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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 treatment¹¹ 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-union¹⁵ 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 fractures²⁹ 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-analyses³²⁻³⁹ 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 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 therefore 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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