were presented as proportion or odds ratio (OR) with their 95% confidence interval (CI). Since the analysis involved multiple observations by the same group of surgeons, Generalized Estimating Equation (GEE) analyses were performed in order to adjust the precision of the estimations. Statistical analyses were performed using SPSS version 20 (Statistical Package for the Social Sciences Inc., Chicago Il, USA).

RESULTS

After sending 242 invitations, a total of 134 of questionnaires (55%) were returned. Of these, 32 were excluded from the analysis, mainly because they were incomplete (Figure 2). The majority (70%) of the remaining 102 respondents were trauma surgeons (n=71), the other respondents were orthopaedic surgeons (n=7), general surgeons (n=13), trauma fellows (n=5) and surgical residents (n=6).
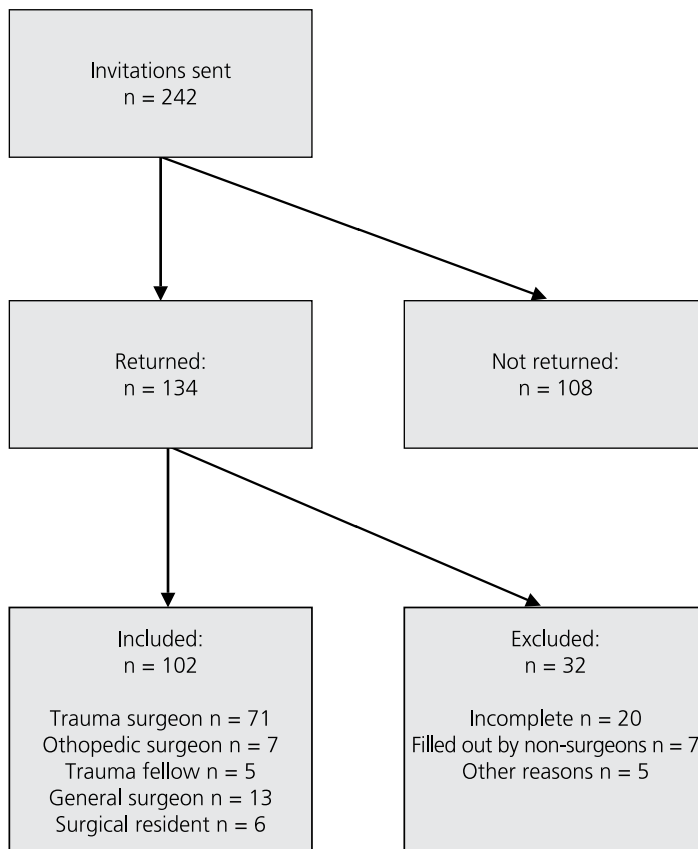

Figure 2   Flowchart of invitations sent and numbers of response per professional subgroup.

Choice between non-operative and operative treatment

For all 17 fractures together non-operative treatment was chosen by 49% of the respondents (95%-CI: 43 – 56). Non-operative treatment was more often preferred for the displaced type 2B1 fractures than for comminuted type 2B2 fractures (OR 3.24, 95%-CI: 2.55 – 4.12). The percentage of respondents choosing operation ranged from 34% for surgical residents, to 73% for trauma fellows (Figure 3a). The difference between these two professional groups was statistically significant (P=0.045).

Choice between surgical modalities

Within the subgroup of cases for which operative treatment was opted, locking plate fixation was chosen in 61% of the cases (95%-CI: 56 – 73), non-locking plate fixation in 23% (95%-CI: 14 – 29), intramedullary fixation in 12% (95%-CI: 6 – 15) and other surgical modalities in 4% (95%-CI: 2 – 9). Locking plate fixation was more often preferred to other surgical modalities for comminuted type 2B2 fractures than for displaced type 2B1 fractures (OR 1.50, 95%-CI: 1.17 – 1.91). Intramedullary fixation was more often chosen for type 2B1 fractures (OR 4.06, 95%-CI: 1.88 to 8.81). None
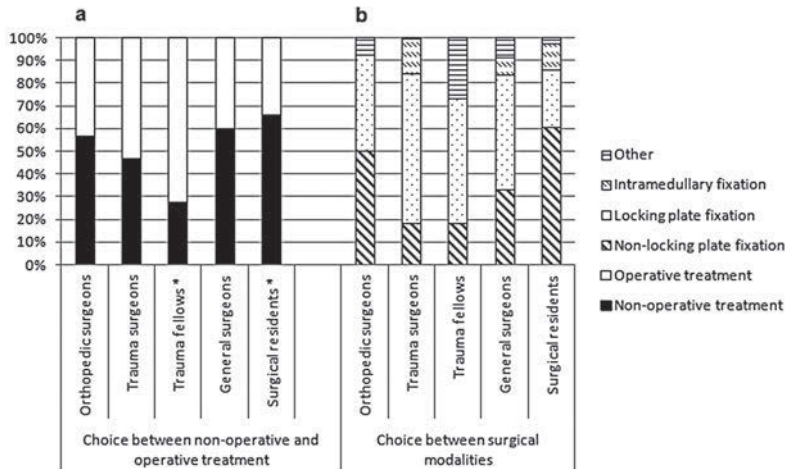
* P=0.045 for comparison of choice for operative treatment between trauma fellows and surgical residents.

Figure 3 Choice of treatment for type 2B fractures by profession: (A) choice between non-operative and operative treatment, and (B) choice between surgical modalities.

of the orthopaedic surgeons and trauma fellows opted for intramedullary fixation for any of the presented fractures (Figure 3b). No differences in preferred type of fixation were found with respect to professional background and experience (P>0.10).

DISCUSSION

The results of our online survey showed that there is no consensus between surgeons on the choice of treatment for displaced or comminuted midshaft clavicular fractures, visualised by AP-radiography. Non-operative treatment was chosen in 49% of the cases. In general, locking plate fixation was the most preferred type of fixation, in particular for comminuted type 2B2 fractures. No differences were found between the specific backgrounds of the professionals regarding the preferred type of treatment.

Two recent meta-analyses on the treatment of displaced midshaft clavicular fractures comparing different surgical methods to non-operative treatment, showed that after the first year the non-union rate was higher in the non-operatively treated group (14.2% versus 1.4%), whereas disability and function between both groups were comparable.[18,19] The number needed to operate in order to prevent one non-union and symptomatic mal-union was 4.6, and for non-union alone 7.6,[18] which is relatively high. Despite several randomised controlled trials, no definite answer has yet been given to the question what type of fixation is the most appropriate for displaced midshaft clavicular fractures.[14,20-24] This could clarify the diversity in answers given by the respondents in the current study.

Most of the respondents in our study were trauma surgeons, since in the Netherlands 80% of the fracture treatment is performed by trauma surgeons. The results of our survey suggested that the preference for non-operative treatment and for specific types of fixation depends on the background and experience of the surgeon, but the differences were not statistically significant. This may have been due to the fact that the power to detect relevant differences between the professional groups was low because of the small number of orthopaedic surgeons, trauma fellows and surgical residents in the survey, which presents a limitation of this study. With respect to the choice between surgical fixation techniques, the given answers

were quite divers. Intramedullary fixation was not at all chosen by orthopaedic surgeons as treatment for displaced fractures, whereas trauma surgeons did so in nearly 10% of the cases. Familiarity with this particular technique or material may account for these results.

Another limitation of this study is the relatively low response rate (55%), which may in part be due to the fact that some of the invited surgeons were retired or no longer practising in a trauma-related profession. With respect to the surgeons who responded to the survey, it is likely that they represent the opinion of those with an interest in upper extremity fractures.

Our study aimed to determine the preferred treatment for type 2B midshaft clavicular fractures based on evaluation of the AP-radiograph. In practice, clinical decision making for midshaft clavicular fractures is also based on characteristics of the patient, such as age, the level of sports activity or profession.[25,26] If early mobilization is wished for, surgery may be preferred because non-operative treatment involves two weeks of immobilization without any weight bearing activities for at least six weeks whereas after surgical fixation of the fracture early abduction until 90 degrees without any weight bearing is possible after the first couple of days and mobilization is less painful. Choice of treatment may also be affected by the preference of the surgeon for a specific type of fixation. Furthermore, the patient's views and wishes may also play a role in determining the treatment strategy, such as cosmetic considerations, or the patient's appreciation of the risk of wound infection after operative treatment, the risk of a potential re-intervention, and the risk of re-fracture within the first three months after operation. These aspects of decision making were not taken into account in this survey. This may limit the generalizability of our results to the daily clinical practice.

In conclusion, there is no consensus on the choice of treatment for displaced or comminuted midshaft clavicular fractures. The choice for non-operative or operative treatment seems to depend on the professional background and experience of the surgeon, the preference for method of surgical fixation does not. The obvious influences of personal preferences and the lack of consensus call for evidence-based treatment guidelines for displaced or comminuted midshaft clavicular fractures.

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CHAPTER 7

The relationship between trauma mechanism, fracture type and treatment of midshaft clavicular fractures.

Sylvia A. Stegeman, Charlotte W.J. Roeloffs, Jephta van den Bremer, Pieta Krijnen, Inger B. Schipper

ABSTRACT

Objective

The debate on whether midshaft clavicular fractures should preferably be treated operatively or non-operatively still continues. Several patient-related factors may influence this treatment decision. A retrospective study was carried out to investigate the relation between fracture type and trauma mechanism, age and sex, and the influence of these factors on the choice of primary treatment.

Methods

Data on trauma mechanism and treatment of 232 adult patients, who presented with a midshaft clavicular fracture in two hospitals in the Netherlands during the years 2006-2009, were collected. The extent of clavicular shortening, displacement, and fracture type on the primary X-ray were scored.

Results

Traffic accidents are the main cause of midshaft clavicular fractures. After correction for age, no relation was found between trauma mechanism and fracture type. Older age correlated with more comminuted and displaced fractures. Extensive shortening (>20mm) was identified as the main clinical indication for primary surgery, whereas displacement and fracture classification seemed less relevant. Operative treatment was increasingly favored from 5% in 2006 to 44% in 2009, which could not be explained by an increase of more complex fractures, nor by age-related or trauma mechanism-related factors.

Conclusion

Age has a major influence on the fracture type, whereas the trauma mechanism does not. The choice for the surgical treatment of midshaft clavicular fractures is primarily determined by the amount of axial shortening of the clavicle, rather than by overall displacement or fracture type. Over the years, the choice of treatment seems, increasingly influenced by the patient's and surgeon's preferences.

INTRODUCTION

Clavicular fractures represent five percent of all fractures in adults. The vast majority (69-82 percent) of these fractures are located in the midshaft of the clavicle.[1-5] Most midshaft clavicular fractures are caused by a direct axial compressive force to the shoulder after a sudden stop or fall during sports, such as cycling and horse riding.[5,6] It is currently not known how trauma mechanism and patient characteristics relate to the degree of comminution of the fracture.

Furthermore, the optimal management of midshaft clavicular fractures is still unclear. Several Randomised Controlled Trials (RCTs) have been conducted to determine whether displaced and comminuted midshaft clavicular fractures should be treated operatively with plate fixation or intramedullary nailing, or non-operatively with sling immobilization, in order to optimize union rates and functional outcomes. These studies seemed to favor operative treatment with plate fixation, which was also found in a meta-analysis of these studies.[7] However, the effect of operative treatment may have been overestimated due to methodological flaws in some of the RCTs. In the RCTs by Altamimi and McKee[8], Judd *et al.*[9] and by Mirzatolooei *et al.*[10] significantly more patients in the non-operative group were lost to follow-up than in the plate fixation group. This difference in the length of follow-up may have favored the functional outcomes and union rates in the plate fixation groups in these studies. Research has not shown convincingly that operative treatment is better for displaced and comminuted fractures, because the treatment outcome may depend on patient characteristics as well.

In this retrospective study, we examined whether the type of midshaft clavicular fractures depends on trauma mechanism, age and sex. Furthermore, we investigated whether the choice of primary operative treatment is influenced by any of these factors.

METHODS

Patients

In this retrospective cohort study, all patients of 18 years of age and older, who presented with a midshaft clavicular fracture between January 2006 and December 2009 in two hospitals in the mid-western region of the Netherlands, were selected from the hospital registries. Patients were excluded if no primary radiograph of the midshaft clavicular fracture taken within two weeks after injury was available or if no information was available on primary and final treatment, because the patient received further treatment in another hospital.

Data

Data on year of trauma, sex, age at fracture, trauma mechanism, fracture characteristics, type of treatment, treatment period and clinical outcome were gathered from the medical files. Trauma mechanisms were subdivided into (a) traffic accidents involving bikes, mopeds, motorcycles and cars (fractures induced by direct pressure of the seat belt), (b) fall from height, such as a fall from a staircase or a household ladder (c) sports injuries, and (d) low-energy injuries, such as fall from standing. Age was classified into: (a) 18-29 years, (b) 30-49 years, and (c) 50 years and older. This classification was made on the basis of age-related changes in bone mass, structure and strength, as bone starts to degenerate from the age of 25-30 years,[11] and the chance of a fragility fracture is increased above the age of 50 years.[12,13] The following fracture characteristics were determined from the anteroposterior radiograph: fracture side, fracture type according to the Robinson classification defined as type 2A (undisplaced or with only an angulation) and type 2B (simple or wedge comminuted and isolated or comminuted segmental fractures; Figure 1),[4] displacement ad latum defined as (a) less than one shaft width or (b) more than one shaft width in the craniocaudal or the anteroposterior direction, and clavicular axial shortening categorized as follows: (a) 0–14mm, (b) 15–19mm and (c) at least 20mm. Treatment was classified as operative or non-operative. A distinction was made between the primary treatment and the final treatment. The follow-up period was defined as the number of weeks between the first presentation at the emergency department or the outpatient clinic and the last visit to the outpatient clinic.
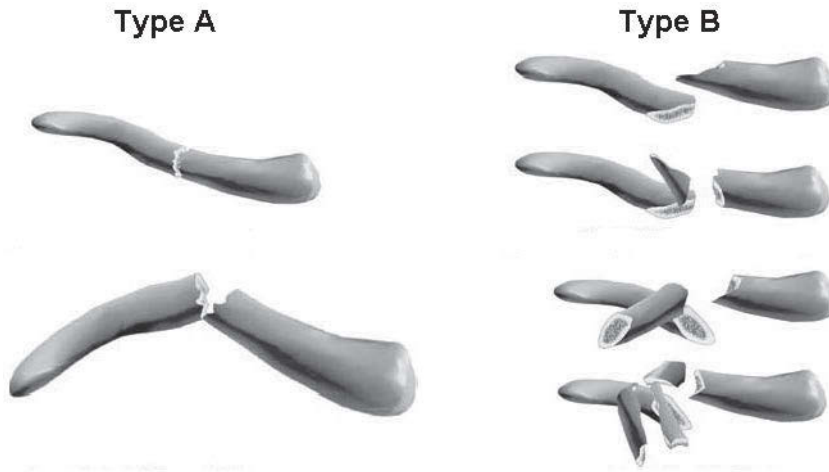
Figure 1 Robinson classification of midshaft clavicular fractures.

Figure reprinted with permission of C.M. Robinson.[4]

Statistical analyses

Univariate comparisons between patient groups were tested using the *t*-test or analysis of variance for continuous variables, and with the χ^2-test for categorical data. Multivariate analyses for binary outcome parameters were performed using logistic regression analysis, in which variables with a univariate association ($P<0.05$) with the outcome variable were included as independent factors. Statistical analyses were carried out using statistical package for the social sciences version 17.0 (SPSS Inc., Chicago Illinios, USA).

Results

In the study period, 257 adult patients with a midshaft clavicular fracture were seen in the Emergency Departments of the two hospitals. After excluding the patients of whom radiographs or information on treatment were missing, 232 patients remained (188 men, 44 women; mean age 41.2 years, SD±16.6). Of this group, 189 patients had received primary non-operative treatment by means of a sling and 43 patients had received primary operative treatment using plate fixation. The characteristics of the study group are presented in Table 1.

Trauma mechanism by age and gender

Type of trauma mechanism, subdivided into four categories, was associated with age (P<0.001; Figure 2). Traffic accidents were the main trauma mechanism in the study group as a whole (60%), as well as in the separate age groups (Figure 2). Sports injuries were the second most common trauma mechanism in the youngest age groups, whereas low-energy injuries were the second most common trauma mechanism in patients older than 50 years of age. Men more often sustained a clavicular fracture during traffic accidents, whereas women sustained a clavicular fracture equally frequent because of traffic accidents as low-energy accidents, such as a fall on the street (P<0.001; Figure 2).
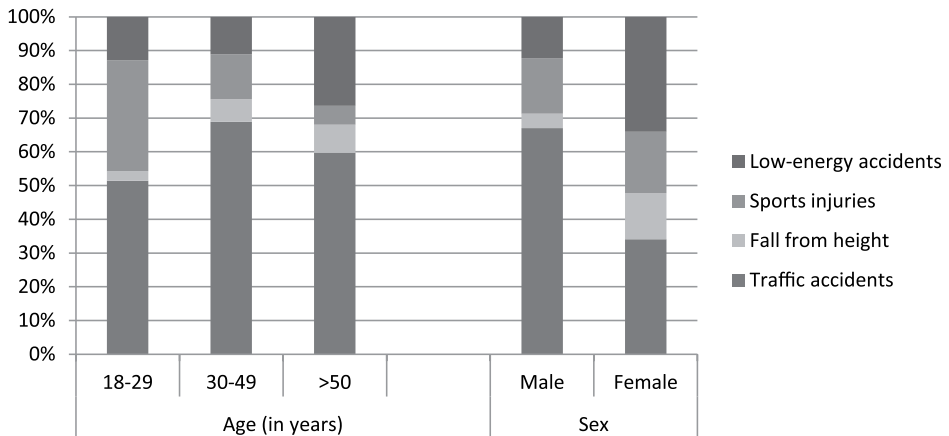

Figure 2   Trauma mechanism by age and gender in patients with midshaft clavicular fractures.

Table 1   Characteristics of 232 patients with midshaft clavicular fractures, according to primary treatment.

Parameter		Total N (%)*	Non-operative treatment N (%)*	Operative treatment N (%)*	P-value
Total fractures		232	189	43	
	Gender				P=0.947
	Male	188 (81)	153 (81)	35 (81)	
	Female	44 (19)	36 (19)	8 (19)	
Age at trauma					P=0.305
	18-29 yr	70 (30)	60 (32)	10 (32)	
	30-49 yr	90 (39)	69 (37)	21 (49)	
	>50 yr	72 (31)	60 (32)	12 (28)	
Trauma mechanism					P=0.275
	Traffic accident	141 (60)	115 (61)	26 (61)	
	Fall from height	14 (6)	14 (7)	0 (0)	
	Sports injury	39 (17)	30 (16)	9 (21)	
	Low-energy injury	38 (16)	30 (16)	8 (19)	
Side of fracture					P=0.962
	Left	121 (52)	98 (52)	23 (53)	
	Right	111 (48)	91 (48)	20 (47)	
Fracture type					P=0.004
	2A1	15 (7)	14 (7)	1 (2)	
	2A2	24 (10)	23 (12)	1 (2)	
	2B1	132 (57)	111 (58)	21 (49)	
	2B2	61 (26)	41 (22)	20 (47)	
Displacement ad latum					P=0.016
	No dislocation	28 (12)	26 (14)	2 (5)	
	< 1 shaft width	102 (44)	75 (40)	27 (63)	
	> 1 shaft width	102 (44)	88 (47)	14 (33)	
Axial shortening					P<0.001
	0-14 mm	143 (62)	132 (70)	11 (26)	
	15-19 mm	24 (10)	21 (11)	3 (7)	
	> 20 mm	65 (28)	36 (19)	29 (67)	
Length of follow-up (weeks), median (range)		7.2 (0-185)	6.3 (0-185)	15.6 (1-88)	P<0.001
Year of diagnosis					P<0.001
	2006	59 (25)	57 (30)	2 (5)	
	2007	51 (22)	45 (24)	6 (14)	
	2008	66 (28)	50 (26)	16 (37)	
	2009	56 (24)	37 (20)	19 (44)	

*Percentages may not add up to 100% due to rounding

Fracture characteristics by gender, age and trauma mechanism

Comminuted and displaced (type 2B) fractures were far more common than undisplaced (type 2A) fractures (73 vs. 17%). Fracture type did not differ between men and women (P=0.24), but the proportion of type 2B fractures increased with age (P=0.002, data not shown). The probability of sustaining a comminuted displaced (type 2B) fracture increased with age: compared with the youngest age group, the odds ratio (OR) was 2.96 (95% confidence interval (CI) 1.26–6.98) for a type 2B fracture in the intermediate age group and 3.12 (95%-CI: 1.20 – 8.06) in the eldest age group (Table 2). Fracture type and trauma mechanism were univariately associated (P=0.04, Figure 3). In a multivariate analysis, this association was no longer present after correction for age.

Table 2 Multivariate logistic regression analysis for predicting a comminuted (type B) fracture in patients with a midshaft clavicular fracture.

	OR	95%-CI	P
Age (in years)			
18-29	1		
30-49	2.96	1.26-6.98	0.01
>50	3.12	1.20-8.09	0.02
Trauma mechanism			
Traffic accident	1		
Fall from height	0.70	1.14-3.49	0.66
Sports injury	0.43	0.18-1.06	0.07
Low-energy injury	0.48	0.18-1.27	0.14

Displacement ad latum, scored as more than one shaft width, was observed on 88% of the primary radiographs (Table 1). The nondisplaced fractures were caused, in similar numbers, by sports injuries and by traffic accidents, whereas the fractures with more than one shaft width displacement resulted less often from sports accidents and more often from traffic accidents (Figure 3). Few fractures showed extensive axial shortening on the primary radiograph: shortening of 15 - 20 mm was seen in 10%, and shortening of at least 20 mm in 28% (Table 1). Trauma mechanism was not related to the extent of shortening (P=0.73, Figure 3).
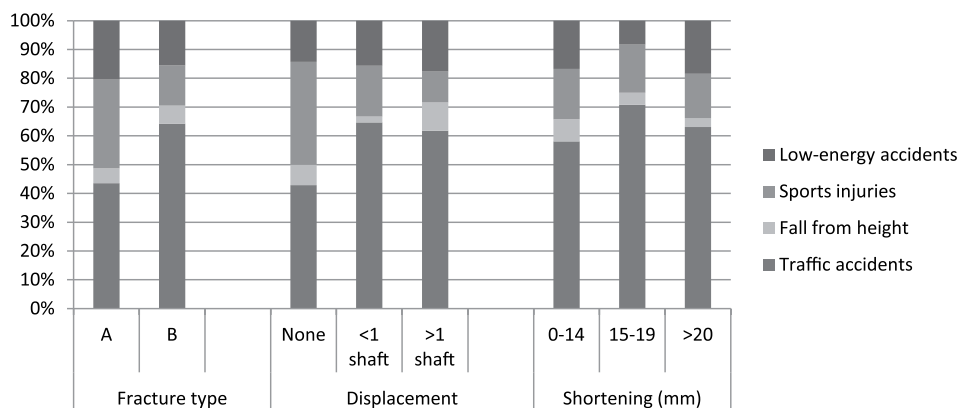
Figure 3 Fracture characteristics of patients with a midshaft clavicular fracture, by trauma mechanism.

Choice of primary treatment

According to the medical files, shortening of the clavicle of at least 20 mm was the main indication for surgery for the 43 patients who were operated as primary treatment (*n*=25). Other indications for primary surgery included skin perforation (*n*=1) and significant displacement of the fracture fragments (*n*=5). In the other patients (*n*=12), surgical treatment was preferred by the patient, for instance to enable early mobilization of the shoulder and return to work (p<0.001). In the univariate analyses, the primary operative treatment was not associated with age, sex and trauma mechanism (*P*>0.05, Table 1). Primary surgery was associated, however, with type B fractures, more displaced fractures and extensive (≥20 mm) clavicular shortening (p<0.001). After combining the fracture characteristics in a logistic regression analysis, the choice of primary treatment seemed mainly to be determined by the extent of clavicular shortening: the OR for primary surgery was only statistically significantly increased for patients with a clavicular shortening of 20 mm or more (Table 3). In a multivariate regression analysis, the probability of primary operative treatment increased markedly over time within the study period of 4 years (for 2009 compared with 2006: OR 34.49, 95%-CI: 5.53 – 182).

Table 3 Logistic regression analysis for predicting surgery as primary treatment in patients with a midshaft clavicular fracture.

Classification	Shortening	Displacement	OR*	95%-CI	P
A			1 (reference)		
B	0-14 mm	<1 shaft	2,37	0,43-12,99	0,32
B	0-14 mm	>1 shaft	1,30	0,23-7,45	0,77
B	15-19 mm	<1 shaft	4,11	0,51-33,27	0,19
B	15-19 mm	>1 shaft	1,68	0,14-20,35	0,68
B	≥ 20 mm	<1 shaft	21,77	4,56-103,87	<0.0001
B	≥ 20 mm	>1 shaft	8,76	1,72-44,68	0,009

The header group "Fracture characteristics" spans Classification, Shortening, Displacement.

* OR=Odds Ratio for primary operative treatment.

Final treatment

Sixteen of the 189 non-operatively treated patients developed pain and impaired shoulder function. Of these 16 patients, 11 patients were operated an average of 21 weeks (4-106 weeks) after trauma because of incomplete fracture healing. Thus, a total of 54/232 patients had received operative treatment at the end of the follow-up period.

DISCUSSION

This study was carried out to determine whether the type of midshaft clavicular fractures and choice of primary operative treatment depend on trauma mechanism, age and sex.

Theoretically, it would seem likely that the force and the energy of a direct blow onto the shoulder strongly correlate with the amount of comminution of the fracture, and therefore, would determine the type of fracture. However, in our study, no association was found between the trauma mechanism and fracture type after correction for age. Midshaft clavicular fractures were caused by different trauma

mechanisms in different age groups, which might explain why age and not trauma mechanism was shown to be the principal determinant of fracture type in this study. In the elderly, it is likely that less force is required to produce a comminuted fracture, as it has been established that bone quality declines slowly after 30 years of age and that osteoporosis sets in after the age of 50.[11-13]

In this study, clavicular axial shortening of 20 mm or more was found to be the main indication for operative treatment. The other fracture characteristics on the radiograph, the Robinson classification and the extent of displacement ad latum, seemed less relevant for the choice of treatment. However, the decision to operate in daily clinical practice does not only depend on the findings on radiograph, but may depend on the patient's and surgeon's preference for a specific type of treatment because of the patient's work or social activities such as sports. In the present study, 12 patients were operated on because of their preference for early mobilization and fast return to work and not because of the surgeon's preferences or surgical indication. If medically admissible, it is advised to weigh the patient's goals and activity level in choice for method of treatment of midshaft clavicular fractures.[14]

The proportion of midshaft clavicular fractures that were operated upon has increased markedly during the study period of 4 years. This increase could not be explained by an increased proportion of more complex fractures, and was therefore probably because of surgeons' and patients' preferences for surgical intervention. The publication of an RCT of Altamimi and McKee *et al.*,[8] showing that operative treatment with plate fixation might be better than non-operative treatment for shortened and displaced (type 2B) midshaft clavicular fractures, may have led surgeons to operate more often over time during the study period. However, the results and conclusions of this study[8] should be interpreted with caution, because of the selective loss to follow-up that occurred mainly in the non-operatively treated group. For this reason, yet another RCT is currently being performed by the authors.[15]

Similar to all retrospective studies, the present study has its limitations. The retrospective design led to the exclusion of 25 patients (9.8%), however random, because not all relevant data could be retrieved from the medical files. Moreover, the data on trauma mechanism could not be further specified. More detailed information may have helped to further clarify the relation between trauma mechanism and fracture type.

Conclusion

Age and not trauma mechanism seems to be the principal determinant of fracture type. In terms of the choice for primary surgical treatment of midshaft clavicular fractures, extensive axial shortening (>20mm) is the most relevant clinical factor. Yet, the patient's and surgeon's preferences also seem to play an important role.

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CHAPTER 8

Displaced midshaft fractures of the clavicle: *non-operative treatment versus plate fixation (Sleutel-TRIAL). A multicentre Randomised Controlled Trial.*

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ABSTRACT

Background

The traditional view that the vast majority of midshaft clavicular fractures heal with good functional outcomes following non-operative treatment may be no longer valid for all midshaft clavicular fractures. Recent studies have presented a relatively high incidence of non-union and identified specific limitations of the shoulder function in subgroups of patients with these injuries.

Aim

A prospective, multicentre randomised controlled trial (RCT) will be conducted in 21 hospitals in the Netherlands, comparing fracture consolidation and shoulder function after either non-operative treatment with a sling or a plate fixation.

Methods/design

A total of 350 patients will be included, between 18 and 60 years of age, with a dislocated midshaft clavicular fracture. The primary outcome is the incidence of non-union, which will be determined with standardised X-rays (Antero-Posterior and 30-degrees caudocephalad view). Secondary outcome will be the functional outcome, measured using the Constant Score. Strength of the shoulder muscles will be measured with a handheld dynamometer (MicroFET2). Furthermore, the health-related Quality of Life score (ShortForm-36) and the Disabilities of Arm, Shoulder and Hand (DASH) Outcome Measure will be monitored as subjective parameters. Data on complications, bone union, cosmetic aspects and use of painkillers will be collected with follow-up questionnaires. The follow-up time will be two years. All patients will be monitored at regular intervals over the subsequent twelve months (two and six weeks, three months and one year). After two years an interview by telephone and a written survey will be performed to evaluate the two-year functional and mechanical outcomes. All data will be analysed on an intention-to-treat basis, using univariate and multivariate analyses.

Discussion

This trial will provide level-1 evidence for the comparison of consolidation and functional outcome between two standardised treatment options for dislocated midshaft clavicular fractures. The gathered data may support the development of a clinical guideline for treatment of clavicular fractures.

Trial registration

Netherlands National Trial Register NTR2399

Background

Epidemiology

Fractures of the clavicle account for 2.6 to 4 percent of all adult fractures and 35 percent of all injuries to the shoulder girdle.[1,2] The annual incidence of clavicular fractures is estimated between 29 and 64 per 100 000. Fractures of the middle third (midshaft) account for 69 to 82 percent of all clavicular fractures, whereas distal fractures represent 21 to 28 percent. Medial-end injuries are less common, approximately 2 to 3 percent of all clavicular fractures.[2,3] The average age of patients sustaining a midshaft clavicular fracture is 33 years, 70 percent of the patients is male.[4] A fall or a direct blow to the shoulder, giving an axial compressive force on the clavicle, is the most common trauma mechanism of injury for any clavicular fracture.[5-7]

Current treatment concepts

Midshaft fractures have traditionally been treated non-operatively, even when substantially displaced.[8] The non-operative treatment strategy was based on early reports suggesting that clavicular non-unions are very rare. Clavicular mal-union, if present, was reported as being of radiographic interest only, without clinical importance.[9] Moreover, surgical treatment of acute midshaft fractures was not favoured due to relatively frequent and serious complications such as infection, non-union, pin migration, broken plates, and necessity of removal of hardware.[2] However, the prevalence of non-union or mal-union in dislocated midshaft clavicular fractures after conservative treatment is higher than previously presumed and fixation methods have evolved. Of all midshaft clavicular fractures, about two-thirds end up having some degree of mal-union.[5] Recent studies reported a non-union rate up to 15 percent and more[4,10,11] and a potential 20 to 25 percent decrease in shoulder function and arm strength.[4,11-17]

The currently described indications for surgical treatment are open fractures, neurovascular involvement, skin compromise and wide separation of bone fragments with soft tissue interposition. Initial clavicular shortening exceeding 20 mm is upcoming as an indication for operative treatment, because shortening caused by dislocation has been associated with potential shoulder dysfunction.[12,18] An associated

floating shoulder or a scapular neck fracture, are relative indications for operative treatment of the clavicular fracture. Non-union and mal-union are mentioned as a delayed indication for operative treatment. If an operation is considered for displaced midshaft clavicular fractures, the preferred method of fixation is reduction and internal fixation by means of wires, pins, or plates with screws.

Valid and scientific evidence showing primary operative intervention to be superior compared to closed treatment for dislocated fractures, still lacks.[19,20] Surgery is accepted more and more as primary treatment for dislocated midshaft clavicular fractures, mainly because the results of non-operative treatment are interpreted as inferior to operative treatment.[9,15,21,22] Several studies have examined the safety and efficacy of primary open reduction and internal fixation (ORIF) for completely displaced midshaft clavicular fractures and have noted a high union rate with a low complication rate.[9,11,23,24] However, all these studies were retrospective and only one recent study prospectively compared locking plate fixation with non-operative treatment.[9] In this multicentre, prospective randomised trial 132 patients with a displaced midshaft clavicular fracture were allocated to either operative treatment with plate fixation (n=67) or non-operative treatment (n=65). The investigators concluded that operative treatment results in improved functional outcome and a lower rate of mal-union and non-union compared with non-operative treatment after one year of follow-up.[9] One of the important limitations of this prospective randomised trial was a selective loss to follow-up, which occurred predominantly in the non-operatively treated group. This may have obscured the true difference in the outcome parameters between the study groups.

A cost-effectiveness analysis[4] has been performed in this multicentre, prospective randomised trial,[9] showing that the cost-effectiveness of ORIF of displaced midshaft clavicular fractures is dependent on the duration and magnitude of functional benefit after ORIF, the disutility before union and increased time to union associated with non-operative treatment, and the actual cost of treatment.

Rationale for the trial

A multicentre randomised clinical trial with sufficient power is needed to provide scientific support for a preferred treatment strategy for dislocated midshaft fractures of the clavicle. The aim of this trial is to compare the results of plate fixation with

non-operative management of dislocated midshaft fractures of the clavicle with respect to the incidence of non-union, functional outcome, pain scores, Quality of Life, cosmetic aspects, and complications.

METHODS/DESIGN

Study design

The Sleutel-TRIAL is designed as a multicentre randomised controlled trial. In total twenty-one academic and non-academic centres in the Netherlands will participate. The study started 15 June, 2010. The trial has been developed to meet the Declaration of Helsinki (59th World Medical Association General Assembly, Seoul, October 2008) and in accordance with the Medical Research Involving Human Subjects Act.[25] It will follow the CONSORT (CONsolidation of Standards of Reporting Trials) guidelines.[26-28]

Recruitment, consent and randomisation

All eligible persons presenting at the Emergency Department (ED) or at the outpatient clinic with a new, dislocated midshaft clavicular fracture are informed about this trial. They receive information and a consent form from the attending physician, the physician assistant or the clinical investigator. After written informed consent has been obtained, the patient is randomised for either operative therapy with a plate fixation or for non-operative therapy. Minimisation randomisation is accomplished via the trial website using TenALEA (Trans European Network for Clinical Trials Services), an online registration and randomisation program. All patients are randomly allocated to one of the two treatment arms in a 1:1 ratio in each participating hospital. For each subsequent participant the allocation depends on the included participants to minimise the imbalance.[29]

Study population

All patients with a dislocated midshaft clavicular fracture have to meet the following inclusion criteria before enrolment:

1. Fully displaced midshaft fracture (no fracture side contact of distal and proximal fragments) according to Robinson classification 2B1 and 2B2 (see Figure 1). The classification of the fracture will be confirmed on an anterior-posterior X-ray with a 30-degree caudocephalad view;

2. Age between 18 and 60 years;

3. No medical contra-indications to general anaesthesia;

4. Signed informed consent by the patient or a legal representative;

Cortical Alignement Fractures (Type 2A)   **Displaced Fractures (Type 2B)**
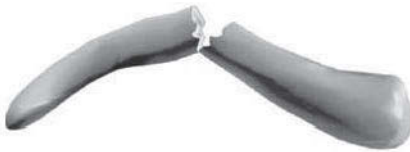
Undisplaced (Type 2A1)   **Simple or wedge comminuted (Type 2B1)**

Angulated (Type 2A2)   **Isolated or comminuted segmental(Type 2B2)**

Figure 1   Robinson Classification type 2 fractures.

Figure reprinted with permission of C.M. Robinson.[39]

Right side of the figure shows type 2B1 and type 2B2 fractures.

If one of the following exclusion criteria applies, the patient is not eligible for the study:

1. Fracture in the proximal or distal third of the clavicle;
2. Pathologic fracture (bony abnormalities at the side of the fracture) or an open fracture;
3. Neurovascular injury of the shoulder region with objective neurological findings on physical examination;
4. Associated head injury (Glasgow Coma Scale <12);
5. A significant ipsilateral upper extremity fracture, that would delay the functional recovery of the arm;
6. A midshaft clavicular fracture more than 14 days old at first hospital visit;
7. Inability to comply with follow-up;
8. Prior surgery to the shoulder or pre-existing shoulder complaints with subsequent loss of function;

Interventions

For patients assigned to operative treatment, the procedure of applying the plate is performed according to standard procedures, including the position of the patient (beach chair position) and anaesthesia (i.e., general anaesthesia or interscalene nerve block or a combination of both). All patients admitted to the hospital for operative intervention receive antibiotic prophylactics (single dose) pre-operatively and after operation thromboprophylaxis is applied during the hospital stay (e.g., unfractionated heparin, Low Molecular Weight Heparin (LMWH), or equivalent). All operations are performed by skilled trauma surgeons, i.e. those who have performed more than five operations with a plate fixation, or by surgical residents under supervision of a skilled trauma surgeon. No restrictions are specified regarding the brand of plate fixation that will be used. Patients assigned to conservative therapy wear a sling for the first two weeks.

All patients, in both treatment arms, are advised to mobilise the shoulder functionally without weight bearing during the first six weeks. The exercise protocol consists of pendulum exercises up to functional movements without weight bearing in the first six weeks after trauma or operation. In the first two weeks pendulum exercises are started and more active exercise is initiated between two and four weeks postoperatively or after trauma. After six weeks, initial strengthening is started.

Outcome measures

The primary outcome is the incidence of non-union. This is determined objectively on X-rays by an independent radiologist and two surgeons, and subjectively by evaluation of the clavicular and the arm function. The function of the arm is measured with the Constant Score. The Constant score consists of four variables, reflecting both function and pain of the shoulder joint.[30,31] The subjective variables in the Constant Score are pain, activities of daily living and arm positioning. The objective variables are range of motion (ROM) without pain and strength.[32] The arm strength is measured with the MicroFET2 (Micro Force, Evaluating and Testing 2, Hoggan Health Industries Inc, West Jordan, UT, USA), a hand-held dynamometer. This device measures the force a patient can produce against the force of the examiner in Newton (N). All arm movements (i.e., retroflexion, anteflexion, abduction, adduction, endorotation and exorotation) are evaluated six weeks after initial trauma or operation in comparison with the contralateral side and thereafter at each follow-up moment. For all measurements the Make Test is used. The Make Test is characterised by the examiner holding the dynamometer stationary while the subject exerts a maximal force against the dynamometer and the examiner.[33] The results produced with the hand-held dynamometer have been shown to be reproducible, especially when measured by one single examiner at each hospital (intra-rater reliability).[33] The inter- and intra-rater reliability of hand-held dynamometry varied in the range from good to high.[34,35]

Secondary outcomes are clinical function measured with the DASH Outcome Measure, pain scores, cosmetic aspects, quality of life and complications of the allocated treatment. The Disabilities of Arm, Shoulder and Hand (DASH) Outcome Measure is a validated 30-item, self-report questionnaire designed to describe the disability experienced by people with upper-limb disorders and to monitor changes in symptoms and function over time. The DASH Outcome Measure consists of two components: the disability / symptom section (30 items) and the optional high performance Sport/Music module (4 items). The questions involve the degree of difficulty in performing a variety of physical activities because of problems with the arm, shoulder, or hand. The severity of pain, activity-related pain, tingling, weakness and stiffness is investigated, as well as the effect of upper limb problems on social activities, work, sleep, and self-image.[32,36,37] The questionnaire is filled out at each follow-up moment.

Cosmetic aspects are included in the follow-up questionnaires. These questions are subjective and involve satisfaction with the appearance of the shoulder with and without surgery. The Health Related Quality of Life (HR-QOL) will be evaluated using the Short Form-36 (SF-36). The SF-36 is a validated survey on general health with 36 questions, representing eight health domains that are combined into a physical and a mental component scale.[38] The Physical Component Scale (PCS) contains the health domains physical functioning, role limitations due to physical health, bodily pain and general health perceptions. The Mental Component Scale (MCS) contains the health domains vitality, energy, fatigue, social functioning, role limitations due to emotional problems and general mental health. Scores ranging from 0 to 100 points are derived for each domain, with lower scores indicating poorer function. These scores will be converted in a norm-based score and compared with the norm values for the general population of the United States (1998), in which each scale was scored to have the same standardized average (50 points) and the same standard deviation (10 points).[32]

Follow-up of patients

After inclusion, all patients will be followed for two years in total. Patients will visit the outpatient clinic after two weeks, six weeks, three months and one year. After two years an interview by telephone and written survey will be conducted to evaluate two-year functional and mechanical outcome. In the operative group follow-up starts on the day of surgery. For the non-operative group this is the day of inclusion (see Table 1).

At each hospital visit various intrinsic (patient-related) and injury-related variables are collected. As part of standard care, X-rays are taken at admission and each follow-up moment. The X-rays are performed in anterior-posterior view and 30° caudocephalad view. After two weeks an X-ray of the contralateral shoulder is taken for comparison with the affected shoulder. The DASH outcome measure and SF-36 are filled out by the patient after two weeks, six weeks, three months and one year. The Constant score of both shoulders is determined after six weeks. The Constant score of the affected shoulder is also determined after three months and one year. The functional tests are performed by a single-blinded researcher or other single-blinded qualified personnel. During these tests, the patients have a sticker on

Table 1 Flowchart Sleutel-TRIAL.

Date Visit	1 Emergency Room (ER)	2 Phone call 48 hours after ER visit	3 † First visit (pre-operative care)
Eligible? (checking in- and exclusion criteria)	•		
Patient information	•		
Obtaining Informed Consent		•	•[2]
Randomisation (operative vs. non-operative treatment)		•[1]	
Case Record Form + Randomisation form			•
Preparing patient for operation (aneasthesia i.e.) †			•
Peroperative Form †			
X-rays	•[3]		
Follow-up Forms			
DASH-score			
SF-36 score (Quality of Life)			
Constant score (+MicroFET2)			
Telephone interview and written survey			

• [1]: obtaining Informed Consent (verbally) for randomisation and planning of clinic visit

• [2]: obtaining definitive written Informed Consent

• [3]: X-rays: AP-view and 30 degrees cephalad view

• [4]: Panorama view

• [5]: Forms for the corresponding visit

†: only for participants allocated to operative treatment

the affected shoulder and they are not allowed to tell the examiner which therapy they have undergone. Furthermore, at each visit the researcher collects medical information according to the follow-up list (i.e., complications/adverse events, secondary interventions). Serious adverse events will be reported directly.

4 †	5	6	7	8	9
Operation	2 weeks	6 weeks	3 months	1 year	2 years

	• 2				
•					
•	• 4	• 3	•	•	
	• 5	• 5	• 5	• 5	
	•	•	•	•	
	•	•	•	•	
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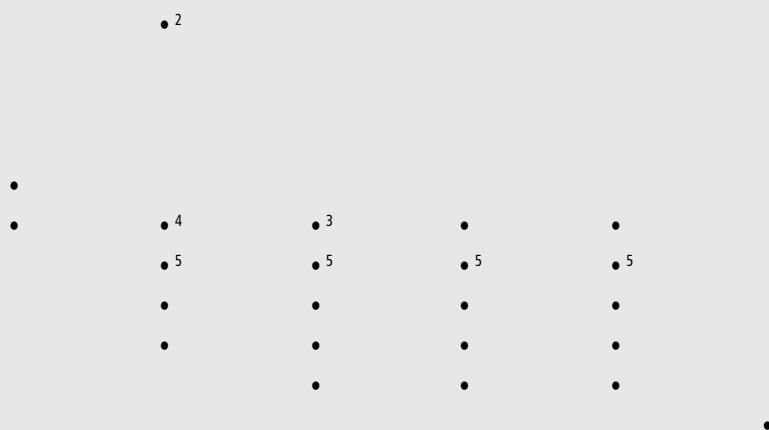
Sample size calculation

Based on a non-union difference of 15 percent in a previous study,[9] the sample size of 175 patients per treatment group was calculated with a power $(1-\beta)$ of 80 percent and a type I error (α) of 5 percent, allowing for 12 percent drop-out. In total 350 patients will be included.

Statistical analysis

The research data will be reported following the CONsolidated Standards of Reporting Trial (CONSORT).[26-28] Complication rates and recovery of function of the shoulder will be compared between the two intervention groups using the Chi-squared test. All other endpoints will be compared using co-variate analysis and student's T-test or Mann-Whitney U-test for, respectively, parametric or non-parametric data. Multivariate linear regression analysis will be performed to model the relation between binary outcome variables and treatment, adjusted for covariates. Data will be presented as mean ± SD (Standard Deviation) for parametric data or medians and percentiles (non-parametric data). P-values lower than 0.05 will be considered statistically significant. The data will be analysed using SPSS version 17 or higher (Statistical Package for the Social Sciences Inc, Chicago IL, USA).

Ethical considerations

The study will be carried out in compliance with the Declaration of Helsinki on ethical principles for medical research involving human subjects.[25] The Medical Ethics Committee Leiden University Medical Centre (LUMC) acts as central ethics committee for this trial (reference number P10.033 and P10.169; NL31044.058.10 and NL33925.058.10). Approval has also been obtained from the local Medical Ethics Committees of all participating centres. The Medical Ethics Committee LUMC has given dispensation from the statutory obligation to provide insurance for subjects participating in medical research (Medical Research (Human Subjects) Compulsory Insurance Decree of 23 June 2003), because the study concerns two standard treatments and does not introduce extra risks.

DISCUSSION

The best treatment strategy for dislocated midshaft clavicular fractures remains a topic of debate. Currently, the decision for non-operative or operative treatment of dislocated midshaft clavicular fractures is predominantly based upon the personal preferences of the treating surgeon. In a similar way, when operative treatment is

favoured, the type of fixation, intramedullary or (locking) plate fixation, is at the discretion of the surgeon. Research has been done to establish a general consensus on how to treat these types of fractures. The Canadian Orthopaedic Study[9] has provided some insight into how the outcomes after locking plate fixation relate to those after conservative treatment. However, this study has the limitation of a considerable loss to follow-up, predominantly in the non-operatively treated group, which makes it impossible to conclude with certainty that plate fixation is preferred over conservative treatment in active adults. ORIF is most cost-effective for patients who are sensitive to mild functional deficits and strongly value a more rapid return to normal function[4]. Considering these statements, a new randomised controlled trial with sufficient power is needed to provide evidence for a definitive, generally acceptable guideline for the treatment of dislocated midshaft clavicular fractures. The results of this study will help to clarify the question whether plate fixation is superior to non-operative treatment in adults, thereby considering incidence of non-union, functional outcome, pain scores, Quality of Life, cosmetic aspects and complications.

Competing interests

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PART IV

BIOMECHANICS

CHAPTER 9

Post traumatic midshaft clavicular shortening does not result in relevant functional outcome changes

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ABSTRACT

Background and purpose

Shoulder function may be changed after healing of a non-operatively treated clavicular fracture, especially in case of clavicular shortening or mal-union. We explored scapular orientations and functional outcome in healed clavicular fractures with and without clavicular shortening.

Patients and Methods

32 participants with a healed non-operatively treated midshaft clavicular fracture were investigated. Motions of the thorax, arm and shoulder were recorded by standardized electromagnetic 3D motion tracking. DASH and Constant-Murley scores were used to evaluate functional outcome. Orientations of the scapula and humerus in rest and during standardized tasks, strength and function of the affected shoulders were compared with the uninjured contralateral shoulders.

Results

Mean clavicular shortening was 25 mm (SD 16). Scapula protraction had increased with mean 4.4 degrees in rest position in the affected shoulders. During abduction, slightly more protraction, lateral rotation and less backward tilt was found for the affected shoulders. For anteflexion the scapular orientations of the affected shoulders also showed slightly increased protraction, lateral rotation, and decreased backward tilt. Scapulohumeral kinematics, maximum humerus angles and strength were not associated with the extent of clavicular shortening. All participants scored excellent on the Constant-Murley score and DASH score.

Interpretation

Scapulohumeral kinematics in shoulders with a healed clavicular fracture differ from those in an uninjured shoulder, but these changes are small, do not result in clinically relevant outcome changes and do not relate to the amount of clavicular shortening. These findings do not support routinely operative reduction and fixation of shortened midshaft clavicular fractures based on the argument of functional outcome.

INTRODUCTION

Displaced midshaft clavicular fractures are often treated non-operatively with good results, despite the frequently present initial clavicular shortening.[1-4] Studies on clinical outcome after clavicular shortening have reported conflicting results: some show shortening to be associated with poor functional outcome,[1,5,6] whereas others suggest no such relation.[7-10] Mal-union of the clavicle leads to an altered position of the scapula relative to the thorax,[11,12] which may cause shoulder problems, such as acromioclavicular osteoarthritis, decreased arm-shoulder functionality, and symptomatic winging of the scapula.[11,13,14] Primary operative treatment may therefore be preferred in patients with substantial clavicular shortening[15] or to prevent non-union.[16] Operative treatment of clavicular midshaft fractures has become more common.[17] However, the influence of shortening on clavicular and scapulohumeral movement and on functional outcome has not been sufficiently studied to substantiate the need for primary operative reduction and fixation of displaced clavicular fractures, in order to prevent poor functional outcome.

Our primary goal was to assess scapular orientation and arm-shoulder kinematics of patients with healed non-operatively treated midshaft clavicular fracture, and compare this to their uninjured contralateral shoulder. The secondary goal was to assess the relation between clavicular shortening and scapular orientation and between clavicular shortening and functional outcome.

PATIENTS AND METHODS

Inclusion criteria and participants

No sample size calculation was performed. 30 participants were considered sufficient for this exploratory study. Eligible candidates who sustained a unilateral, non-operatively managed, midshaft clavicular fracture healed within 4 months, were selected from the medical databases of 2006-2010 of the Leiden University Medical Centre and the Rijnland Hospital in the Netherlands. Further inclusion criteria were age between 18 and 60 years and no associated injuries at the time of trauma. Exclusion criteria were pathological fractures, neurovascular injury and other conditions influencing arm and shoulder function of either the affected or contralateral arm, current or previous acromioclavicular (AC) injury, such as AC luxation or symptomatic AC-osteoarthritis not caused by the clavicular fracture and a fracture in the proximal or distal third of the clavicle. Since an electromagnetic field was used in this study, candidates with a cardiovascular pacemaker were also excluded. All 74 eligible candidates received written information on this study and were subsequently contacted by phone, of whom 32 were willing to participate.

Motion recording

To collect 3D motion data of the arm and scapula with respect to the thorax, the "Flock of Birds" 3D Electromagnetic Motion Tracking Device (FoB, Ascension Technology Corp, Burlington, VT, USA) and specialized computer software for skeletal motion (FOBVis, Clinical Graphics, Delft, The Netherlands) were used. The FoB motion sensors were taped to the skin covering the posterolateral surface of the acromion, the sternum, on both arms on the posterior aspect just proximal from the humeral epicondyles, and on the wrist (Figure 1). Another

Figure 1   Positioning of the sensors during maximum internal rotation.

sensor was used to localize standardized pre-defined bony landmarks in 3D relative to the other sensors. Sensors were positioned in a standardized way by the primary researcher. The glenohumeral joint center was determined using a regression method. The recorded landmarks were used to create 3D local bone coordinate systems, based on the participants' individual anatomy.[18] For this purpose, the International Society of Biomechanics (ISB) definitions of joint coordinate systems were used.[19] Samples were taken at a sample rate of ± 30 Hz.

Participants were asked to perform a number of standardized tasks with both arms while seated with their trunk in erect position and the hip and knees flexed about 90 degrees. First, scapular orientation was measured in rest, expressed in degrees of protraction, lateral rotation and backward tilt (Figure 2). By convention, protraction means anterior rotation of the lateral border of the scapula, lateral
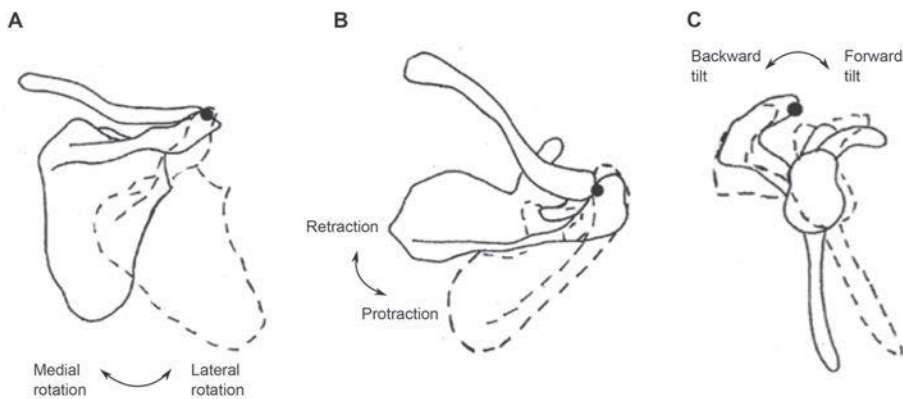

Figure 2   Scapular orientation.

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We adapted the terminology used in the original figure in (A) from downward rotation/ upward rotation to medial rotation/ lateral rotation, in (B) from external rotation/ internal rotation to retraction / protraction, and in (C) from posterior tilting/anterior tilting to backward tilt/forward tilt.

rotation means lateral rotation of the inferior angle; backward tilt means that the scapula rotates in such a way that the cranial border of the scapula moves dorsally.[19] Second, maximum angles of humerus exertions relative to the thorax were measured for abduction (AB), anteflexion (AF), retroflexion (RF), and humerus internal and external rotation with the arm at 90 degrees of abduction with 0 degrees of horizontal abduction (Figure 1). Third, scapular orientations (protraction, lateral rotation and backward tilt) during AB and AF were measured. All measurements were acquired for both arms simultaneously, whereas the contralateral non-affected shoulder acted as control shoulder.

Clinical outcome

Arm strength of both arms was tested with a handheld dynamometer (MicroFET2, Hoggan Health Industries Inc, West Jordan, UT, USA). To measure maximum force (Newton), the Make Test was used, in which the examiner is holding the dynamometer stationary while the participant exerts a maximum force against the dynamometer and examiner.[20] The dynamometer was placed at the medial side of the elbow joint to measure strength during adduction, 1-2 cm above the elbow joint at the lateral side for AB, anterior of the elbow (distal of the upper arm) for AF, posterior of the elbow for RF, and on the ventral and dorsal side of the wrist for subsequent external and internal rotation, while the participant was seated with the elbow flexed in 90 degrees.

Objective functional outcome was measured using the Constant-Murley score, which ranges from 0 (worst function) to 100 (best function). The scores for the affected shoulders were adjusted for gender and age in decades to obtain relative Constant scores, which were compared with published reference values of the general population. Subjective functional outcome was measured using the Disabilities of the Arm, Shoulder and Hand (DASH) score. A lower DASH score indicates less disability and dysfunction. The scores were compared to reference values.[21]

Radiography

Clavicular shortening was expressed as a proportion of the total clavicular length before fracture, in order to obtain a relative measure that accounts for inter-individual variation in clavicular length. The length before fracture was calculated by adding the

length of the affected clavicle to the amount of measured fracture overlap, as we did not have information of the length of the clavicle prior to fracture. The contralateral clavicle was not used as a reference, because of possible pre-existent clavicular asymmetry.[22,23] To calculate this relative shortening, the initial anteroposterior (AP) trauma radiograph was used as well as an AP panorama radiograph comprising both clavicles that was acquired during the study visit (i.e. after consolidation) of all participants. It was ensured that the participants were standing straight and that the spinous processes of the thoracic vertebrae were projected in the midline, to eliminate thoracic rotation and clavicular protraction on the panorama radiograph. On both radiographs, the length of the affected clavicle was digitally measured as the straight line between the mid-medial border of the sternoclavicular (SC-) joint and the most lateral edge of the acromioclavicular (AC-) joint. Overlap of fracture fragments was measured on the trauma radiograph as the axial distance between the cortical fragments ends. As a measure for relative shortening, the Clavicle Shortening Index after fracture consolidation (CSI_{cons}) was calculated:

$$CSI_{cons} = 1 - \frac{Lpanorama}{(Ltrauma + fracture\ overlap)} \tag{Eq. 1}$$

In which L_{trauma} is the length of the affected clavicle after trauma, *Fracture overlap* is the overlap between the fracture fragments measured on the trauma radiograph, and $L_{panorama}$ is the length of the consolidated affected clavicle. This equation is an adjustment of the equation proposed by Smekal et al.[24]

Statistics

Scapular orientation in rest and maximum humerus angles of the affected shoulders were compared to those of the patients' control shoulder using paired t-tests. The association of clavicular shortening (CSI_{cons}) on scapular orientation and maximum humerus angles was assessed using linear regression analysis. If a statistically significant association between CSI_{cons} and scapular orientation and maximum humerus angles was found, an interaction term with arm dominance was tested.

Scapular orientations during AB and AF were plotted for the complete range of motion. In the analysis of scapular orientations during AB and AF, measurements above 90 degrees of humerus elevation were not included, because above 90

degrees the accuracy of FoB acromion sensor recording is known to be reduced due to skin and soft tissue motion artifacts.[25] The association between humerus elevation and scapular orientations was analyzed using linear mixed models with a random effect per subject to account for repeated measures. To study whether the association between humerus elevation angle and scapular orientations was non-linear, a squared term for humerus elevation angle was tested and included in the model if statistically significant. To analyze whether scapular orientations during AB and AF differed between the affected and contralateral shoulder, side (control vs. affected) was also included as independent variable in the mixed models. To test whether the difference in scapular orientation between the affected and contralateral shoulders was constant during AB and AF, an interaction term between side and humerus elevation angle was tested in each model and included if statistically significant. To illustrate the effect of humerus elevation angle on scapular orientations during AB and AF, the model's predicted values for scapular orientations are plotted for affected and control shoulders. Also, predicted values for scapular orientations at 15, 30, 60 and 90 degrees of humerus elevation for affected and contralateral shoulders are tabulated for illustrative purposes. To assess the associations of clavicular shortening on scapular orientation of the affected shoulder during AB and AF, similar linear mixed models were fitted for only the affected shoulders, with CSI_{cons} as independent variable.

Arm strength was compared between affected and contralateral arms using paired t-tests. Linear regression analyses were performed to estimate the influence of CSI_{cons} on AB and AF strength.

All statistical analyses were performed with SPSS version 20.0 (Statistical Package for Social Sciences Inc, Chicago, IL). P-values <0.05 were considered statistically significant.

Ethics and registration

Approval for this exploratory study was obtained from the Medical Ethics Review Committee of the Leiden University Medical Center, the Netherlands. Each participant provided written informed consent. The study was registered in the Dutch Trial Registry (NTR3167) as an observational study and was conducted between December 2011 and April 2012. The study is reported according to the STROBE Statement for observational studies.[26]

RESULTS

32 subjects with a history of a midshaft clavicular fracture, (27 males, median age 31 (21-62) years) participated in the study (Table 1). 30 participants were right-handed and in 15, the consolidated clavicular fracture was on the dominant side. Mean clavicular shortening after consolidation was 25 mm (SD 16) and mean CSI_{cons} was 0.13 (SD 0.08). For 1 patient the CSI_{cons} could not be calculated, because the trauma radiograph had not been calibrated.

Scapular orientation in rest position

In rest position there was more scapula protraction in affected shoulders (mean difference 4.4 degrees; p=0.05; Table 2). No statistically significant effect of CSI_{cons} on the rest position of the scapula was found (regression coefficients for protraction: 0.11, lateral rotation: 0.07, and backward tilt: -0.1; all p>0.10).

Maximum humerus angles

Maximum humerus angles during AB, AF, RF, internal and external rotation were similar between affected and control shoulders (Table 2). No statistically significant effect of CSI_{cons} on the differences in maximum humerus angles was found (regression coefficients for AB: 0.01, AF: 0.07, RF: -0.07, internal rotation: -0.05, and external rotation: -0.1; all p>0.10).

Scapular orientations during abduction and anteflexion

The raw values for measurements of scapular orientations during AB and AF were plotted against humerus elevation angle in Figures 3A and 3B.

During AB, overall scapula protraction decreased by 1.8 degrees per 10 degrees increase in humerus angle. Over the studied range of humerus elevation (0-90 degrees), the difference in scapula protraction between the affected and contralateral shoulders was constant (4.4 degrees) (Figure 4; Table 3). Scapula lateral rotation increased exponentially during AB for both affected and control shoulders. Scapula lateral rotation of the affected shoulder was 2.4 degrees higher than that of the contralateral shoulder over the complete range of humerus elevation angles. Scapula backward tilt increased linearly during AB and was -1.9

**Table 1**   Demographic characteristics of the 32 participants.

Parameter		Total n=32	Male n=27	Female n=5
Age in years, median (range)				
		31 (21-62)	36 (21-62)	27 (25-31)
Side of fracture, n				
	Left	16	14	2
	Right	16	13	3
Dominant side affected, n				
	Yes	15	12	3
	No	17	15	2
Shortening after consolidation, mm ± SD		24.8 ± 16.2	26.3 ± 15.5	15.8 ± 18.7
Clavicle Shortening Index, mean ± SD		0.13 ± 0.08	0.14 ± 0.07	0.09 ± 0.11
Trauma mechanism, n				
	Bicycle	15	12	3
	Traffic (motorized vehicles)	6	5	1
	Sports injury	7	6	1
	Other	4	4	0
Occupation, n				
	Manual worker	12	10	2
	Office work	19	16	3
	Unemployed	1	1	0
Current complaint, n				
	None	13	11	2
	Crepitation	4	4	0
	Irritation/weary feeling	13	10	3
	Pain	2	2	0

Table 2 Differences between affected and contralateral (control) arms for scapular orientation in rest position and for maximum humerus angles.

Task	Affected		Control		Affected vs. Control		
	Mean	SD	Mean	SD	Mean diff	95%-CI	p-value
Scapular orientation in rest position (degrees)							
Protraction	27.9	9.6	23.5	6.9	4.4	0.0 – 8.9	0.05
Lateral rotation	3.4	5.0	1.8	6.3	1.6	-0.9 – 4.1	0.21
Backward tilt	-12.2	6.4	-10.7	5.3	-1.6	-3.5 – 0.4	0.11
Maximum humerus angle (degrees)							
Abduction	151.3	11.9	150.3	11.0	1.0	-1.8 – 3.8	0.48
Anteflexion	146.9	10.7	144.9	9.5	2.1	-0.5 – 4.6	0.11
Retroflexion	61.2	9.8	60.3	8.9	1.0	-1.3 – 3.3	0.40
Internal rotation	53.7	16.5	52.8	16.8	0.9	-3.7 – 5.5	0.70
External rotation	70.3	11.7	72.4	10.6	-2.1	-6.3 – 2.0	0.31

degrees lower for the affected shoulders with a systematic increase of 2.2 degrees. The difference between the affected and contralateral shoulders increased with 0.4 degrees per 10 degrees increasing humerus elevation angle (Figure 4; Table 3). No statistically significant effects were found for CSI_{cons} on the affected scapular movements per 10 degrees of humerus elevation for protraction (0.4 degrees), lateral rotation (-2.4 degrees), and backward tilt (-0.6 degrees).

During AF, scapula protraction increased hyperbolic (Table 3; Figure 4). Up to an angle of 90 degrees humerus elevation, protraction of the affected shoulders was constantly 3.8 degrees higher compared to the contralateral side. Scapula lateral rotation increased linearly during AF and was higher for the affected shoulders. The difference in scapula lateral rotation between the affected and contralateral shoulders increased with 0.3 degrees per 10 degrees increasing humerus elevation angle during AF. Scapula backward tilt increased linearly during AF. In the same way as during AB, backward tilt during AF was lower for the
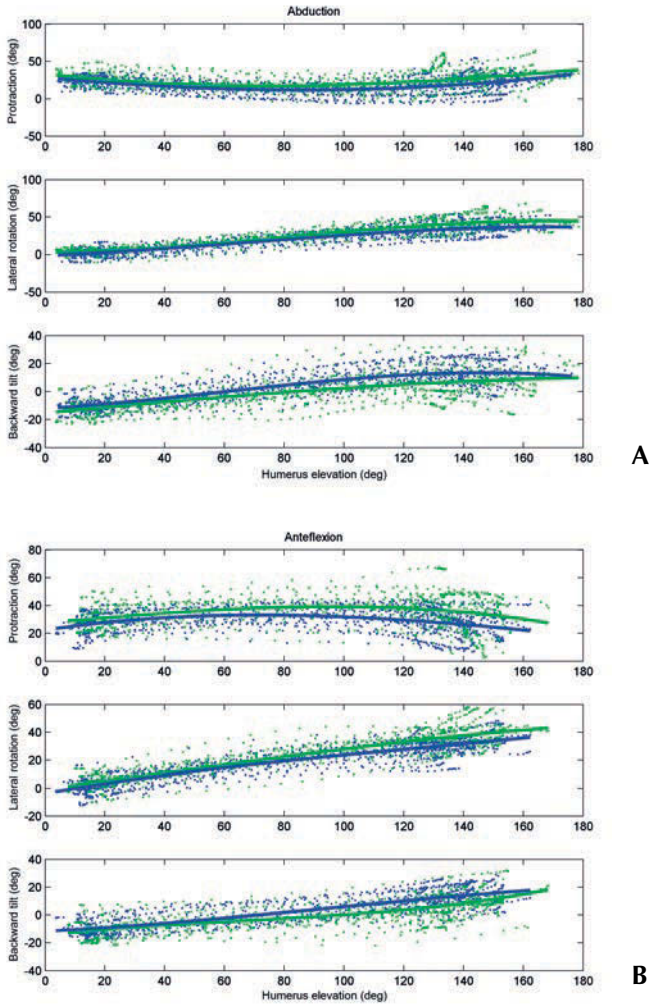
Figure 3   Scapular orientation during active arm abduction (A) and anteflexion (B) in affected
shoulders (green lines) and contralateral shoulders (blue lines).*
*Values above 90 degrees were not included in analysis because of possible inaccuracy.
Overall, affected shoulders have more scapula protraction, more lateral rotation and less
backward tilt compared to the contralateral control shoulders.
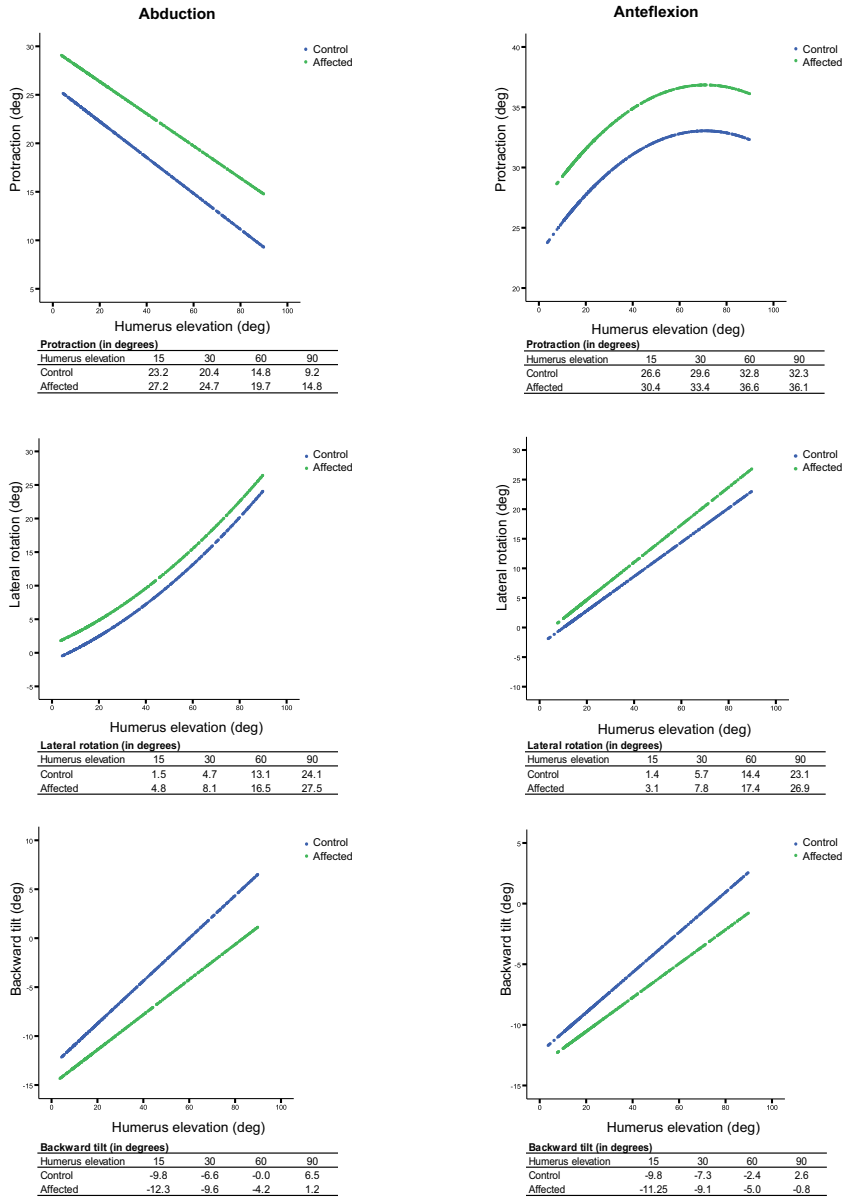
Figure 4 Estimated outcomes of the mixed model analyses on scapular orientations during abduction and anteflexion in affected and control shoulders.

Table 3   Outcomes of linear mixed model analyses on scapular orientations during abduction and anteflexion.

	Abduction			Anteflexion		
	Mean estimate	p-value	95%-CI	Mean estimate	p-value	95%-CI
Protraction						
Affected side	4.4	<0.0001	3.6 - 5.2	3.8	<0.0001	3.1 - 4.5
Humerus angle (per 10°)	-1.8	<0.0001	-1.9 - -1.6	2.9	<0.0001	2.1 – 3.7
Humerus angle squared (per 10°)	N/A	-	-	-0.02	<0.0001	-0.02 - -0.01
Affected side x humerus angle (per 10°)	N/A	-	-	N/A	-	-
Lateral rotation						
Affected side	2.4	<0.0001	2.0 - 2.8	1.3	<0.0001	0.6 - 1.9
Humerus angle (per 10°)	1.5	<0.0001	1.1 - 2.0	2.9	<0.0001	2.8 - 3.0
Humerus angle squared (per 10°)	0.01	<0.0001	0.01 – 0.02	N/A	-	-
Affected side x humerus angle (per 10°)	N/A	-	-	0.3	0.001	0.1 - 0.4
Backward Tilt						
Affected side	-1.9	<0.0001	-2.6 - -1.2	-1.0	0.001	-1.7 - -0.4
Humerus angle (per 10°)	2.2	<0.0001	2.1 - 2.3	1.7	<0.0001	1.5 - 1.8
Humerus angle squared (per 10°)	N/A	-	-	N/A	-	-
Affected side x humerus angle (per 10°)	-0.4	<0.0001	-0.5 - -0.2	-0.3	0.001	-0.4 - -0.1

affected shoulders and the difference increased with 0.3 degrees per 10 degrees increasing humerus elevation angle (Table 3; Figure 4). No statistically significant effect of CSI_{cons} on the affected scapular movements per 10 degrees of humerus elevation was found for protraction (-1.7 degrees), lateral rotation (-2.6 degrees), and backward tilt (-0.4 degrees).

Clinical outcome

19/32 included participants reported irritation, weary feeling and pain of the affected shoulder, mostly during prolonged activity of the shoulder (Table 1). None of the participants was under treatment for these complaints.

No statistically significant systematic differences in arm strength between control and affected shoulders were found for adduction (mean difference 7.2N; 95%-CI: -3.5-18), AB (mean difference -0.10N; 95%-CI: -8.8-8.6), AF (mean difference 9.6N; CI: -3.1-22), RF (mean difference 1.6N; CI: -6.7-9.8), external rotation (mean difference 2.0N; CI: -3.2-7.3) and internal rotation (mean difference 5.1N; -0.8-11.1). There was no association of CSI_{cons} with arm strength for all shoulder movements (adduction beta -1.29, p=0.07; AB beta -0.47, p=0.4; AF beta 0.59, p=0.5; RF beta -0.08, p=0.9; external rotation beta 0.08; p=0.8; internal rotation beta 0.37, p=0.3).

The mean Constant-Murley score was 96 points (SD 5.3). All participants scored in the normal range for controls of the same sex and age.[27] The DASH outcome measure had an overall score of 5.2 (SD 6.3), which is low compared to the normative values of 10 (SD 14.7).[21] Since all participants scored in range of normal values for the subjective and objective scores additional analysis was not found to be relevant.

Discussion

In this study we observed more scapular protraction in rest for affected arms, elevated scapula protraction and lateral rotation, and reduced backward tilt during motion. Clavicular shortening was not related to scapula rotation or to maximum humerus angles and strength. Clinical outcomes for the affected arms were similar to those of the control arms and not affected by clavicular shortening.

To our knowledge, this is the first study to assess changes in scapular orientations during active motion after consolidation of clavicular fractures and in relation to clavicular shortening. A few studies have been conducted to examine the kinematics of the scapula after clavicular fracture compared to the contralateral shoulder by means of computed tomography (CT),[11,14] cadaveric dissection[13,28,29] and computational models of shortened clavicles.[30] These studies all involved static or passive anatomic measurements and smaller numbers of patients. In our study, participants actively moved their arms symmetrically as instructed, which provided a more fluent motion of the humerus combined with scapular orientations instead of static measurements.

For scapular orientation in rest, only an increased protraction of the scapula on the affected shoulder could be demonstrated, which was not related to clavicular shortening. This increased protraction was also reported in other studies.[11,13,14] The more profound protraction may explain some of the subjective shoulder complaints reported by some of the participants, although this could not be objectified by a subjective or objective reduction of arm strength, range of motion or in the outcomes of the DASH and Constant-Murley score. It is questionable whether the difference we found between affected and control shoulders is clinically relevant. With an 95%-CI of 0.0–8.9 between affected and control arms, this 4.4 degrees difference seems to lay in the range of normal intra-individual variation.[31] Also, the maximum humerus angles were not influenced by the extent of clavicular shortening. These results are in concordance with several other studies testing range of motion after midshaft fractures of the clavicle.[13,15,32]

In healthy subjects, 3D scapulohumeral movement during arm elevation leads to increased protraction,[18,31] decreased lateral rotation, and increased

backward tilting of the scapula.[33] In concordance with the findings of 2 other studies[13,29] we found more protraction, more lateral rotation and less backward tilt of the scapula in affected shoulders. We found no association between clavicular shortening and scapulohumeral movements, which is in contrast with the findings of Matsumura et al. (2010). Who found that during elevation of the humerus backward tilt decreased and protraction increased significantly, in case of 10% or more of clavicular shortening. However, his data was acquired in cadavers with manually created fractures, in which active motion is difficult to reproduce and pain is irrelevant. Pain could lead to coordinative dysfunction of the scapula and in severe cases to scapula dyskinesia, which would negatively influence scapular orientations. This cannot be evaluated in cadaveric studies. In our study population pain was not a limitation for subjective or objective functional outcome of the shoulder, although over half of the participants complained of some irritation, pain or weary feeling in the shoulder during prolonged activities when asked. As another explanation for the structural changes, one could speculate that changed axial rotation of the clavicle after mal-union and not clavicular shortening could have caused the altered 3D scapular orientations.

Changed muscular balance and altered kinematics of the closed chain mechanism of the shoulder may lead to a decrease in arm strength, especially in anteflexion, adduction and internal rotation.[11,32] In previous studies an association between shortening and clinical outcome was demonstrated if clavicular shortening was more than 15 mm.[1,5,6,11,34] In contrast to these studies, we found no evidence that the affected arms had less strength than the contralateral arms, or that the amount of shortening or altered scapular orientations influenced strength. Also, both Constant-Murley and DASH scores were excellent for the affected arms. These results are supported by the findings of other studies.[7-10] The lack of endurance and rapid fatigability was however not tested in our participants.

Concerning the limitations of our study, selection bias may have occurred because not all invited patients were willing to participate. The most frequent reason for non-participation was that candidates were not willing to invest time to participate in research. 4 of the 74 invited candidates had moved and were lost to follow-up, 1 developed non-union and 1 candidate was operated in another

hospital. Since the FoB required static length of the clavicles to calculate the different angles, only former patients with a healed clavicular fracture could participate in our study. However, we do think that the participant group is a good representation of the total field of midshaft clavicular fracture patients at our hospitals, as all patients presenting with a midshaft clavicular fracture at the Emergency Department received primarily non-operative treatment in that period.

For all comparisons in our study, the unaffected shoulder of the participants served as a control, because we assumed that the scapular orientations of the control shoulder had remained unchanged after the contralateral clavicular fracture. One could speculate that the position of control shoulder may have altered also, due to the changed position of the affected side. This is known to happen in unilateral diseases such as stroke patients with hemiplegia.[35]

A limitation to our data analysis was that we could not obtain data of the scapula rotations achieved above 90 degrees of anteflexion and abduction. This was due to potential errors in position of the acromion sensor caused by skin and soft tissue motion. Therefore our conclusion can only be sustained for arm movements up to 90 degrees. More research is needed to assess this aspect of scapular orientation and possible functional limitations during overhead elevation (above 90 degrees).

In conclusion, midshaft clavicular fractures tend to affect the scapulohumeral rhythm for arm movements below 90 degrees compared to the unaffected sides, but these changes are small, do not seem to influence functional outcome of the shoulder and do not seem to be related to the amount of clavicular shortening. Therefore, it seems less important than previously assumed to reacquire the initial clavicle length for good functional outcome. On account of the clinically irrelevant changed scapulohumeral rhythm below 90 degrees after clavicular shortening and no significant differences in functional outcome compared to the unaffected shoulders, we cannot support the current tendency towards more routinely operative reduction and fixation of all shortened midshaft clavicular fractures based on these arguments. This conclusion does not include patients with an increased risk of non-union or those with a wish for early mobilization of the shoulder.

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PART V

GENERAL DISCUSSION AND SUMMARY

CHAPTER 10

General discussion

GENERAL DISCUSSION

Until the 1960s the treatment of clavicular fractures was primarily non-operative but the optimal treatment strategy has since then become a subject of debate. Fractures of the lateral or distal end of the clavicle are known to require operative treatment in most cases due to instability of the ligamental complex and high percentage of non-union (>20%).[1,2] For midshaft clavicular fractures it was thought that the percentage of non-union was low (<1%) and that the fracture did not require surgical intervention.[1,3] Some large cohort studies published in the last two decades showed non-union rates of 5-15% after conservative treatment, which was much higher than previously assumed.[4-7] Improved surgical techniques, new materials and the use of routine prophylactic antibiotics have led to lower post-operative complication rates. Since then, the preference for operative management for midshaft clavicular fractures has increased considerably. This is reflected in the annual number of published papers on this topic in MEDLINE and other databases accessed by PubMed, which increased from 97 in 2007 to 174 in 2013.

Another reason for operative treatment that is often mentioned is the supposed change in the anatomic relation of the shoulder after fracture of the clavicle. Clavicular shortening is considered to have a negative influence on the functional outcome of the shoulder[4,8-10] and arm and may cause a deviating position of the scapula, although the opinions on this subject may differ. To make decisions on treatment of clavicular fractures, a number of fracture characteristics that may affect outcome need to be assessed during diagnostic work-up. The diagnosis of a clavicular fracture is based on the history of the patient and physical examination, and is confirmed with radiographic imaging. The way in which the fractures are presented and assessed on the radiographs and the required number of radiographs from different angles is topic of debate. Fracture characteristics such as comminution, displacement ad latum, and shortening seem to be important for prediction of the final outcome after treatment[11] and the radiographic presentation of these fracture characteristics should therefore be optimized. These are subject to discussion as well in the literature.

The aim of this thesis was to provide more insight in unsolved issues regarding clavicular fractures including the diagnostic work-up, biomechanical aspects of the

shoulder after a midshaft clavicular fracture and treatment of clavicular fractures. The results of the combined studies may be used to optimize the diagnostic work-up and treatment and, consequently, the clinical outcome of clavicular fractures.

Radiography of clavicular fractures

To make valid decisions on clavicular treatment, several aspects of the fracture such as comminution, displacement ad latum and clavicular shortening should be evaluated. Of these, displacement and comminution are incorporated in the Robinson classification to differentiate between fracture subtypes. The Robinson classification is often used in studies to describe the fracture type of midshaft clavicular fractures, because fracture subtype relates to treatment outcome.[11] However, the way these fracture characteristics are presented on radiographs may depend on the angulation and direction of the x-ray beam. At the start of this thesis it was standard procedure in our hospital to perform only an anteroposterior (AP) radiograph for diagnosing clavicular fractures instead of an AP radiograph in combination with the 30-degree caudocephalad radiograph, which was more common in other hospitals. This inspired us to study the additional value of the 30-degree caudocephalad radiograph on the classification of clavicular fractures according to Robinson and on treatment decisions.

The results of our nation-wide online survey confirmed that the inter- and intra-observer agreement on the Robinson classification of displaced and comminuted midshaft clavicular fractures was better when based on two-plane radiography (AP and 30-degree) instead of on one view (only AP radiograph) for both surgeons and radiologists. The overall agreement was found to be moderate. Radiologists were found to classify these fractures more reliably than surgeons with a substantial agreement for the two-plane radiography. It is therefore advisable to consult a radiologist with expertise in skeletal imaging for fracture classification in complex cases or to have the fracture classification routinely included in the radiology reports on midshaft clavicular fractures. In our studies we did not compare the Robinson classification to other classifications, but the results of our study show that the Robinson classification can reliably be used with two-plane radiography.

Choice of treatment was affected by the way of presentation as well: in half of the cases surgeons chose non-operative treatment after displaying the AP radiograph,

and in half of these cases the surgeons changed their preference to operative treatment after seeing the accessory 30-degree caudocephalad radiograph of the same fracture. This change of opinion was probably induced by the comminution, displacement and shortening seen on the 30-degree caudocephalad radiograph, which was less clearly visible on the AP radiograph alone. The fact that the addition of one radiograph has a considerable impact on treatment decisions emphasizes the importance of projecting the fracture in different angles. The protocol for judging clavicular fractures on two-view radiographs is now standard practice in our hospital. In other studies the increased preference for operative treatment after viewing one or more additional radiographs was found as well,[12-14] but the recommended number of radiographs and angulation of the x-ray beam differ in literature. We recommend to evaluate midshaft clavicular fractures on at least two angles, as in for example an AP radiograph in combination with an 30-degree caudocephalad radiograph. The value of more than two radiographs is unclear and more radiographs increase the radiation load directed at the thorax of the patient. This extra burden would probably not outweigh any additional but limited advantages.

Measurement of clavicular length and shortening, and their influence on scapulohumeral rhythm

Comminution and displacement ad latum, as well as severe clavicular shortening are increasingly considered as an indication for operative treatment of midshaft clavicular fractures, because of their supposed relation with poor functional outcome[4,8-10] and non-union[15] after non-operative treatment. These assumptions have, however, not been invariably confirmed.[16-19] A possible explanation for the conflicting study results might be that in these studies clavicular shortening was not measured in a uniform and correct manner. The determination of clavicular length on radiographs is complicated in several ways. First, the length of the affected clavicle is often compared to the contralateral side, although it has been shown that the right and left clavicle of healthy individuals may differ in length.[20,21] Second, the angle in which the radiograph is taken may introduce both a projection and a magnification error, especially in panorama radiographs. In most cases, the x-ray beam cannot be exactly directed towards the clavicle in a perpendicular line because of the S-shape of the clavicle, which can cause the projection to be out of

plane. Another explanation for the conflicting study results is that a certain amount of clavicular shortening will not have the same biomechanical effect on the shoulder in every person because clavicular length differs between individuals.

Asymmetry in clavicular length and the relative impact of shortening in relation to poor functional outcome has also been mentioned in other studies.[22-24] To bypass the possible pre-existing asymmetry of the clavicles in the research in this thesis, the Clavicle Shortening Index (*CSI*) was introduced in Chapter 3. In this study, the CSI was defined as the ratio of the absolute shortening (i.e., axial distance between the cortical fracture fragments ends) and the initial, pre-fracture length of the fractured clavicle, both measured on the AP (panorama) radiograph. The initial, pre-fracture length of the fractured clavicle is defined as the sum of the absolute shortening and the residual length of the clavicle after the fracture. Thus, the *CSI* is a proportional or relative measure for the amount of shortening of the fractured clavicle, and takes into account the inter-individual differences in clavicular lengths on the radiographs.

The results of length and shortening measurements on trauma AP radiographs and AP panorama radiographs after consolidation were compared between two observers. The measurements were highly reproducible, so the *CSI* was reproducible as well. To test the validity of these measurements, the data were also compared with length measurements of a three-dimensional (3D) motion tracking device in which magnification and projection effects are considered to be absent. Length was measured 3-dimensionally from acromioclavicular to sternoclavicular joint based on the coordinates of these bony landmarks. The length measurements performed with the 3D motion tracking device compared to the length measurements on radiography showed substantial differences. Several remarks regarding these results can be made. Theoretically the 3D length measurements are considered to reflect reality more closely, because the clavicles cannot be projected out of plane and therefore cannot cause any projection or magnification errors. However, the length measurements of this motion-tracking device cannot be indicated as the 'gold standard', because the device has not been developed and tested for this purpose. Also, absolute shortening and associated *CSI* cannot be defined with this device, because there are no predefined bony landmarks marking the beginning and end of the fracture fragments. Since neither method can be regarded as gold standard, it is not known if either of them represents the actual clavicular length. By using AP

panorama radiographs for our research there is a high probability that projection and/or magnification errors were introduced. However, we did not find any systematic errors indicating a projection or magnification error comparing it to the 3D length measurements. The 3D measurements would preferably be used in practice for length measurements of the clavicle on theoretical grounds. Still, this would be a time consuming procedure for both patient as physician and in acute stage painful for the patients.

From a biomechanical perspective, we demonstrated that a statistically significant but clinically irrelevant (<5 degrees) alteration in the protraction in rest position and in the scapulohumeral movement of the affected shoulder arises after non-operative treatment, compared to the contralateral shoulder. These findings were not related to the amount of proportional shortening as measured by the CSI, which is in contrast with previous findings.[25-27] The difference between those studies and our study is that the previous studies involved passive or static movements and absolute clavicular shortening measurements, whereas our study involved active movements and measurements of proportional shortening. Moreover, the subjects in our study did not report a decreased shoulder function measured by both the Constant-Murley scale and the DASH questionnaire, and no statistically significant differences in measured strength in Newton for the different muscle groups between the affected and control shoulder were found. Also, no statistical difference was found for the maximal humerus range of motion angles of both shoulders. These findings render the argument of changed biomechanical aspects after clavicular shortening to sanction operative treatment for every shortened midshaft clavicular fracture less valid.

In conclusion, the measurements of clavicular length and shortening are reproducible on AP panorama radiographs, but these probably do not reflect the actual length. On theoretical grounds, absolute shortening should not be used, because it does not account for inter-individual clavicular length differences. The *CSI* seems the most suitable measure to assess clavicular shortening using radiographs and can very well be used in future research to confirm or reject that operative treatment for shortened and displaced midshaft clavicular fractures leads to evidently better clinical outcomes compared to non-operative treatment. Before use in clinical practice, the relation between *CSI* and functional outcome should be

more deeply investigated on a larger scale so that a cut-off point for the *CSI* for deciding whether or not to operate can be determined.

Treatment

Unstable Neer type-II lateral clavicular fractures are generally operated upon, because the incidence of non-union and malunion after non-operative treatment is high (>20%).[1,2] Based on our review of the available literature, hook plate fixation should be avoided in these fractures because of the increased risk of major complications of this procedure compared to intramedullary nailing and suture anchoring. Intramedullary fixation seems preferable for type Neer-II lateral clavicular fractures. To confirm this conclusion more well-designed RCT's should be performed, because the quality of the included studies in the meta-analysis was low. However, to date no high-quality RCT's have been published that compare different types of operative treatment of lateral clavicular fractures, which makes it difficult to substantiate any choice of operative treatment.

For midshaft clavicular fractures there is less consensus on operative versus non-operative treatment. In 2007, a randomised controlled trial (RCT) was published comparing non-operative treatment and operative treatment with plate fixation for midshaft clavicular fractures.[28] The one-year results of this RCT showed a lower non- and mal-union rate as well as improved functional outcome in the plate fixation group compared to the non-operatively treated group.[28] However, some flaws in the enactment of this trial had occurred, such as the large, and possibly selective, drop-out in the non-operative group. Nevertheless this RCT initiated a worldwide debate on the treatment of midshaft clavicular fractures[29] and stimulated further research on treatment of these clavicular fractures.

The influence of this RCT was assessed retrospectively in two hospitals between 2006-2009. An increase in operative treatment of midshaft clavicular fractures was found in these hospitals over the years, which is consistent with the results of a register based study in Finland.[30] These results are expected to be representative for all hospitals in the Netherlands and were probably caused by the positive results of operative treatment in the Canadian RCT.[28]

When investigating patient-related factors such as gender, age and trauma mechanism on choice of treatment in our retrospective study, we found that with

increasing age the comminution and displacement of the fracture was more severe, independent of the trauma mechanism. This can be explained by the presence of osteoporotic bone in the elderly: less force is needed to sustain a comminuted fracture. The trauma mechanism was not associated with the fracture type after correction for age. On the other hand, fracture type itself was related to the choice of primary treatment: more displaced and shortened fractures received operative treatment. Our analysis of these data showed that shortening was the main reason for operative treatment and not displacement. This was also seen in other studies, even though no formal guidelines for treatment were present.[4,7,31] Another motive for operative treatment was the clear wish of these patients as reported in the medical registries for early mobilisation and return to work. This coincides with the generally perceived changes in patient expectations: nowadays, patients are more outspoken and expect a rapid return to pain-free function following a fracture.[28]

Surgeon-related factors on the current choice of treatment for midshaft clavicular fractures were assessed amongst practitioners in the nation-wide survey. When looking at the current opinion of the Dutch trauma and orthopaedic surgeons, the choice of treatment was not straightforward. In half of the cases operative treatment was chosen. Treatment choice depended on the professional background of the respondent: trauma fellows opted more often for operative treatment than surgical residents. The severity of the fracture was of most interest for choice of treatment, because displaced midshaft clavicular fractures received 3 times more often non-operative treatment than comminuted fractures. If the respondents opted for operative treatment locking plate fixation was more often preferred for comminuted fractures and intramedullary fixation for displaced fractures compared to the other available methods (1.5 and 4 times). These differences are illustrative for the different opinions of the practitioners on the preferred treatment for midshaft clavicular fractures. The disagreement of the surgeons on operative or non-operative treatment or between the different surgical techniques when presented with a case, underlines the need for uniform and evidence-based treatment guidelines. Within these guidelines there should be room for the needs and wishes of the patient, which is in line with the general wish for shared decision making in clinical practice. With changing life styles, availability of medical information on the internet and patients who want to be more actively involved in their treatment, the traditional physician-

patient has changed and shared decision making has been added to the already complex variety of arguments that influence the choice of treatment.

Overview of current research on treatment of midshaft clavicular fractures

To provide more high-quality evidence on treatment of midshaft clavicular fractures, a large multicenter RCT (the "Sleutel-TRIAL"), of which the study protocol is described in Chapter 8, was started in the Netherlands. This RCT started including patients in the first half of 2010 and will be finished at the end of 2015 after completing a two year follow-up of all included patients. Since the start of the Sleutel-TRIAL, several RCT's and meta-analyses[32-39] have been published in which midshaft clavicular fractures union rates and functional outcome for conservative and surgical treatment are compared. Most systematic reviews and meta-analyses recommend, to some extent, operative treatment because of the low non-union rate and a more rapid recovery of function compared to non-operative treatment.[32-36,38,39]

The number needed to treat in order to prevent one case of non-union or symptomatic mal-union is 4.6 and to prevent one case of non-union alone 7.6.[35] Although these numbers are acceptable, it is unclear what the effect of operative treatment is on long-term function. In the two most recently published high-level RCT's on acute displaced midshaft clavicular fractures there again was no convincing evidence to prove that operative treatment with plate fixation is preferred over non-operative treatment.[37,38] Virtanen *et al.* found in their RCT no differences in functional outcome after one year, although the non-operatively treated group showed a higher percentage of non-union.[38] Robinson *et al.* published a RCT of 200 patients that does not support routinely primary operative treatment of displaced midshaft clavicular fractures, because of the risk of implant-related complications and the costs.[37] The quality of earlier RCT's was not optimal.[34-36] Also, the data from these RCT's cannot be compared directly because different definitions for non-union and complications were used.[36]

Despite the general tendency towards operative treatment of midshaft clavicular fractures, it is important to emphasize that the risk to develop adverse events such as infection and implant failure is considerable, whereas the risk of refracture or neurologic symptoms is twice as high as in non-operative treatment.[33] Consequently, the risks and consequences of non-union after non-operative treatment and those of

implant-related complications after operative treatment should be well discussed with the patient. Furthermore, the cost-effectiveness of operative and non-operative treatment should be should be taken into account. A cost-analysis of multiple RCT's comparing non-operative treatment versus plate fixation showed that non-operative treatment is the most cost-effective approach in the USA, despite the fact that delayed surgery may be necessary to treat mal- or non-union. In this analysis, loss of productivity was accounted for.[40] According to this cost-analysis study we should not even consider surgery as primary treatment. It is however unclear whether this conclusion holds for the Netherlands.

As yet, the available evidence from the published RCT's is insufficient to conclude with certainty which treatment is to be preferred in order to optimize relevant clinical outcomes after displaced midshaft clavicular fractures.[34-36] The question whether all patients with a displaced and comminuted clavicular fracture should be operated upon to prevent non-union or only those patients who develop (symptomatic) non-union, is still unanswered. In the near future, we expect that the results of the Sleutel-TRIAL will substantially contribute to define evidence-based guidelines on optimal treatment for displaced midshaft clavicular fractures.

Clinical consequences of this thesis

The current literature shows that the best treatment for midshaft clavicular fractures is not unequivocal. The research described in this thesis adds more knowledge to the process of substantiation of a treatment decision. Fracture characteristics are best seen and scored using two-view radiography. We advise to use the anteroposterior radiograph in combination with the 30-degree caudocephalad radiograph. The intra- and inter-observer reliability for the fracture classification on these radiographs was sufficient, but in complex cases it is advised to consult a radiologist or to routinely include this classification in the radiology reports. Clavicular shortening is often used as an argument to opt for operative treatment. Nonetheless we found no biomechanical effects of clavicular shortening on the shoulder or scapula kinematics that led to poor functional outcome. Clavicular shortening alone does therefor not justify the choice of operative treatment. If shortening is measured on the radiographs, we recommend to use a proportional shortening, based on the former length of the fractured clavicle. Absolute measurements performed on radiographs

should be used with caution as they may not reflect the actual length. Also, we found that there is no consensus amongst the orthopaedic and trauma surgeons on preferred treatment or type of surgical fixation. To reduce treatment variation between surgeons and hospitals, evidence-based treatment guidelines should be developed. These guidelines should consider clinical outcome as well as patient-related factors, such as age, occupation, sport activities and the wish of the patient.

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CHAPTER 11

Summary

Summary

With an overall incidence of 29 to 80 per 100 000 people a year, clavicular fractures are among the most common fractures of the shoulder. In about 70% of these fractures, the fracture is located in the midshaft of the clavicle, whereas about 30% involves the lateral part of the clavicle. In rare cases the fracture is located in the medial part of the clavicle. A fracture in one of these parts has consequences for the position of the clavicle in relation to the scapula, humerus and the adherent muscles. Displacement or comminution of the fracture fragments and the subsequent shortening may cause a change in the position of the clavicle. These fracture characteristics may not only lead to a shortened clavicle after consolidation, but also to mal-union or non-union and are therefore important in clinical decision making. Shortening, mal-union, or non-union of the clavicle may possibly lead to poor functional outcome of the shoulder and arm.

This thesis consists of three parts. The first part concerns diagnostic aspects of clavicle fractures which are described in chapters 2, 3 and 4. The second part describes studies on treatment and clinical outcomes in chapters 5, 6, 7 and 8. The third part, chapter 9, focuses on the complex biomechanics of the shoulder after a displaced midshaft clavicular fracture. Chapter 10 holds the general discussion of this thesis.

Diagnostic aspects

Chapter 2 describes an online survey amongst 102 surgeons and 52 radiologists to evaluate the reliability of the Robinson classification of displaced comminuted midshaft clavicular fractures. For both surgeons and radiologists the inter-observer and intra-observer agreement for the Robinson classification significantly improved after showing the 30-degree caudocephalad radiograph in addition to the anteroposterior (AP) radiograph. Also, radiologists had a significantly higher inter- and intra-observer agreement than the surgeons after judging both radiographs. Therefore, two-plane radiography should be used for the classification of comminuted displaced midshaft clavicular fractures. Secondly, it is advisable to routinely incorporate the Robinson classification in the radiology reports.

Shortening of the clavicle is a parameter that is used in clinical practice to decide on type of treatment. Clavicles with severe shortening are believed to require operative treatment, because it is supposed to lead to potentially unsatisfactory functional outcome. Shortening is measured on AP (panorama) radiographs. These measurements are likely to be inaccurate however, due to out of plane projection. In **chapter 3** clavicular length measurements with planar roentgen photogrammetry are compared to measurements performed with a spatial electromagnetic digitizer. Two observers performed length and shortening measurements of the clavicle on trauma AP radiographs and on AP panorama radiographs of 32 patients after consolidation. The inter-observer agreement on clavicular length and shortening on radiographs was almost perfect (Intra-class correlation coefficient [ICC]>0.90). The Bland-Altman plot comparing measurements of length on AP panorama radiographs and with spatial digitization showed wide limits of agreement, indicating that the clavicular length measured on the radiographs may be up to 37 mm longer or 34 mm shorter than measured with spatial digitization. Because clavicular length measurements on radiography may not reflect the actual length, we propose proportional shortening as an alternative, more appropriate measure to quantify clavicular shortening. This parameter also accounts for the inter-individual clavicular length variation and was named Clavicle Shortening Index (*CSI*).

In **chapter 4** the value of the additional 30-degree caudocephalad radiograph for choice of treatment of displaced and comminuted midshaft clavicular fractures is studied based on the survey described in chapter 2. The 102 surgeons who completed the survey decided on treatment based on the provided AP radiographs. Thereafter the additional 30-degree caudocephalad radiograph was shown, and the surgeons again decided on treatment. Choice of treatment was changed in 24% of cases (95%-CI: 20.5 – 27.8) after the 30-degree caudocephalad radiograph was displayed, mostly from non-operative to operative treatment. The results confirm earlier findings that two-plane radiography for clavicular fractures treatment decisions should be used in the standard work-up of clavicular fractures.

Clinical outcome

Distal clavicular fractures can be divided in several types according to the Neer classification. Neer type-II fractures are unstable fractures: the clavicle has become separated from the underlying coraco-clavicular ligament complex, but the most distal end of the clavicle and the acromioclavicular joint are left intact. Operative management of Neer type-II distal clavicular fractures is standard because of the high non-union rate (> 20%). **Chapter 5** describes a meta-analysis of the available literature on surgical techniques for these fractures. The meta-analysis included 21 studies, of which 8 were prospective and 13 retrospective cohort studies with in total 350 patients. The included studies described four surgical techniques: hook-plate fixation, plate fixation, intramedullary fixation (pins), and suture anchoring. Union was achieved in 98% of the patients. The time to union was on average 10 weeks longer with hook-plate fixation than with pin fixation (p=0.02). No statistically significant differences in functional outcome were found between the different surgical techniques. However, hook-plate fixation was associated with an 11-fold increased risk for major complications compared to intramedullary fixation and a 24-fold increased risk compared to suture anchoring. In the interest of the patient with a Neer type-II distal clavicular fracture, a fixation procedure with a low complication risk is preferable, such as intramedullary fixation or plate fixation.

In **chapter 6** the choice of treatment for midshaft clavicular fractures is discussed based on the results of the online survey among Dutch trauma and orthopaedic surgeons. There was no consensus between the surgeons on choice of treatment. The 102 respondents preferred non-operative treatment more often for displaced fractures than for comminuted fractures (Odds Ratio [OR] 3.24, 95%-CI: 2.55- 4.12). Locking plate fixation was preferred over the other surgical modalities more often for comminuted than for displaced fractures (OR 1.50, 95%-CI: 1.17 – 1.91). The preferred type of treatment did not depend on the background of the respondents. This lack of consensus among professionals calls for evidence-based treatment guidelines.

Chapter 7 describes a retrospective study in which the influence of fracture type, trauma mechanism, age and sex on the primary treatment decisions in clinical practice was assessed. Older age correlated with more comminuted and displaced fractures. Extensive shortening (>20mm) was identified as the main clinical indication for primary surgery, whereas displacement and fracture classification seemed less relevant. Over time, operative treatment was increasingly favored from 5% in 2006 to 44% in 2009, which could not be explained by an increase of more complex fractures, nor by age-related or trauma mechanism-related factors.

In **chapter 8** the rationale and protocol of a prospective, multicentre randomised controlled trial is described in which patients with a displaced midshaft clavicular fracture are randomised between non-operative treatment with a sling and operative treatment with plate fixation and compared with respect to consolidation and functional outcome. The trial will provide level-1 evidence on optimal treatment for midshaft clavicular fractures, which combined with the results of similar trials, can be used for development of an evidence-based treatment guideline.

Biomechanics

One of the most intriguing questions in clavicular fracture research is if clavicular shortening after a midshaft fracture lead to unsatisfactory functional outcome due to changes in the closed-chain-mechanism of the shoulder. We assessed this question in **chapter 9**. In this study, 32 patients with a consolidated midshaft clavicular fracture 1 to 5 years prior to the study visit were seen in the outpatient clinic. We studied their scapular rotations in rest and during anteflexion and abduction of the arm, strength of both arms and maximum arm exertions. The *CSI* after consolidation in this patient group was 12.9% (SD 7.8). Scapula protraction was increased by 4.4 degrees (95%-CI: 0.0-8.9) in rest position in the affected shoulders. During abduction, more protraction (4.4 degrees; 95%-CI: 3.6-5.2), more lateral rotation (2.4 degrees; 95%-CI: 2.0-2.8) and less backward tilt (-1.9 degrees; 95%-CI: -2.9- -1.2) were found for the affected shoulders compared to the contralateral side. During anteflexion the scapula rotations for the affected shoulders were also increased for protraction (3.8 degrees; 95%-CI: 3.1-4.5) and lateral rotation (1.3 degrees; 95%-CI: 0.6-1.9), and decreased for backward tilt (-1.0 degrees; -1.7- -0.4).

Scapulohumeral kinematics were not associated with the extent of proportional clavicular shortening. Strength of affected and control shoulders did not differ within patients. We concluded from these results that although the scapulohumeral kinematics of the affected shoulder somewhat differed from those of the control shoulder, this did not lead to relevant functional outcome changes. Furthermore, these changed scapulohumeral kinematics did not relate to clavicular shortening.

Discussion

In **chapter 10** the results of the studies in this thesis are discussed and conclusions are drawn. The findings on diagnostic aspects underline the importance of fracture characteristics for classification and of two-view radiography for treatment decisions for clavicular fractures. Since the accuracy of the length and shortening measurements performed on radiographs is questionable and because there is inter- and intra-individual length variation of the clavicle, we propose to use of the Clavicular Shortening Index (*CSI*), which reflects the proportional shortening relative to the initial length of the fractured clavicle. Clavicular shortening is deemed the most important factor in deciding whether or not to operate, probably because it is assumed to be related to possible dysfunctional outcome. However, these assumptions were not substantiated in our study on biomechanics after consolidated conservatively treated fractures. The presence of a consolidated clavicular fracture did not lead to clinically relevant changes in the scapular kinematics and functional outcome. Clavicular shortening should therefore not be used as the only reason to justify operative treatment.

For both lateral and midshaft clavicular fractures more high-quality research is needed to determine optimal treatment. The risks of complications and non-union after treatment should be taken into account. Evidence-based treatment guidelines should be developed based on a concise classification system which includes the fracture characteristics. The future results of the Sleutel-TRIAL will most probably contribute to the development of these guidelines.

CHAPTER 12

Nederlandse samenvatting
(Dutch summary)

NEDERLANDSE SAMENVATTING (DUTCH SUMMARY)

Met een incidentie van 29 tot 80 per 100 000 mensen per jaar is de claviculafractuur één van de meest voorkomende fracturen van de schouder. In ongeveer 70% van de gevallen is de fractuur gelokaliseerd in de midschacht van de clavicula en een kleine 30% in het buitenste laterale gedeelte van de clavicula. In zeldzame gevallen bevindt de fractuur zich in het mediale deel bij het sternum. Een fractuur in ieder van deze delen heeft consequenties voor de positie van de clavicula ten opzichte van de scapula, humerus en de aanliggende spieren. Deze verandering van positie kan worden veroorzaakt door dislocatie of comminutie van de fractuurfragmenten en de daardoor veroorzaakte verkorting. Deze fractuurkarakteristieken kunnen echter niet alleen leiden tot verkorting van de clavicula na consolidatie, maar ook tot het getordeerd consolideren van de fractuurfragmenten (mal-union) of zelfs tot het niet consolideren van de fractuur (non-union), en zijn daarom van belang bij de behandelkeuze. Een verkorte, getordeerde of niet geconsolideerde clavicula kan mogelijk leiden tot functieverlies van de schouder en arm.

Dit proefschrift is opgedeeld in drie delen. Het eerste deel gaat over de diagnostische aspecten bij het beoordelen van een claviculafractuur (hoofdstuk 2 t/m 4). De klinische uitkomsten van de behandeling van claviculafracturen worden behandeld in het tweede deel van dit proefschrift (hoofdstuk 5 t/m 8). Het derde deel gaat in op de biomechanische aspecten van de schouder na een gedisloceerde midschacht claviculafractuur (hoofdstuk 9). In hoofdstuk 10 worden de resultaten van dit proefschrift bediscussieerd.

Diagnostische aspecten

Hoofdstuk 2 beschrijft een online vragenlijst waarin de betrouwbaarheid van de Robinson classificatie van midschacht claviculafracturen is bestudeerd door het achtereenvolgens tonen van een anteroposterieure (AP) en 30-graden röntgenopname van gedisloceerde comminutieve claviculafracturen. Aan dit onderzoek deden 102 chirurgen en 52 radiologen mee. De intra- en interbeoordelaar overeenstemming voor de Robinson classificatie nam significant toe na het tonen van de 30-graden opname ten opzichte van de AP opname. Daarnaast hadden de radiologen een significant hogere intra- en interbeoordelaar

overeenstemming dan de chirurgen na het beoordelen van beide opnamen. Het is daarom aan te bevelen om voor de classificatie van claviculafracturen altijd een AP en een 30-graden opname te maken. Tevens bevelen we aan om de Robinson classificatie standaard op te nemen in de radiologieverslagen.

Eén van de parameters die gebruikt wordt om een keuze voor behandeling te maken is de verkorting van de clavicula. Claviculafracturen met veel verkorting worden vaak geopereerd vanwege mogelijk slechte functionele uitkomsten. Deze verkorting wordt gemeten op AP (panorama) opnamen. Het is echter de vraag hoe accuraat deze radiologische metingen zijn. Deze onnauwkeurigheid kan veroorzaakt worden door projectiefouten doordat de röntgenstralen, vanwege de retractie en vorm van de clavicula, niet altijd loodrecht geprojecteerd worden op de clavicula. In **hoofdstuk 3** worden de radiologische metingen vergeleken met driedimensionale metingen. Twee onderzoekers hebben de lengte en verkorting van de clavicula van 32 patiënten na consolidatie gemeten op trauma AP opnamen en AP panorama opnamen. De overeenkomst tussen beide onderzoekers voor de metingen van lengte en verkorting op de opnamen was bijna perfect (Intra-class correlatie coëfficiënt [ICC]>0,90). Substantiële verschillen werden wel gevonden op de Bland-Altman plot tussen de lengtemetingen verricht op de panorama en de driedimensionale opnamen, waarbij de clavicula op de röntgenopnamen tot 37 mm langer of 34 mm korter werden gemeten dan met driedimensionale metingen. Het kan dus zijn dat deze metingen op de röntgenopnamen niet de werkelijke lengte van de clavicula weergeven. Het gebruik van proportionele verkorting is daarom aanbevolen als een alternatieve, meer accurate maat om de verkorting van de clavicula te meten. Tevens corrigeert deze methode voor inter-individuele variatie in clavicula lengte. Deze parameter werd de "Clavicular Shortening Index (*CSI*)" genoemd.

De toegevoegde waarde van de 30-graden caudocephale opname op de keuze van behandeling van gedisloceerde en comminutieve midschacht claviculafracturen wordt besproken in **hoofdstuk 4**. Deze studie is gebaseerd op de vragenlijsten besproken in hoofdstuk 2. De 102 chirurgen die de vragenlijst hadden ingevuld, baseerden eerst hun behandelkeuze op de AP opnamen. Vervolgens werd de bijbehorende 30-graden opname getoond waarna opnieuw een behandelkeuze werd bepaald. De keuze voor een bepaalde behandeling veranderde in 24% van de gevallen (95%-Betrouwbaarheidsinterval [BI]: 20,5 – 27,8), waarvan in de meeste

gevallen van conservatief naar operatief, na het tonen van de 30-graden opname. De resultaten laten zien dat het toevoegen van de 30-graden caudocephale opname aan de standaard AP opname kan leiden tot een verandering in de behandelkeuze en de diagnostische work-up van claviculafracturen zou moeten bestaan uit röntgenopnamen in twee richtingen.

Behandeling

Distale claviculafracturen kunnen worden onderverdeeld op basis van de Neer classificatie. De Neer type-II claviculafracturen zijn instabiele fracturen, omdat hierbij de verbinding tussen het coracoclaviculaire ligament complex en de clavicula is verbroken. Bij deze fracturen is het distale ossale deel en het acromioclaviculaire gewricht wel intact. Deze fracturen worden standaard geopereerd vanwege het hoge percentage aan non-union (>20%). **Hoofdstuk 5** beschrijft een meta-analyse van de literatuur over verschillende chirurgische operatietechnieken voor deze fracturen. In totaal werden 21 onderzoeken geïncludeerd, waarvan er 8 prospectief en 13 retrospectieve cohort onderzoeken waren met in totaal 350 patiënten. De studies beschreven vier chirurgische technieken: haakplaatfixatie, plaatfixatie, intramedullaire fixatie (pennen) en cerclage. In 98% van de patiënten werd volledige consolidatie na chirurgische behandeling bereikt. De tijd tot consolidatie was gemiddeld 10 weken langer voor haakplaatfixatie dan voor intramedullaire fixatie (p=0.02). Er werden geen statistisch significante verschillen tussen de functionele uitkomsten van de chirurgische technieken gevonden. Haakplaatfixatie was echter geassocieerd met 11-voudig verhoogd risico op grote complicaties vergeleken met intramedullaire fixatie en zelfs een 24-voudig verhoogd risico ten opzichte van cerclage. In het belang van de patiënt heeft een fixatieprocedure met een laag aantal complicaties de voorkeur, zoals intramedullaire fixatie of plaatfixatie.

In **hoofdstuk 6** wordt de keuze van behandeling voor midschacht claviculafracturen besproken gebaseerd op de resultaten van de online vragenlijst gehouden onder Nederlandse traumachirurgen en orthopeden. Er was geen consensus tussen de chirurgen met betrekking tot de keuze van behandeling. De 102 respondenten kozen vaker voor de conservatieve behandeling bij gedisloceerde fracturen dan bij comminutieve fracturen (Odds Ratio [OR] 3,24; 95%-BI: 2,55 –

4,12). Daarnaast werd vaker voor hoekstabiele plaatfixatie gekozen bij comminutieve dan bij gedisloceerde fracturen ten opzichte van de overige mogelijkheden (OR 1,50; 95%-BI: 1,17 – 1,19). Er waren geen statistisch significante verschillen tussen de respondenten wat betreft achtergrond en ervaring. Dit gebrek aan overeenstemming tussen de verschillende professionals vraagt om evidence-based richtlijnen.

Hoofdstuk 7 beschrijft een retrospectieve studie die werd uitgevoerd om de invloed van fractuurtype, traumamechanisme, leeftijd en geslacht op de primaire behandelkeuze te bepalen. Een hogere leeftijd was gecorreleerd met comminutieve en gedisloceerde fracturen. Veel verkorting (>20mm) werd geïdentificeerd als de voornaamste reden voor primair operatieve behandeling, waarbij dislocatie en fractuurclassificatie minder relevant bleken te zijn. Operatieve behandeling kwam door de jaren heen steeds vaker voor met 5% in 2006 en 44% in 2009. Dit kon niet verklaard worden door een stijging van het aantal complexe fracturen, door leeftijd of door traumamechanisme.

In **hoofdstuk 8** wordt de rationale en het protocol van een prospectieve multicenter gerandomiseerde gecontroleerde trial beschreven, waarin patiënten met een gedisloceerde midschacht claviculafractuur worden gerandomiseerd tussen conservatieve behandeling met een sling en operatieve behandeling met plaatfixatie. Beide groepen worden vergeleken wat betreft consolidatie en functionele uitkomsten. De trial zal level-1 bewijs leveren voor de optimale behandeling van midschacht claviculafracturen en zal in combinatie met de resultaten van al gepubliceerde trials bijdragen aan de ontwikkeling van evidence-based richtlijnen.

Biomechanica

Een van de meest intrigerende vragen in onderzoek naar claviculafracturen is of verkorting van de clavicula na een fractuur zal leiden tot verslechtering van functionele uitkomsten door het optreden van veranderingen in de schouderketen. In **hoofdstuk 9** onderzochten we deze vraag. In totaal werden 32 voormalig patiënten met een 1 tot 5 jaar oude geconsolideerde claviculafractuur onderzocht op de polikliniek. De scapula rotaties in rust en gedurende anteflexie en abductie

van de arm, de kracht van beide armen en de maximale bovenarmsbewegingen werden genoteerd. De gemiddelde *CSI* in deze patiëntengroep was 12,9% (Standaard Deviatie [SD] 7,8). De scapula protractie van de aangedane schouders was in rust 4,4 graden (95%-BI: 0,0 – 8,9) groter dan die van de contralaterale schouder. Tijdens de abductie beweging van de schouder werd er meer protractie (4,4 graden; 95%-BI: 3,6 – 5,2), meer laterale rotatie (2,4 graden; 95%-BI: 2,0 – 2,8) en minder achterwaartse kanteling van de scapula (-1,9 graden; 95%-BI:-2,9 – -1,2) gevonden voor de aangedane schouders. De scapula rotaties waren gedurende de anteflexie beweging van de humerus statistisch significant verschillend voor de aangedane schouders ten opzichte van de controle schouders. Er werd meer protractie (3,8 graden; 95%-CI: 3,1 – 4,5), meer laterale rotatie (1,3 graden; 95%-CI: 0,6 – 1,9) en minder achterwaartse kanteling van de scapula (-1,0 graden; -1,7 – -0,4) gevonden. De proportionele verkorting van de clavicula was niet geassocieerd met de veranderde scapulohumerale kinematica. De controle en aangedane schouders verschilden onderling niet in kracht. Uit deze resultaten concludeerden wij dat hoewel de scapulohumerale kinematica van de aangedane schouder verschilde ten opzichte van de controle schouder, dit niet heeft geleid tot relevante veranderingen in de functionele uitkomst. Bovengenoemde veranderde scapulohumerale kinematica kon niet worden gerelateerd aan de verkorting van de clavicula.

Discussie

In **hoofdstuk 10** worden de resultaten van de studies uit dit proefschrift bediscussieerd en worden conclusies getrokken. Uit de bevindingen van het eerste deel over diagnostische aspecten blijkt het belang van radiologische opnamen in verschillende richtingen voor behandelkeuze en het beoordelen van de fractuurkarakteristieken voor de classificatie. De accuraatheid van de verkorting en lengtemetingen op röntgenopnamen is echter discutabel. Om deze onnauwkeurigheid te ondervangen en rekening te houden met de inter- en intra-individuele variatie in lengte van de clavicula, hebben we de "Clavicular Shortening Index (*CSI*)" geïntroduceerd. Deze index is gebaseerd op de initiële lengte van de gefractureerde clavicula en geeft de proportionele verkorting weer. Verkorting van de clavicula werd aangemerkt als de belangrijkste reden voor operatieve behandeling, waarschijnlijk omdat het in verband

gebracht werd met mogelijke dysfunctionele uitkomsten. Echter in ons onderzoek naar de biomechanica na een geconsolideerde claviculafractuur werd deze aanname niet bevestigd. De aanwezigheid van een geconsolideerde claviculafractuur leidde niet tot klinisch relevante veranderingen in de scapula kinematica en functionele uitkomsten. Verkorting van de clavicula lijkt daarom geen op zichzelf staande reden voor operatieve behandeling.

Meer kwalitatief hoogstaand onderzoek is nodig om voor zowel de laterale als de midschacht claviculafracturen de complicaties van operatieve behandeling op de langer termijn te beoordelen. De risico's op complicaties na operatieve behandeling en de risico's op non-union moeten tegen elkaar afgewogen worden. Evidence-based richtlijnen moeten worden ontwikkeld op basis van een bondig classificatiesysteem waarin de fractuurkarakteristieken zijn beschreven. De toekomstige resultaten van de Sleutel-TRIAL zullen zeer waarschijnlijk bijdragen aan de ontwikkeling van deze richtlijnen.

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Curriculum vitae

CURRICULUM VITAE

Sylvia Alexandra Stegeman werd op 28 december 1983 geboren te Delft. Zij behaalde in 2002 haar gymnasium diploma aan het Christelijk Lyceum Delft. In datzelfde jaar werd zij, door middel van de decentrale selectie, toegelaten tot de opleiding geneeskunde aan de Universiteit Leiden. De doctoraal fase heeft zij in 2006 afgesloten met een wetenschapsstage op de afdeling Klinische Epidemiologie met een onderzoek naar de kwaliteit en validiteit van web-based vragenlijsten. Haar semi-artsstage heeft zij uitgevoerd op de afdeling heelkunde en het Wondcentrum van het Rijnland Ziekenhuis Leiderdorp. Gedurende die periode heeft zij onderzoek gedaan naar de waarde van donorhuid als voorspeller voor het aanhechten van een Split Skin Graft bij (chronische) wonden. Voor dit onderzoek heeft zij de Wetenschapsprijs van het Rijnland Ziekenhuis 2008 gewonnen. Na haar artsexamen in augustus 2008 heeft zij één jaar als ANIOS heelkunde gewerkt in het Rijnland Ziekenhuis. Aansluitend heeft zij één jaar gewerkt als ANIOS heelkunde in het Leids Universitair Medisch Centrum. In 2010 heeft zij een studieprotocol en subsidie-aanvraag geschreven om een multicenter randomised controlled trial op te zetten over de behandeling van midschacht claviculafracturen in samenwerking met prof. dr. I.B. Schipper. Deze subsidieaanvraag werd gehonoreerd, waardoor Sylvia de mogelijkheid had om vanaf september 2010 twee jaar fulltime aan deze studie te besteden. In deze periode heeft zij meerdere studies met betrekking tot claviculafracturen opgezet, die in de daaropvolgende jaren konden worden geanalyseerd. Haar meta-analyse over distale claviculafracturen is genomineerd voor beste abstract Chirurgendagen 2012. Sinds november 2014 is zij werkzaam als ANIOS ouderengeneeskunde.