MIDSHAFT CLAVICLE FRACTURES

OPTIMIZING RADIOGRAPHIC EVALUATION AND INNOVATIONS IN SURGICAL MANAGEMENT

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Innovations in Surgical Management

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Part B: Innovations in surgical management of midshaft clavicle fractures

1

General introduction and outline of this thesis

GENERAL INTRODUCTION

Clavicle fractures are one of the most common fractures accounting for 5-10% of all fractures and approximately 35% of those involving the shoulder girdle.[1-3] The clavicle is the only osseous connection between the chest and upper extremity, functioning as a strut between the sternum and the acromion of the scapula. The clavicle has a unique shape with curvatures in two planes and its minimal soft tissue coverage makes it a challenging bone to manage surgically. The sternal portion of the clavicle is circular or ellipsoid in cross section, and the acromial portion is flatter on its superior and inferior surfaces (Figure 1.1).[4]

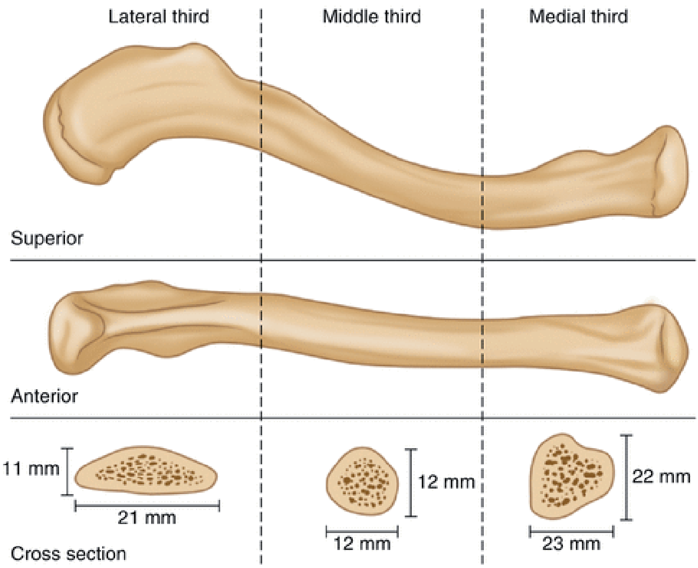

Figure 1.1. Geometry of the clavicle. Adapted from Phadnis J., Bain G.I. (2015) Clavicle Anatomy. In: Bain G., Itoi E., Di Giacomo G., Sugaya H. (eds) Normal and Pathological Anatomy of the Shoulder. Springer, Berlin, Heidelberg.

When fractured, the vast majority of these fractures is located at the middle third of the clavicle.[1, 3, 5] Due to its specific muscle insertions and gravitational forces a typical and reproducible configuration of shortening and displacement of the fracture elements occurs in which the medial fragment is displaced superiorly and the lateral fragment is directed more inferiorly. Clavicle fractures are most commonly classified according to the Allman classification or Robinson classification. The Allman classification describes the location of the fracture according to its incidence (Allman 1: middle third, Allman 2: lateral third, Allman 3: medial third). The Robinson Classification (Figure 1.2) is a more descriptive classification dating back to 1998.[3] It has been validated as reliable in subsequent years[6] and describes location, alignment and number and shape of the fracture elements.

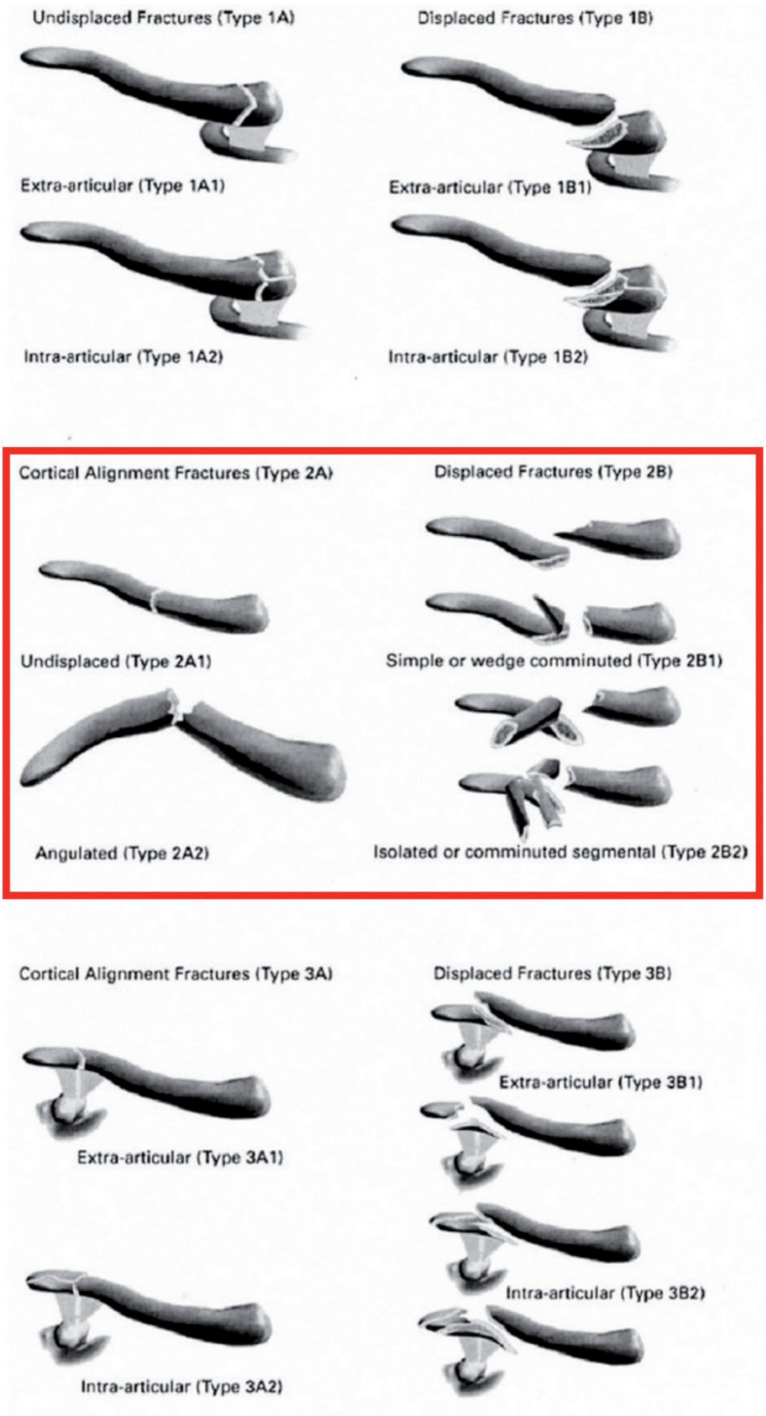

Figure 1.2. Robinson Classification of midshaft clavicle fractures. Adapted from Lazarus MD. Fractures of the Clavicle. Highlighted area indicating midshaft clavicle fractures. Chapter-26-Rockwood and Green's fractures in adults, 5th edition, Philadelphia: Lippincott Williams and Wilkins, 2001; 1041-1078).

Historically, displaced midshaft clavicle fractures have been treated non-operatively by means of a sling, collar and cuff or figure-of-eight bandage. However, one could imagine that theoretically it would be advantageous to restore the appropriate alignment and length of the fractured clavicle, but this is amongst one of the most debated subjects for decades. To date, it remains difficult to discern which patients with midshaft clavicle fractures would benefit from surgical management and which ones would be better off going the non-operative route. There have been reports that a shortened and malunited clavicle could lead to impaired functional outcomes, persistent pain, cosmetic complaints, neurological symptoms and possibly gleno-humeral osteoarthritis in the longterm.[7-14] Since the change of the millennium, more reports have been published indicating that surgical management may be more beneficial in terms of lower non- and malunion rates as well as an earlier functional recovery and increased patient satisfaction.[15-19] The pendulum has swung towards surgical management by means of plate osteosynthesis or intramedullary fixation more often than before.[5] Subsequent reports have emphasized the fact that, in spite of the benefits of surgery, there are risks associated with surgical intervention and therefore should not be offered routinely to every patient with a displaced midshaft clavicle fracture.[16, 18, 20-24] Furthermore, on the subject of cost-effectiveness of surgical treatment there are equivocal reports and consensus is absent.[25-28]

Classical indications for surgery include open fractures, compromised skin, neurovascular complications or an additional fracture of the scapular neck (floating shoulder). More recent relative indications proposed for surgical management are vertical displacement > 100% of the shaft's width, shortening of > 15 mm, activity level, age and dominant side. The latter two, possibly three indications are rather specific, while the first two are inferences based on non-uniform methods of measuring and radiographic imaging.

There are contradictory reports on the importance of shortening and vertical displacement as a relative indicator for surgery and different cut-off values have been proposed. Some studies report that shortening is a predictor of inferior union rates and functional outcomes[7-11, 13, 29-31] while others report no association between shortening and functional outcomes.[32-34] These conflicting reports may be confounded by a plethora of described modalities and techniques on how to quantify shortening and displacement in the first place. Due to the unique shape of the clavicle, consisting of a sigmoid shape in both the coronal and transverse plane, reliable and reproducible measurements of the vertical displacement and shortening can be challenging on a 2-dimensional rendition of a 3-dimensional reality.

Shortening has been described to be assessed using a tape measure,[30] tilted AP views of the clavicle,[7, 11, 13, 35, 36] (ranging from a 45° cranio-caudal to 45° caudo-cranial views) AP panoramic views[9, 10, 29, 32, 34] or CT scans.[33] Multiple different techniques for quantifying shortening have been reported (Figure 1.3).[37] No methods for absolute

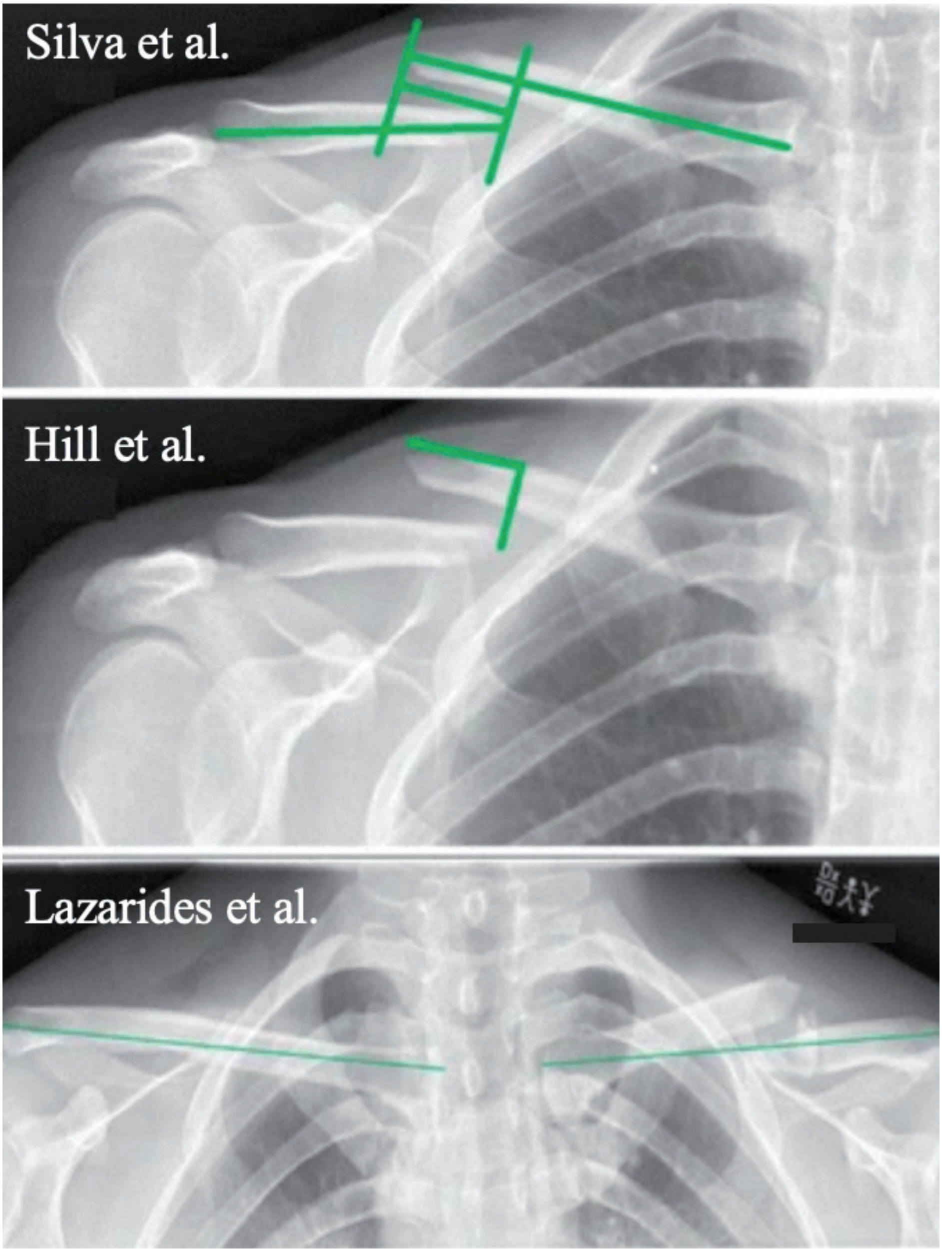

Figure 1.3. Three methods described for measuring shortening of midshaft clavicle fractures. Adapted from Thorsmark et al.[37] Silva et al.[41] a line is drawn through the middle of each fragment. From each middle line, a perpendicular line between each fragment is drawn. Shortening is defined as the distance between the perpendicular lines on single anterior-posterior view. Hill et al.[9] a line is drawn from the bottom fragment perpendicular to the top fragment. Shortening is defined from the line to the tip of the top fragment on single anterior-posterior view. Lazarides et al.[10] the length of each clavicle is measured from acromioclavicular joint to sternoclavicular joint. Shortening is defined as uninjured clavicle length minus injured clavicle length on a panoramic shoulder view.

measurements on vertical displacement have been described but may be of value. This radiographic parameter and relative indication for surgery so far has only been described in categorical manners. The most commonly reported way to do this is by describing vertical displacement as 0-50%, 51-100% or > 100% of the shaft's diameter. Other variables, besides the shape of the clavicle or radiographic projection influencing measurements on the fractured clavicle, are patient positioning, magnification and measuring technique.[37-40]

To evaluate whether shortening and vertical displacement can be used, or should be discarded, as an indicator for surgery it is important to evaluate the radiographic parameters more in-depth and to identify an evidence-based, standardized, accurate and reliable method to measure shortening and vertical displacement.

The results from multiple systematic reviews published in the last decade are relatively uniform in its conclusion that surgical management of the displaced midshaft clavicle fracture is superior to non-operative management. As mentioned earlier, many authors report that surgical management leads to a decrease in non- and malunions, a quicker return to work and sports, higher patient satisfaction rates and a similar or improved functional outcome as measured by the Constant-Murley Score or DASH score.[16,18,20,22-24] However, the operative management is not without risks or complications. These include infection, hardware failure, hardware irritation, hardware migration, deep venous thrombosis, cosmetically displeasing scar formation and neuropathy of the supraclavicular nerve. Furthermore, hardware removal, with its own associated morbidity, is frequently described for both intramedullary and plate fixation.

Over half a dozen systematic reviews have been published in the last 5 years evaluating and comparing plate fixation in the setting of midshaft clavicle fractures with intramedullary constructs (Figure 1.4).

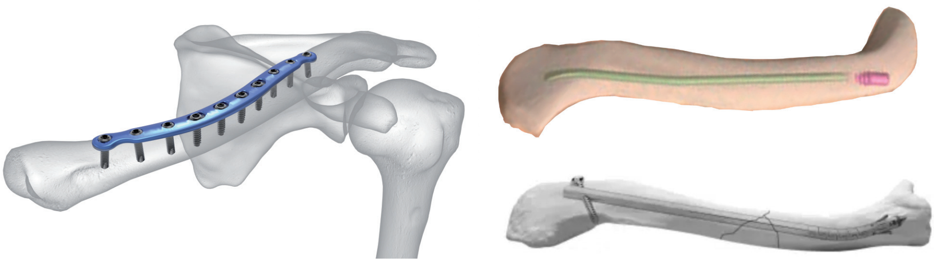

Figure 1.4. Examples of different midshaft clavicle fixation devices.
a) Pre-contoured clavicle plate (adapted from https://www.acumed.net/products/shoulder/clavicle-plating-system/),
b) Titanium elastic Nail (TEN) (adapted from http://synthes.vo.llnwd.net/o16/LLNWMB8/INT%20Mobile/Synthes%20International/Product%20Support%20Material/legacy_Synthes_PDF/DSEM-TRM-0115-0290-3_LR.pdf),
c) Sonoma CRx (adapted from http://www.scientificsurgical.co.za/clavicle-nail/).

Most authors conclude that these different techniques are equivalent concerning union rate and functional outcomes. Intramedullary fixation is deemed superior by most due to shorter surgical times, lower infection rates, less re-fractures after hardware removal and a better cosmetic result.[21, 42-47]

To repeat a similar systematic review, in light of this thesis, would most likely not add any new insights. However, it is important to realize that in the beforementioned systematic reviews, all available intramedullary devices were pooled together and compared to the results of plate fixation. Since the available intramedullary devices differ considerably in their specifications and characteristics it is believed to be important to evaluate these individually. By doing this, factors that could lead to improvements in patient-related outcomes and adaptations that could potentially lower complication rates may be identified.

Optimal design of clavicle fixation devices requires knowledge of the forces that act on the clavicle during shoulder movements and activities of daily living. However, it remains unclear what loading magnitudes the fixation constructs have to withstand because these forces are difficult if not impossible to measure directly *in vivo*.[48] In order to address this knowledge gap, cadaveric biomechanical testing or biomechanical computer models, such as the Delft Shoulder and Elbow Model (DSEM)[49-52] can be used to estimate these forces.

To address the disadvantages of the current surgical techniques, it may require not just an adaptation of current devices or procedures, but possibly the introduction of an entirely new concept. This notion has led to the design of the Anser Clavicle Pin (Figure 1.5).

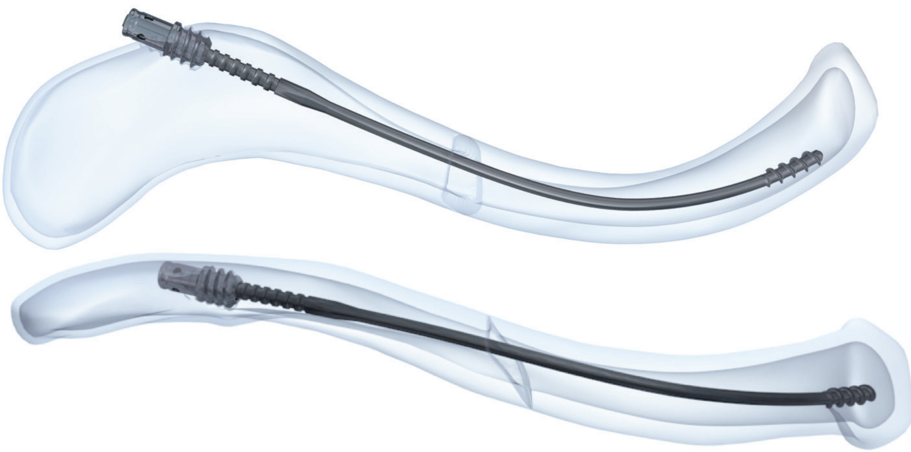

Figure 1.5. Rendering of the Anser Clavicle Pin.

This device is developed to re-align the fractured clavicle and maintain its length in an intramedullary fashion whilst allowing rotation along the longitudinal axis to occur. By adopting this concept, all torsional forces that occur during motion of the upper extremity will theoretically dissipate through the fracture site or the implant-implant interface. Therefore, no rotational forces will occur on the bone-implant interface reducing the likelihood for loss of fixation, hardware migration or hardware failure. Also, by not attempting to control rotational forces within its design, the specifications and hardware prominence of the Anser Clavicle could be kept as minimal as possible. This was deemed essential to reduce the need for hardware removal and therefore reducing morbidity, costs and societal burden.

OUTLINE OF THIS THESIS

The main body of this thesis consists of two parts. Part A aims to optimize the radiographic evaluation of midshaft clavicle fractures while Part B is geared towards improving the surgical management strategy.

In **chapter 2** the available literature is reviewed in order to describe the current concepts and treatment strategies involved in the management of displaced midshaft clavicle fractures. It aims not only to create a general understanding of the available options and the multi-facetted decision-making process, but also to identify opportunities for improving upon patient selection, surgical indications, patient-related outcomes and treatment options.

Part A: Optimizing radiographic evaluation of midshaft clavicle fractures

In order to evaluate the reliability and reproducibility of measurements of shortening in midshaft clavicle fractures **chapter 3** describes a systematic review aiming to answer this question. In **chapter 4** a clinical measurement study is described that assesses the physiological side-to-side variation in clavicle length. Comparing the side of the fractured clavicle to the contralateral intact clavicle is a commonly used technique for quantifying shortening. This technique presumes side-to-side symmetry which may not be present in a significant portion of the population. The aim of this study is to comment on its applicability for quantifying shortening of the fractured clavicle.

The next question that is addressed in **chapter 5** of this thesis aims to investigate whether there is a difference in measurements of shortening and length of fracture elements between 5 different (30 and 15 caudo-cranial, AP, and 15 and 30 cranio-caudal) projections. This chapter also evaluates the inter- and intra-observer agreement using a standardized method for measuring the shortening and length of fracture elements. A similar research question focused on the influence of different projections on the measured vertical displacement, its inter- and intra-observer agreement and the association between categorical and continuous descriptions of vertical displacement is described in **chapter 6**.

Possible statistically significant differences in measurements of shortening and vertical displacement do not necessarily equate to clinically relevant differences in the results of the physician's decision-making algorithm when managing the fractured clavicle. Therefore, **chapter 7** describes a study investigating if different projections of the same midshaft clavicle fracture would lead to a different choice in treatment strategy. In **chapter 8** a prospective clinical case series using proper X-ray images in acute displaced midshaft clavicle fractures is described. It evaluates the influence of different radiographic projections and various positions of the patient and the upper extremity on the quantification of shortening and vertical displacement.

Part B: Innovations in surgical management of midshaft clavicle fractures

Through a systematic review, **chapter 9** provides an insight in the functional outcomes and complications per currently available intramedullary device for the managing midshaft clavicle fractures. These results, and especially the described complication profiles, shed a light on where potential improvements in operative technique or device design could be made in order to decrease the adverse effects of surgical intervention.

In **chapter 10** the Delft Shoulder and Elbow Model (DSEM) is used to quantify the forces acting on the human clavicle in abduction, forward humeral elevation and three activities of daily living (washing axilla, eating and combing hair). The DSEM was used to simulate the mechanical behavior and loading of all major muscles and bones of the shoulder and to generate data that may be helpful in the development of future clavicular fixation devices.

In the final section of part B, **chapter 11** presents the results of a prospective first-in-man case series reporting on the union rate, functional outcomes and complications of the Anser Clavicle Pin at 1 year follow up. The Anser Clavicle Pin is a novel concept that was designed in collaboration with the Radboud University Medical Center and its conception was funded by the Stichting Technologie & Wetenschap Valorisation and Take off grants as well as the MKB Innovation and Technique fund.

A summary and general discussion of the findings from the studies comprising this thesis will be delineated in **chapter 12**. In **chapter 13** the conclusions of this thesis, proposed implications for clinical practice and perspectives on future research will be discussed.

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Midshaft clavicle fractures: Current concepts

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ABSTRACT

- Clavicle fractures are common fractures and the optimal treatment strategy remains debatable. The present paper reviews the available literature and current concepts in the management of displaced and/or shortened midshaft clavicle fractures.
- Operative treatment leads to improved short-term functional outcomes, increased patient satisfaction, an earlier return to sports and lower rates of non-union compared with conservative treatment. In terms of cost-effectiveness, operative treatment also seems to be advantageous.
- However, operative treatment is associated with an increased risk of complications and re-operations, while long-term shoulder functional outcomes are similar.
- The optimal treatment strategy should be one tailor-made to the patient and his/her specific needs and expectations by utilizing a shared decision-making model.

Keywords: clavicle; fracture; midshaft; treatment; operative; conservative; cost effectiveness; shared decision-making

INTRODUCTION

Clavicle fractures are common fractures, comprising 5% to 10% of all fractures.[1] They occur due to falls on the lateral aspect of the shoulder, the outstretched hand or due to high-energy direct impact over the bone. The incidence of clavicle fractures has increased in recent years and the operative treatment of these fractures increased disproportionately.[2, 3] Clavicle fractures are most commonly classified according to the Allman classification and/or the Robinson classification. The location and type of fracture is important in the decision-making as it influences management strategies. This paper focuses on the most common clavicle fractures, which are those in the mid-diaphyseal third (Allman 1 and Robinson 2).[1, 4-6] Described conservative treatment options for the clavicle fracture consist of pain reduction by temporary immobilization using a sling or collar and cuff in combination with analgesics and/or kinesiotape. Operative treatment comprises open reduction and internal fixation (ORIF) using plates and screws or intramedullary fixation (IF), of which titanium elastic nails (TEN) are most commonly used and described.[7-16] Classical operative treatment indications are open fractures, compromised skin, neurovascular complications or an additional fracture of the scapular neck (floating shoulder).[17, 18] Others have described relative indications for operative management which are displaced midshaft clavicle fractures, a shortening of ≥2 cm, age, activity level and dominant side.[17, 19]

Even though the ancient Egyptians reported on the fractured clavicle and numerous studies have been conducted to fill the gaps in evidence, there is still no consensus regarding the management of these fractures. In this article, conservative and operative treatment will be discussed, based on a broad literature search, the current concepts and available evidence for both methods.

Physical examination and radiological assessment

During physical examination, a dropping shoulder on the affected side, swelling and haematoma at the middle third of the clavicle are usually observed. Often the fractured bones are palpable. Assessment of possible skin compromise and neurovascular status is important. In addition to the physical assessment, radiological assessment using radiography is part of the diagnostic work-up.

Operative treatment

Current radiological indicators for surgery are displacement and shortening. Displacement is a reproducible measure,[20, 21] but its implications for long-term results remain unclear. There is no clear cut-off point that discerns which patients will benefit from operative management. As for shortening, a decrease of >10% in length is suggested to affect scapular kinematics *in vivo*.[22, 23] It is reported that scapular upward rotation, posterior tilting and internal rotation increase.[22, 24, 25] A shortening of >2 cm or >10%

is presumed to be an indicator for poorer outcomes in those treated conservatively and a possible increased risk of gleno-humeral arthritis.[19, 26-34] Others report the that the amount of shortening is not influential in the long-term functional outcomes.[35-37] To the authors' knowledge, there is no universal standardized method of measuring and imaging the fracture reliably and accurately, which could account for these discrepancies. The direction and magnification of the divergent radiographs, as well as the patient's position, affect the imaging and subsequent measurements.[38-40] A variety of imaging and measuring techniques are reported, ranging from a tape measure[31] to anteroposterior (AP) panoramic radiograph views,[19, 29, 35, 37, 41] tilted AP views (ranging from a 45° craniocaudal to 45° caudocranial views)[27, 30, 33, 42, 43] or CT scans.[36] Measuring shortening by comparing the fractured side with the contralateral non-fractured side seems less reliable than expected, since 30% of the population has a physiological asymmetry of ≥6 mm.[44] Accurate and reproducible imaging and measurement methods should be developed if shortening is to be used as a radiological indicator for surgery.

Non-operative treatment

Conservative treatment consists of pain reduction by temporary immobilization using a sling or collar and cuff with or without analgesics. Although there are no clinical trials on its efficacy as yet, kinesiotape is also used. The use of a figure-of-eight bandage is not advised. Research from the 1980s and a recent study from 2015 compared conservative treatment with a sling and figure-of-eight bandage.[45, 46] They showed that both techniques have similar outcomes but that the patients in the latter group suffered more from pressure sores in the axillae. Range of motion exercises can be increased as tolerated to prevent adhesive capsulitis.

An important complication of conservative treatment is the development of a non-union, which occurs in 15% to 17% of conservatively treated patients.[47-49] It appears that this risk is highest in patients with clavicular fractures displaced more than a shaft width or a shortening of >2 cm.[17, 19] Approximately two-thirds of patients with a non-union undergo operative management because of persistent complaints.[49]

Other risks of conservative management include mal-union and (temporary) neurological issues.[19, 30, 50-52] Scapulo-thoracic kinematics in patients with shortened clavicles differ significantly from those in uninjured shoulders in the resting position and in movement.[22, 23] These changes do not seem to lead to decreased functional outcomes after four months,[43] but can be associated with an increased risk of gleno-humeral arthritis.[34] Several papers demonstrate that corrective surgery for mal-union is challenging but will lead to good results.[26, 51] Late reconstruction of mal-union results in restoration of objectively assessed muscle strength similar to those receiving immediate fixation; however, there are subtle decreases in endurance.[53] The aforementioned arguments may lean towards a predominantly conservative management and operative management only being indicated for symptomatic mal- and non-unions.

ORIF using plates and screws

ORIF using plates and screws is considered the current gold standard for the operative management of displaced and/or shortened midshaft clavicular fractures (Figure 2.1a). The advantage of operative intervention is the restoration and preservation of the natural anatomy and length of the fractured clavicle. There are uniform reports of lower non-union rates of approximately 2%.[49, 54, 55] An improved patient satisfaction and earlier return to work compared with conservative treatment is also reported.[47, 48, 52]

As for all operative interventions, the risk of complications should not be ignored. Risks associated with operative management of the fractured clavicle include neuropathy of the supraclavicular nerve, infection, pneumothorax, implant failure and the need for hardware removal due to hardware-related complaints.[30] Nineteen per cent of patient have persistent loss of sensation around the scar and the anterior aspect of the chest wall due to neuropathy of the supraclavicular nerve.[54] A recent randomized clinical trial (RCT) of 160 patients reported 10.7% of patients undergoing a re-intervention because of complications from ORIF within one year.[54] The most common reason for this was early implant failure, followed by deep infection, late implant failure and non-union. A database study involving 1350 patients found that one out of four patients underwent re-operation (24.6%) within two years.[56] Primary implant removal was most common (77%), median time to implant removal was 12 months. A re-operation secondary to non-union, deep infection and mal-union occurred in 2.6%, 2.6% and 1.1% of the patients after a median of six, five and fourteen months, respectively.

Concerning the type of incision, patients are reported to be cosmetically more satisfied when a necklace incision is used compared with a longitudinal incision.[57]

Whether an operation leads to better shoulder function is debatable.[47, 48, 54] Short-term data show that ORIF using plates and screws results in a more rapid return to normal function compared with conservative treatment.[47, 48] Shoulder function after six weeks may therefore play a role in choosing operative management.[55] Long-term results show no significant difference in functional outcomes according to a recent meta-analysis of 614 patients.[49]

The type of plate can affect plate-related complications. A reconstruction plate is easily contoured to the morphology of the clavicle, but biomechanical studies show that it is a weaker construct than other plates such as the Low Contact Dynamic Compression Plate (LC-DCP) or a anatomically pre-contoured plate.[58, 59] A retrospective review of 111 patients reported that the use of reconstruction plates leads to 5% hardware failure.[60] Comparing the LC-DCP plate with the reconstruction plate, more plate-related complications are found in the latter, 1% *versus* 9%.[61] Lower patient satisfaction and high rates of plate prominence have led to the use of lower profile and smaller plates. The position of the plate remains controversial. Superior plating is the most commonly used technique, but anterior-inferior plating, anterior plating or double plating with mini-fragment plates are described as well.[62-64] A biomechanical study comparing anterior and superior plate placement showed that, for all fracture patterns, more construct stiffness was achieved in axial compression and with a superior plate, whereas more construct stiffness was achieved in cantilever bending with an anterior plate.[65] Antero-inferior plating of midshaft clavicle fractures results in lower hardware removal due to plate prominence.[62, 66] It was found that anterior-inferior plating reduces the time to union, but the location of the plate does not seem to influence functional outcomes or infection rates.[63]

Dual mini-fragment plating was investigated in a small retrospective study (17 patients).[64] Neither of these patients required a second operation to remove at least one of the plates within one year. No non-union was reported and functional outcomes were similar to other studies.[52] Compared with single plating, dual plating is biomechanically equivalent in axial loading and torsion.[64]

Intramedullary fixation

Another option in the operative management of the displaced and/or shortened midshaft clavicle fracture is using an intramedullary device. Classically these comprise Rockwood Pins and Hagie Pins, but the current most used and described implants are TEN (Figure 2.1b).[7-16] The use of TEN leads to equivalent results as the ORIF in terms of function and union rates.[16] The advantage of this method is that the incision is smaller, causing less tissue damage and superior cosmetic results.[67] Besides these clinical outcomes, it has been reported in a finite element study that intramedullary treatment of the midshaft clavicle fracture with a TEN could be preferable over ORIF because it shows a stress distribution similar to the intact clavicle.[68]

The disadvantages of TEN are hardware migration, secondary shortening, telescoping and the need for routine removal.[9, 13, 15, 16, 67, 69, 70] Most of these complications are attributed to the fact the TEN aligns but does not fix itself in the fracture elements. The re-intervention ratio related to implant failures is reported to be in the range of 0% to 36%.[7, 10, 71] In cases where TEN is removed, this can be done under local anaesthesia, but is more commonly done under general anaesthesia. In general, up to 100% of TENs are removed.[9, 13, 15, 16, 67, 69, 70]

A more recent development for intramedullary fixation is the Sonoma CRx. Although the body of evidence concerning this type of implant is small, it seems to lead to similar functional outcomes and reduced rates of implant removal. However, all papers report on hardware failure of up to 5.7%.[72-76]

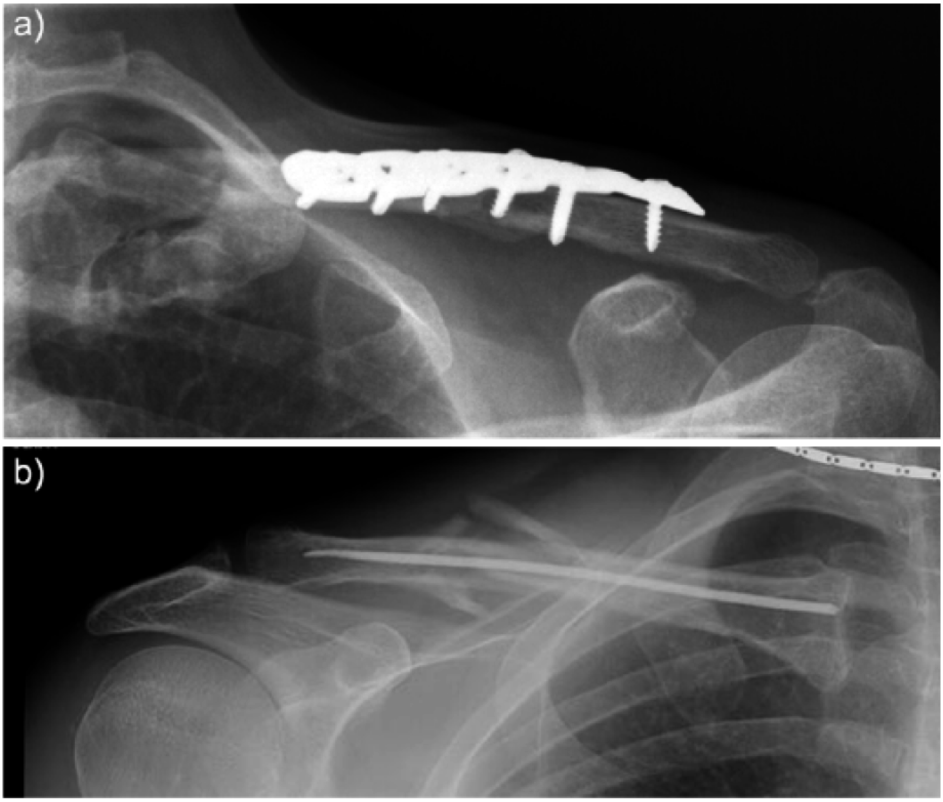

Figure 2.1. a) Example of plate fixation of a clavicle fracture (patient treated in OLVG Amsterdam); **b)** example of intramedullary fixation of a clavicle fracture (patient treated in OLVG Amsterdam).

Cost-effectiveness

In a society in which health costs continue to increase, it is imperative to refrain from unnecessary costs. Few data are available on the cost-effectiveness of operative management of the displaced and/or shortened midshaft clavicle fracture. A study published in 2010 reported that cost-effectiveness is not only defined by the actual cost of treatment but was also highly dependent on the duration and magnitude of functional benefit after operative management and the disability and increased time to union associated with non-operative treatment.[77] When functional benefits persisted for >9 years, operative management using ORIF had a favourable value outcome. Another study with a follow-up of 2.5 years concluded that operatively managed patients cost more during their hospital stay but missed fewer days off work (8.4 days *versus* 35.2 days), required less assistance for care at home (3 days *versus* 7 days) and incurred lower costs for physical therapy ($971.76 *versus* $1,820).[78] An overall cost reduction of $5,091.33 in favour of the operatively managed patient was found.

Return to sport

For athletes and the active population, return rates and time to return to sport can be an important factor in deciding the treatment modality. In case of non- or minimally displaced midshaft clavicle fractures, the return rate to sports was equal between the conservatively and operatively managed patients.[79] Time for return to sport was significantly longer in the conservatively managed patient when comparing the two treatment options for displaced midshaft clavicle fractures; 21.5 weeks (12 to 78) *versus* 10.6 weeks (10 to 13).[79]

In this review, operative management using intramedullary fixation was included.[79] No statistically significant differences were identified between ORIF and IF groups concerning return rates (98% *versus* 99%). In those treated with ORIF, mean return time was 9.4 weeks (2 to 24); in the IF group, return time was 9.9 weeks (2 to 14). It was concluded that operative management of displaced midshaft fractures offers improved return rates and times to sport compared with non-operative management.

Shared decision-making

Defining the most suitable treatment for patients with midshaft clavicle fractures is controversial. A frequently used model is Shared Decision-Making (SDM). It is widely used in treatment strategies for diabetes mellitus, cardiovascular disease and cancer. SDM is on the more patient-centred side of the spectrum, between paternalistic decision-making and informed decision-making.

Joint decision-making is subject to several conditions:

- both the patient and the physician are involved in the decision-making;
- both the patient and the physician exchange information;
- both the patient and the physician indicate their preferences regarding diagnostic methods and treatments;
- both the patient and the physician agree with the final decision.[80]

During a study in the Netherlands, the current daily practice of shared decisional behaviour in clavicle fracture treatment is evaluated.[81] After the decision-making moment a questionnaire is filled in. The mean score for perceived degree of SDM was 74 out of 100. In 68% of patients, the preferred role matched the actual role in making the decision. Thirty-two per cent of patients would have preferred either a less or a more active role. As a health provider it is meaningful to be aware of these nuances.

CONCLUSIONS

Operative treatment with either ORIF or IF leads to improved short-term functional outcomes, increased patient satisfaction, an earlier return to sports and lower rates of non-union compared with conservative treatment. In terms of cost-effectiveness, operative treatment seems to be advantageous. However, operative treatment is associated with an increased risk of complications and re-operations, while long-term shoulder functional outcomes are similar.

Functional outcomes and union rates are similar between ORIF and IF. Both ORIF and IF are subject to implant-specific complications and should be evaluated with the patient before opting for operative management. The optimal treatment strategy should be one tailor-made to the patient and his/her specific needs and expectations by utilizing a shared decision-making model.

Further research on better discerning those who will benefit most from operative management remains necessary. A uniform method of imaging, measuring and reporting radiological parameters as possible indicators for operative management is a consideration for future studies.

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Part A

Optimizing radiographic evaluation of midshaft clavicle fractures

3

Reliability of measurements of the fractured clavicle: A systematic review

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ABSTRACT

Background: The objective of this systematic review was to evaluate the reliability and reproducibility of measurements of shortening in midshaft clavicle fractures (MSCF) using any available imaging technique.

Methods: Electronic databases (PubMed, EMBASE and Cochrane) were searched. The 4-point scale COSMIN checklist was used to evaluate the methodological quality of studies.

Results: Four studies on reliability of measurement of MSCF were identified. These studies were of fair and poor quality. The reported intra-rater reliability varied between none to fair and intra-rater reliability was minimal.

Conclusion: No definite conclusions could be drawn. In order to optimize future studies and the realization of comparable results, more research is necessary to identify a standardized method of imaging and measuring.

Level of evidence: 3.

Keywords: clavicle; fracture; imaging; shortening; reliability; reproducibility

BACKGROUND

Fractures of the clavicle are common, comprising up to 5% of all fractures in adults.[1] Most clavicle fractures are localized at the level of the mid-diaphyseal third.[2] Dislocation of the fracture elements in midshaft clavicle fractures (MSCF) occurs due to the actions of the sternocleidomastoid muscle, which displaces the medial fragment superiorly and posteriorly, and of the deltoid and great pectoral muscles, which shift the lateral fragment inferiorly and anteriorly. These shifts cause a misaligned fracture that may result in symptomatic mal-union of the clavicle and increase the risk of a non-union.[3-6]

In the last decade, many studies have reported that a shortened clavicle can lead to worse functional outcomes, pain, loss of strength, rapid fatigue, hyperesthesia of the hand and arm, difficulty sleeping on the affected side, and aesthetic complications.[5-14] Godfrey et al.[15] reported that the degree of symptomatology and occurrence of mal- and non-union after MSCF is related to the extent of shortening and displacement of the fracture elements. Mean post-traumatic shortening of the fractured clavicle has been reported to be approximately 1.2 cm, however shortening of up to 3 cm has been reported.[16] It has been described that there are poorer outcomes when shortening of the clavicle is more than 15-20 mm or 9.7-15% as compared to the original length.[5, 7-14]

For this reason, lately the tendency has been to surgically reduce and fixate MSCF if shortened more than 15-20 mm, or if displaced more than the diameter of the clavicle's shaft. However, due to the unique shape of the clavicle, consisting of an S-shape in two planes, reliable and reproducible measurements of the displacement and shortening can be challenging.

Although there is a plethora of available modalities and techniques to measure shortening of the MSCF, it still remains unclear which method is most accurate, reproducible and useful in daily practice.

Therefore, the objective of this systematic review was to evaluate the reliability and reproducibility of measurements of shortening in MSCF using any available imaging technique.

METHODS

Electronic databases (PubMed, EMBASE and Cochrane) were searched from their inception to November 2016. Keywords used to develop our search strategy were 'clavicle', 'fractures', 'imaging', 'shortening', 'displacement', and 'reliability'. The detailed search strategy is described in Appendix 3.1. The inclusion criteria and method of analysis were specified in advance and documented in a protocol that was registered in PROSPERO.

Inclusion criteria

All titles and abstracts were screened and study inclusion was decided on by two reviewers (PH/GH). In case of discrepancy in study inclusion disagreements were discussed until consensus on eligibility was reached. References of retrieved eligible articles were searched for supplementary studies. Studies meeting the following criteria were included:

- Studies aiming to assess shortening of the fractured clavicle for intrarater and interrater reliability.
- Studies investigating methods of imaging of the fractured clavicle for intra-rater and interrater reliability.
- Only original studies were included.
- Studies in Dutch or English.
- Study population aged 9 years and older.

Abstracts, theses, and conference proceedings were not included.

Data extraction and quality assessment

An electronic data extraction form was created and used to record data. Data from all included studies were extracted with respect to specific characteristics, that is, number of clavicles reviewed, study design, imaging technique, method of measurements, statistical analysis, and the authors conclusion. PH and GH extracted data independently. If disagreement persisted after discussion, consensus was met consulting AvK.

Methods and quality were independently assessed (PH and GH, any discrepancies were discussed to achieve consensus, using a third reviewer (AvK) for all included studies. The 4-point scale COSMIN checklist box B for assessment of reliability was used.

The "worst score counts" algorithm was used for the analysis.[17] Briefly, each item from COSMIN Box B was rated individually as "excellent", "good", "fair", or "poor", and an overall score was given by taking the lowest score of any of the items.

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, both the PRISMA flowchart and checklist, were followed during the preparation of this review (Figure 3.1).

RESULTS

In total, 184 studies were identified. After the removal of duplicates, 122 studies were selected for screening of titles and abstracts. Reference tracing and hand searching yielded 2 more possibly eligible studies. After the selection of titles and abstracts, 15 studies were selected for a full text evaluation. After full-text evaluation, 4 studies were

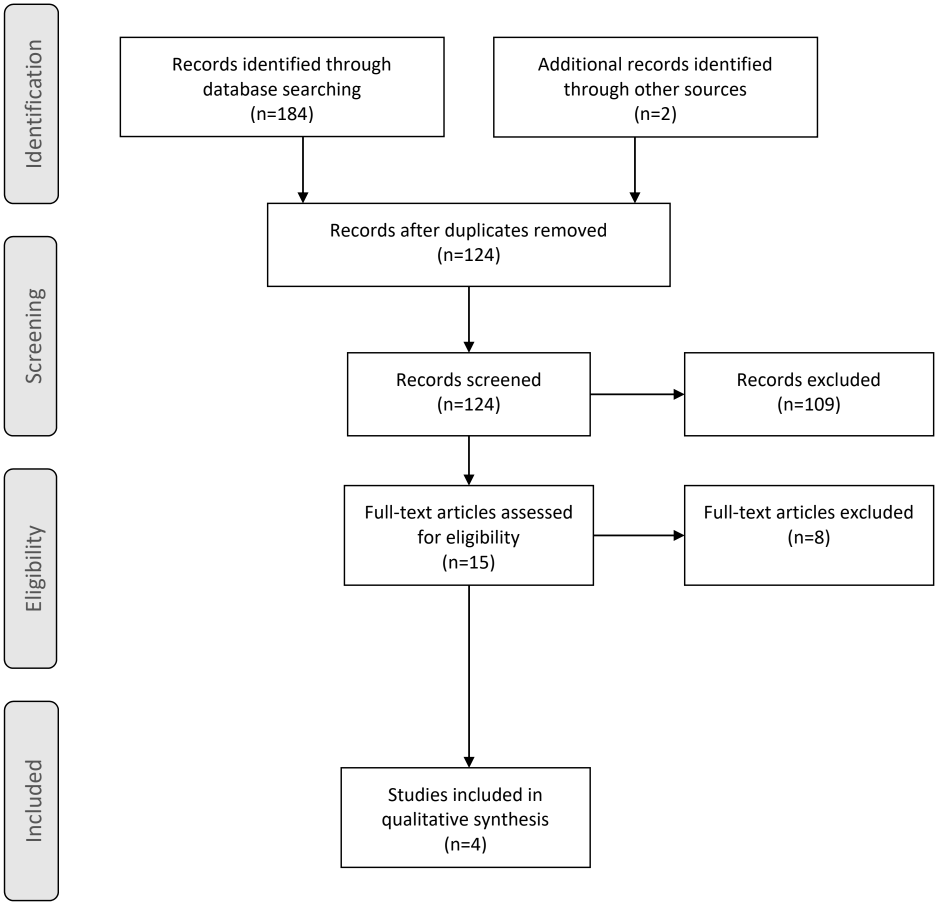

Figure 3.1. Prisma flow diagram.

included in this systematic review and were used for data extraction. Table 3.1 shows the extracted data of the 4 studies included in this systematic review.

Methodological quality of the studies

Using the 4-point scale COSMIN checklist box B for assessment of reliability 3 included studies were rated as fair and 1 as poor. The quality classification per study per item is described in Table 3.2.

Studies included in the systematic review

Jones et al.[18] assessed the interrater and intra-rater agreement for shortening and displacement using AP and 30° caudo-cranial X-ray views in 30 patients. The measurements were performed by 13 observers on two occasions. The amount of shortening

Table 3.1. Extracted data included studies

Author	Number of patients	Goal of study	Modality	Measurements	Observers (role)/Occasions	Statistics	Conclusion
Jones (2014) [18]	30	Reliability Shortening in mm Displacement in % Communited Y/N Surgery Y/N	X ray AP 30° caudo-cranial	Calibrated measuring tool	13 (13 Surgeons) 2 (after 4 months)	Power analysis + Intraobserver shortening 0.38 Interobserver shortening 0.33 K values stated	Strong inter- and intraobserver agreement for displacement and communition Weak to no interobserver and minimal intraobserver agreement for shorthening
Silva (2013) [19]	32	Interobserver and intraobserver reliability shortening in MSCF in adolescents (9-18)	Xray 15° caudo-cranial AP	1.Observers method of choice 2.Standardized method Digital measurement system	7 (3 pediatric orthopedic surgeons, 1 pediatric orthopedic fellow, 2 orthopedic residents, 1 medical student) 2 (1 week)	1. 1.Interrater reliability 0.771 and 0.743 Intrarater reliability 2.62 2. 2.Interrater reliability 0.741 and 0.685 Intrarater reliability 3.34	Standardized method of measuring not better than method of choice Interrater no significant difference Intrarater significant difference

Table 3.1. *Continued*

Author	Number of patients	Goal of study	Modality	Measurements	Observers (role)/Occasions	Statistics	Conclusion
Smekal (2008) [20]	30	Asses different measuring methods and determine most accurate method compared to CT	X ray PA thorax 15° caudo-cranial AP of both clavicles 15° caudo-cranial AP clavicle CT	Standardized methods as described in article	4 (3 orthopedoc surgeons, 1 radiologist 2 (after 1 month)	Determination of differences of mean values: paired t-test or nonparametric Wilcoxon signed-rank test Distribution from: Kolmogorov-Smirnov test Repeatability: RC according to Bland-Altman A $p<0.05$	Differences amongst measurements on X ray and CT NOT significant Repeatability coefficient on AP 15 clavicle and clinical measurement low Also smallest agreement with CT PA thorax to determine length differences
Archer (2016) [21]	22	identify correlation between plain film and computed tomography (CT) measurement of displacement and the inter- and intraobserver reliability of repeated radiographic measurements.	Xray AP plain film CT	No standardized method of measurement	6 (3 orthopedic surgeons 3 Residents)	Correlation using the Bland–Altman reliability coefficient Limits of agreement using the standard deviation (SD): 3.48 reliability using the Cronbach α coefficient. 0.90 Intraobserver reliability using paired t tests for each observer: all but one >0.05	Plain film measurements of acute MSCF do not reliably predict shortening

Table 3.2. COSMIN checklist box B for assessment of reliability per included study per item

Author	% of missing items given?	Description of how missing items were handled?	Adequate sample size?	At least two measurements available?	Were the administrations independent?	Was the time interval stated?	Were patients stable in the interim period?	Was the time interval appropriate?	Were test conditions similar for both measurements?	Any important flaws in design or methods?	Quality of statistical methods?		**Overall scores**
Jones et al. (2014)[18]	Excellent	Good	Fair	Excellent	Good	Excellent	Excellent	Excellent	Excellent	Fair	Good		Fair
Silva et al. (2013)[19]	Excellent	Good	Fair	Excellent	Good	Excellent	Excellent	Excellent	Excellent	Fair	Good		Fair
Smekal et al. (2008)[20]	Excellent	Good	Fair	Excellent	Good	Excellent	Excellent	Excellent	Excellent	Fair	Fair		Fair
Archer et al. (2016)[21]	Excellent	Good	Poor	Excellent	Good	Excellent	Excellent	Excellent	Excellent	Fair	Fair		Poor

Excellent	Good	Fair	Poor

measured on radiograph was divided into 7 categories: 0-5 mm, 5.1-10.0 mm, 10.1-15.0 mm, 15.1-20.0 mm, 20.1-25.0 mm, 25.1-30 mm, and >30 mm. No to weak interrater agreement was found for shortening in the different categories. Displacement was divided into 3 categories: 0%-49%, 50%-99%, and 100%. Interrater agreement was minimal to weak. Intra-rater agreement was moderate for displacement and minimal for shortening (Table 3.1).

Silva et al.[19] compared 2 methods of measuring shortening in 30 patients (32 fractures). The first was the method of choice of the observer, the second a standardized method. They used AP and 15° caudo-cranial views. Measurements were performed twice by 7 observers. Intraclass correlation coefficients (ICC) with confidence intervals (CI) were calculated to determine interrater agreement, and average differences between the 2 time points with 95% CI were calculated to determine intra-rater agreement.

For method 1, the interrater agreement was 0.771 (95% CI, 0.655-0.865) and 0.743 (95% CI, 0.604-0.851) at the 2 time points for fair agreement. The intra-rater agreement for method 1 was 2.62 mm (95% CI 2.24-3.00) average difference between the 2 time points. For method 2, the interrater agreement was 0.741 (95% CI, 0.629-0.842) and 0.685 (95% CI, 0.554-0.805) at the 2 time points for fair and poor agreement, respectively. The intra-rater agreement for method 2 was 3.34 mm (95% CI, 2.88-3.80) average difference between the 2 time points.

Smekal et al.[20] assessed different modalities and views to determine the most accurate method compared to the CT in 30 patients. They used a standardized method of measuring. Measurements were performed by 4 observers on 2 occasions. A paired t-test or a nonparametric Wilcoxon signed-rank test for determination of differences of mean values in paired samples was performed. The Kolmogorov-Smirnov test was used for determination of the distribution form. For the assessment of repeatability between occasions 1 and 2, the repeatability coefficient according to Bland and Altman was used. The differences among measurements on the 4 plain radiographs and CT scans were not significant. Also there was no significant difference shown in measurements on both occasions. Repeatability coefficients were comparable for CT measurements, the posteroanterior thorax radiographs and the 15° caudo-cranial anteroposterior panorama radiographs of the shoulder girdle. Repeatability coefficients for the clinical measurements and measurements on 15° caudo-cranial radiograph of the clavicle were markedly higher indicating lower repeatability.

Archer et al.[21] aimed to identify correlation between plain AP film and computed tomography (CT) measurement of displacement and the inter- and intraobserver reliability of repeated radiographic measurements. 6 observers (3 orthopedic surgeons and 3 residents) measured the clavicles of 22 patients with an interval of two weeks. Shortening was assessed using the contralateral unfractured side as a reference. Participants were not instructed on what specific points within the fracture should be measured to estimate shortening and was therefore not standardized. The limits of agreement calculated using the Bland–Altman repeatability coefficient revealed a mean of ± 3.48 cm. The error inherent in plain film measurements in this study is 6.96 cm. Intraobserver agreement calculated with the paired t-tests demonstrating a $p>0.05$ in 5 of 6 observers. The authors conclude that plain AP film measurements of acute MSCF do not reliably predict shortening.

DISCUSSION

In this systematic review we evaluated the reliability and reproducibility of measurements of shortening in MSCF. The results of this systematic review demonstrate that the literature on this topic did yield only 3 fair and 1 poor quality studies. Since shortening plays an increasingly important role in deciding on surgical intervention of MSCF it is important to have a reliable and accurate method of measuring. Despite the lack of high-quality studies, the available knowledge and literature should not be discarded.

Smekal et al.[20] published a paper validating the accuracy/reliability of measurements of different imaging modalities and techniques. They found that the PA thorax approximated the measurements on CT the best. Measurements on 15° tilted caudo-cranial radiograph of the clavicle and clinical measurements showed the smallest agreement with CT measurements. However, they did not state the reproducibility of measurements. The measurements were performed in healed malunited clavicle fractures and not in the acute phase. This was done to ensure static conditions in time. This is a strong feature of the study since Plocher et al.[22] described progressive shortening in acute MSCF in time.

The PA thorax means a higher dose for the patient of 0.1mSv compared to 0.02mSv for a clavicle AP.[23] It also relies on symmetry of the clavicle using the unfractured side for comparison. A study by Cunningham et al.[24] reported asymmetry of the intact clavicle of more than 5mm in almost 30% of patients. This may mean that measuring shortening of the MSCF compared to the unfractured side may be less reliable than assumed.

Archer et al.[21] also used the assumption of symmetry which may compromise reliability. They found a limit of agreement of 3.48 cm indicating that plain AP film of the fractured clavicle is not reliable in the prediction of the shortening measured on the CT scan. However they found an ICC of 0.90. The statistical method for calculating intra-rater variability using the paired t-test may be debatable but they report no significant differences in measurements in 5 of 6 observers.

Jones et al.[18] reported weak to no agreement in inter- and intra-rater agreement for radiological shortening using AP and 30° caudo-cranial views. They did not report a standardized method of measuring the shortening on these views. In addition, they also reported minimal to moderate interrater agreement for displacement and comminution. Intra-rater agreement was strong for comminution, moderate for displacement and minimal for shortening.

In contrast to current standard practice in which AP and 15° caudo-cranial views are made, papers have been published that support the use of a 15-30° cranio-caudal AP or PA or PA thorax view as being the most accurate in measuring the shortening of MSCF.[20, 25-27] Although commenting on accuracy, these studies did not report the reproducibility of these views. Silva et al.[19] proposed a standardized mode of measuring shortening in MSCF. Their paper focused on adolescents, not adults, and also did not report the imaging modality or technique used. After contacting the corresponding author it was verified that measurements were performed on standard AP and 15° caudo-cranial views. They reported no difference in a standardized measurement or method of choice concerning inter- and intra-observer variability. More recent studies find both a moderate and excellent interrater agreement using a standardized method of measuring.[28, 29]

Two studies were not included in the review because these studies did not meet the inclusion criteria as only interrater agreement and not intra-rater agreement was reported. However, we believe these studies are worth mentioning here. Stegeman et al.[29] found an intraclass correlation coefficient of 0.97 (CI 0.95-0.99) between 2 observers measuring shortening in a standardized way on 32 AP X-rays of the fractured clavicle. Interestingly, they found only a moderate agreement (0.45 CI 0.12-0.69) for measuring absolute shortening on the AP panoramic view after consolidation indicating that the imaging technique may be influential on the reliability of measurements as well. Malik et al.[28] report a ICC of 0.926 (CI 0.909-0.941) between 4 observers using a standardized method of measuring shortening of the fractured clavicle in 196 AP Chest X-rays. These images were made with the patient varying between supine, semi-upright and upright positions. The goal of this study was to evaluate differences in measured shortening between the different positions of the patients. No additional information on statistical analysis or interrater agreement per subgroup was reported.

Other factors reported to influence reliable and reproducible measurements are variation in magnification due to X-ray positioning and possibly positioning of the patient.[18, 28, 30] Backus et al.[30] reported a statistically significant difference between upright and supine patient positioning concerning shortening and displacement. Malik et al.[28] found a significant step-wise progression of measured shortening between supine, semi-upright and upright positioning of the patient.

Some limitations of this study have to be discussed. First, there is only limited available literature on the topic of measuring the fractured clavicle. Since 4 studies were included and none of them were rated as good or excellent quality according to the COSMIN checklist it was not possible to draw definite conclusions or make definite recommendations. Second, although the COSMIN checklist is considered the best available option to evaluate the methodological quality of studies on measurement properties, the "worst score counts" algorithm might underestimate the overall quality of a paper (e.g. 1 poor score out of a total of 11 items results in a poor overall score). For that reason, we provided the scores for all items using the 4-point scale. Other limitations of this study include the possibility of publication bias and language restrictions. Third, the inclusion criteria used might have been too strict. Two papers that did not meet the inclusion criteria were identified but yet could be of value on the topic. Including these papers,[28, 29] however does not influence the final conclusion pertaining the lack of evidence on the subject.

In order to optimize future studies and the realization of comparable results a standardized method of imaging and measuring is of great importance. When considering the optimal method of imaging and measuring the fractured clavicle one should consider the following: Imaging modality and technique, patient positioning, radiation exposure, costs and the method for measuring shortening and/or displacement. To identify a standardized method a compromise between these factors should be made based on further research.

CT scans and PA thorax seem more accurate but the first is more expensive and both expose the patient to a much higher radiation dose. Supine positioning of the patient may underestimate the actual shortening and displacement, which in turn can negatively influence the decision to surgically reduce and fixate the MSCF. Calibrated views will prevent magnification errors while measuring. Although not proven better it might be a consideration to optimize consistency by measuring shortening and displacement in a standardized and possibly proportional way as proposed by other authors.[9, 13, 19, 30, 31]

CONCLUSION

The objective of this systematic review was to evaluate the reliability and reproducibility of measurements of shortening in MSCF using any available imaging technique.

We identified 4 studies on reliability of measurement of MSCF. Since these studies were only of fair and poor quality it was impossible to draw definite conclusions. Shortening is one of the reasons to surgically treat the fractured clavicle so further research is needed to identify the most effective, reproducible and reliable method of imaging and measuring. In order to optimize future studies and the realization of comparable results a standardized method of imaging and measuring is of great importance.

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APPENDIX 3.1

Search Pubmed

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(shorten OR shortened OR shortened' OR shortening OR shortening' OR shortenings OR shortens)
(displace OR displaced OR displaced' OR displaceing OR displacement OR displacement' OR displacements OR displaces)
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(radiograph OR radiographs OR radiographical OR radiograph')
(image OR images OR imaging OR imagings)
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Quantifying shortening of the fractured clavicle assuming clavicular symmetry is unreliable

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ABSTRACT

Background: One of the more commonly used methods of determining the amount of shortening of the fractured clavicle is by comparing the length of the fractured side to the length of contralateral unfractured clavicle. A pre-existing natural asymmetry can make quantification of shortening using this method unreliable. The goal of this study is to assess the side-to-side variation in clavicle length in 100 uninjured, skeletally mature adults.

Materials and methods: In order to assess the side-to-side difference in clavicle length the length of both clavicles of 100 patients on thoracic computed tomography (CT) scans were measured. Patients without a history of pre-CT clavicular injury were included. The measurements were allocated into 3 groups based on the amount of asymmetry (<5 mm, ≥5-10 mm and >10 mm). Dominant side and sex were analyzed to determine influence on the length of the clavicle.

Results: In 30 patients (30%) an asymmetry of 5 mm or more was found. 2% of the patients had a side-to-side difference of more than 10 mm. The absolute side-to-side length difference (LD) was 3.74 mm (95%CI 3.15 to 4.32; p<0.001) A significant association between clavicle length and dominant side or sex was found (p<0.001).

Conclusion: These results show that by utilizing a treatment algorithm based upon clavicular symmetry has a potential for error and can lead over- or under-treatment of the fractured clavicle. A significant association between clavicle length and dominant side or sex was found (p<0.001).

Level of evidence: 2.

Keywords: clavicle; length; symmetry; interobserver agreement; imaging

INTRODUCTION

Clavicle fractures are common fractures with a prevalence of 59.3 per 100,000 person-years.[1] The majority of these fractures are shortened and/or displaced due to the specific anatomy and muscle insertions. There is still no consensus on how to treat these displaced and/or shortened midshaft clavicle fractures (DMCF). Operative treatment leads to better rates of union, less mal-unions and increased patient satisfaction in comparison to conservative therapy but it is accompanied by a higher rate of adverse events.[2, 3] A recent meta-analysis by Kong et al.[4] of 6 Randomized Controlled Trails (RCTs) comparing conservative and operative treatments supports these findings. Other studies report on increased pain, loss of strength, rapid fatigue, hyperesthesia of the hand and arm, difficulty sleeping on the affected side and aesthetic complications in conservatively treated, malunited and shortened clavicles.[5-7] These may be the reasons why in recent years there is a tendency to surgically reduce and fixate DMCF.[5-10] Current treatment paradigms support the indication for surgery if the fractured clavicle is shortened more than 15 mm, or displaced more than the diameter of the clavicle's shaft.[2, 5, 7, 9, 11-13]

Since the clavicle has a sigmoid shape in two planes, adequately quantifying shortening of the fracture elements is challenging. Other variables influencing measurements on the fractured clavicle are patient positioning, magnification, direction of the X-rays.[14-16] Various methods to quantify shortening, such as clinical measurements and the use of CT scans have been described.[16-18]

A commonly used technique is by using AP and 15 degrees caudo-cranial views. However, there are papers support the use of a 15-30 degrees cranio-caudal AP or PA views. Also a PA thorax view is used in measuring the shortening of DMCF[14, 16-18] Silva et al.[17] proposed a standardized method of measuring shortening in DMCF even though no better interobserver agreement was shown.

It remains unclear which method or technique would be best to quantify shortening of the fractured clavicle.

Another commonly used method is to determine the amount of shortening by comparing the fractured side to the contralateral unfractured clavicle on a panoramic AP view of both clavicles. This presumes clavicular symmetry. To our knowledge there is only one study that investigated clavicular symmetry. Cunningham et al.[19] reported an asymmetry of clavicular length of 5 mm or more in 28.5% of the studied population and found no association between side-to-side differences and sex. However, they did not exclude pre-CT clavicular injuries or investigate associations between side-to-side differences and hand dominance. This might be valuable since hand dominance is associated with differences in upper-limb bone mineralization and hand size.[20, 21]

Because in recent years an absolute shortening of 15 mm is thought to be a relative indication for surgery,[5, 9, 13] a pre-existing asymmetry of 5 mm or more in an important part of the population may lead to the conclusion that quantifying shortening using this method is unreliable.[19]

The goal of this study was to assess the side-to-side difference in clavicle length in 100 skeletally mature adults without any pre-CT clavicular injuries, and to investigate possible associations between clavicular length and sex or hand dominance.

METHODS

Design

In order to assess the side-to-side differences in clavicle length we measured the length of both clavicles of 100 patients on 100 thoracic computed tomography (CT) scans. The study protocol was approved by our institutional review board (CMO 2014-1432).

Patients

Each thoracic CT scan that was made between September 2014 and February 2015 in our institution for any reason was first assessed if both clavicles were completely and adequately imaged. If so, we contacted each patient of whom we would like to use the CT scan. During the phone interview verbal consent was given by patient involved to use their images. All patients were over 18 years old. Only those patients without a history of pre-CT clavicular injury were included. All patients included stated their dominant side.

A total of 132 scans were evaluated. 2 patients did not want their thoracic CT scan to be included. 12 patients could not be reached on multiple occasions. 3 patients were deceased. 15 were excluded due to a clavicular fracture in the past.

Measurements

Two observers (SF (radiologist) and AA (medical student)) measured both clavicles in random order on a 3D reconstruction of the CT-scan using TeraRecon Aquarius Intuiton (Foster City, CA, USA). Measurements on a patient's right and left clavicle were performed on separate occasions at least 2 weeks apart in order to prevent bias. Before the start of the study a training session with both observers took place and the measurement methodology was standardized. The observers agreed upon the precise definitions of the reference points. The reconstructions were projected in such a way that the length of the clavicle was maximized according to the observer. Clavicle length was defined as the distance between the lateral-most point of the clavicle in the acromioclavicular joint and the medial-most point of the clavicle in the sternoclavicular joint. The clavicle length was measured between these points using the same software (Figure 4.1). The absolute side-to-side length difference (LD) between the right and left clavicles was calculated by subtracting the length of the short side (SS) from the length of the long side (LS). The LD were categorized into 3 groups based on the amount of asymmetry. One group included all patients in which the side-to-side difference was <5 mm. The other two groups consisted of those patients with an asymmetry of ≥5-10 mm and >10 mm side-to-side difference. These criteria were chosen since a 5mm side-to-side difference might be clinically relevant when deciding on a surgical intervention of the fractured clavicle.

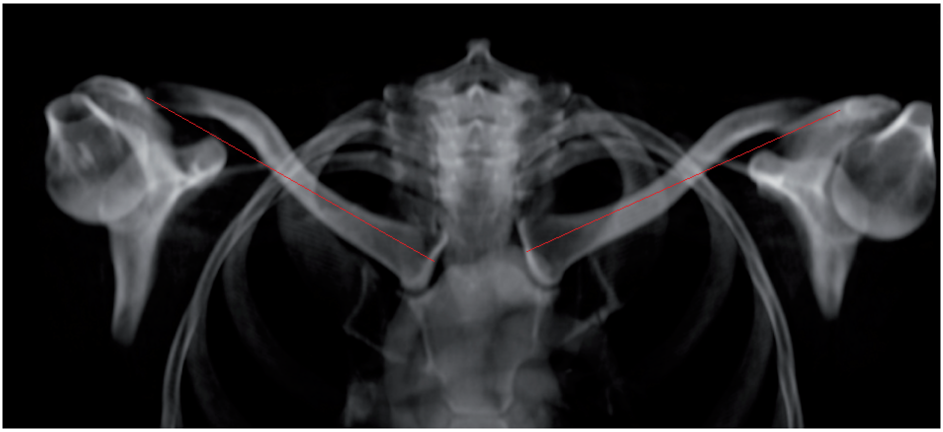

Figure 4.1. Example of measurements on 3D reconstruction of a CT scan showing both clavicles.

Statistical analysis

Interobserver agreement was assessed by calculation of concordance correlation coefficients (CCC). The CCC for repeated measurements (left & right clavicle) were estimated using the variance components from a linear mixed model estimated by restricted maximum likelihood.[22, 23] Limits of agreement (LoA) were calculated to assess systematic and random measurements error between both observers.

Measurements were only performed once since intraobserver agreement for measurements performed on CT-scans is known to be high.[19, 24] Measurements of both observers were averaged when interobserver agreement was almost perfect (i.e. CCC ≥ 0.99).[25]

Descriptive statistics were used to summarize the data. Paired sample t-tests were used to test side-to-side length differences. The associations between clavicle length and dominant side and sex were tested using linear mixed models using dominant side and sex as fixed factors and patient as random factor. P-values <0.05 were considered statistically significant. Statistical analyses were performed using R 3.3.2 (R Foundation, Vienna, Austria) with package 'cccrm'.[26]

RESULTS

The mean systematic difference in measured clavicle length between both observers was 0.88 mm (LoA -2.47 to 4.48). The observers showed an almost perfect agreement (CCC 0.99 (95%CI 0.98 to 0.99) and the measurements of both observers were averaged.

Of the 100 included CT scans, 42 belonged to male and 58 to female patients. The mean age of the patients was 55.5 years (range 18 to 80 years). 91 patients were right-handed and 9 were left-handed. The clavicle length measurements are presented in Table 4.1.

Table 4.1. Clavicle length measurements

Clavicle length (mm)	Mean (range)
Side	
Left	147.8 (122.5 to 175)
Right	146.0 (121.5 to 171.5)
Gender	
Male	154.8 (130 to 175)
Female	141.2 (121.5 to 161)
Dominance	
Dominant	146.0 (121.5 to 171.5)
Non-dominant	147.9 (122.5 to 175)

Right clavicles were 1.79 mm (95%CI 0.91 to 2.66; $p<0.001$) shorter than the left. The absolute side-to-side length difference (LD) was 3.74 mm (95%CI 3.15 to 4.32; $p<0.001$). 28 patients (28%) had an asymmetry between the right and left clavicle of between 5 mm-10 mm and 2% had an asymmetry of more than 10 mm (Figure 4.2). Both sex (regression coefficient for males: 13.26 mm (95%CI 9.85 to 16.67; $p<0.001$) and dominant side (regression coefficient for non-dominant side: 1.77 mm (95%CI 0.90 to 2.63); $p<0.001$) were associated with clavicle length.

DISCUSSION

The goal of this study was to assess the side-to-side variation in clavicle length in 100 uninjured, skeletally mature adults using CT scans. In order to exclude the possibility of variation due to prior clavicular fractures, only patients of whom it was ascertained no prior clavicular fractures had occurred were included. The most important finding in this study is that 30% of the studied population had an asymmetry between the right and left clavicle of 5 mm or more. 2% had an asymmetry of more than 10 mm. This difference could be clinically significant when adhering to the treatment paradigm of surgically

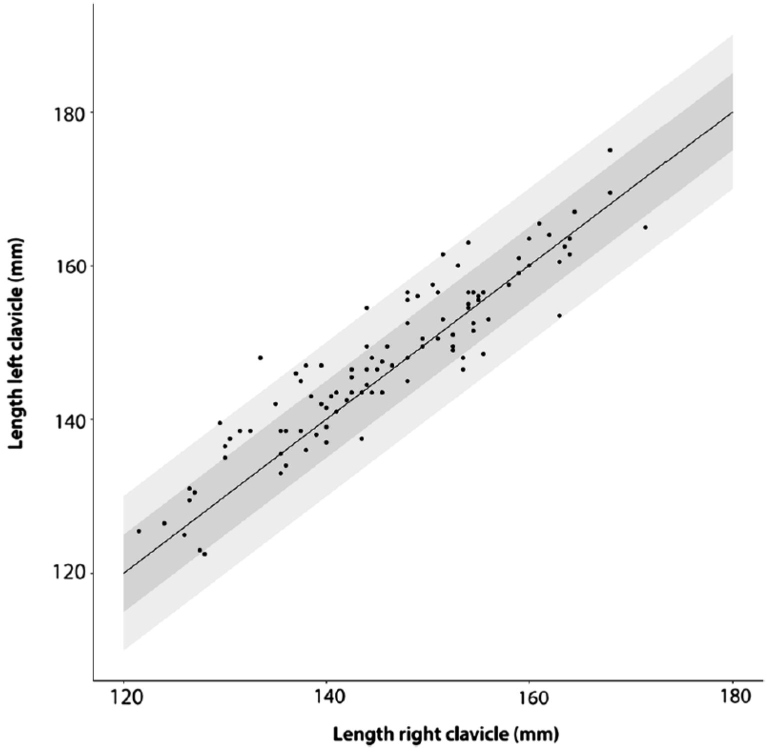

Figure 4.2. Scatterplot of right versus left clavicle lengths. Dots in the dark grey area represent length differences <5 mm. Length differences between 5 and 10 mm are within the light grey area.

treating DMCF when shortened more than 15 mm. There is a large potential for error that could lead over- or under-treatment of the fractured clavicle. It is debatable whether shortening should be used as an indicator for surgery but since there is no standardized method of measuring and imaging the fractured clavicle it also cannot be discarded. A uniform method that takes into account natural asymmetry, patient positioning, imaging technique and measuring technique could potentially answer this question in the future.

CT-scans were used since this technique provides the most accurate measurements in comparison to others, such as conventional X-rays or clinical measurements.[18] Cunningham et al.[19] were the first to describe an asymmetry of 28.5% of ≥5 mm in their researched population. This may lead to the conclusion that quantifying shortening using this method may be unreliable for a significant portion of the population. Unlike Cunningham et al.[19] the present study did investigate the effect of dominant side on clavicular length.

To our knowledge, this study is the first to describe the statistically significant association between clavicle length and dominant side and sex ($p<0.001$).

A significantly shorter length of the right clavicle and dominant side of respectively 1.79 mm and 1.77 mm was found. The negative association between hand size and dominant side found by Manning et al.[20] seems also to be true for clavicle length and dominance. The number of right sided dominance found in our study is in concordance with that of the normal population.[19]

Some potential limitations have to be discussed. It should be noted that the only way of assessing fractures of the clavicle in the past is by using the patient history. This could introduce the chance of recall-bias. It can be argued that not everybody who denied having had a fracture of the clavicle would remember the event of clavicle fractures during birth. However only 2.0-2.7% of deliveries cause a birth-related clavicle fracture so the influence of this could be deemed insignificant since an asymmetry ≥5 mm in 30% in the studied population was found.[27-29] Another limitation could be that it can be difficult of identify the true extent of the lateral end of the clavicle on CT, particularly on 3D-CT reconstructions. In order to minimize variability a training session for the observers and using a standardized measurement methodology was included. A CCC of 0.99 showed this strategy results in a reliable identification of the right point at the lateral end of the clavicle. A third limitation could be the fact that the measurements were performed once by each observer. However, Cunningham et al.[19] reported a strong interobserver reliability with an ICC ranging from 0.70 to 0.86 as well as similar observed length differences (within 1-2 mm) for all observers. Furthermore, a recent study by Goudie et al.[24] used one observer under the assumption CT measurements of the clavicle are precise.

CONCLUSION

This study demonstrates that 30% of patients have clavicular side to side asymmetry of 5 mm or more. A significant association between clavicle length and dominant side or sex was found ($p<0.001$). Utilizing a treatment algorithm based upon symmetry therefore has a potential for error and can lead over- or under-treatment of the fractured clavicle. In order to optimize reliability of imaging and measuring shortening of the fractured clavicle more research is needed. One should consider natural asymmetry, imaging modality and technique, patient positioning, and method for measuring in order to identify a standardized and reliable method to adequately use the amount of shortening in the treatment algorithm the fractured clavicle.

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5

Influence of X-ray direction on measuring shortening of the fractured clavicle

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ABSTRACT

Background: Midshaft clavicle fractures (MSCF) are often associated with a certain degree of shortening. There is a great variety in imaging techniques and methods to quantify this shortening. This study aims to quantify the difference in measurements of shortening and length of fracture elements between 5 views of the fractured clavicle. Furthermore, the inter- and intra-observer agreement between these views using a standardized method is evaluated.

Materials and methods: Digitally Reconstructed Radiographs (DRR) were created for 40 CT data sets in AP, 15° and 30° cranio-caudal, 15° and 30° caudo-cranial views. A standardized method for measuring length of the fracture elements and the amount of shortening was used. Inter- and intra-observer agreement for each of the 5 views was calculated.

Results: The inter- and intra-observer agreement was excellent for all 5 views with all ICC values greater than 0.75. The measured differences in relative and absolute shortening between views were statistically significant between the 30° caudo-cranial view and all other views. The increase in median shortening measured between the commonly used 30° caudo-cranial view (2.7 mm) and the AP view (8.5 mm) was 5.8 mm ($p<0.001$). The relative median shortening between these views increased 3.4% ($p<0.001$).

Conclusion: The length of fracture elements and the amount of shortening in the fractured clavicle can be reliably measured using a standardized method. The increase in absolute and relative shortening when comparing the caudo-cranial view measurements to the AP and cranio-caudal measurements may indicate that the AP and cranio-caudal views provide a more accurate representation of the degree of shortening.

Level of evidence: 2.

Keywords: clavicle; fracture; imaging; shortening; interrater agreement; intra-rater agreement

INTRODUCTION

In the last decades, there has been an increased tendency to surgically treat displaced, shortened and/or comminuted clavicle fractures as operative treatment provides a significantly lower rate of nonunion as well as an earlier functional return and increased patient satisfaction compared to non-operative treatment.[1-4]

Due to the specific anatomy of the clavicle and its surrounding tissues, mid-shaft clavicle fractures (MSCF) are often associated with a certain degree of shortening. This shortening is identified as a determinant for poorer outcomes concerning union rates and long-term effects such as pain, loss of strength, rapid fatigue, hyperesthesia of the hand and arm, difficulty sleeping on the affected side, and aesthetic complications.[5, 6] Godfrey et al. reported that the degree of symptomatology and occurrence of mal- and non-union after MSCF is related to the extent of shortening and displacement of the fracture elements.[7]

Biomechanical studies and simulations have shown that a shortened clavicle can lead to altered scapular kinematics and shoulder function.[8-10] Weinberg et al.[11] reported that there is a strong association between shortened clavicles and the occurrence of gleno-humeral joint arthritis.

Recently, Woltz et al.[12] performed a systematic review regarding the influence of shortening on shoulder function after union of non-operatively treated midshaft clavicular fractures. They concluded that shortening alone is currently not an evidence-based indication to operate for the goal of functional improvement. However, this conclusion is based on a heterogeneous group of methods, definitions and measuring techniques. Furthermore, functional improvement is not the only important outcome parameter in the treatment of MSCF. To evaluate whether shortening can be used, or should be discarded, as an indicator for surgery it is important to identify an evidence-based, standardized, accurate and reliable method to measure shortening.

There is a great variety in imaging techniques and measurements of the fractured clavicle and adequate measurements of the fractured clavicle are subject to a plethora of influences such as patient positioning,[13, 14] timing,[15] methods of measuring,[16] physiological side-to-side difference[17] and direction of the X-ray beams.[18, 19]

In acute MSCF the most commonly used views to determine shortening are the standard AP and a 15-30° caudo-cranial view. However, there are reports that suggest this view might not be the most accurate and reliable.[19-21]

Therefore, the aims of this study were 1) to quantify the difference in measurements of shortening and length of fracture elements between 5 different (30 and 15 caudo-cranial, AP, and 15 and 30 cranio-caudal) views of the fractured clavicle, and 2) to identify and quantify the differences in inter- and intra-observer agreement between the 5 different views using a standardized method for measuring the shortening and length of fracture elements.

MATERIALS AND METHODS

A clinical measurement study quantifying the difference in measurements of shortening and length of fracture elements between 5 different views of the fractured clavicle was conducted. The database of the National Trauma Registration (NTR) was used to search for consecutive patients who were diagnosed with a clavicle fracture on the Emergency Department (ED) and underwent a thoracic CT-scan during advanced trauma life support (ATLS) screening in our hospital between June 2009 and August 2014. Patients with 1) a Robinson type 2B1 fracture of the clavicle, and 2) an adequate and complete imaging of the fractured clavicle on CT-scan and 3) skeletally mature (≥18 years old) were eligible for inclusion. The study protocol was approved by our Institutional Review Board (CMO Arnhem-Nijmegen 2015-1768).

The CT scans were made using a Toshiba Aquilion One (Tustin, CA, USA), Siemens Somatom 16 or Siemens Somatom 64 (Erlangen, Germany) scanner and scans were uploaded and analyzed with TeraRecon Aquarius iNtuiton (Foster City, CA, USA). Digitally reconstructed radiographs (DRR) were created for each CT data set at 5 angles; AP, 15° and 30° cranio-caudal, as well as a 15° and 30° caudo-cranial view. Each DRR represented a two-dimensional X-ray film of the fractured clavicle (Figure 5.1).

A standardized method for measuring as described by Silva et al.[16] was used as shown in Figure 5.2. In short, lines through both the medial and lateral fragment of the clavicle were drawn from the center of the AC or SC joint to the center of the fracture plane. The lengths of these lines represent the lengths of the fragments. Next a perpendicular line was drawn from the line through the medial fragment at the fracture plane. Subsequently, a parallel line was drawn to this line at the point where the line through the lateral fragment intersects the fracture plane. The difference between the latter two lines indicates the amount of shortening in millimeters (mm).

All measurements were performed on the five different DRR views of each patient to determine the length of fracture elements and amount of shortening. 3 observers (two orthopedic residents (PH, AG), one medical student (AA)) evaluated the 5 DRRs for each patient in random order as described above. In order to calculate intra-observer agreement, the same observers performed a second evaluation of the same randomized DRRs 2-4 weeks after the first measurements were performed. Before the start of the study, a training session with each observer took place. The precise definition of the reference points was agreed upon between the observers. Measurements were performed using the hospitals IMPAX software (version 6.5.3.1005).

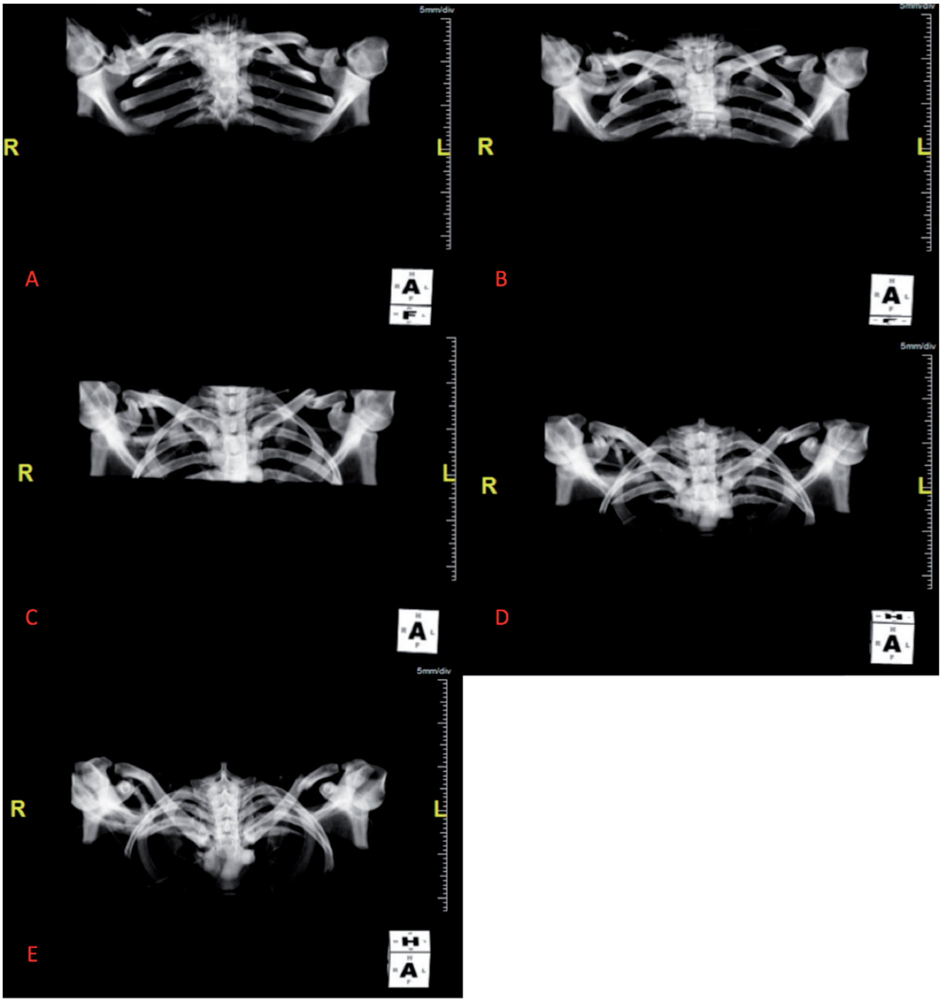

Figure 5.1. Set of 5 Digitally Reconstructed Radiographs in 5 different views of the same fractured clavicle in 1 individual. **A:** 30° caudo-cranial, **B:** 15° caudo-cranial, **C:** AP, **D:** 15° cranio-caudal, **E:** 30° cranio-caudal.

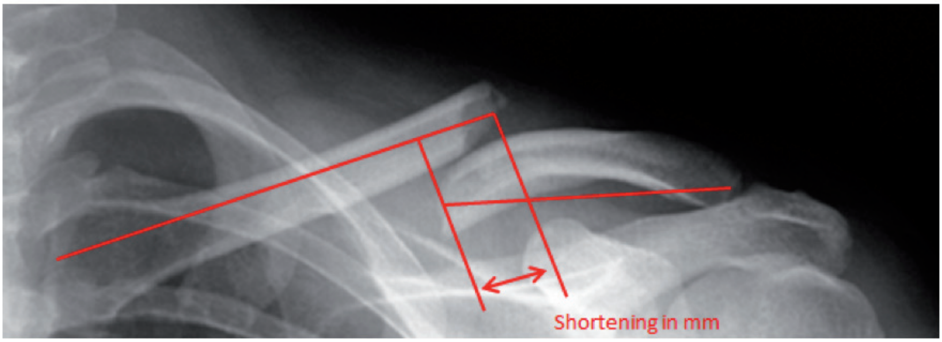

Figure 5.2. Standardized method of measuring shortening of the MSCF as adapted from Silva et al.[22]

Descriptive statistics were used to summarize the data. Intra-class correlation coefficients (ICCs) were used to assess the inter- and intra-observer agreement for each of the five views. ICC values were interpreted as follows: <0.40 poor; 0.40 to 0.59 fair; 0.60 to 0.74 good, 0.75 to 1.00 excellent.[22] The ICC was calculated from a two-way random effects model, for absolute agreement. The mean of the shortening as measured by the three observers was used in descriptive statistics and further statistical analyses when ICC values were excellent. The 'limits of agreement with the mean', a modification to the Bland–Altman type methodology described by Jones et al.[21] that can be used for more than two observers and retains the ability to evaluate consistency of agreement over different magnitudes of continuous measurements, were calculated.

Friedman's one-way repeated measures analysis of variance by ranks was used to test for differences in (absolute and relative) shortening obtained from the five different views followed by Wilcoxon signed-rank tests for pairwise comparisons. The Benjamini-Hochberg procedure with a false discovery rate (FDR) of 0.05 was used for multiple testing corrections.[23] False discovery rate (FDR) control is a statistical method used in multiple hypotheses testing to correct for multiple comparisons. Among tests that are declared significant, the false discovery rate is the expected fraction of those tests in which the null hypothesis is. Statistical analyses were performed using R version 3.4.0 (R Foundation, Vienna, Austria). P-values <0.05 were considered statistically significant.

RESULTS

A total of 269 patients diagnosed with a clavicle fracture were identified through screening of the Dutch Trauma Registry (Nederlands Trauma Register, NTR). These patients presented to the Emergency Department (ED) between 2009-2014. 229 of patients were excluded because the clavicle fracture was either medial, lateral, in a patient <18 years old, no CT scan was made or the CT scan was not showing the entire clavicle. 40 patients with displaced midshaft clavicle fractures and adequate CT imaging were included and for all 40 patients DRRs in 5 different views were created. The study population included 27 males and 13 females, 17 fractures concerned the right side and 23 the left side. Average age was 43.5 (range 19-78).

The ICCs were excellent for all intra-observer measurements and inter-observer measurements (Table 5.1 and 5.2). Since the intra- and interobserver agreement were excellent, the average of the shortening as measured by the three observers was used. However, the maximum limits of agreement with the mean was –9 to 9 mm for the 15° cranio-caudal view, indicating that individual observers can be discordant with the mean estimated shortening on a 15° cranio-caudal view by as much as 9 mm (Table 5.2).

The measured absolute lengths of the medial fragment, lateral fragment and thus total length showed an increase from caudal-cranial to cranial-caudal views (Table 5.3).

The median absolute shortening measured from the 30° caudo-cranial view (2.7 mm) was significantly less compared to the 15° caudo-cranial view (5.6 mm; $p<0.001$), AP view (8.5 mm; $p<0.001$), 15° cranio-caudal view (7.6 mm; $p<0.001$), and 30° cranio-caudal view (8.7 mm; $p<0.001$) (Figure 5.3). Median absolute shortening measured on both the AP (8.5 mm; $p=0.01$) and 15° cranio-caudal (7.6 mm; $p=0.01$) views were significantly more compared to the median absolute shortening measured on the 15° caudo-cranial view (5.6 mm).

Table 5.1. Interobserver agreement; values representing mean (95% CI)

View	ICC (95% CI)		
	Observer 1	Observer 2	Observer 3
30° caudo-cranial	0.96 (0.91-0.98)	0.84 (0.71-0.91)	0.81 (0.65-0.89)
15° caudo-cranial	0.98 (0.96-0.99)	0.90 (0.81-0.95)	0.81 (0.64-0.90)
AP	0.86 (0.75-0.92)	0.87 (0.61-0.94)	0.80 (0.64-0.89)
15° cranio-caudal	0.97 (0.94-0.98)	0.87 (0.71-0.93)	0.79 (0.61-0.89)
30° cranio-caudal	0.94 (0.89-0.97)	0.79 (0.63-0.88)	0.87 (0.72-0.94)

ICC, Intraclass Correlation Coefficient. CI, confidence interval. AP, anteroposterior.

Table 5.2. Intra-observer agreement; values representing mean (95% CI)

View	ICC (95% CI)	Limits of agreement with the mean (mm)
30° caudo-cranial	0.83 (0.74-0.90)	-7.4 to 7.4
15° caudo-cranial	0.83 (0.73-0.90)	-7.6 to 7.6
AP	0.79 (0.67-0.88)	-8.3 to 8.3
15° cranio-caudal	0.76 (0.64-0.86)	-9.0 to 9.0
30° cranio-caudal	0.76 (0.63-0.85)	-8.9 to 8.9

ICC, Intraclass Correlation Coefficient. CI, confidence interval. AP, anteroposterior.

Table 5.3. Measurements of the 5 different views

View	Length medial fragment, median (range), mm	Length lateral fragment, median (range), mm	Total length, median (range), mm	Shortening, median (range), mm	Relative shortening
30° caudo-cranial	70.6 (46-99)	54.2 (24-89)	124.8 (96.1-155.2)	2.7 (-10.5-29.4)	3.5%
15° caudo-cranial	75.4 (58-97)	56.1 (36-76)	131.6 (101-158)	5.6 (-4-35)	5.9%
AP	80.1 (56-101)	59.9 (41-82)	140.0 (106-172)	8.5 (-3.7-40.3)	6.9%
15° cranio-caudal	84.0 (56-106)	63.4 (44-86)	147.3 (101-181)	7.6 (-4-42)	6.9%
30° cranio-caudal	86.2 (62-109)	67.1 (50-97)	153.3 (121-181)	8.7 (-35.8-37.9)	6.7%

AP, anteroposterior.

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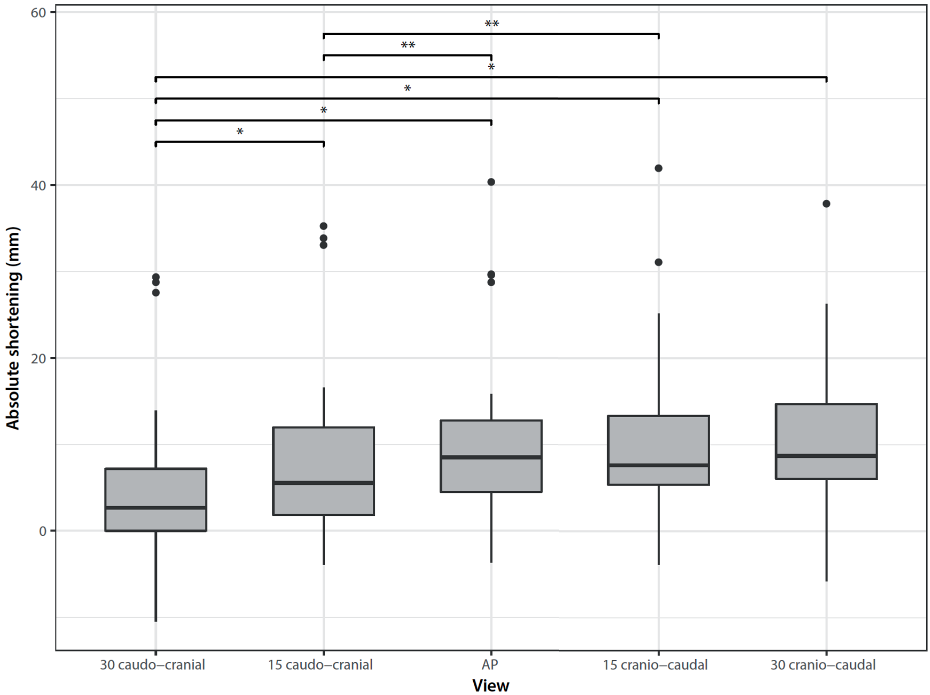

Figure 5.3. Boxplot showing absolute shortening (mm) for the 5 different views. * p<0.001, ** p=0.01.

The median relative shortening measured from the 30° caudo-cranial view (3.5%) was significantly less compared to the 15° caudo-cranial view (5.9%; p<0.001), AP view (6.9%; p<0.001), 15° cranio-caudal view (6.9%; p<0.001), and 30° cranio-caudal view (6.7%; p=0.002) (Figure 5.4).

No statistically significant differences in median absolute or relative shortening were found between the other views.

DISCUSSION

We aimed to identify and quantify differences in inter- and intra-observer agreement between the 5 views using a standardized method for measuring the shortening and length of fracture elements. Using a standardized method of measuring the fractured clavicle, as described by Silva et al.,[16] both intra-and interobserver agreements in all 5 views were >0.75 indicating an excellent agreement.[22] This indicates that the observers are able to reliably measure the shortening and that the direction of the X ray view itself is not influencing this reliability when using this standardized method. However, the estimated limits of agreement with the mean of approximately –8 to 8 mm indicate

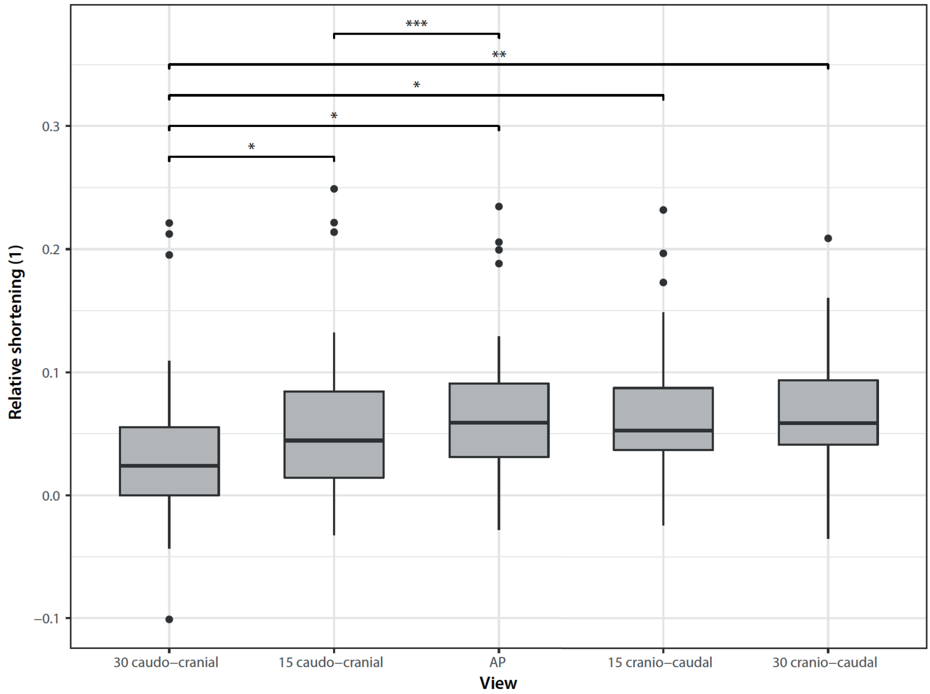

Figure 5.4. Boxplot showing relative shortening (1) for the 5 different views. * p<0.001, ** p=0.002, *** p=0.04.

that individual observers can be discordant with the mean estimated shortening by as much as 8 mm.

Silva et al.[16] compared two different methods of measuring shortening; 1) by method of choice or 2) by using a standardized method. They did not report in which direction the X ray was made, nor on which methods of choice were used and whether these may have been similar to their proposed method. When considering the inter-observer agreement, neither method was statistically superior to the other. When looking at the intra-observer agreement, method 2 had a significantly greater difference at the 2 time points than method 1.[16]

Jones et al.[21] scaled shortening into 5mm increments (from 0 to >30 mm) and found weak agreement for shortening of 0-5.0 mm (k=0.58, p<0.001) and 30.0 mm (k=0.51, p<0.001), minimal agreement for shortening of 5.1-10.0 mm (k=0.22, p<0.001), and no agreement for the other 4 categories. Intra-observer agreement was minimal for shortening (k=0.38, p<0.001).

The other aim of this study was to quantify the difference in measurements of shortening and length of fracture elements between 5 views of the fractured clavicle.

5

We found statistically significant differences in measurements of shortening between the 30° caudo-cranial view and all other views and the 15°caudo-cranial view and all others except the 30° cranio-caudal view. No statistically significant differences were found between the AP and cranio-caudal views. Our results show a difference in median shortening between the commonly used 30° caudo-cranial and AP view of 5.8mm ($p<0.001$). It is important to realize this difference exists and that the choice on which X-ray view to measure shortening could theoretically alter the choice of treatment.

We chose to use the method of measuring shortening by quantifying the overlap between fragments as described by Silva et al.[16] Even though some authors[24-26] use the AP panoramic view to measure shortening by comparing the fractured side to the contralateral side, we did not use this method since there are reports on natural side-to-side differences of ≥5 mm in 28.5% in the population.[17]

As for the relative shortening a statistically significant difference in shortening was found between the 30° caudo-cranial view and all other views and for the 15° caudo-cranial view and the AP and 30° caudo-cranial views. No statistically significant differences were found between the relative shortening of the AP and cranio-caudal views. To express shortening as a proportion is propagated by some authors since the same absolute shortening on a long clavicle could be less influential than on a short clavicle.[27-29] Our results show a 3.4% ($p<0.001$) difference in median of relative shortening between the commonly used 30° caudo-cranial and the AP view. Whether the statistically significant difference in measurements between views, both absolute and relative, would translate to a clinically relevant change in therapy remains unclear.

Another result of this study was the increase in measured absolute lengths from caudal-cranial to cranial-caudal views. It is still a debate which projection of the MSCF is the most accurate. Smekal et al.[19] reported that measurements on 15° AP caudo-cranial radiograph and clinical measurements showed the smallest agreement with CT measurements. Other papers have been published that support the use of a PA 15°-30° cranio-caudal view as being the most accurate in measuring the shortening of MSCF.[18,30] Axelrod et al.[20] created DRRs of fractured clavicles in different views to investigate which view was most accurate compared to a CT-scan. They found that the 2D clavicle shortening measured on an AP view with 20° cranio-caudal tilt consistently yielded measurements closest to, and not significantly different from the "gold standard" 3D CT measurements. By using DRRs a 2-dimensional image of a 3-dimensional situation is created. These DRRs are not subject to magnification by diverging X-ray beams so it can be argued that it is impossible to create an image of the clavicle larger than reality. With that in mind a more cranial view resulting in a larger measurement therefore would be approximating reality the best and supports the notion of it being a more accurate view than a caudo-cranial view.

A major strength of this study is the use of DRRs. By using DRRs, the different views of the fractured clavicle are not influenced by for example movement of the patient between X-rays or by the diverging beams and different distances to the detector. However, it is unknown how the DRRs relate to standard radiographs and further research on this is warranted. Another strength of this study is the use of a standardized method for measuring shortening as proven by the reported excellent intra- and interobserver agreement. A potential limitation of this study can be that all CT-scans, and as a consequence the DRRs, were fabricated in supine position. This may lead to an underestimation of the measured shortening according to Backus et al.[13] and Malik et al.[14] This would be a very important limitation when reporting on choice of treatment and/or its results, however in this study the main goal was to identify differences in measurements between different views and the intra- and interobserver agreement.

CONCLUSION

The length of fracture elements and the amount shortening in the fractured clavicle can be reliably measured using a standardized method. The increase in absolute and relative shortening when comparing the caudo-cranial view measurements to the AP and cranio-caudal measurements may indicate that the AP and cranio-caudal views provide a more accurate representation of the degree of shortening. Whether the differences in shortening between views translate to a clinically relevant change in treatment strategy when using shortening as an indicator for surgery remains unclear.

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6

Measurement of midshaft clavicle vertical displacement is not influenced by radiographic projection

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ABSTRACT

Background: Measured shortening of midshaft clavicle fracture fragments is known to be influenced by multiple factors. The influence of radiographic projection on vertical displacement is unclear. The aims of this study were 1) to quantify the difference in measurements of vertical displacement in an absolute, relative and categorical manner between 5 different projections, 2) to quantify the differences in inter- and intra-observer agreement using a standardized method for measuring the vertical displacement, and 3) to assess the association between categorical and continuous descriptions of vertical displacement.

Materials and methods: A clinical measurement study was conducted on 31 sets of digitally reconstructed radiographs (DRRs) in 5 different projections (15° and 30° caudo-cranial, AP, 15° and 30° cranio-caudal views). Categorical data on vertical displacement in quartiles from 0-200% were obtained followed by measurements using a standardized method by three observers at two points in time. Inter- and intra-observer agreement for each of the 5 views was calculated.

Results: The absolute and relative vertical displacement showed no statistically significant difference between any of the caudo-cranial, AP and cranio-caudal views. ICCs for intra-observer and interobserver agreement were good to excellent. The correlation between categorical outcomes and both absolute and relative vertical displacement was very strong.

Conclusion: Unlike for shortening, absolute and relative vertical displacement of the midshaft clavicle fracture is not significantly influenced by radiographic projection. Standardized measurements of vertical displacement may not be necessary for clinical use since the correlation between categorical and continuous measurements was found to be very strong.

Level of evidence: 2.

Keywords: clavicle; fracture; imaging; displacement; interrater agreement; intrarater agreement

BACKGROUND

Multiple studies have commented on the lack of a standardized and uniform method of measuring shortening and displacement of the fractured midshaft clavicle.[1-4] Various techniques and modalities have been described and it seems that their measurements of the fractured clavicle do not produce the same results.[2, 3] Measured shortening of midshaft clavicle fracture fragments is known to be influenced by factors such as patient positioning, timing after trauma and radiographic projection.[1, 2, 5-7] The influence of radiographic projection on measured shortening has previously been investigated.[2, 5] It was shown that there exists a significant difference between projections, and that cranio-caudal projections represent the length of the fracture elements and the amount of shortening most accurately.[2, 5] However, a recent study reported an increased tendency to surgically treat the same clavicle fracture when projected in caudo-cranial direction.[8] This discrepancy could be explained by possible vertical displacement differences between radiographic projections and its influence on the decision making. This is in contrast to the results of a survey amongst surgeons indicating that shortening and not the vertical displacement is considered most important in the decision algorithm.[9]

The influence of radiographic projection on measured vertical displacement, however, is unclear. Since the clinical consequence of vertical displacement of more than 100% between the fracture elements on the initial radiograph is associated with inferior clinical outcomes it is important to evaluate what the influence of projection on the measured vertical displacement is.[10] An increased amount of vertical displacement has been reported to be found compared to CT measurements when quantifying displacement on a 20 degrees caudo-cranial view compared to an AP (anteroposterior) view.[11] Studies commenting on vertical displacement do not necessarily quantify this in absolute numbers but in a categorical manner. Some studies have reported good to excellent reproducibility of qualifying displacement according to fracture classification.[1, 4, 9, 12]

An unanswered question remains whether a categorical description of vertical displacement is sufficient to be used in the decision-making algorithm (rather than necessitating quantitative measurements) to identify those who could benefit from operative intervention. Since vertical displacement may, just like shortening,[2] be influenced by projection further research on this topic is warranted. The specific aims of this study were: 1) to quantify the difference in measurements of vertical displacement in an absolute, relative and categorical manner between 5 different (30 and 15 caudo-cranial, AP, and 15 and 30 cranio-caudal) views of the fractured clavicle, 2) to quantify the differences in inter- and intra-observer agreement using a standardized method for measuring the vertical displacement and for categorical data per projection, and 3) to assess the association between categorical and continuous descriptions of vertical displacement.

MATERIALS AND METHODS

A clinical measurement study quantifying the difference in the absolute measurements of vertical displacement and in categorical manner between 5 different views of the fractured clavicle was conducted. A previously used de-identified database extracted from the National Trauma Registration (NTR) in the Netherlands was used.[2] This database contained consecutive patients who were diagnosed with a clavicle fracture on the Emergency Department (ED) and underwent a thoracic CT-scan during advanced trauma life support (ATLS) screening in the Radboud University Medical Center (RUMC), the Netherlands between June 2009 and August 2014. Patients with 1) a Robinson type 2B1 fracture of the clavicle, and 2) an adequate and complete imaging of the fractured clavicle on CT-scan and 3) skeletally mature (≥18 years old) were eligible for inclusion. The study protocol was approved by the RUMC's Institutional Review Board (Commissie Mensgebonden Onderzoek CMO Arnhem-Nijmegen 2018-4195).

The CT scans were made using a Toshiba Aquilion One (Tustin, CA, USA), Siemens Somatom 16 or Siemens Somatom 64 (Erlangen, Germany) scanner and scans were uploaded and analyzed with the hospitals IMPAX software version 6.5.3.1005 (Mortsel, Belgium). Digitally reconstructed radiographs (DRRs) were created for each CT data set at 5 equally spaced angles; AP, 15° and 30° cranio-caudal, as well as a 15° and 30° caudo-cranial view. Each DRR represented a two-dimensional X-ray film of the fractured clavicle.

First, categorical data on vertical displacement were obtained. The arbitrarily chosen categories were quartiles of displacement from 0 to 200%: no displacement, displacement of 1-50%, 51-100%, 101-200% or >200% of the shaft's width.

A standardized method for measuring displacement was used as follows (Figure 6.1).

To determine the diameter of the clavicle, a line perpendicular to the shaft on either the medial or lateral side closest to the fracture was drawn. In case of an oblique fracture this line was be drawn at the point where the shaft was intact in its entire circumference (Ds). To quantify the amount of vertical displacement a perpendicular line to the axis of the medial fragment was drawn between matching cortices of both fracture elements. In case the fracture elements were not overlapping, a reference line (dashed line in Figure 6.1) was drawn parallel with the medial fragment cortex followed by a perpendicular line between the matching cortex on the lateral fragment. The length of this perpendicular line in millimeters (mm) was considered the absolute amount of displacement (Da). A relative displacement (Dr) was calculated by the formula: $Dr = Da/Ds \times 100\%$.

All measurements were performed on the five different DRR projections of each patient. 3 observers (2 trauma-fellowship trained orthopaedic surgeons (ANEN, ZMW) and 1 medical student (AC)) evaluated the 5 DRRs for each patient in random order as described above. In order to calculate intra-observer agreement, the same observers

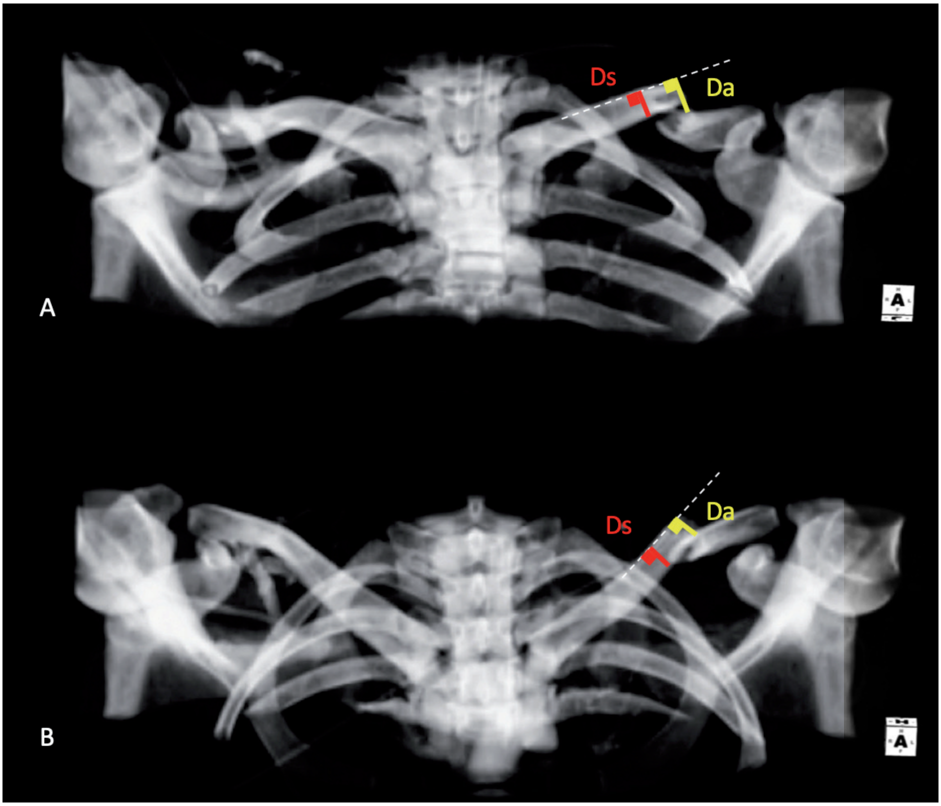

Figure 6.1. Example of a Digitally Reconstructed Radiograph (DRR) of the same clavicle fracture in **A)** 15° caudo-cranial and **B)** 15° cranio-caudal view and the standardized measurements. Ds = diameter of the clavicle. Da = absolute amount of vertical displacement.

performed a second evaluation of the same randomized DRRs 2-4 weeks after the first round of measurements were performed. Before the start of the study, a training session with each observer took place. The precise definition of the reference points was agreed upon between the observers. Measurements were performed using the hospitals IMPAX software (version 6.5.3.1005).

Descriptive statistics were used to summarize the data. Intra-class correlation coefficients (ICCs) were used to assess the inter- and intra-observer agreement for each of the five radiographic projections. Inter- and intraobserver agreement for the categorical data concerning vertical displacement classification was reported using Gwet AC_1 coefficient[13] The Gwet AC_1 coefficient was used as an alternative to Cohen's kappa, since it provides a chance-corrected agreement coefficient, which is better in line with the percentage level of agreement and less sensitive to prevalence and symmetry compared to Cohen's kappa.[13, 14] ICCs and Gwet AC_1 coefficient were interpreted as follows: <0.40 poor; 0.40 to 0.59 fair; 0.60 to 0.74 good, 0.75 to 1.00 excellent.[15] For intra-observer agreement, ICC estimates and their 95% confident intervals were calculated based on a single observer, absolute-agreement, 2-way mixed-effects model. For inter-observer agreement, ICC estimates and their 95% confident intervals were calculated based on a single observer, absolute-agreement, 2-way random-effects model. The mean of the displacement as measured by the three observers was used in descriptive statistics and further statistical analyses. The 'limits of agreement with the mean', a modification to the Bland–Altman type methodology described by Jones et al.[9] that can be used for more than two observers and retains the ability to evaluate consistency of agreement over different magnitudes of continuous measurements, were calculated for agreement between the 3 observers. Friedman's one-way repeated measures analysis of variance by ranks was used to test for differences in (absolute and relative) vertical displacement obtained from the five different views followed by Wilcoxon signed-rank tests for pairwise comparisons. The Benjamini-Hochberg procedure with a false discovery rate (FDR) of 0.05 was used for multiple testing corrections. FDR control is a statistical method used in multiple-hypotheses testing to correct for multiple comparisons. Among tests that are declared significant, the FDR is the expected fraction of those tests in which the null hypothesis is true. The association between the absolute and relative vertical displacement and the categorical outcomes was calculated using Spearman's rank correlation coefficient. The correlation coefficients were interpreted as follows: <0.20 very weak, 0.20 to 0.39 weak, 0.40 to 0.59 moderate; 0.60 to 0.79 strong, 0.80 to 1.00 very strong.[16]

Statistical analyses were performed using R version 3.5.2 (R Foundation, Vienna, Austria). P-values <0.05 were considered statistically significant.

RESULTS

Thirty-one patients with displaced midshaft clavicle fractures and adequate CT imaging were included and for all 31 patients DRRs in 5 different projections were created.

The study population included 23 males and 8 females, the average age was 39.7 years (range 19-78), 12 fractures concerned the right side and 19 the left side.

The ICCs were excellent for the intra-observer measurements of both absolute vertical displacement (range 0.81-0.94) and the calculations of the relative displacement (range 0.77-0.94) for the two trauma-fellowship trained observers in all projections (Table 6.1). For the third observer, the ICCs for absolute displacement on the 15° caudo-cranial and AP view were good (0.61) and fair (0.45), respectively. The ICCs for relative displacement on these two previously mentioned projections were good (0.65) and fair (0.52).

The inter-observer agreement was found to be good for the AP and both caudo-cranial views (range 0.64–0.69). For the craniocaudal projections the inter-observer agreement was excellent (range 0.75-0.79) (Table 6.2). The maximum limits of agreement with the mean was –5.2 to 5.2 mm for the AP view, indicating that individual observers can be discordant with the mean of the estimated vertical displacement measured by the 3 observers on an AP view by as much as 5.2 mm (Table 6.2). The limits of agreement were the smallest for the two cranio-caudal views.

Table 6.1. a) Intra-observer agreement of measurements of absolute vertical displacement. **b)** Intra-observer agreement of measurements of relative vertical displacement.

a.	ICC absolute vertical displacement (95% CI)		
Projection	Observer 1	Observer 2	Observer 3
30° caudo-cranial	0.77 (0.58-0.88)	0.83 (0.68-0.91)	0.86 (0.72-0.93)
15° caudo-cranial	0.61 (0.33-0.79)	0.85 (0.70-0.92)	0.94 (0.88-0.97)
AP	0.45 (0.12-0.69)	0.82 (0.66-0.91)	0.92 (0.85-0.96)
15° cranio-caudal	0.79 (0.62-0.90)	0.88 (0.69-0.95)	0.86 (0.73-0.93)
30° cranio-caudal	0.79 (0.62-0.90)	0.89 (0.75-0.95)	0.81 (0.65-0.90)

b.	ICC relative vertical displacement (95% CI)		
Projection	Observer 1	Observer 2	Observer 3
30° caudo-cranial	0.78 (0.60-0.89)	0.87 (0.74-0.94)	0.83 (0.68-0.92)
15° caudo-cranial	0.65 (0.39-0.81)	0.83 (0.67-0.91)	0.92 (0.85-0.96)
AP	0.52 (0.22-0.74)	0.79 (0.61-0.89)	0.94 (0.88-0.97)
15° cranio-caudal	0.86 (0.73-0.93)	0.84 (0.65-0.93)	0.86 (0.73-0.93)
30° cranio-caudal	0.83 (0.67-0.91)	0.90 (0.76-0.95)	0.77 (0.57-0.88)

ICC, intraclass correlation coefficient (ICC). CI, confidence interval. AP, anteroposterior.

Table 6.2. Inter-observer agreement of continuous measurements and categorical descriptions of vertical displacement

Projection	ICC (95% CI)	Gwet's AC_1/AC2	Limits of agreement with the mean (mm)
30° caudo-cranial	0.64 (0.44-0.79)	0.56 (0.4-0.73)	-4.9 to 4.9
15° caudo-cranial	0.69 (0.52-0.82)	0.45 (0.28-0.65)	-5.1 to 5.1
AP	0.65 (0.47-0.80)	0.50 (0.33-0.67)	-5.2 to 5.2
15° cranio-caudal	0.75 (0.60-0.86)	0.64 (0.49-0.79)	-4.3 to 4.3
30° cranio-caudal	0.79 (0.65-0.89)	0.50 (0.35-0.65)	-3.7 to 3.7

ICC, intraclass correlation coefficient (ICC). CI, confidence interval. AP, anteroposterior.

The smallest measured median vertical displacement was 6.4 mm on the 30° caudo-cranial projection and 8 mm on the AP (Table 6.3).

The median absolute vertical displacement of the fracture elements relative to each other showed no statistically significant difference between any of the caudo-cranial, AP and cranio-caudal views (Figure 6.2a). No statistically significant differences were found for the measured median shaft diameter and the relative displacement (Figure 6.2b and 6.2c).

Table 6.3. Measurements of the 5 different views

Projection	Measured absolute vertical displacement Median IQR (range), mm	Measured diameter shaft Median IQR (range), mm	Calculated relative vertical displacement Median IQR (range), %
30° caudo-cranial	6.4 (5.3, 2-15)	10.9 (2.5, 8-16)	57.9 (57.5, 16-172)
15° caudo-cranial	7.5 (7.1, 2-17)	11.4 (2.3, 9-17)	76.9 (64.2, 21-149)
AP	8.0 (5.4, 0-15)	12.0 (1.5, 9-16)	69.5 (46.6, 0-132)
15° cranio-caudal	7.6 (6.3, 2-17)	12.7 (2.2, 9-16)	59.3 (40.4, 17-162)
30° cranio-caudal	7.1 (5.6, 2-18)	12.3 (2.5, 9-16)	58.4 (47.3, 19-180)

IQR, interquartile range. AP, anteroposterior.

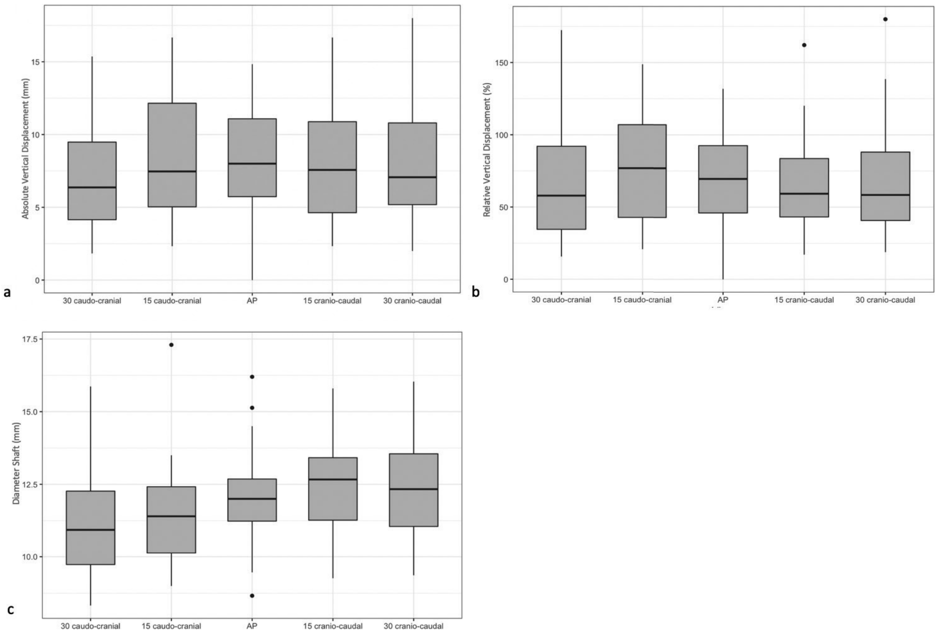

Figure 6.2. a) Boxplot showing median absolute vertical displacement (mm) per radiographic projection. **b)** Boxplot showing median relative vertical displacement (%) per radiographic projection. **c)** Boxplot showing median Diameter Shaft (mm) per radiographic projection.

The correlation between the categorical outcomes and the absolute vertical displacement (range 0.83-0.94) and the relative vertical displacement (range 0.87-0.96) was found to be very strong (Table 6.4). However, the Gwet AC_1 coefficient for inter-observer agreement was fair to good (range 0.45-0.64) (Table 6.2). The intra-observer agreement ranged from fair to excellent (0.58-0.85) for the fellowship-trained orthopaedic surgeons (Table 6.5).

Table 6.4. Correlation between categorical outcomes and absolute vertical displacement and relative vertical displacement; values representing Spearman's correlation coefficient and 95% confidence interval (CI)

	Spearman's rank correlation coefficient	
Projection	Category – absolute vertical displacement	Category – relative vertical displacement
30° caudo-cranial	0.88 (0.76-0.94)	0.90 (0.80-0.95)
15° caudo-cranial	0.94 (0.87-0.97)	0.96 (0.92-0.98)
AP	0.83 (0.67-0.91)	0.87 (0.74-0.94)
15° cranio-caudal	0.90 (0.80-0.95)	0.92 (0.83-0.96)
30° cranio-caudal	0.90 (0.79-0.95)	0.90 (0.80-0.95)

AP, anteroposterior.

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Table 6.5. Intra-observer agreement of categorical descriptions of vertical displacement; values representing Gwet's AC and 95% confidence interval (CI)

	Gwet's AC_1 (95% CI)		
Projection	Observer 1	Observer 2	Observer 3
30° caudo-cranial	0.50 (0.28-0.72)	0.65 (0.46-0.85)	0.58 (0.36-0.79)
15° caudo-cranial	0.39 (0.17-0.61)	0.65 (0.45-0.85)	0.69 (0.50-0.88)
AP	0.55 (0.33-0.76)	0.69 (0.49-0.88)	0.68 (0.48-0.88)
15° cranio-caudal	0.77 (0.60-0.94)	0.65 (0.45-0.85)	0.73 (0.55-0.91)
30° cranio-caudal	0.58 (0.37-0.79)	0.81 (0.64-0.97)	0.85 (0.70-0.99)

AP, anteroposterior.

DISCUSSION

In the present study we aimed to quantify and describe the difference in measurements of vertical displacement in an absolute, relative and categorical manner between 5 different radiographic projections of the midshaft clavicle fracture. We did not find a statistically significant difference in absolute or relative vertical displacement between the 5 different views. This is an important finding because together with shortening and comminution, vertical displacement is an important factor in the decision-making algorithm.[9] The reason for this is that vertical displacement of more than 100% between the fracture elements on the initial radiograph is associated with inferior clinical outcomes.[10] While projection does not seem to be influential on vertical displacement, other variables such as patient positioning and time are.[1,6,17] Alternatively, projection is influential on the amount of measured shortening and choice of treatment strategy.[2, 8]

We found excellent intra-observer agreement in measurements between the 5 different radiographic projections using a standardized method for measuring the vertical displacement signifying the proposed method is reproducible and could be used for future quantification of vertical displacement. Concerning the inter-observer agreement, we found the ICCs were higher for the cranio-caudal views. These cranio-caudal views also seem to be the projections that most accurately visualize length of the fracture elements and shortening.[2, 5, 7, 18, 19] Given the findings in previous reports[2, 5, 7, 18, 19] and the present study it may be a consideration to include a cranio-caudal view into the standard work up of the displaced midshaft clavicle fracture. One must be aware that adding projections to the standard work up of displaced midshaft clavicle fractures may lead to increased rates of operative treatment.[20]

Furthermore, we assessed the association between categorical and continuous descriptions of vertical displacement and found the correlation to be very strong. The Gwet AC_1 coefficient for inter-observer agreement was fair to good and the intra-observer agreement ranged from fair to excellent for the fellowship-trained orthopaedic surgeons. The intra-observer agreement was lower when performed by the medical student. This is possibly caused by a lack of experience in evaluating x-rays and classifying the fracture accordingly. Interestingly, the cranio-caudal projections again seem to show a trend to a higher agreement. Jones et al. reported similar poor to good interrater agreement for the categorical analysis of fracture displacement. They reported an ICC of 0.76 for intra-rater agreement.[9] Stegeman et al. found moderate to almost perfect agreement for fracture classification of the displaced clavicle fracture.[12] Li et al. report an excellent agreement for categorical descriptions of vertical displacement. However, the latter only used the categories: 1) none or minimal, 2) mild or angulated and 3) complete. The very strong correlation between continuous measurements and categorical descriptions leads to the conclusion that the latter would suffice in reporting vertical displacement in the future. On the other hand, continuous measures were found to have higher ICCs which could be helpful in discerning more reliably what amount of vertical displacement would be clinically important in the treatment of displaced midshaft clavicle fractures.

One of the strengths of this study is that DRRs were used. These DRRs are not subject to magnification by diverging X-ray beams, nor influenced by positioning of the patient, movement of the patient between X-rays or different distances of the fracture to the detector. This creates static conditions to truly evaluate the possible differences in vertical displacement per projection, however it is also one of the limitations of the study since it is unknown how the DRRs relate to standard radiographs and further research on this topic is warranted.

Another strength of this study is the use of a standardized method for measuring the vertical displacement as proven by the good to excellent intra- and interobserver agreement.

A potential limitation of this study is that all CT-scans, and as a consequence the DRRs, were fabricated in supine position. This may lead to an underestimation of the measured vertical displacement in reality.[1, 6] This would be a very important limitation when reporting on choice of treatment and/or its results, however in this study the main goal was to identify differences in measurements between different projection and to evaluate the intra- and interobserver agreement. The results of the present study can be used in further discerning the optimal imaging and measurement techniques of the fractured midshaft clavicle fracture.

CONCLUSION

Unlike for shortening, absolute and relative vertical displacement of the midshaft clavicle fracture is not significantly influenced by radiographic projection. Though reproducible and possibly useful for research purposes, the standardized measurements of vertical displacement may not be necessary for clinical use since the correlation between categorical and continuous measurements was found to be very strong.

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7

Does altering projection of the fractured clavicle change treatment strategy?

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ABSTRACT

Background: Shortening of the fractured clavicle is proposed and debated as an indicator for surgical intervention. There is no standardized or uniform method for imaging and measuring shortening. Different methods and techniques may can lead to different measured outcomes. However, the question remains whether a difference in measured shortening using a different technique has any short-term clinical relevance in terms of treatment strategy. The aim of this study was to investigate whether a different projection of the same midshaft clavicle fracture would lead to a different choice in treatment strategy.

Methods: 36 AO/OTA 15A.1-3 midshaft clavicle fractures were digitally reconstructed into radiographs in both a 15° caudo-cranial and a 15° cranio-caudal projection. The 72 projections were rated in random order by 23 orthopaedic trauma or upper extremity surgeons for necessitating either conservative or operative treatment.

Results: On average, the raters altered their treatment strategy with a different projection of the same midshaft clavicle fracture in 12.2 times of the 36 cases (33.9%) ranging from 5 times (13.9%) to 19 times (52.8%). A statistically significant increase in choice for surgical treatment when using the 15° caudo-cranial projection was identified ($p=0.01$).

Conclusion: This study reveals the influence the projection of the midshaft clavicle fracture has on the surgeon's decision of treatment strategy. The decision changes from operative to non-operative or vice versa in 33.9% of the cases.

Level of evidence: 2.

Keywords: clavicle; fracture; shortening; imaging; interobserver agreement; treatment strategy

INTRODUCTION

In recent years, more evidence has emerged that surgical treatment of displaced and shortened midshaft clavicle fractures reduces the rate of non- and malunion as well as increases patient satisfaction and return to work.[1-6] However, caution should be taken not to subject all patients to surgery since surgical treatment, irrespective of the type of fixation used, comes with its complications and disadvantages.[7, 8] Identifying those patients that will benefit most from surgery remains challenging.

Numerous parameters are used to decide on treatment strategy. Classically, these are open fractures, neurovascular compromise, associated scapular neck fractures and skin tenting.[1, 9, 10] More recently, age, dominance, activity level, displacement and shortening are advocated as indicators for surgery.[11-13]

There are contradictory reports on whether shortening can be used as an indicator for surgery. While some authors report that shortening of >15-20 mm or >15% is associated with worse union-rates and functional outcomes when treated conservatively,[12, 14-21] others report no association between shortening and functional outcome.[22-24]

Since there is no standardized and uniform method for measuring shortening, these reported associations, or lack thereof, are based on a heterogeneous group of methods. Shortening is described to be assessed using a tape measure,[19] tilted AP views of the clavicle,[14, 18, 21, 25, 26] (ranging from a 45° cranio-caudal to 45° caudo-cranial views) AP panoramic views[12, 16, 17, 22, 24] or CT scans.[23]

These different methods lead to varying degrees of measured shortening.[27, 28] For identification of shortening as a possible parameter in the treatment algorithm, and future research purposes standardization of the radiographic techniques may be of great importance. However, the question remains whether a difference in measured shortening using a different technique has an effect on the surgeon's decision-making. Therefore, the aim of this study was to investigate whether a different projection of the same midshaft clavicle fracture would lead to a different choice in treatment strategy.

MATERIALS AND METHODS

This study was approved by our Institutional Review Board (CMO Arnhem Nijmegen, study-ID 2015-1769). 15° caudo-cranial and the 15° cranio-caudal Digitally Reconstructed Radiographs (DRRs) from 36 cases with AO/OTA 15A.1-3 midshaft clavicle fractures from an existing database were used in the present study. These two projections were chosen because they are the views with the smallest difference in tilt away from the AP view in the range of views described in the literature to determine shortening. Furthermore, a recent study reported that the measured absolute shortening of the same fracture between these two projections was the smallest.[29] Therefore, it was reasoned that if a difference in treatment strategy between the two projections used was identified it would be likely that projection would also be influential between other views, including the AP. An example of these DRRs is shown in Figure 7.1.

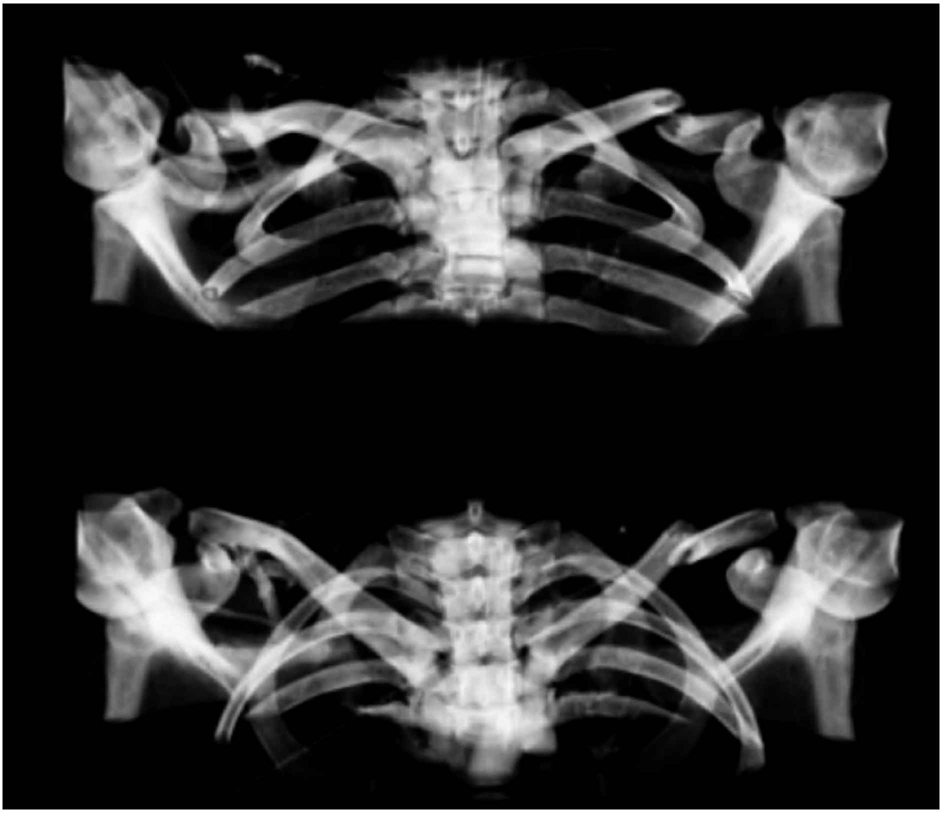

Figure 7.1. Example of a Digitally Reconstructed Radiograph (DRR) of the same clavicle fracture in a 15° caudo-cranial and 15° cranio-caudal view.

The 72 projections were randomly assigned a case number and uploaded onto a secure website (www.traumaplatform.org). To ensure high quality images, an online survey tool was developed to evaluate radiographical images using an embedded DICOM viewer.

55 orthopedic and trauma surgeons in the Netherlands considered experts in the field of traumatology or upper extremity pathology were approached via email to participate in the study. In case of no response, two rounds of reminders, two weeks apart, were sent out.

All participants were shown 72 (36 paired) DRRs of the midshaft clavicle fractures and were asked how they would treat the fracture shown. The answer options were either "operative" or "conservative". No additional information on the case was presented to the raters. In this way, the investigators reasoned all participants used their own frame of reference ensuring the only variable in this study would be the different projection of the fractured clavicle.

Statistical analysis

The number of changes in treatment strategy (i.e. "operative" or "conservative") between the different projections, and the number of times an "operative" treatment was chosen for each of the projections were calculated. Descriptive statistics were used to summarize the data. Continuous variables were reported as median (range). Categorical variables were reported using frequencies. Interobserver agreement coefficients were calculated for the 15° caudo-cranial and the 15° cranio-caudal projections using Gwet's AC_1.[30] Agreement coefficients were interpreted according to methods described by Landis and Koch[31] <0, poor agreement; 0-0.20, slight agreement; 0.21-0.40, fair agreement; 0.41-0.60, moderate agreement; 0.61-0.80, substantial agreement; and 0.81-1.00, almost perfect agreement).

To evaluate the difference in agreement between observers between the two projections, the difference between the two correlated agreement coefficients were tested for statistical significance.[32] Statistical analyses were performed using R version 3.4.2 (R Foundation for Statistical Computing, Vienna, Austria). P-values <0.05 were considered statistically significant.

RESULTS

Twenty-four invited surgeons from 16 different hospitals completed the survey, resulting in a response rate of 44% (Table 7.1).

One of the participants responded "conservative" on all cases. Because this is not according to current standard of care these results were excluded from further analysis. A total of 23 observers on 36 paired DRRs were analyzed.

On average, the observers altered their treatment strategy with a different projection of the same midshaft clavicle fracture in 12.2 times of the 36 cases (33.9%). This ranged from 5 times (13.9%) to 19 times (52.8%). Figure 7.2 shows the number of changes per observer.

All but one observer showed an increase in choice of surgical treatment of the midshaft clavicle fracture when using the 15° caudo-cranial DRR (Figure 7.3). Overall the participants elected surgical treatment 415 times on the 15° caudo-cranial view and 251 times on the 15° cranio-caudal view.

Table 7.1. Characteristics of the raters

	n
Specialization	
Orthopedic trauma	15
Shoulder	5
Other	3
Position	
Attending	21
Resident	2
Years in practice	
0-5	6
6-10	8
11-20	7
N/A	2
Number of clavicles treated yearly	
0-5	3
6-10	4
11-20	9
21-40	7

NA, not applicable.

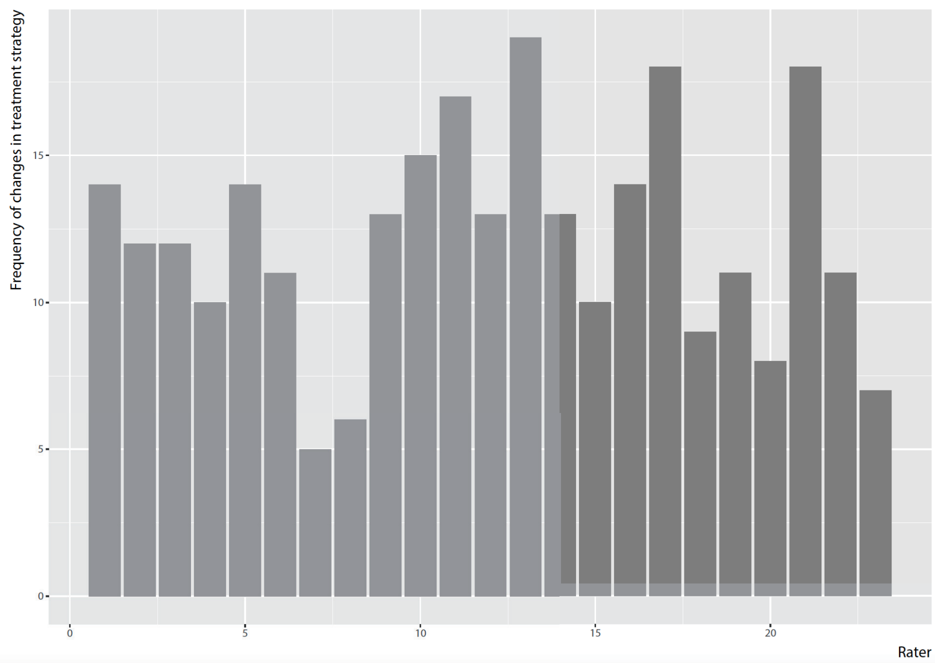

Figure 7.2. Number of changes in treatment strategy per rater.

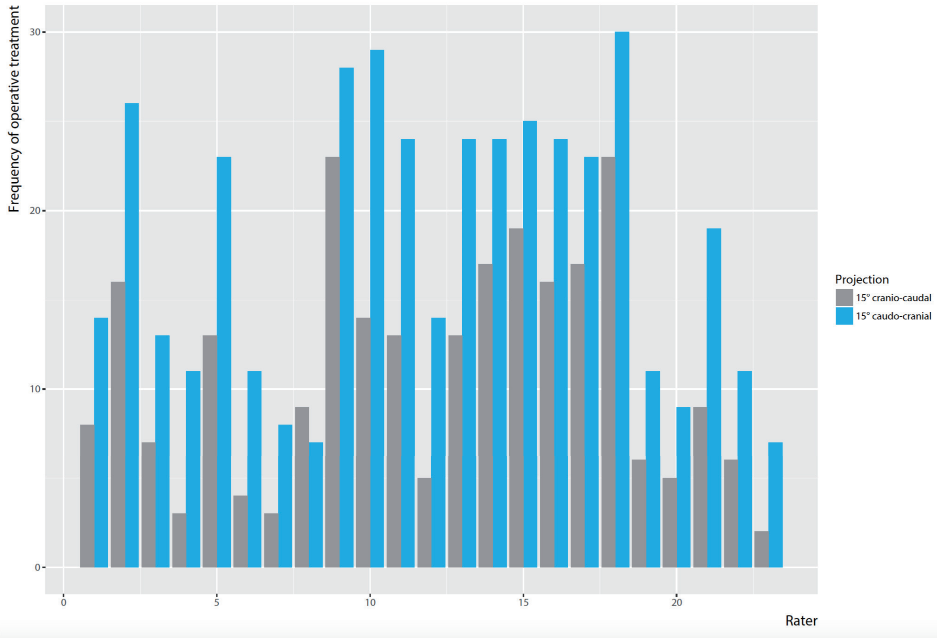

Figure 7.3. Number of times chosen for operative treatment by projection and rater.

The percent agreement was 0.66 and 0.73, respectively. Interobserver agreement based on the agreement coefficient was fair for the 15° caudo-cranial projection (Gwet's AC_1 coefficient 0.32 (95% CI 0.22-0.42)) and moderate for the 15° cranio-caudal projection (Gwet's AC_1 coefficient 0.52 (95% CI 0.37-0.68)). The interobserver agreement was significantly different between the 15° caudo-cranial and 15° cranio-caudal projections (p=0.01). Respondent background was not identified to be influential on agreement.

DISCUSSION

The goal of this study was to investigate whether a different projection of the same midshaft clavicle fracture would lead to a difference in choice of treatment strategy. The results of this study show that on average the decision changed in 33.9% of the cases, solely based on the projection of the fractured clavicle. Due to the shape of the clavicle and frequently oblique fracture patterns, measurements can be challenging, as can the evaluation of displacement. Besides direction of the x-ray beam these measurements are subject to other variables such as patient positioning and method of measuring.[27, 28, 33-37]

Interestingly, we found an increased tendency to treat a midshaft clavicle fracture operatively when using the 15° caudo-cranial DRR. There are reports that state that the cranio-caudal views are more accurate projections and that the caudo-cranial views show a low agreement with CT measurements.[27, 28, 36] Therefore, one would expect an increased amount of shortening and thus increased choice for surgical treatment with the 15° cranio-caudal projection. The results of the present study also show a statistically significant difference in agreement between the 15° caudo-cranial and 15° cranio-caudal view in favour of the latter. It seems that it is not just the shortening that changes the surgeon's decision. In fact it may be the projected displacement that causes this difference. This however, is not in line with the findings of Wright et al.[38] who reported an underestimation of actual displacement on 20° caudo-cranial x-rays compared to the shortening measured on CT-scans. Still even the underestimated displacement on the caudo-cranial view may be more than on the cranio-caudal view. Further research to answer this question is needed.

A question raised in recent publications is whether shortening is important as an indicator for surgery. There are some authors that report the degree of shortening, absolute or relative, is important[12, 14-17, 19-21] and others that dispute this.[22-24, 39] The latter groups do this on the basis of similar functional outcomes but do not comment on other possibly important factors such as union rates, cosmetic satisfaction or altered glenoid and scapular orientation which may increase the risk of future gleno-humeral osteoarthritis.[40-42]

Strengths of this study include the use of DRRs to guarantee static conditions between the two projections of the fractured clavicle, the number of expert observers that participated, and number of cases included. Some potential limitations have to be discussed. First, this study can not differentiate whether it is shortening or displacement that is the most influencial factor for choosing between treatment strategies. Second, more projections of the fractured clavicle could have been used. For example, a comparison between the 30° caudo-cranial and the AP projection might result in an even larger number of changes in treatment strategy. However, with the two projections used in this study we already identified a clear influence of different projections.

With the results of this study we do not advocate the use of only 1 view of the fractured clavicle to base a treatment strategy on, it is merely to show the projection is influential in the decision making process. Austin et al.[43] investigated wheter additional projections of the fractured clavicle would influence the surgeon's treatment decision. They added a 45° cephalic and caudal tilt to the standard 20° caudo-cranial tilt and AP views. Using a 4-view radiographic series, surgeons were more likely to treat clavicular fractures operatively. A possible explanation is the improved visualization of the anterior-posterior displacement of the fracture elements.

The plethora of projections currently used to base research questions or treatment strategies on do not seem interchangable. An explanation for our results is that in current practice other factors play a more prominent role in the treatment algorhitm than shortening, partially because there is no uniform method for quantifying this even though a study by Jones et al. reported otherwise.[34] This does not mean shortening should be discarded but that it is actually important to identify and use a uniform method of imaging and measuring shortening in the fractured clavicle in order to create comparable results for future research purposes.

CONCLUSION

This study shows the influence the projection of the midshaft clavicle fracture has on the surgeon's decision of treatment strategy. We found an increased tendency to treat a midshaft clavicle fracture surgically when using the 15° caudo-cranial view compared to the 15° cranio-caudal view. The decision changed from operative to non-operative or vice versa in 33.9% of the cases based solely on the projection.

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8

Influence of radiographic projection and patient positioning on shortening and displacement of the fractured clavicle

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ABSTRACT

Background: Radiographic measurements of shortening and vertical displacement in the fractured clavicle are subject to a variety of factors such as patient positioning and projection. The aims of this study were 1) to quantify differences in shortening and vertical displacement in varying patient positions and X-ray projections and 2) to identify the view and patient positioning indicating the largest amount of shortening and vertical displacement and 3) to identify and quantify the inter- and intra-observer agreement.

Methods: A prospective clinical measurement study of 22 acute Robinson type 2B1 clavicle fractures was performed. Each patient underwent 8 consecutive standardized and calibrated X-rays in one setting.

Results: In the upright patient position, the difference of absolute shortening was 4.5 mm (95% CI 3.0-5.9, $p<0.0001$) larger than in the supine patient position. For vertical displacement, the odds of being scored a category higher in the upright patient position were 4.7 (95% CI 2.2-9.8) times as large as the odds of being scored a category higher in supine position. The odds of being scored a category higher on the caudo-cranial projection were 5.9 (95% CI 2.8-12.6) times as large as the odds of being scored a category higher on the cranio-caudal projection.

Conclusion: Absolute shortening, relative shortening and vertical displacement were found to be the greatest in the upright patient positioning with the arm protracted orientation on a 15° caudo-cranial projection. No statistically significant differences were found for a change in position of the arm between neutral and protracted.

Level of evidence: 2.

Keywords: clavicle; fractures; radiological imaging; shortening; displacement; inter-rater agreement; intra-rater agreement

INTRODUCTION

Radiographic measurements of shortening and vertical displacement in the fractured clavicle are subject to a variety of factors such as patient positioning,[1-3] point in time after trauma,[3,4] anatomical side-to-side difference[5,6] and projection.[7-9] Combined with the sigmoid shape of the clavicle in two planes, adequate and reliable measurements of the shortening and vertical displacement on a 2-dimensional radiographic image are challenging. All the above-mentioned factors can lead to differences in measured results and thus varying degrees of shortening and vertical displacement which subsequently could influence the choice of treatment.[10]

In spite of this knowledge, there is not a universal and standardized protocol that is being used throughout the body of literature to obtain comparable results. Methods used to assess shortening include clinical evaluation using a tape measure[11] and radiographic evaluation by means of a tilted AP (anteroposterior) views of the clavicle (ranging from a 45° cranio-caudal to 45° caudo-cranial views),[12-17] AP panoramic views,[18-22] tilted PA (posteroanterior) views,[7] CT scans[23] or the method used is not reported.[24]

There is increasing evidence supporting surgical management of displaced, shortened and/or comminuted clavicle fractures because of lower rates of non- and mal-unions as well as an earlier functional return and increased patient satisfaction in.[25-31]

There are contradictory reports on the importance of shortening as a relative indicator for surgery. Some studies report that shortening of 15-20 mm or >8.9% is a predictor of a worse union-rates and functional outcomes when treated conservatively[11,14-16,20-22,24,32] Others report no association between shortening and functional outcome.[18,19,23] A survey study among upper extremity surgeons reported that 60% uses shortening as the most important factor in the decision for surgical versus nonsurgical treatment.[33]

A previous study by our group showed differences in measurements of shortening up to 6.0 mm between different projections on digitally reconstructed radiographs (DRRs) of the same fractured clavicle.[10] To our knowledge, no studies have been performed that evaluated the extend of these differences using proper X-ray images.

The aims of this study were 1) to quantify the difference in measurements of shortening and vertical displacement by using a standardized method of measuring displaced midshaft clavicle fractures in varying patient positions (supine vs upright and arm in neutral vs protracted position) and direction of the X-ray beam (15° caudo-cranial vs 15° cranio-caudal) in absolute and relative measures and 2) to identify the view and patient positioning indicating the largest amount of shortening and vertical displacement and 3) to identify and quantify the differences in inter- and intra-observer agreement between these variables.

MATERIALS AND METHODS

A prospective clinical measurement study quantifying the influence of patient positioning and X-ray direction on the measurement of shortening and vertical displacement of the fractured clavicle was conducted in two Dutch hospitals (Radboud UMC and AdRZ) between May 2016 and November 2017. This study was approved by our Institutional Review Board (CMO Arnhem-Nijmegen 2015-1770). Informed consent was obtained from all participants.

All patients aged ≥18 years with an acute Robinson type 2B1 clavicle fracture were asked to participate. Patients with multiple traumas, intoxication, inability to follow instruction, pathological fractures or soft tissue damage were excluded.

In order to evaluate the influence of patient positioning (supine vs upright and arm in neutral vs protracted position) and influence of projection (15° caudo-cranial vs 15° cranio-caudal), each patient underwent 8 consecutive standardized and calibrated X-rays in one setting after administration of sufficient analgesics. All possible combinations of the three evaluated variables were included.

The protracted positioning of the arm, which would occur if the X ray image would be taken with the arm in a sling or collar and cuff, was simulated by placing the hand of the affected side on the contralateral anterior superior iliac spine (ASIS). To measure differences between X-ray projections the 15° caudo-cranial and 15° cranio-caudal were used. Earlier research on this topic found that the difference between these views of 2.0 mm was the smallest that was statistically significant.[10] It was assumed if these views show statistically significant differences in this study, the differences between 30° caudo-cranial and all other views would be statistically significant as well. Additional views were omitted to keep the radiation exposure to a minimum.

A standardized method for measuring shortening as described by Silva et al.[34] was used (Figure 8.1). This methodology and the precise definition of the reference points was discussed and agreed upon by the observers. In short, lines through both the medial and lateral fragment of the clavicle were drawn from the center of the AC (acromioclavicular) or SC (sternoclavicular) joint to the center of the fracture plane. The lengths of these lines represent the lengths of the fragments. Next a perpendicular line was drawn from the line through the medial fragment at the fracture plane. Subsequently, a parallel line was drawn to this line at the point where the line through the lateral fragment intersects the fracture plane. The difference between the latter two lines indicates the amount of shortening in millimeters (mm). Relative shortening was calculated by dividing the shortening in mm by the sum of the length of the medial and lateral fragments in mm x 100. Displacement was documented by allocating it to one of three categories (0-50%, 50-100% or >100%). The authors did not compare the fractured side to the

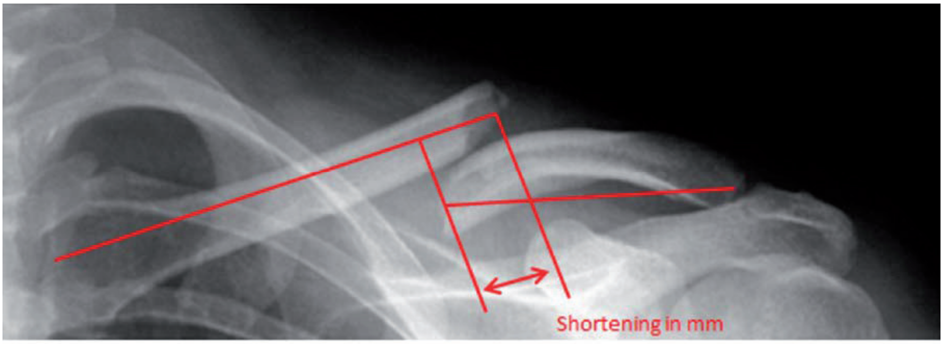

Figure 8.1. Standardized method of measuring shortening of the midshaft clavicle fracture as adapted from Silva et al. 2013.

contralateral side since the existing anatomical side-to-side difference of ≥5 mm in 30% in the population would introduce additional margins for error.[5, 6]

Two observers (two orthopedic surgeons PH, AG) evaluated the images for each patient in random order. In order to calculate intra-observer agreement, one of the observers (PH) performed a second evaluation of the same images 2-4 weeks after the first measurements were performed. Measurements were performed using the hospitals IMPAX software (version 6.5.3.1005).

Descriptive statistics were used to summarize the data. Intra-class correlation coefficients (ICCs) were used to assess the intra- and interobserver agreement for each of the projections and patient positions for numerical data. Intra- and interobserver agreement for the categorical data concerning vertical displacement classification was reported using Gwet's AC_1.[35] The Gwet's AC_1 was used as an alternative to Cohen's kappa, since it provides a chance-corrected agreement coefficient, which is better in line with the percentage level of agreement and less sensitive to prevalence and symmetry compared to Cohen's kappa.[35, 36] ICCs and Gwet's AC_1 were interpreted as follows: <0.40 poor; 0.40 to 0.59 fair; 0.60 to 0.74 good, 0.75 to 1.00 excellent.[37] The ICC was calculated from a two-way random effects model, for absolute agreement.

Linear and ordinal mixed models were used to study the effect of patient position, arm position, and X-ray projection on shortening and displacement, respectively. Patient position (upright/supine), arm position (neutral/protracted), and X-ray projection (15 degrees craniocaudal/15 degrees caudo-cranial) were used as fixed factors. Patient id was used as random factor. Statistical analyses were performed using R version 3.6.0 (R Foundation, Vienna, Austria). P-values <0.05 were considered statistically significant.

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RESULTS

Twenty-four patients with Robinson type 2B1 clavicle fractures were included and for all patients the imaging protocol was completed. Two patients did not have calibrated images, leaving 22 patients (21 male: 1 female) available for analysis. Fracture laterality was equally distributed (11 right: 11 left). Average age of the participants was 46.7 years (SD 15.8, range 19-74).

The intra-observer measurements of absolute shortening (0.91, 95% CI 0.87-0.93), relative shortening (0.92, 95% CI 0.89-0.94), and vertical displacement (0.77, 95% CI 0.69-0.85) were excellent (Table 8.1).

Table 8.1. Intra-observer agreement for absolute displacement, relative displacement and vertical displacement (ICC and Gwet's AC_1) overall and per variable (patient positioning, position of arm and projection)

	Variable		ICC (95% CI)
Absolute displacement		*Overall*	**0.91 (0.87-0.93)**
	Patient positioning		
		Supine	0.87 (0.81-0.91)
		Upright	0.93 (0.89-0.96)
	Positioning arm		
		Neutral	0.91 (0.86-0.94)
		Protracted	0.90 (0.84-0.94)
	Direction X-ray beam		
		15° caudo-cranial	0.92 (0.88-0.95)
		15° cranio-caudal	0.88 (0.83-0.92)
Relative displacement		*Overall*	**0.92 (0.89-0.94)**
	Patient positioning		
		Supine	0.89 (0.83-0.93)
		Upright	0.94 (0.89-0.96)
	Positioning arm		
		Neutral	0.92 (0.88-0.95)
		Protracted	0.92 (0.86-0.95)
	Direction X-ray beam		
		15° caudo-cranial	0.93 (0.90-0.96)
		15° cranio-caudal	0.90 (0.84-0.94)
			Gwet's AC_1
Vertical displacement		*Overall*	**0.77 (0.69-0.85)**
	Patient positioning		
		Supine	0.70 (0.57-0.82)
		Upright	0.86 (0.77-0.95)
	Positioning arm		
		Neutral	0.78 (0.67-0.90)
		Protracted	0.77 (0.65-0.88)
	Direction X-ray beam		
		15° caudo-cranial	0.78 (0.67-0.89)
		15° cranio-caudal	0.78 (0.67-0.89)

The interobserver measurements of absolute shortening (0.67, 95% CI 0.50-0.77), relative shortening (0.72, 95% CI 0.56-0.81), and vertical displacement (0.67, 95% CI 0.57-0.78) were good (Table 8.2).

The measured average absolute (11.7 mm, SD 9.5) and relative (7.9%, SD 6.2) shortening was found to be the smallest in the supine patient positioning with the arm in neutral orientation on a 15° caudo-cranial projection. This scenario was also the one resulting in the least vertical displacement (median 100%, IQR 0%-50% – 50%-100%). The average absolute (17.7 mm, SD 10.2) and relative (11.9%, SD 6.6) shortening (17.7 mm, 11.9%) was found to be the greatest in the upright patient positioning with the arm protracted

Table 8.2. Interobserver agreement for absolute displacement, relative displacement and vertical displacement (ICC and Gwet's AC_1) overall and per variable (patient positioning, position of arm and projection)

	Variable		ICC (95% CI)
Absolute displacement		*Overall*	**0.67 (0.50-0.77))**
	Patient positioning		
		Supine	0.60 (0.43-0.73)
		Upright	0.69 (0.45-0.82)
	Positioning arm		
		Neutral	0.67 (0.50-0.78)
		Protracted	0.66 (0.46-0.79)
	Direction X-ray beam		
		15° caudo-cranial	0.70 (0.34-0.84)
		15° cranio-caudal	0.63 (0.48-0.74)
Relative displacement		*Overall*	**0.72 (0.56-0.81)**
	Patient positioning		
		Supine	0.65 (0.49-0.76)
		Upright	0.74 (0.51-0.85)
	Positioning arm		
		Neutral	0.72 (0.56-0.82)
		Protracted	0.71 (0.51-0.83)
	Direction X-ray beam		
		15° caudo-cranial	0.75 (0.39-0.87)
		15° cranio-caudal	0.68 (0.54-0.78)
			Gwet's AC_1
Vertical displacement		*Overall*	**0.67 (0.57-0.78)**
	Patient positioning		
		Supine	0.53 (0.38-0.68)
		Upright	0.81 (0.71-0.92)
	Positioning arm		
		Neutral	0.68 (0.55-0.81)
		Protracted	0.65 (0.52-0.79)
	Direction X-ray beam		
		15° caudo-cranial	0.64 (0.51-0.78)
		15° cranio-caudal	0.71 (0.59-0.84)

orientation on a 15° caudo-cranial projection. This scenario also was the one resulting in the most vertical displacement. (median ">100%", IQR ">100%" – ">100%").

As for the individual variables, the average difference in results of measurements of absolute shortening when evaluating the influence of patient positioning between supine (12.9 mm, SD 8.7) and upright (17.4 mm, SD 9.1, range 0-38) positioning was 4.5 mm (95% CI 3.0-5.9, $p<0.0001$) The difference in relative shortening between supine (8.5%, SD 5.5) and upright (11.7%, SD 5.8) positioning was 3.2% (95% CI 2.2-4.1, $p<0.0001$) (Table 8.3). In the upright patient position, the odds of being scored a category higher were 4.7 (95% CI 2.2-9.8) times as large as the odds of being scored a category higher in supine position when all other variables in the model were held constant (Table 8.4).

Table 8.3. Results of measurements for absolute and relative shortening per variable including the differences per variable (largest measurement minus smallest measurement)

	Variable		Mean (mm)	SD	Difference (mm) (95% CI)	p-value
Absolute shortening						
	Patient positioning					
		Supine	12.9	8.7	4.5 (3.0-5.9)	<0.0001
		Upright	17.4	9.1		
	Positioning arm					
		Neutral	14.8	9.4	0.7 (-0.8-2.2)	0.84
		Protracted	15.5	9.0		
	Direction X-ray beam					
		15° caudo-cranial	15.2	9.9	0.1 (-1.3-1.6)	0.36
		15° cranio-caudal	15.1	8.5		
Relative shortening						
	Patient positioning					
		Supine	8.5	5.5	3.2 (2.2-4.1)	<0.0001
		Upright	11.7	5.8		
	Positioning arm					
		Neutral	9.9	6.0	0.4 (-0.5-1.3)	0.42
		Protracted	10.3	5.7		
	Direction X-ray beam					
		15° caudo-cranial	10.3	6.4	0.4 (-0.5-1.3)	0.42
		15° cranio-caudal	9.9	8.5		

Table 8.4. Proportional Odds Ratios and 95% confidence intervals of increasing a category (0-50%, 50-100%, >100%) in vertical displacement per variable

Variable	Odds Ratio (OR) (95% CI)	p-value
Supine: upright	4.7 (2.2-9.8)	<0.0001
Neutral: protracted	1.0 (0.5-1.9)	0.95
15° cranio-caudal: 15°caudo-cranial	5.9 (2.1-12.6)	<0.0001

No statistically significant differences were found for either absolute (0.7 mm, 95% CI (-0.8-2.2) or relative shortening (0.4, 95% CI (-0.5-1.3) and vertical displacement (OR 1.0, 95% CI 0.5-1.9) concerning a change in position of the arm between neutral and protracted (Table 8.3 and 8.4). No statistically significant differences in measurements were found when evaluating the influence of X-ray projection on both absolute and relative shortening (Table 8.3). However, the odds of being scored a category higher on the caudo-cranial projection were 5.9 (95% CI 2.8-12.6) times as large as the odds of being scored a category higher on the cranio-caudal projection when all other variables in the model were held constant (Table 8.4).

DISCUSSION

In the present study we aimed to quantify the differences in measured shortening by using a standardized method of measuring displaced midshaft clavicle fractures in varying patient positions (supine vs upright and arm in neutral vs protracted position) and direction of the X-ray beam (15° caudo-cranial vs 15° cranio-caudal). We found a statistically significant difference in average measurements of absolute shortening using a standardized method of 4.5 mm between the supine and upright views when keeping all other variables constant. This difference is in line with Malik et al.[2] who report a measured absolute shortening of -0.41 mm (95% CI: -2.53-1.70 mm and 4.86 mm (95% CI: 1.66-8.06 mm) in supine and upright patient positioning respectively; A difference of 5.27 mm. We also found a statistically significant difference in relative shortening between supine and upright patient positioning of 3.2%. Since DeGiorgi et al.[14] predict an increase of failure in conservatively managed midshaft clavicle fractures that are shortened >9.8% the differences measured in the present study between patient positions (8.5%, SD 5.5 for supine vs 11.7%, SD 5.8 for upright) may be relevant in the decision making algorithm.

Differences in orientation of the arm during imaging (neutral vs protracted) did not result in either absolute or relative differences in measured shortening that may be of clinical relevance. It seems that the gleno-humeral joint is mostly responsible for the different in orientations of the arm evaluated and therefore do not translate into different positions of the fracture elements and thus do not influence the measured shortening. We did not calculate a statistically significant difference between the average absolute and relative shortening when evaluating the direction of X-ray beam in 15° caudo-cranial and 15° cranio-caudal views. This is different than what is reported in another study by our group in which we identified a clear and statistically significant difference between caudo-cranial and cranio-caudal views.[10] The fact that no difference was found here could be caused by inherent differences between Digitally Reconstructed Radiographs (DRRs) and proper X-ray projection used in this study. The different projections are well controlled in DRRs which may not be the case for proper X-rays. We used 15° caudo-cranial and 15° cranio-caudal projections since this was found to be the smallest difference in between projections resulting in statistically significant differences.[10] It is possible that by using larger angulations of projections (i.e. 30° caudo-cranial and 30° cranio-caudal views) a statistically significant and possibly clinically relevant difference could be identified.

As for vertical displacement, we found a statistically significantl larger odds of 4.7 (95% CI 2.2-9.8) to be scored a category higher between the supine and upright patient positioning. Multiple other authors[1-3] also report an increase in vertical displacement between supine and upright patient positioning. Unlike the present study they do not report these differences in categories but in absolute measurements. Backus et al.[1] report an average increase of vertical displacement of 7.5 mm comparing supine to upright radiographs. Malik et al.[2] found an increase in vertical displacement from 9.42 mm to 15.72 mm between the two patient positions. Lastly, Onizuka et al.[3] report an increase of 2.4 mm in vertical displacement. No statistically significant differences in vertical displacement were found between the different orientations of the arm.

A statistically significant difference was found when evaluating the caudo-cranial to cranio-caudal projections for vertical displacement. A proportional odds ratio of 5.9 (95% CI 2.8-12.6) was calculated for an increase in category. Caudo-cranial projections were scored in a higher category of vertical displacement more often. This is in line with the findings of Hoogervorst et al.[38] who found an increase in choice for surgical management for caudo-cranial projections of the same fractured clavicle compared to its cranio-caudal projections. Since shortening was found to be greater on the latter projections (cranio-caudal) it was hypothesized vertical displacement may have been larger on the caudo-cranial projection explaining the increased choice for surgical management.

Supine patient positioning with the arm in neutral orientation on a 15° caudo-cranial projection resulted in the smallest amount of shortening and vertical displacement. Upright patient positioning with the arm in protracted orientation on a 15° caudo-cranial projection resulted in the largest amount of shortening and vertical displacement. In order to create comparable results based on shortening and vertical displacement of the midshaft clavicle fracture it may be advised to report these measurements on an upright patient positioning on a 15° caudo-cranial projection irrespective of the orientation of the arm.

We found excellent intra-observer agreement in measurements of absolute shortening, relative shortening and vertical displacement similar to those reported when using DRRs.[10] Inter-observer agreement for the three outcome measures was found to be good, however, agreement was lower than when DRRs were used.[10]

One of the strengths of this study is that multiple factors influencing the measurements on the fractured clavicle were evaluated in a clinically relevant manner. Another strength of this study is the use of a standardized method for measuring shortening and categorizing vertical displacement as proven by the good to excellent intra- and interobserver agreements.

A potential limitation of this study is that even though the protocol for the different patient positions, orientations of the arm and X-ray beam direction was standardized it was, unlike the use of DRRs, not a static condition. However, it is a good reflection of the process in clinical practice and therefore should not diminish its validity. Another limitation is the use of only the 15° caudo-cranial vs 15° cranio-caudal projections. Adding 30° angulated projections would have increased the radiation exposure to the participants in this study greatly. In a study more focused on the influence of projection in measurements of the fractured clavicle this may be interesting to investigate.

The results of the present study can be used in further discerning the optimal imaging and measurement techniques of the fractured midshaft clavicle fracture.

CONCLUSION

Absolute shortening, relative shortening and vertical displacement were found to be the greatest in the upright patient positioning with the arm protracted orientation on a 15° caudo-cranial projection. There is a statistically significant and possibly clinically relevant difference in shortening of the same fractured midshaft clavicle between the supine and upright positions. No statistically significant differences were found for a change in position of the arm between neutral and protracted. Vertical displacement has a statistically significant larger odds to be scored in a higher category for patient positioning and X-ray projection.

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Part B

Innovations in surgical management of midshaft clavicle fractures

9

Functional outcomes and complications of intramedullary fixation devices for midshaft clavicle fractures: A systematic review and meta-analysis

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ABSTRACT

Background: An alternative to the current gold standard in operative treatment of displaced midshaft clavicle fractures using plate osteosynthesis, is internal fixation by means of an intramedullary fixation device. These devices differ considerably in their specifications and characteristics and an adequate evaluation of their clinical results is warranted.

Methods: A systematic review was conducted to identify all papers reporting functional outcomes, union rates and/or complications using an intramedullary fixation device for the management of midshaft clavicle fractures. Multiple databases and trial registries were searched from inception until February 2020. Meta-analysis was conducted based on functional outcomes and type of complication per type of intramedullary fixation device. Pooled estimates of functional outcomes scores and incidence of complications were calculated using a random effects model. Risk of bias and quality was assessed using the Cochrane risk of bias and ROBINS-I tools. The confidence in estimates were rated and described according to the recommendations of the GRADE working group.

Results: Sixty-seven studies were included in this systematic review. The majority of studies report on the use of Titanium Elastic Nails (TEN). At 12 months follow up the Titanium Elastic Nail and Sonoma CRx report an average Constant-Murley score of 94.4 (95% CI 93-95) and 94.0 (95% CI 92-95) respectively. The most common reported complications after intramedullary fixation are implant-related and implant-specific. For the TEN, hardware irritation and protrusion, telescoping or migration, with a reported pooled incidence 20% (95% CI 14-26) and 12% (95% CI 8-18), are major contributors to the total complication rate. For the Rockwood/Hagie Pin, hardware irritation is identified as the most common complication with 22% (95% CI 13-35). The most common complication for the Sonoma CRx was cosmetic dissatisfaction in 6% (95% CI 2-17) of cases.

Conclusion: Although most studies were of low quality, in general, good functional results and union rates irrespective of the type of device are found in the reviewed literature. However, there are clear device-related and device-specific complications for each. The results of this systematic review and meta-analysis can help guide surgeons in choosing the appropriate operative strategy, implant and informing their patient.

Level of evidence: 4.

BACKGROUND

Clavicle fractures are common fractures with an incidence reported of 59.3 per 100,000 person years.[5] Historically, these fractures were predominantly treated non-operatively. However, it has been reported that surgical treatment of displaced mid-shaft clavicle fractures (DMCF) leads to better union rates, improved early functional outcomes, and increased patient satisfaction.[6-8] The current gold standard in operative treatment is Open Reduction Internal Fixation (ORIF) using plates and screws. An alternative to this technique is internal fixation using intramedullary fixation devices. These devices aim to reduce the DMCF in a minimally invasive manner and thereby improving cosmetic satisfaction and union rates while lowering infection rates.[13] There are multiple different intramedullary devices available. Some of these devices are made out of rigid stainless steel while others consist of flexible titanium alloys. Some are not fixated within the bone while others are fixated on either one or both sides of the midshaft clavicle fracture. Since these devices differ considerably in their specifications and characteristics the array and distribution of complications and functional outcomes may vary as well.

The aim of this systematic review is to generate an overview of functional outcomes and complications in the management of DMCF per available intramedullary devices.

METHODS

Electronic databases (PubMed, ScienceDirect, Embase and Cochrane) and clinical trial registries (ClinicalTrials.gov, controlled-trials.com (ISRCTN), Australian New Zealand Clinical Trials Registry (ANZCTR), Chinese Clinical Trial Registry (CCTR), EU Clinical Trials Register (EU-CTR) and The Netherlands National Trial Register (NTR)) were searched from their inception to February 2020. Keywords used to develop our search strategy were 'clavicle', 'fracture', 'intramedullary fixation'. The detailed search strategy is described in Appendix 9.1.

Inclusion criteria

All titles and abstracts were screened and study inclusion was decided on by two reviewers (PH/TvD). In case of discrepancy in study inclusion, disagreements were discussed until consensus on eligibility was reached. If disagreement persisted after discussion, consensus was met consulting GH. References of retrieved eligible articles were searched for supplementary studies. Studies meeting the following criteria were included:

- Studies describing the functional outcomes, with use of any type of intramedullary fixation for DMCF.
- Studies describing complications, with use of any type of intramedullary fixation for DMCF.

- Only original studies were included.
- Studies written in English, Dutch, and German.
- Studies concerning skeletally mature patients.

Abstracts, theses, case reports, biomechanical studies, surgical technique papers, editorials, letters and conference proceedings were not included. Studies using Kirschner wires and screws were excluded. Studies concerning intramedullary fixation for open fractures, pathological fractures, multi-trauma patients, floating shoulders, non-unions or mal-unions were also excluded.

Data extraction

Studies in the final study selection were divided into subgroups depending on type of implant and ranked according to their study design and level of evidence (Oxford Centre of Evidence Based Medicine) by 2 authors (PH, TvD). The level of evidence (LoE) rating is divided into 5 levels: level I indicates the highest evidence studies, level II high, level III moderate, level IV low and level V very low-evidence studies.[14] Disagreement between the reviewers concerning quality assessment was resolved by discussion.

Data from all included studies were extracted with respect to specific characteristics including title, author, year of publication, number of clavicles reported, type of fracture, intramedullary device used, length of follow-up, functional outcomes, and type and number of complications. Date were extracted and checked for accuracy by PH and TvD. Discrepancies were resolved by discussion. This study was conducted and reported in accordance with the reporting guidance provided in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[15] The protocol was prospectively registered in PROSPERO (CRD42018086518).

Risk of bias and quality assessment

The Cochrane risk of bias tool was used for assessing risk of bias in randomized trials. The risk of bias tool covers six domains of bias: selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias. Within each domain, assessments are made for one or more items, which may cover different aspects of the domain, or different outcomes.[16]

The ROBINS-I tool was used for assessing risk of bias in non-randomized studies of interventions.[17] This tool assesses seven domains through which bias might be introduced. The first two domains, covering confounding and selection of participants into the study, address issues before the start of the interventions. The third domain addresses classification of the interventions themselves. The other four domains address issues after the start of interventions: biases due to deviations from intended interventions, missing data, measurement of outcomes, and selection of the reported result.

Publication bias was assessed only if 10 or more studies were included in the meta-analysis using funnel plots and Egger's (for continuous outcomes) and Peters' test (for proportions) for funnel plot asymmetry.[18-20] Sensitivity analyses were performed to assess the influence of study quality when there was more than 1 high quality study available according to the ROBINS-I.

The confidence in estimates were rated and described according to the recommendations of the GRADE working group as each outcome was assessed for potential risk of bias, inconsistency, imprecision, indirectness and publication bias.[21]

Data analysis

A meta-analysis was performed whenever three or more studies per intramedullary device that reported on a functional outcome or type of complication could be included.

Despite anticipated heterogeneity, the individual study proportions were pooled. Pooled estimates with their corresponding 95% confidence intervals were calculated using logit transformation (complications) or using untransformed data (functional outcome scores) within a random effects model framework. A continuity correction of 0.5 was applied if a study had an event probability of either 0 or 1. This continuity correction is used both to calculate individual study results with confidence limits and to conduct the meta-analysis. Heterogeneity of combined study results was assessed by I^2, and its connected Chi-square test for heterogeneity, and the corresponding 95% confidence intervals were calculated. Restricted maximum likelihood was used to estimate the heterogeneity variance. 95% Prediction intervals were calculated to present the expected range of true effects in similar studies.[22]

Statistical analyses were performed using R version 3.4.4 (R Foundation for Statistical Computing, Vienna, Austria) with package 'meta'.

RESULTS

The search strategy retrieved 368 unique records. Subsequent selection procedure resulted in 75 eligible articles of which 67 studies could be included in this systematic review and 62 in the meta-analysis (Figure 9.1).

In total, 10 studies concerning the Rockwood (DePuy, Warsaw, IN, USA) and Hagie pin (Smith & Nephew, Memphis, TN, USA) were identified and included in the analysis (two level I,[23, 24] two level III[25, 26] and six level IV[27-32] studies). These devices were evaluated together since they are essentially the same; they both consist of the exact same stainless-steel pin, with a cancellous and machine thread end, and two nuts. The only difference between the two is that the Rockwood pin also has a trocar point on the

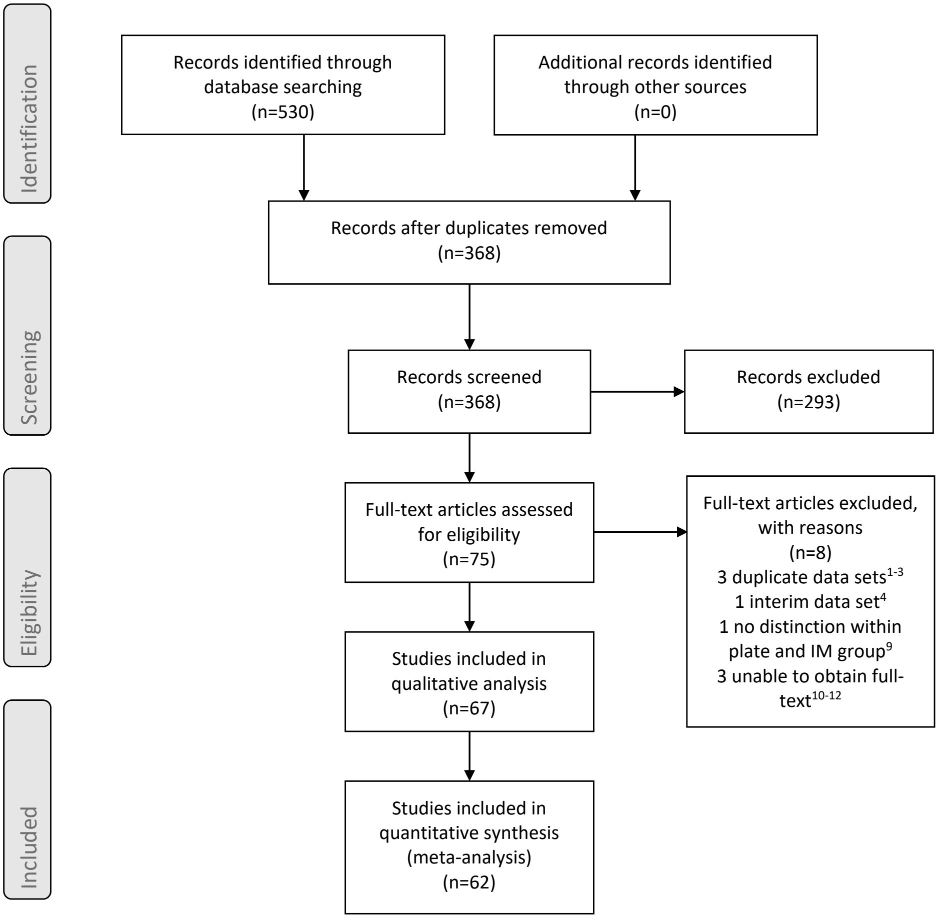

Figure 9.1. PRISMA flow diagram.

machine thread end of the pin. Concerning the Titanium Elastic Nail (TEN) (Depuy Synthes, Warsaw, IN, USA or Stryker, Kalamazoo, MI, USA) the 43 studies that were incorporated in the analysis were comprised of seven level I,[33-39] eight level II,[40-47] eleven level III[48-58] and seventeen level IV1, [13, 59-73] studies. Another type of fixation described was the Sonoma CRx (Arthrex, Naples, FL, USA) for which 6 studies (three level I,[74-76] one level II,[77] one level III[78] and one level IV[79]) were identified. Less frequently described intramedullary fixation devices were the threaded titanium elastic nails (Kang Li Min Medical Devices Co. Ltd., Tianjin, China),[80-82] the Knowles pin (Zimmer Biomet, Warsaw, IN, USA)[83-86] and one study describing a second generation Titanium elastic nail (Puwei Medical Appliances Inc, Shanghai, China).[87] Table 9.1 displays study characteristics including population description, type of intramedullary device, functional outcome scores, and type and number of complications.

Table 9.1. Study characteristics

Author	Year	Level of evidence	Study design	Number of patients	Clavicles	Functional outcomes: CMS (SD) at 12 months	Functional outcomes: DASH (SD) at 12 months	Functional outcomes: Quick DASH (SD) at 12 months	Complications: Number of complications	Hardware irritation	Soft tissue problems	Hardware failure	Infection	Non-union	Protrusion/ Telescoping/ Migration	Delayed union	Mal-union	Pain	Cosmetic dissatisfaction
Rockwood Pin & Hagie Pin																			
Strauss et al.	2007	4	RCS	16	16				8		3	2		0				1	
Judd et al.	2009	1	RCT	29	29				21	9		1	8	1		1			
Ferran et al.	2010	1	RCT	17	17	92.1 (6)			4		1	1		0					
Mudd et al.	2011	4	RCS	18	18				16	3	3		2	3	2	1		1	
Kleweno et al.	2011	3	RCS	18	18				5	2	1	1	1	0					
Millett et al.	2011	4	RCS	51	51				15		5	2	2	5		1			
Payne et al.	2011	4	RCS	68	68				62	30		3	7	2		1		15	
Frye et al.	2012	4	RCS	17	17				11	7	1	2		0					
Marlow et al.	2012	4	RCS	70	70		5.9*		31	12	4		8	2				1	
Wenninger et al.	2013	3	RCS	33	33				3	2			1	0					
TEN																			
Jubel et al.	2002	2	PCS	65	65	96.9 (3.3)			8		2			1	5				
Jubel et al.	2002	3	RCC	20	20	97 (4)			0					0					
Jubel et al.	2003	3	RCS	55	58	97.9 (3.3)			9	3	2		0	1	2				
Jubel et al.	2003	2	PCS	12	12	98.3 (1.5)			0				0	0					
Jubel et al.	2005	2	PCC	26	26				20	8			0	0	2				
Kettler et al.	2005	4	RCS	55	55	81 (7.1)			31	14	2		0	1	6		2	2	
Walz et al.	2006	2	PCS	35	35	98.1 (1.3)			6	5			0	0	1				
Keener et al.	2006	4	RCS	24	24				13	6		2			1	1	3		
Kettler et al.	2007	4	RCS	87	87	84 (9)	6.9 (7.2)		23	4			0	2	4		7		4
Mueller et al.	2007	4	RCS	32	32	95 (1.9)	5 (2.3)		16	5		2	1	0	8				
Witzel	2007	2	RCT	35	35				0										
Hartmann et al.	2008	4	RCS	15	15	95.3 (3.9)			4	4			0	0					
Frigg et al.	2009	4	RCS	34	34		1.5 (3.2)		24	7		1		0	15			1	
Smekal et al.	2009	1	RCT	30	30	97.9 (1.7)			10			2	0	0	7	1			

Table 9.1 continues on next page.

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Table 9.1. *Continued*

						Functional outcomes			Complications										
Author	Year	Level of evi-dence	Study design	Number of patients	Clavi-cles	CMS (SD) at 12 months	DASH (SD) at 12 months	Quick DASH (SD) at 12 months	Number of compli-cations	Hard-ware irritation	Soft tissue problems	Hard-ware failure	Infec-tion	Non-union	Protrusion/ Telescoping/ Migration	De-layed union	Mal-union	Pain	Cosmetic dissatis-faction
Liu et al.	2010	3	RCC	51	51	86.7 (5.3)	13.5 (3.9)		20	4		4	3	5			4		
Frigg et al.	2011	3	RCC	44	44		1.4 (3.1)		14	5		1		1	6				
Chen et al.	2011	1	RCT	30	30	97 (4.3)	2.74 (3.6)		10	3		1	1	0	3				
Assobhi	2011	1	RCT	19	19	95.5 (5.3)			4	3		0	0	0					1
Smekal et al.	2011	1	RCT	60	60	98 (3.6)	0.5 (1.8)		19	5		2	1	0	7	2			
Kadakia et al.	2012	4	RCS	38	38			6.7 (3.4)	11	18			0	0	1				
Wijdicks et al.	2012	4	RCS	47	47				60	29		1	4	0	26			2	
Tarng et al.	2012	3	RCC	25	25	96 (2)			4		4		0	0					
Chen et al.	2012	3	RCC	57	57	95 (3.2)	4 (4.4)		32	4		3	1	1	17				
Prokop et al.	2013	4	RCS	136	136	97 (3)			1			1							
Langenhan et al.	2014	4	RCS	37	37	96.0 (5.3)	3 (5)		4				1	0	3				
Saha et al.	2014	2	PCC	34	34	93.5 (4.4)			13	12			0	0					
Shokouh et al.	2014	4	RCS	12	13				0				0	0					
Braun et al.	2014	4	RCS	40	40	86.3 (8.1)	5.5 (6.9)		19	1	2			0	12				
Narsaria et al.	2014	2	PCC	33	33	94.6 (3.2)			4			1	1	1					
Suresha et al.	2014	4	RCS	20	20	94.6*			0			0	0	0					
Lu et al.	2014	4	RCS	27	27	93.6 (9)	6.2 (11.1)		17	8		0	0	0	9				
Wang et al.	2015	3	RCC	25	25	93.8 (8.9)	5.5 (10.5)		12	5		0	0	0	5				
Andrade-Silva et al.	2015	1	RCT	25	25	91.8 (8.8)	7.5 (12.5)		10	10				1					
van der Meijden et al.	2015	1	RCT	62	62	96.3 (11.8)	3.9 (10.2)		43	33									
Eden et al.	2015	2	PCC	24	24				5	1			1	1	2	1			
Mishra et al.	2016	3	PCC	73	73	96.8 (2.3)			15	7			3	0	2	3			
Lechler et al	2016	3	RCC	36	36	87.7 (10.7)	3.9 (6.6)		12					3					
Fuglesang et al.	2017	1	RCT	60	60				36	19	4	2		1					
Govindasamy et al.	2017	4	RCS	54	54	97.8 (1)			19	15			3	0	1	1			
Eickhoff et al.	2018	3	RCC	99	99				39	29	1			2	26				
Eisenstein et al.	2018	4	RCS	7	7				4	2	1				1				

Table 9.1. *Continued*

							Functional outcomes			Complications										
	Author	Year	Level of evi-dence	Study design	Number of patients	Clavi-cles	CMS (SD) at 12 months	DASH (SD) at 12 months	Quick DASH (SD) at 12 months	Number of compli-cations	Hard-ware irritation	Soft tissue problems	Hard-ware failure	Infec-tion	Non-union	Protrusion/ Telescoping/ Migration	De-layed union	Mal-union	Pain	Cosmetic dissatis-faction
	Frima et al.	2018	4	RCC	34	34				20			4	0						
	Zhang et al.	2019	3	RCC	37	37	97.3 (13.7)			2			0	1				0		
Sonoma CRx																				
	Zehir et al.	2015	1	RCT	24	24			7.7 (2.2)	8			1	0	0				3	4
	King et al.	2015	2	PCS	47	47	90 (13)	11 (18)		3			2	1	0					
	Zehir et al.	2015	4	RCS	17	17	94.3 (2.8)	11.8 (2.5)		2			1	1	0					
	Calbiyik et al.	2016	1	RCT	35	35	92.9 (4)		3.8 (1.6)	5			2	1	0		1			1
	Zehir S et al.	2016	3	RCC	33	33	94.3 (5.3)			4			1	2	0				2	1
	King et al.	2019	1	RCT	35	35	97 (5)	5 (6)		3		1	1	0						
Threaded Pin																				
	Zenni et al.	1981	4	RCS	21	21				7			1	0		0				
	Grassi et al	2001	3	RCC	40	40	82.9 (8)			15				8	2		2			
	Bi et al.	2015	2	PCS	45	45	96.5 (9)	1.4 (12.5)		20		19	1	0	0					
Knowles Pin																				
	Chu et al	2002	4	RCS	78	78	92 (13.8)			4			1				3			
	Lee et al	2007	2	RCT	32	32	85 (8.8)			0										
	Lee et al.	2008	3	RCC	56	56				4	4									
	Wu et al.	2013	4	RCC	337	337				19					19					
2nd Generation TEN																				
	Fu	2016	4	RCC	36	36	93.4 (2.7)	2.5 (1.6)		3	1					2				

* No range or SD reported.
RCS, Retrospective Case Series; RCC, Retrospective Comparative Cohort; PCS, Prospective Case Series; PCC, Prospective Comparative Cohort; RCT, Randomized Clinical Trail.

Risk of bias assessment

The results of the Cochrane risk of bias tool are summarized in Table 9.2 and shows high risk of bias in domains 3 and 4 assessing performing and detection bias. The results of the ROBINS-I risk of bias assessment, summarized in Table 9.3 shows that the overall ROBINS-I score for most studies were subject to serious or critical risk of bias.

Table 9.2. Cochrane risk of bias assessment of randomized trials

		Domain 1: Selection bias (Random sequence generation)	Domain 2: (Selection bias) Allocation concealment	Domain 3: Performance bias Blinding (participants and personnel)	Domain 4: Detection bias Blinding (outcome assessment)	Domain 5: Attrition bias Incomplete outcome data	Domain 6: Reporting bias	Domain 7: Other bias
Sonoma CRx								
Zehir et al.	2015	+	+	-	-	?	?	+
Calbiyik et al.	2016	+	+	-	-	+	?	+
King et al.	2019	+	+	-	-	-	?	+
Rockwood & Hagie Pin								
Judd et al.	2009	+	+	-	-	?	?	+
Ferran et al.	2010	?	+	-	-	+	-	+
TEN								
Witzel	2007	?	?	-	-	?	?	+
Smekal et al.	2009	+	+	-	-	-	?	+
Chen et al.	2011	?	?	-	-	?	?	+
Asshobi	2011	?	?	-	-	+	?	+
Smekal et al	2011	+	-	-	-	?	?	+
Andrade-Silva	2015	+	+	-	-	+	+	+
Van der Meijden et al.	2015	+	+	-	-	+	+	+
Fuglesang et al.	2017	+	+	-	-	+	?	+
Knowles Pin								
Lee et al.	2007	-	-	-	-	?	-	+

Green = Low risk, Red = High risk, Yellow = Unknown risk.

Table 9.3. ROBINS-I assessing risk of bias in non-randomized studies of interventions

Author	Year	Domain 1: Confounding	Domain 2: Selection of participants	Domain 3: Classification of intervention	Domain 4: Deviation from interventions	Domain 5: Missing data Domain	Domain 6: Measurement of outcomes	Domain 7: Selection of reported results	ROBINS-I overall
Sonoma CRx									
Zehir et al.	2015	2	2	2	1	2	2	2	2
King et al.	2015	3	3	2	1	2	2	2	3
Zehir et al.	2015	3	3	2	1	3	2	2	3
Calbiyik et al.	2016	2	1	1	1	1	2	2	2
Zehir S et al.	2016	3	2	2	1	2	2	3	3
Rockwood Pin & Hagie Pin									
Strauss et al.	2007	4	3	3	1	2	3	3	4
Judd et al.	2009	2	2	1	1	1	2	2	2
Ferran et al.	2010	2	2	2	1	1	2	2	2
Mudd et al.	2011	3	3	2	1	1	3	2	3
Kleweno et al.	2011	3	2	2	1	1	3	3	3
Millett et al.	2011	3	3	3	1	2	2	2	3
Payne et al.	2011	3	2	2	1	2	2	2	3
Frye et al.	2012	3	3	3	1	2	3	3	3
Marlow et al.	2012	3	3	2	1	2	2	2	3
Wenninger et al.	2013	3	2	2	1	2	3	2	3
TEN									
Jubel et al.	2002	2	2	1	1	2	2	2	2
Jubel et al.	2002	2	3	2	1	1	2	2	3
Jubel et al.	2003	3	3	2	1	2	2	3	3
Jubel et al.	2003	3	3	1	1	2	2	2	3
Jubel et al.	2005	2	3	1	1	1	2	2	3

Table 9.3 continues on next page.

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Table 9.3. *Continued*

Author	Year	Domain 1: Confounding	Domain 2: Selection of participants	Domain 3: Classification of intervention	Domain 4: Deviation from interventions	Domain 5: Missing data Domain	Domain 6: Measurement of outcomes	Domain 7: Selection of reported results	ROBINS-I overall
Kettler et al.	2005	4	3	1	1	2	2	2	4
Walz et al.	2006	2	2	1	1	1	2	2	2
Keener et al.	2006	4	3	2	1	3	2	3	3
Kettler et al.	2007	3	3	2	1	2	2	2	3
Mueller et al.	2007	2	2	1	1	1	2	1	2
Witzel	2007	3	2	2	1	2	2	2	3
Hartmann et al.	2008	3	3	2	1	2	2	3	3
Frigg et al.	2009	3	2	1	2	2	2	3	3
Smekal et al.	2009	2	2	1	1	1	2	2	2
Liu et al.	2010	3	3	2	1	2	2	3	3
Frigg et al.	2011	2	2	1	1	3	2	2	3
Chen et al.	2011	2	2	1	1	1	2	2	2
Assobhi	2011	2	2	2	1	1	2	2	2
Smekal et al.	2011	2	2	1	1	1	2	2	2
Kadakia et al.	2012	4	3	2	1	2	3	2	4
Wijdicks et al.	2012	3	2	3	1	2	3	2	3
Tarng et al.	2012	3	3	3	1	2	2	2	3
Chen et al.	2012	3	3	2	1	2	2	2	3
Prokop et al.	2013	3	3	2	1	3	2	3	3
Langenhan et al.	2014	2	3	2	1	2	2	3	3
Saha et al.	2014	3	2	2	1	2	2	2	3
Shokouh et al.	2014	2	3	2	1	2	3	2	3
Braun et al.	2014	2	3	2	1	2	2	2	3
Narsaria et al.	2014	2	2	1	1	2	2	2	2

Table 9.3. *Continued*

Author	Year	Domain 1: Confounding	Domain 2: Selection of participants	Domain 3: Classification of intervention	Domain 4: Deviation from interventions	Domain 5: Missing data Domain	Domain 6: Measurement of outcomes	Domain 7: Selection of reported results	ROBINS-I overall
Suresha et al.	2014	3	3	2	1	2	2	2	3
Lu et al.	2014	2	3	1	1	2	2	2	3
Wang et al.	2015	2	3	1	1	2	2	2	3
Andrade-Silva et al.	2015	2	1	1	1	1	2	1	2
van der Meijden et al.	2015	2	1	1	1	1	2	1	2
Eden et al.	2015	3	2	2	1	2	2	2	3
Mishra et al.	2016	2	2	2	1	2	2	2	2
Lechler et al	2016	3	3	2	1	2	2	2	3
Fuglesang et al.	2017	2	2	1	1	2	2	2	2
Govindasamy et al.	2017	3	3	2	1	3	2	2	2
Eickhoff et al.	2018	2	2	1	1	2	2	2	2
Eisenstein et al.	2018	3	2	2	1	2	2	2	3
Frima et al.	2018	2	2	2	1	2	2	2	2
Zhang et al.	2019	2	3	2	1	3	3	3	3
Threaded Pin									
Zenni et al.	1981	4	4	2	1	2	3	2	4
Grassi et al	2001	3	3	2	1	2	2	2	3
Bi et al.	2015	2	2	2	1	2	2	2	2
Knowles Pin									
Chu et al	2002	3	3	2	3	3	2	3	3
Lee et al	2007	3	2	2	1	2	2	2	3
Lee et al.	2008	3	3	2	1	2	2	2	3
Wu et al.	2013	3	2	2	1	2	3	2	3

1 = Low risk of bias, 2 = Moderate risk of bias, 3 = Serious risk of bias, 4 = Critical risk of bias.

Studies concerning the Rockwood Pin and Hagie Pin

All studies identified concerning these devices described an identical surgical technique. All pins were removed after union between 6-20 weeks through a secondary surgical intervention. Average follow-up of the studies ranged between 6 months and 7 years. The functional outcome scores reported were heterogeneous and therefore not comparable. Only two studies reported a Constant-Murley (92.1±6)[23] or DASH (5.9).[27] Other functional outcome scores reported were the Oxford Shoulder Score (45.2±2.3),[23] L'Insalata (95.5±7.3),[24] and ASES (88.6 and 89).[28, 32]

Meta-analysis

It was not possible to perform a meta-analysis for functional outcomes. A meta-analysis was performed for 6 different complications. Data from 10 studies were used to evaluate nonunion followed by data from 7 studies for infection. Seven studies reported hardware irritation, soft tissue problems[23, 25, 27-29, 31, 32] and hardware failure.[23-25, 28, 30-32] Four studies were included in a meta-analysis for persistent pain (Figure 9.2). The highest pooled incidences were found for complications hardware irritation (22%, 95% CI 13-35 in 253 clavicles), soft tissue problems (9%, 95% CI 6-13 in 207 clavicles) and infection (9%, 95% CI 5-16 in 287 clavicles). A pooled incidence of unspecified persistent pain was reported in 6% (95% CI 2-20 in 172 clavicle) of cases. The pooled incidence of hardware failure and nonunion was 6% (95% CI 3-10 in 216 clavicles) and 3% (95% CI 1-8 in 337 clavicles) respectively.

The confidence in the estimates from the meta-analyses according to GRADE ranged between low and very low (Table 9.4 and Appendix 9.2).

Studies concerning the Titanium Elastic Nail (TEN)

The first reports on using TEN in the treatment of DMCF dated from 2002.[43] TENs with a diameter varying between 2 and 3.5 mm were used. Closed reduction rates were reported in 28 of 35 studies. The rates ranged from 15%[54] to 93%.[35] Most studies report a routine removal of the TEN in all cases mostly through a second surgical intervention but also removal under local anesthesia was described. The earliest routine nail removal was performed at 3 months[64] and the latest on average at 8.8 months.[33]

Meta-analysis

A meta-analysis was performed for functional outcomes based on 30 studies reporting the Constant-Murley Score and 15 studies reporting a DASH score (Figure 9.3). The pooled data for the Constant-Murley score and DASH score at 12 months is 94.4 (95% CI 93.4-95.4 in 1,290 clavicles) and 4.6 (95% CI 2.6-6.7 in 647 clavicles), respectively (Figure 9.3). The confidence in the estimates from the meta-analyses according to GRADE concerning the functional outcomes were considered high due to the consistency and

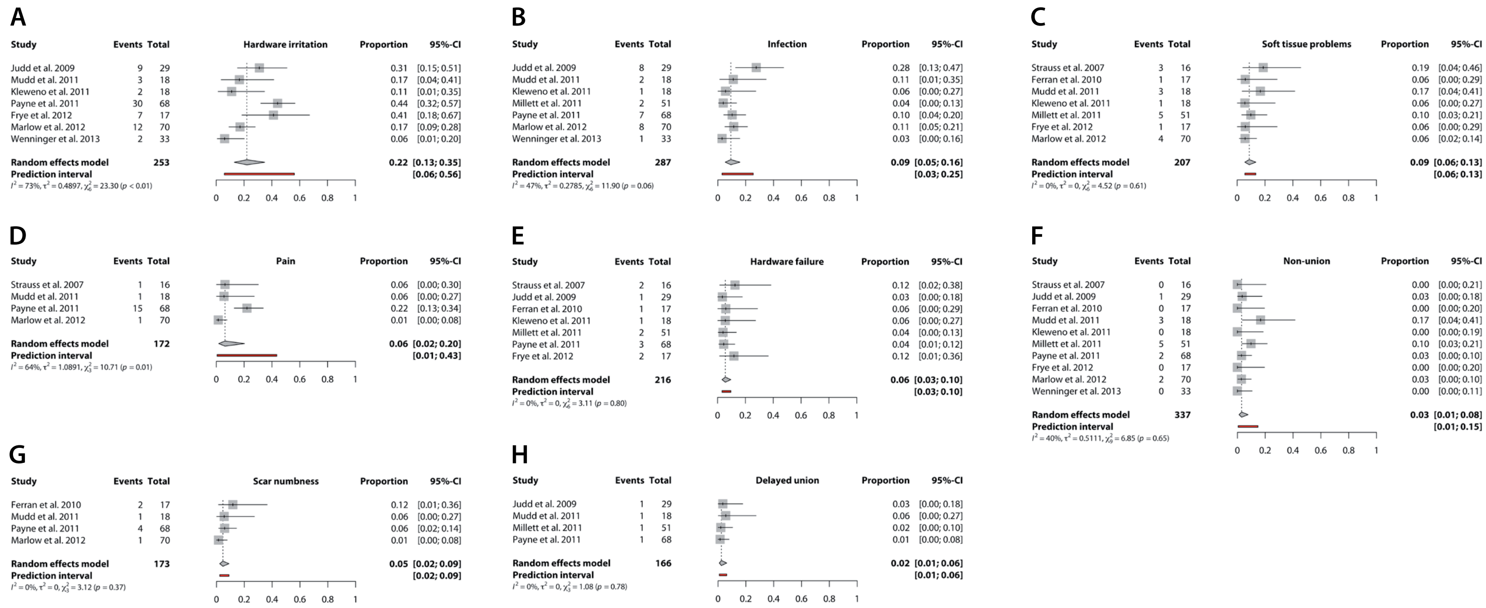

Figure 9.2. Forest plots of the included studies using the **Rockwood and Hagie Pin** reporting on **(A)** hardware irritation, **(B)** infection, **(C)** soft tissue problems, **(D)** persistent pain, **(E)** hardware failure, **(F)** nonunion, **(G)** scar numbness, and **(H)** delayed union. Forest plots display the mean proportion of complications **(A-F)**, 95% confidence interval and the relative weight of the individual studies. The diamond indicates the pooled estimate and its 95% confidence interval. The red bar indicates the 95% prediction interval. Prediction intervals illustrate which range of true effects expected to occur in similar studies in future settings.

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precision of the data in combination with the large number of clavicles involved (Table 9.4 and Appendix 9.2). The functional outcomes of two studies were not included in the meta-analysis.[36, 39] Fuglesang et al.[36] report the Constant-Murley and DASH scores

Table 9.4. Summary of findings table including GRADE

Device	Outcome	No. of studies	No. of clavicles	Effect estimate (95% CI)	Quality of evidence (GRADE)
Rockwood Pin & Hagie Pin					
	Hardware irritation	7	253	0.22 (0.13 – 0.35)	⊕⊕⊙⊙ LOW
	Infection	7	287	0.09 (0.05 – 0.16)	⊕⊕⊙⊙ LOW
	Soft tissue problems	7	207	0.09 (0.06 – 0.13)	⊕⊕⊙⊙ LOW
	Pain	4	172	0.06 (0.02 – 0.20)	⊕⊙⊙⊙ VERY LOW
	Hardware failure	7	216	0.06 (0.03 – 0.10)	⊕⊕⊙⊙ LOW
	Nonunion	6	191	0.00 (0.00 – 0.04)	⊕⊕⊙⊙ LOW
	Scar numbness	4	173	0.05 (0.02 – 0.09)	⊕⊙⊙⊙ VERY LOW
	Delayed union	4	166	0.02 (0.01 – 0.06)	⊕⊙⊙⊙ VERY LOW
TEN					
	CMS	29	1270	94.40 (93.43 – 95.37)	⊕⊕⊕⊕ HIGH
	DASH	15	647	4.65 (2.61 – 6.68)	⊕⊕⊕⊕ HIGH
	Hardware irritation	30	1273	0.20 (0.14 – 0.26)	⊕⊕⊕⊙ MODERATE
	Protrusion	25	1105	0.12 (0.08 – 0.18)	⊕⊕⊕⊙ MODERATE
	Malunion	3	193	0.07 (0.04 – 0.11)	⊕⊕⊙⊙ LOW
	Soft tissue problems	8	406	0.04 (0.03 – 0.08)	⊕⊙⊙⊙ VERY LOW
	Pain	3	136	0.04 (0.02 – 0.09)	⊕⊙⊙⊙ VERY LOW
	Nonunion	36	1436	0.03 (0.02 – 0.04)	⊕⊕⊕⊙ MODERATE
	Hardware failure	19	800	0.03 (0.02 – 0.05)	⊕⊕⊙⊙ LOW
	Delayed union	6	265	0.03 (0.02 – 0.06)	⊕⊙⊙⊙ VERY LOW
	Infection	29	1084	0.02 (0.01 – 0.03)	⊕⊕⊕⊙ MODERATE
Sonoma CRx					
	CMS	5	167	94.03 (92.31 – 95.76)	⊕⊕⊕⊙ MODERATE
	DASH	3	99	9.16 (3.94 – 14.37)	⊕⊕⊕⊙ MODERATE
	Cosmetic dissatisfaction	3	92	0.06 (0.02 – 0.17)	⊕⊙⊙⊙ VERY LOW
	Hardware failure	6	191	0.04 (0.02 – 0.08)	⊕⊕⊙⊙ LOW
	Infection	6	191	0.03 (0.01 – 0.07)	⊕⊕⊙⊙ LOW
	Nonunion	6	191	0.00 (0.00 – 0.04)	⊕⊕⊙⊙ LOW
Threaded Pin					
	Infection	3	106	0.01 (0.00 – 0.64)	⊕⊙⊙⊙ VERY LOW

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

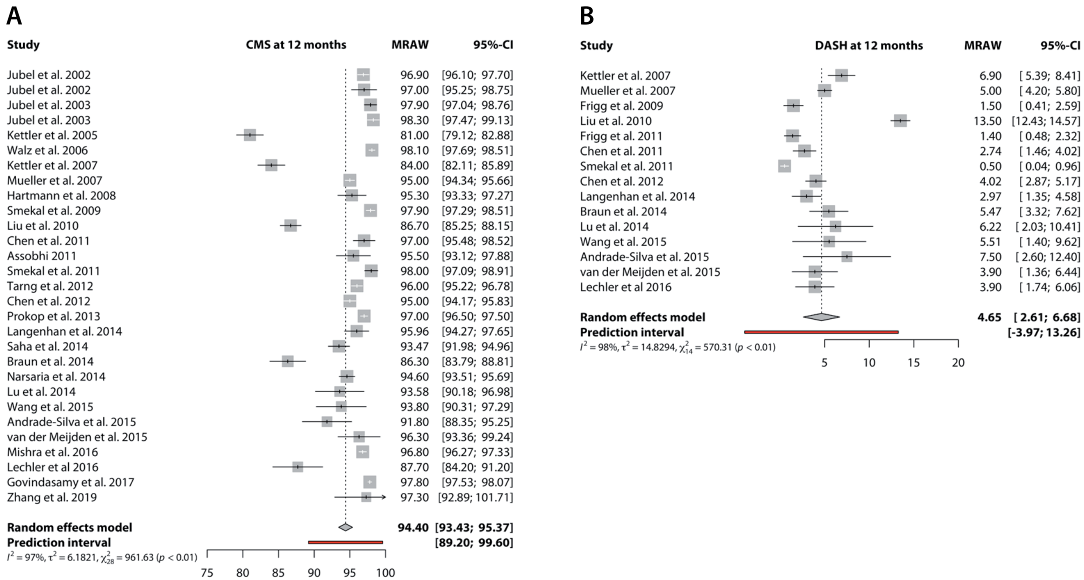

Figure 9.3. Forest plots of the included studies using the **Titanium Elastic Nail** reporting on **(A)** Constant-Murley score at 12 months, and **(B)** DASH score at 12 months. 95% confidence interval and the relative weight of the individual studies. The diamond indicates the pooled estimate and its 95% confidence interval. The red bar indicates the 95% prediction interval. Prediction intervals illustrate which range of true effects expected to occur in similar studies in future settings.

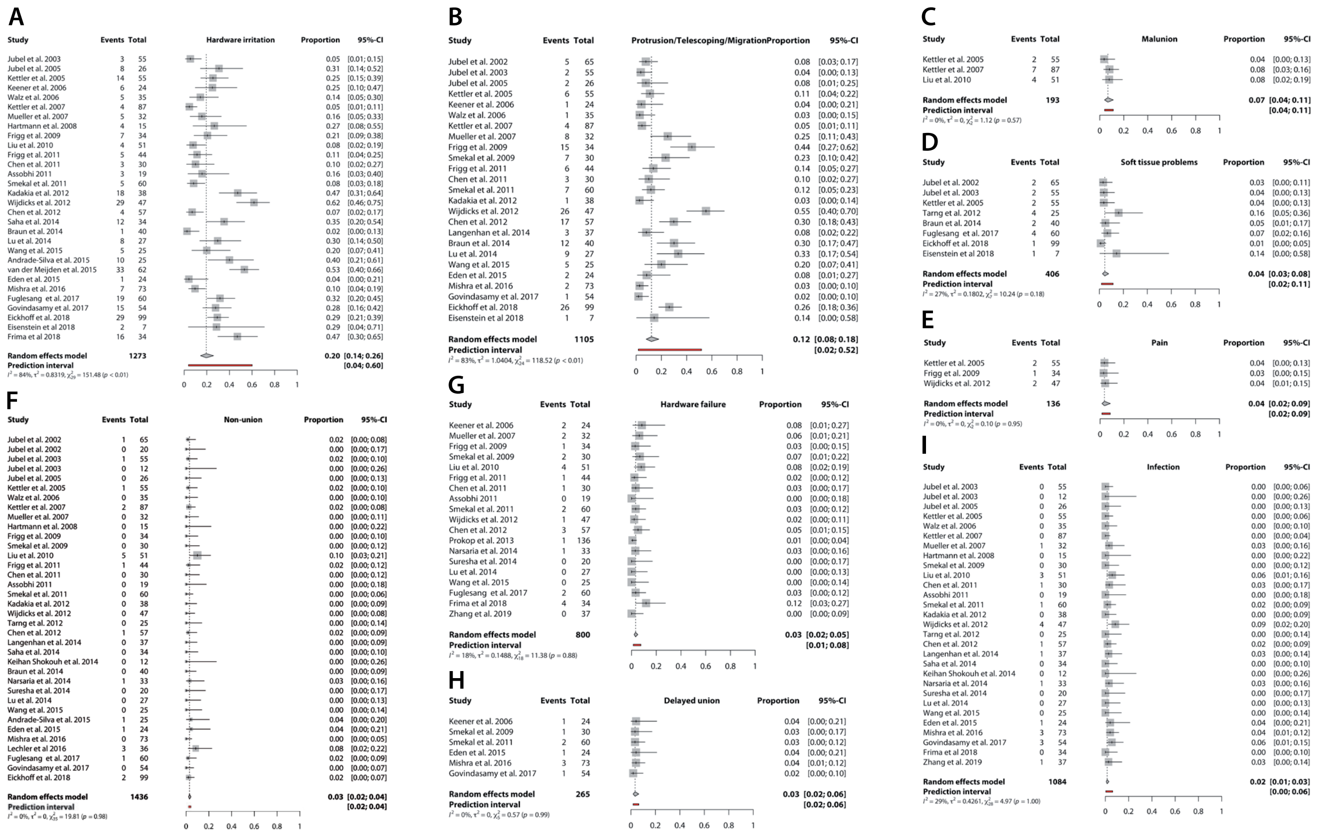

Figure 9.4. Forest plots of the included studies using the **Titanium Elastic Nail** reporting on **(A)** hardware irritation, **(B)** protrusion/telescoping/migration, **(C)** malunion, **(D)** soft tissue problems, **(E)** pain, **(F)** nonunion, **(G)** hardware failure, **(H)** delayed union, and **(I)** infection. Forest plots display the mean proportion of complications **(A-H)**, 95% confidence interval and the relative weight of the individual studies. The diamond indicates the pooled estimate and its 95% confidence interval. The red bar indicates the 95% prediction interval. Prediction intervals illustrate which range of true effects expected to occur in similar studies in future settings.

of 60 TENs only by means of a line graph and van der Meijden et al.[39] report in-text Constant-Murley scores at 1 year follow up that differ from the line graph displayed. Visual evaluation of the line graphs however seems similar to the pooled incidences from the meta-analysis.

Data from 43 studies were pooled in the meta-analysis for evaluating complications rates using the TEN. Twenty-nine studies reported on infection, 29 studies on hardware irritation, 25 studies on protrusion/telescoping/migration, 19 on hardware failure, 12 on nonunion, 8 on soft tissue problems, 5 on malunion and 3 on pain (Figure 9.4). The two most common complications reported, protrusion/telescoping/migration and hardware irritation, are implant-related. The pooled incidence was 12% (95% CI 8-18 in 1,105 clavicles) and 20% (95% CI 14-26 in 1,273 clavicles), respectively.

Malunion after surgical management by means of a TEN was reported in 7% (95% CI 4-11 in 193 clavicles) and hardware failure was 3% (95% CI 2-5 in 800 clavicles). Pooled infection incidence was 2% (95% CI 0-3 in 1,084 clavicles) and the pooled incidence of a nonunion using a TEN was 3% (95% CI 2-4 in 1,436 clavicles). The confidence in the estimates from the meta-analyses according to GRADE concerning the functional outcomes ranged from moderate to very low (Table 9.4 and Appendix 9.2).

Studies concerning the Sonoma CRx

Meta-analysis

Six studies were included in the meta-analysis. Data from 5 studies were pooled for functional outcomes using the Constant-Murley score. The pooled Constant-Murley score at 12 months was 94.0 (95% CI 92-96 in 167 clavicles). Six studies reported on nonunion, infection and hardware failure. Three studies reported cosmetic dissatisfaction (Figure 9.5). The pooled incidence for cosmetic dissatisfaction was highest at 6% (95% CI 2-17 in 92 clavicles), followed by of hardware failure (4%; 95% CI 2-8 in 191 clavicles) and infection (3%; 95% CI 1-7 in 191 clavicles). No reports of non-union using the Sonoma CRx were reported, the pooled incidence was 0% (95% CI 0-4 in 191 clavicles).

Two studies reported on persistent pain as a complication[75, 78] and 1 study mentions the occurrence of a delayed union.[74]

The confidence in the estimates from the meta-analyses according to GRADE concerning the functional outcomes were considered moderate. Although the results were consistent, the data originate from very limited group of authors. The confidence in the other meta-analyses according to GRADE were low to very low (Table 9.4 and Appendix 9.2).

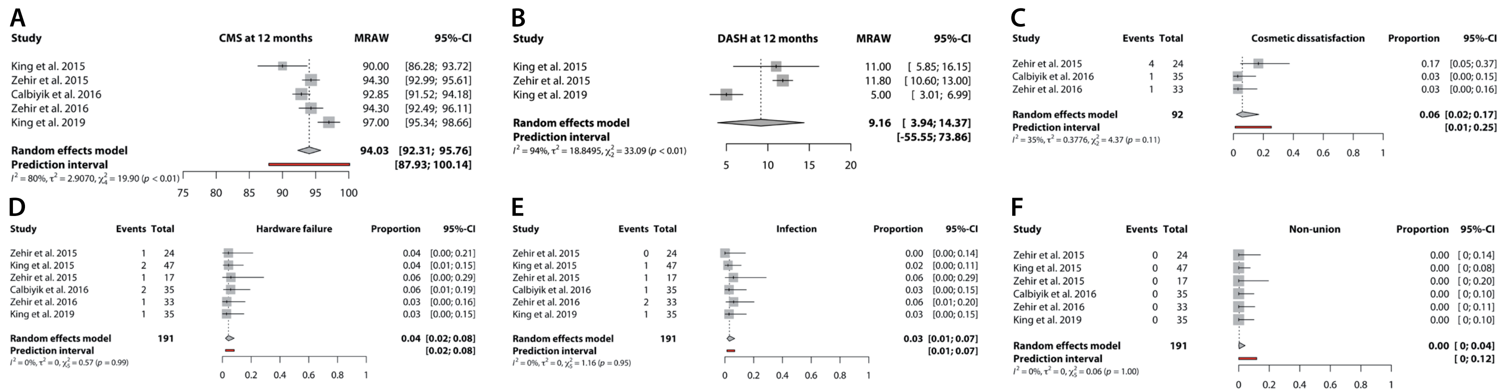

Figure 9.5. Forest plots of the included studies using the **Sonoma CRx** reporting on **(A)** Constant-Murley score at 12 months, **(B)** Disabilities of Arm, Shoulder and Hand Score at 12 months, **(C)** cosmetic dissatisfaction, **(D)** hardware failure, **(E)** infection, and **(F)** nonunion. Forest plots display the mean functional outcome **(A and B)** or proportion of complications **(C-F)**, 95% confidence interval and the relative weight of the individual studies. The diamond indicates the pooled estimate and its 95% confidence interval. The red bar indicates the 95% prediction interval. Prediction intervals illustrate which range of true effects expected to occur in similar studies in future settings.

Studies concerning a threaded elastic nail

Meta-analysis was only possible for infection[80-82] and the pooled incidence was 5% (95% CI 1-34 in 106 clavicles).

The confidence in the estimates from this meta-analysis according to GRADE was very low (Table 9.4 and Appendix 9.2). Other complications described for this type of fixation were soft tissue problems, delayed union and malunion (Table 9.2).

Studies concerning the Knowles Pin

One study reported 4 hardware irritations in 56 patients[84] and another study reported a nonunion rate of 5.6%.[86] No meta-analysis was possible for this device type.

Study concerning a second generation TEN

One level IV study described the results of a second generation TEN in 36 patients.[87] It reported a Constant-Murley score of 93.4 (SD2.7) and 3 complications; 2 protrusions and 1 hardware irritation.

Sensitivity analysis

The sensitivity analysis including only studies with a low risk of bias showed our results to be robust. The complete results of the sensitivity analysis can be found in Appendix 9.3.

Publication bias

In those cases that publication bias could be assessed, its presence was unlikely based on the inspection of the funnel plots and evaluation of Egger's or Peters' tests. Only for the Constant Murley and DASH scores the tests for funnel plot asymmetry were significant, but publication bias seems unlikely here due to ceiling effects in both scores.

DISCUSSION

In this study the functional outcomes and complications after surgical treatment of DMCF with an intramedullary device were systematically reviewed. Good functional results and union rates irrespective of the type of device are found in the reviewed literature. However, there are clear device-related and device-specific complications for each. The pooled Constant-Murley scores of the TEN and Sonoma CRx were 94.4 (95% CI 93-95) and 94.0 (95% CI 92-96), respectively. Since the Constant-Murley score ranges from 0-100 points and higher scores are better, the pooled scores can be considered good. Though the minimally clinical important difference (MCID) for both the Constant-Murley score is unknown for midshaft clavicular fractures in particular it is described that the MCID in Constant Murley scores for shoulder pathology is 10.4

points.[88] Therefore, with an SD reported well within that range our conclusion seems valid as is the confidence in the estimate according to GRADE. The pooled DASH score for the TEN was 4.6 (95% CI 2.6-6.7). The functional outcomes for the Rockwood/Hagie pin could not be analyzed because all identified papers reported different functional outcome measures. This study supports the need for uniform reporting of functional outcomes and in the case of clavicle fracture treatment the Constant-Murley and the DASH are the ones most commonly used.

The most commonly reported complications after intramedullary fixation of DMCFs are implant-related and implant-specific complications. For the TEN, hardware irritation, protrusion, telescoping and migration, are major contributors to the total complication rate. The explanation for this finding may be that the TEN re-aligns but does not fixate in both fracture elements of the DMCF. These TEN-specific complications lead to infection, soft-tissue problems, pain, early re-interventions (removal or additional cutting of the nail) and loss of reduction with subsequent secondary shortening. When using the Rockwood/Hagie Pin, pooled incidence of hardware irritation was 22% (95% CI 13-35). This may be explained by the two bulky nuts at the posterolateral aspect of the clavicle where the pin is inserted and is has been reported to be an important disadvantage of the implant.[23, 27, 30] For the Sonoma CRx no reports on hardware irritation were found since this device has no extra-cortical prominences and is fully embedded in the clavicular cortex.

With regards to the TEN, there is a pooled malunion incidence of 7% (95% CI 4-11). Reports on persistent average shortening after union range between 3.5 and 6.3 mm.[35, 45, 62] Others report on shortening after union of more >1 cm in 2.3%-50% of cases.[49, 65, 68] Since shortening of the DMCF can lead to post-traumatic symptoms, altered scapular kinematics and the occurrence of gleno-humeral joint arthritis, shortening is an important issue to prevent and could be interpreted as a disadvantage of this intramedullary fixation device.

There are no studies specifically reporting on the presence or absence of post-operative shortening after fracture fixation with the Sonoma CRx. Concerning the Rockwood pin only Mudd et al.[29] reports a secondary shortening of 4-7 mm in 22% of patients which all occurred after early pin removal due to complications.

The pooled incidence for infection was 9% (95% CI 5-16) when using the Rockwood/Hagie pin, 3% (95% CI 1-7) when using the Sonoma CRx and 2% (95% CI 0-3) with use of the TEN. The two posterolateral nuts that can cause wound-breakdown and subsequent infection may explain the high infection rate of the Rockwood/Hagie pin.

Hardware failure was 6% (95% CI 3-10) for the Rockwood/Hagie Pin compared to 3% (95% CI 2-5) for TEN and 4% (95% CI 2-8).

Meta-analysis shows nonunion incidences to be similar between the Rockwood/Hagie pin (3%; 95% CI 1-8) and to 3% (95% CI 2-4) with the use of the TEN. The pooled incidence of nonunion for the Sonoma CRx was 0% (95% CI 0-4). Although no non-unions were reported in the Sonoma CRx group the confidence this outcome according to GRADE was low due to the limited number of clavicles included and the select group of authors introducing the risk of bias.

This systematic review furthermore identified the common denominator amongst many authors that routine removal of hardware is not considered a complication. However, a case could be made that every secondary intervention including hardware removal is an additional procedure which subjects the patient to associated morbidity and costs and therefore is not desirable.

As for all systematic reviews this study is limited by the quality of evidence available. In most meta-analyses of reported complications the evidence was graded as low to very low. Furthermore, only studies written in English, German or Dutch were included in this systematic review which could be a potential limitation of this study. Complications and early re-interventions are reported in some studies,[29, 41-43, 59, 62, 65] but underreporting is very likely to occur. Most studies do not clearly report causes for implant failure, measures taken with occurrence of infection or information concerning implant migration or secondary shortening. Only few specifically report on the presence or absence of certain relevant complications such as secondary shortening, neuropathy of the supraclavicular nerve, delayed union and persistent pain. This information could be interesting to fully report in future studies and is a limitation of this review. Another limitation is that not all functional outcomes and complications were reported in a similar manner leading to heterogeneity of the various studies. To account for the expected heterogeneity, a random effects model was used. In the case of functional outcome scores for TEN and Sonoma the confidence in the estimates was high and moderate, respectively. Lastly, the follow up differed between studies ranging from 3 months to 7 years. This may have resulted in differences in reporting of complications and functional outcomes. Although most complications would likely occur within the first 3 months this could lead to underreporting this could further negatively influence the confidence in the estimates reported.

In the last years multiple meta-analysis comparing the gold standard of plate fixation and intramedullary devices (irrespective of device or plate type) for the management of midshaft clavicle fractures have been published.[89-96] These studies report similar[89-91, 93-95] or superior[92, 96] functional outcomes and union rates in the intramedullary fixation group. Furthermore, most report a higher rate of complications (such as infection, refracture rate) and increased surgical time when using plate fixation, making an evaluation of the devices described in the present study even more relevant.[89, 90, 93-96]

The results of this systematic review show there is still room for improvement in treating DMCF in an intramedullary fashion. For newer designs it may be interesting to take the implant-related and implant-specific complications described in this systematic review into account in order to optimize future treatment strategies.

CONCLUSION

Although most studies were of low quality, in general, good functional results and union rates irrespective of the type of device are found in the reviewed literature. However, there are clear device-related and device-specific complications for each. The results of this systematic review and meta-analysis can help guide surgeons in choosing the appropriate operative strategy, implant and informing their patients.

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APPENDIX 9.1

1/31/2020 Search PubMed

(((((((clavic*) OR midclavic*) OR "Clavicle"[Mesh])) AND ((fracture) OR "Fractures, Bone"[Mesh])) AND ((intramedullary) OR "Fracture Fixation, Intramedullary"[Mesh])) AND (((((nail) OR pin) OR rod) OR screw) OR "Bone Nails"[Mesh])) AND (((((((((complication) OR ("Intraoperative Complications"[Mesh] OR "Postoperative Complications"[Mesh]))) OR ((union) OR (("Fractures, Malunited"[Mesh]) OR "Fractures, Ununited"[Mesh]))) OR ((survival) OR "Survival Rate"[Mesh])) OR ((failure) OR "Prosthesis Failure"[Mesh])) OR ((safety) OR "Safety"[Mesh])) OR ((function) OR "Recovery of Function"[Mesh])) OR ((outcome) OR ("Patient Outcome Assessment"[Mesh] OR "Outcome Assessment, Health Care"[Mesh])))

1/31/2020 Search Science Direct Research Articles

In title: (clavicle OR clavicular OR midclavicle OR midclaviclular OR clavicula) AND (fracture) AND intramedullary.

In Abstract, keywords: ((pin or rod) OR (nail or screw)) OR survival OR safety OR outcome OR function OR performance OR union

1/31/2020 Search Embase

((((((clavic*) OR midclavic*)) AND fracture*) AND intramedullary) AND ((((nail) OR pin) OR rod OR screw))) AND ((((((((complication) OR union) OR survival) OR performance) OR failure) OR safety) OR function) OR outcome)

1/31/2020 Search Cochrane

(((((((clavic*) OR midclavic*) OR "Clavicle"[Mesh])) AND ((fracture) OR "Fractures, Bone"[Mesh])) AND ((intramedullary) OR "Fracture Fixation, Intramedullary"[Mesh])) AND (((((nail) OR pin) OR rod) OR screw) OR "Bone Nails"[Mesh])) AND (((((((((complication) OR ("Intraoperative Complications"[Mesh] OR "Postoperative Complications"[Mesh]))) OR ((union) OR (("Fractures, Malunited"[Mesh]) OR "Fractures, Ununited"[Mesh]))) OR ((survival) OR "Survival Rate"[Mesh])) OR ((failure) OR "Prosthesis Failure"[Mesh])) OR ((safety) OR "Safety"[Mesh])) OR ((function) OR "Recovery of Function"[Mesh])) OR ((outcome) OR ("Patient Outcome Assessment"[Mesh] OR "Outcome Assessment, Health Care"[Mesh])))

Research in progress: searched in 1/31/2020

ClinicalTrials.gov (http://clinicaltrials.gov/ct2/home)

Controlled-trials.com (http://www.controlled-trials.com/)

International Clinical Trials Registration Platform (http://apps.who.int/trialsearch/Default.aspx)

Appendix 9.2. Confidence in estimates from meta-analyses according to GRADE

Device	Outcome	No. of studies	No. of clavicles	Effect estimate (95% CI))	GRADE domains								Quality of evidence (GRADE)
					Risk of bias	Inconsist-ency	Impre-cision	Indirect-ness	Publica-tion bias	Large magnitude of effect	Dose repsonse gradient	Residual con-founding	
Rockwood Pin & Hagie Pin													
	Hardware irritation	7	253	0.22 (0.13 – 0.35)	x	x	x	NA	o	o	o	o	⊕⊕⊙⊙ LOW
	Infection	7	287	0.09 (0.05 – 0.16)	x	x	x	NA	o	o	o	o	⊕⊕⊙⊙ LOW
	Soft tissue problems	7	207	0.09 (0.06 – 0.13)	x	x	x	NA	o	o	o	o	⊕⊕⊙⊙ LOW
	Pain	4	172	0.06 (0.02 – 0.20)	x	x	x	NA	o	o	o	o	⊕⊙⊙⊙ VERY LOW
	Hardware failure	7	216	0.06 (0.03 – 0.10)	x	x	x	NA	o	o	o	o	⊕⊕⊙⊙ LOW
	Nonunion	6	191	0.00 (0.00 – 0.04)	x	x	o	NA	o	o	o	o	⊕⊕⊙⊙ LOW
	Scar numbness	4	173	0.05 (0.02 – 0.09)	x	x	x	NA	o	o	o	o	⊕⊙⊙⊙ VERY LOW
	Delayed union	4	166	0.02 (0.01 – 0.06)	x	x	x	NA	o	o	o	o	⊕⊙⊙⊙ VERY LOW
TEN													
	CMS	29	1270	94.40 (93.43 – 95.37)	x	o	o	NA	o	x	o	o	⊕⊕⊕⊕ HIGH
	DASH	15	647	4.65 (2.61 – 6.68)	x	o	o	NA	o	x	o	o	⊕⊕⊕⊕ HIGH
	Hardware irritation	30	1273	0.20 (0.14 – 0.26)	x	o	x	NA	o	x	o	o	⊕⊕⊕⊙ MODERATE
	Protrusion	25	1105	0.12 (0.08 – 0.18)	x	o	x	NA	o	x	o	o	⊕⊕⊕⊙ MODERATE
	Malunion	3	193	0.07 (0.04 – 0.11)	x	x	x	NA	o	o	o	o	⊕⊕⊙⊙ LOW
	Soft tissue problems	8	406	0.04 (0.03 – 0.08)	x	x	x	NA	o	o	o	o	⊕⊙⊙⊙ VERY LOW
	Pain	3	136	0.04 (0.02 – 0.09)	x	x	x	NA	o	o	o	o	⊕⊙⊙⊙ VERY LOW
	Nonunion	36	1436	0.03 (0.02 – 0.04)	x	o	x	NA	o	x	o	o	⊕⊕⊕⊙ MODERATE
	Hardware failure	19	800	0.03 (0.02 – 0.05)	x	x	x	NA	o	o	o	o	⊕⊕⊙⊙ LOW
	Delayed union	6	265	0.03 (0.02 – 0.06)	x	o	x	NA	o	o	o	o	⊕⊙⊙⊙ VERY LOW
	Infection	29	1084	0.02 (0.01 – 0.03)	x	o	x	NA	o	x	o	o	⊕⊕⊕⊙ MODERATE

Appendix 9.2. *Continued*

Device	Outcome	No. of studies	No. of clavicles	Effect estimate (95% CI))	GRADE domains								Quality of evidence (GRADE)
					Risk of bias	Inconsist-ency	Impre-cision	Indirect-ness	Publica-tion bias	Large magnitude of effect	Dose repsonse gradient	Residual con-founding	
Sonoma CRx													
	CMS	5	167	94.03 (92.31 – 95.76)	o	x	o	NA	x	o	o	o	⊕⊕⊕⊙ MODERATE
	DASH	3	99	9.16 (3.94 – 14.37)	o	x	o	NA	x	o	o	o	⊕⊕⊕⊙ MODERATE
	Cosmetic dissatisfaction	3	92	0.06 (0.02 – 0.17)	x	x	x	NA	x	o	o	o	⊕⊙⊙⊙ VERY LOW
	Hardware failure	6	191	0.04 (0.02 – 0.08)	o	o	x	NA	x	o	o	o	⊕⊕⊙⊙ LOW
	Infection	6	191	0.03 (0.01 – 0.07)	x	o	x	NA	x	o	o	o	⊕⊕⊙⊙ LOW
	Nonunion	6	191	0.00 (0.00 – 0.04)	x	x	o	NA	x	o	o	o	⊕⊕⊙⊙ LOW
Threaded Pin													
	Infection	3	106	0.01 (0.00 – 0.64)	x	x	x	NA	o	o	o	o	⊕⊙⊙⊙ VERY LOW

x = Present; o = Not present; NA = Not applicable.

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

APPENDIX 9.3

Sensitivity analysis Low Risk Studies using Random Effects Model
There were no low risk studies available for sensitivity analysis of: malunion TEN, pain TEN, delayed union TEN, infection Rockwood pin and hardware irritation Rockwood pin.

Only 1 low risk study was available for evaluating scar numbness Rockwood pin.

Similar pooled outcomes were calculated for all other meta-analysis.

Device type	Complication	Number of low risk studies	Pooled incidence
Sonoma CRx			
	Cosmetic dissatisfaction	2	8% (95% CI 2 – 24)
	Hardware failure	3	4% (95% CI 2 – 11)
	Infection	3	2% (95% CI 1 – 8)
	Nonunion	3	0% (95% CI 0 – 11)
Rockwood/Hagie Pin			
	Non-union	2	2% (95% CI 0 – 14)
	Hardware failure	2	4% (95% CI 1 – 16)
TEN			
	Hardware irritation	12	23% (95% CI 15 – 33)
	Protrusion/Telescoping/Migration	9	10% (95% CI 5 – 17)
	Soft tissue problems	3	3% (95% CI 1 – 7)
	Hardware failure	8	5% (95% CI 3 – 8)
	Infection	10	3% (95% CI 1 – 5)
	Non-union	13	2% (95% CI 1 – 3)
	Delayed union	4	3% (95% CI 2 – 7)
Device type	**Functional outcome score**	**Number of low risk studies**	**Pooled incidence**
Sonoma CRx			
	CMS	2	94.9 (95% CI 91 – 99)
TEN			
	CMS	12	96.7 (95% CI 96 – 97)
	DASH	5	3.6 (95% CI 1 – 6)

10

Forces acting on the clavicle during shoulder abduction, forward humeral flexion and activities of daily living

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Both authors have contributed equally to the development of this manuscript

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ABSTRACT

Background: The forces across the human clavicle in vivo are difficult if not impossible to measure. The goal of this study is to quantify the forces acting on the human clavicle during shoulder abduction, forward humeral elevation and three activities of daily living using the Delft Shoulder and Elbow Model.

Methods: The Delft Shoulder and Elbow Model and a computed tomography scan of a clavicle were used to calculate the forces and moments acting on the entire clavicle and on three planes within the middle third of the clavicle during the simulated movements.

Findings: The largest resultant force simulated across the clavicle was 126 N during abduction. Maximum resultant moments of 2.4 Nm were identified during both abduction and forward humeral elevation. The highest forces were of a compressive nature along the longitudinal axis of the clavicle, increasing to 97 N during forward humeral elevation and 91 N during abduction. Forces in opposite direction along the y-axis were identified on either side of the conoid ligament. The three simulated activities of daily living had similar ranges of forces and moments irrespective of the sagittal plane in which these activities were performed.

Interpretation: Peak forces occurred at different locations on the middle third of the clavicle during different movements. The results create an understanding of the forces and their distribution across the clavicle during activities of daily living. These data may be helpful in the development of clavicular fixation devices.

Level of evidence: Biomechanical study.

Keywords: clavicle; forces; biomechanics; simulation; Delft Shoulder and Elbow Model

INTRODUCTION

Clavicle fractures are common, comprising 5-10% of all fractures in adults.[1] Though classically managed non-operatively, clavicle fractures are now increasingly treated surgically.[2] This is probably because of better short-term functional results, cosmetic satisfaction, earlier return to sports and cost effectiveness compared to non-operative treatments.[3-7] The rise in surgical interventions has resulted in a plethora of different plate types, configurations and intramedullary devices to surgically reduce and fixate these fractures. These devices have been evaluated biomechanically. Load to failure testing of different fixation techniques[8-14] are reported to range from 100 to 409 N.[9, 11, 12, 14] Biomechanical studies typically conclude that "more and larger metal is stronger" though more metal may not necessarily be the best clinical option.[15, 16]

Optimal design of clavicle fixation devices requires knowledge of the forces that act on the clavicle during shoulder movements and activities of daily living. However, it remains unclear which loading thresholds fixation constructs have to withstand,[16] because these forces are difficult if not impossible to measure directly in vivo.

Cadaver testing has provided some insights into the forces acting on the clavicle. One study measured forces directly on a cadaveric clavicle during shoulder movements using a six degree-of-freedom load cell.[17] Limitations of this study were that the static forces used to stabilize the shoulder before starting a dynamic motion were variably selected and some major muscle groups were not included. Furthermore, only the forces during abduction and internal and external rotation were measured, omitting those during forward humeral elevation or more complex motions used during daily living activities.

Another way to quantify forces acting on the clavicle is by using a biomechanical computer model. Because the clavicle is part of the closed kinematic chain that also comprises the scapula and thorax, a comprehensive description of the shoulder girdle is required to get a realistic estimate of the forces acting on the clavicle. The Delft Shoulder and Elbow Model (DSEM) is a comprehensive musculoskeletal model of the human shoulder and elbow that includes all large bones and muscles of the upper limb.[18-21] The DSEM has been verified qualitatively by comparing predicted muscle forces to measured EMG signals and validated quantitatively by comparing predicted gleno-humeral (GH) joint contact forces to direct measurements made with an instrumented shoulder prosthesis.[22, 23] The DSEM is amongst the most detailed and well-validated models of the human upper limb to date.

The goal of this study is to quantify the forces acting on the human clavicle in abduction, forward humeral elevation and three activities of daily living (washing axilla, eating and combing hair). The DSEM was used to simulate the mechanical behavior and loading of all major muscles and bones of the shoulder and to generate data that may be helpful in the development of future clavicular fixation devices.

METHODS

Since anonymized and publicly available data were used, this study was exempt from approval by an institutional review board. We used the DSEM (version 4-2) and a computed tomography (CT) scan of the same clavicle as used to develop the DSEM[24] to calculate the forces acting on the clavicle during shoulder abduction and forward humeral elevation, as well as three motions used in daily living activities in which the humerus moves in different planes (washing axilla, eating and combing hair).

Quantification of clavicular loading with the Delft Shoulder and Elbow Model

The DSEM[19, 20] was used in the inverse dynamic mode to estimate the forces acting on all shoulder muscles, joints and ligaments. Three-dimensional kinematic data of the forearm, humerus, scapula, clavicula and thorax were obtained from the publicly available Shoulder Movements Database.[18] The kinematic data were used as input to calculate joint torques around the shoulder and elbow joints for each step of the movement. Static optimization with a minimal energy expenditure criterion was used to estimate a set of muscle forces that resulted in the joint torques.[25]

All forces acting on the clavicle were extracted from the model predictions. In total, the DSEM predicts 14 force vectors (point loads) on the clavicle (Figure 10.1), which include the sternoclavicular (SC) and acromioclavicular (AC) joint contact forces; the gravitational and inertial forces of the clavicle; the forces on the conoid, trapezoid and costo-clavicular ligaments; and the forces of the pectoralis major, deltoid (clavicular/anterior part) and trapezius (clavicular part) muscles.

To accurately simulate the mechanical behavior of muscles with broad attachments, the DSEM represents the clavicular parts of the pectoralis major, trapezius and deltoid with two, two and four force vectors, respectively.[26] The magnitude, direction and point of application was calculated for each of the 14 forces, and for each step of the movement. All forces were represented in a local clavicle-based coordinate system and was defined according to the convention of the International Society of Biomechanics.[27] The x-axis is parallel to the line connecting the sternoclavicular (SC) and acromioclavicular (AC) joint centers, the z-axis is perpendicular to the x-axis and the inferior-superior axis of the thorax (because only two bony landmarks can be discerned on the clavicle), and the y-axis is perpendicular to the x- and z-axis.

Estimation of loads on the clavicular surface

We calculated the maximum forces and moments on the clavicle, and the locations within the middle third of the clavicle where these maxima occurred. To estimate the (static) forces and moments acting on the clavicle, a three-dimensional (3D) clavicle surface model was created from a CT scan of the same clavicle used in the DSEM (male,

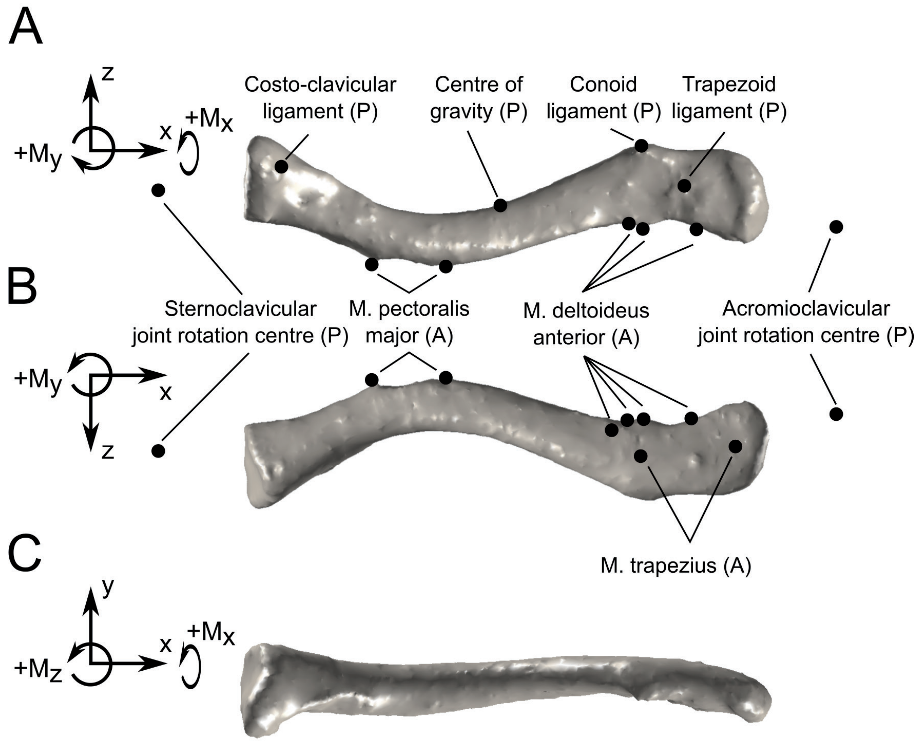

Figure 10.1. Three-dimensional model made from a CT scan showing the 14 points of application of the forces acting on the clavicle as simulated with the DSEM. **(A)** inferior view, **(B)** superior view, **(C)** anterior view. P, passive forces; A, Active forces.

57 years, right-side).[28] After outlining the clavicle on the CT scan using a combination of intensity thresholding and manual correction, a 3D triangulated surface mesh of the clavicular surface was created using image processing software 3D Slicer.[29] The CT-based clavicle model was presented in a different coordinate system than the clavicle in the DSEM, so these coordinate systems were aligned. Prior to CT scanning and cadaver measurements (in which muscle and ligament attachment sites were defined[28]), four screws were drilled into the clavicle. The locations of the screw heads, which were clearly visible on the CT scan, were digitized during the cadaver measurements and were now also (virtually) digitized on the CT scan. The optimal rigid-body rotation was found between the screw head locations from CT and cadaver measurements. After alignment, the residual error between the four screw head locations ranged from 0.3 to 0.8 mm, indicating excellent alignment.

Static forces and moments at all points on the clavicular surface (i.e. all nodes of the surface mesh) using static equilibrium theory ("freebody diagram method") were calculated. For a given point on the clavicle (point P), the clavicle was (virtually) cut in the yz plane (plane perpendicular to the clavicle's long axis) at the x-value of P. To calculate the forces at P, all forces on one side of the cut-plane were summed. To calculate the moments at P, all forces on one side of the cut-plane were multiplied by their moment arm vector around P (the position vectors connecting point P and the point of application of the force) and then summed. Forces in the x-direction were interpreted as compression of the clavicle in the direction of its long axis. Forces in the y- and z-direction were interpreted as shear forces in the plane perpendicular to the clavicle's long axis. Moments around the x-axis were interpreted as torsion while moments around the y- and z-axis were interpreted as bending moments. Furthermore, resultant forces and moments were calculated for all simulated movements.

A focused analysis on the forces and moments in three planes within in the middle third of the clavicle was performed (Figure 10.2), since these are the locations where about 80% of clavicle fractures occur and where the clavicle fixation devices are placed.[1] The three planes were located perpendicular to the clavicle's long axis (yz-plane) on the sternal (medial) and acromial (lateral) side of the middle third of the clavicle, and in the middle of the clavicle (Figure 10.2).

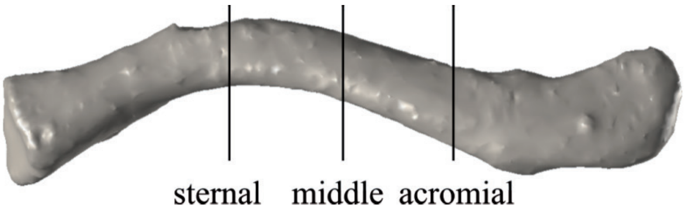

Figure 10.2. Superior view of the clavicle, showing the three planes of interest on the sternal side, the middle and the acromial side of the middle third of the clavicle.

RESULTS

The estimated forces and moments on the clavicular surface were graphically represented at 30 degrees intervals of shoulder abduction (Figure 10.3) and forward humeral elevation (Figure 10.4). The highest forces identified across the clavicle during abduction were of a compressive nature along the x-axis, increasing to 118 N. These compressive forces on the clavicle were predominantly generated by the sternoclavicular and acromioclavicular joint reaction forces forces (Supplementary Figure S10.1). Within the middle third of the clavicle the maximum forces along the x-axis were simulated at 91 N. The maximum resultant force on the entire clavicle was estimated at 126 N during abduction (Table 10.1). The largest moment on the entire clavicle was 2.0 Nm around the y-axis during abduction. The maximum resultant moment was calculated at 2.4 Nm also during abduction.

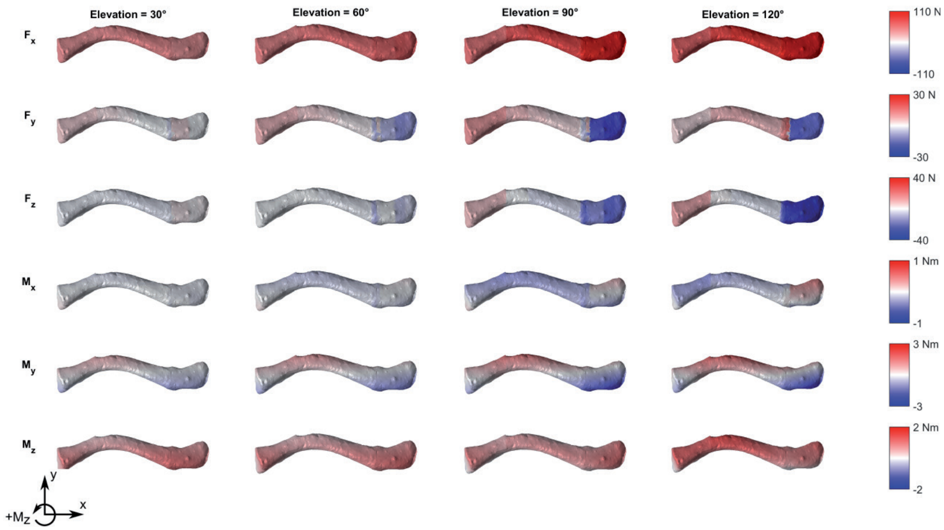

Figure 10.3. Superior view of the clavicle and the estimated forces and moments at 30 degrees intervals of shoulder abduction (increasing elevation from left to right). Forces (top three rows) and moments (bottom three rows) acting on the clavicle in all three orthogonal directions are represented as colours projected on the muscle surface. Note that forces and moments in different directions have different colour scales (see colour bars on the right).

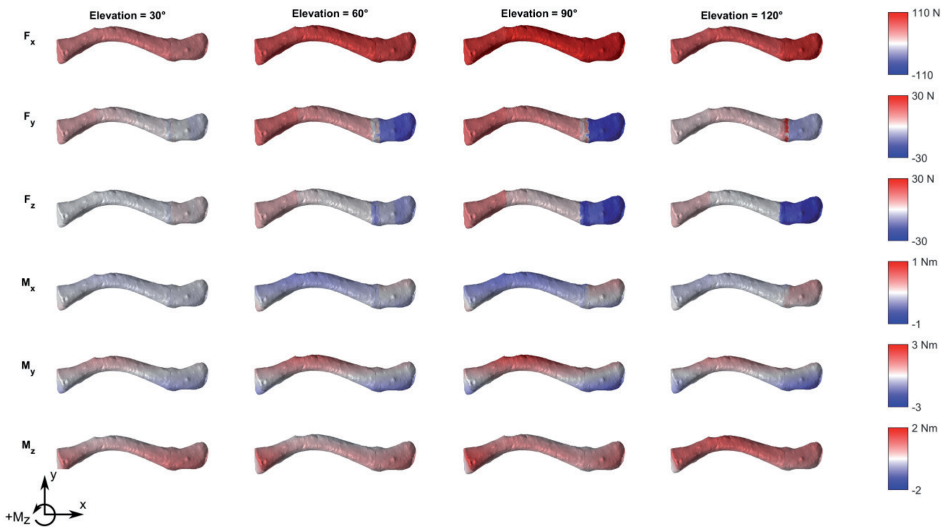

Figure 10.4. Superior view of the clavicle and the estimated forces and moments at 30 degrees intervals of shoulder forward humeral elevation (increasing elevation from left to right). Forces (top three rows) and moments (bottom three rows) acting on the clavicle in all three orthogonal directions are represented as colours projected on the muscle surface. Note that forces and moments in different directions have different colour scales (see colour bars on the right).

Table 10.1. Minimum and maximum forces and moments within the middle third of the clavicle at the three (sternal, middle, acromial) planes for all five simulated movements

Axis	Minimum force (N)	Maximum force (N)	Minimum moment (Nm)	Maximum moment (Nm)
Abduction				
X	37.5 (34.2)	90.9 (118.2)	-0.3 (-0.5)	0 (0.4)
Y	-0.8 (-21.8)	8.0 (19.0)	-0.9 (-1.4)	1.9 (2.0)
Z	-5.3 (-40.3)	13.3 (13.3)	-0.4 (-0.9)	1.2 (1.3)
Resultant		91.3 (**126.1**)		2.1 (2.4)
Forward humeral elevation				
X	29.4 (29.4)	96.5 (105.2)	-0.4 (-0.5)	0.1 (0.4)
Y	-0.9 (-25.9)	13.8 (22.8)	-0.5 (-1.0)	2.2 (**3.2**)
Z	-2.8 (-34.5)	4.3 (13.4)	-0.7 (-0.8)	1.2 (1.4)
Resultant		97.3 (111.3)		2.2 (2.4)
Wash Axilla				
X	27.3 (27.2)	64.2 (64.2)	-0.4 (-0.5)	0.0 (0.3)
Y	-4.6 (-25.9)	9.7 (20.3)	-1.3 (-0.9)	1.5 (1.9)
Z	-5.7 (-8.7)	0.4 (8.7)	-1.2 (-2.2)	1.4 (1.1)
Resultant		64.5 (64.5)		1.6 (1.8)
Eat				
X	26.2 (26.0)	57.1 (60.3)	-0.3 (-0.4)	0.0 (0.2)
Y	-2.6 (-25.2)	13.8 (15.2)	-0.4 (-1.1)	1.2 (1.3)
Z	-2.5 (-16.2)	5.1(15.7)	-0.9 (-1.0)	0.9 (1.2)
Resultant		55.4 (65.8)		1.4 (1.5)
Comb hair				
X	27.6 (27.4)	65.1 (80.0)	-0.3 (-0.4)	0.0 (0.3)
Y	-0.1 (-26.1)	10.6 (11.7)	-0.3 (-1.4)	1.5 (1.5)
Z	-0.9 (-25.9)	8.5 (10.4)	-0.6 (-0.8)	1.0 (1.2)
Resultant		51.2 (84.7)		1.6 (1.6)

The numbers in parentheses represent the maximum forces simulated across the entire clavicle. **Bold** numbers represent the maximum simulated forces and moments.

Shear forces were calculated along the y-axis at the lateral end of the clavicle, at the origin of the conoid ligament. Medial of the conoid ligament the forces along the y-axis were oriented in a positive direction, while lateral of the conoid ligament the forces were directed in a negative direction. These shear forces were simulated at 30, 60, 90 and 120 degrees of shoulder abduction which were 2.7 N, 18.5 N, 34.3 N, 32.0 N. The maximum shear force was calculated at 37 N at 100 degrees during abduction.

Similar to the abduction movement, the maximum resultant forces and moments acting across the entire clavicle during forward humeral flexion were calculated to increase to 111 N and 2.4 Nm at 90 degrees. During this movement, the largest forces were simulated along the x-axis at 105 N. Within the middle third of the clavicle the maximum forces along the x-axis were simulated at 91 N. Force vectors along the y-axis in opposing directions (shear forces) were identified at the lateral side of the clavicle on either side of the conoid ligament These maximum shear forces were calculated at 34 N along the y-axis at 116 degrees of forward humeral flexion. At 30, 60, 90 and 120 degrees of forward humeral flexion these forces were 0 N, 9.1 N, 24.9 N, 31.0 N.

When evaluating the forces and moments across the middle third of the clavicle, the maximum resultant force was calculated to be 97 N and 2.2 Nm around the y-axis, respectively during abduction (Table 10.1). All forces and moments at the middle third of the clavicle when the arm was elevated above 90 degrees remained equal or decreased except for the moments around the z-axis during both abduction and forward humeral elevation. The minimum and maximum forces and moments across the entire clavicle and within the middle third of the clavicle for all five simulated movements are shown in Table 10.1.

Figure 10.5 shows that the magnitude of forces and moments at the sternal, middle and acromial planes within the middle third of the clavicle were similar during abduction and forward humeral elevation, though distributed differently. The maximum forces were calculated along the x-axis at the middle and acromial planes while the minimum forces were calculated at the sternal plane.

When evaluating the three activities of daily living (washing axilla, eating, combing hair) a similar range of forces and moments was identified irrespective of the sagittal plane in which these activities were performed. The simulated moments around the x-axis are similar during all three movements. The maximum positive moments around the y-axis occur at the sternal plane while the maximal negative moments around the y-axis occur at the acromial plane. The maximal positive moments around the z-axis occur at the acromial side while the maximal negative moments around the z-axis occur at the sternal plane (Figure 10.6).

DISCUSSION

The goal of this study was to simulate the forces across the human clavicle using the DSEM in abduction, forward humeral elevation and three activities of daily living in order to better understand their magnitude and behavior.

We identified maximum compressive forces along the x-axis of 97 N during abduction and 91 N during forward humeral elevation. No tensile forces along the x-axis were calculated during these motions signifying a continuous compressive force. The maximum resultant forces were larger outside of the middle third of the clavicle (126 N and 97 N, respectively). All of the maximum moments occurred outside the middle third. The minimum forces around the y-axis showed the largest discrepancy between forces measured in the middle third and the rest of the clavicle. These minimum forces most likely occur at the lateral end of the clavicle distal to the conoid ligament.

Comparing our outcomes to the results reported by Ianollo et al.[17] could only be done for the abduction movement. Their group also identified that compressive forces were dominant with a maximum value of 34.4 N (SD 22.3) during at 79.8 degrees (SD 18.6)

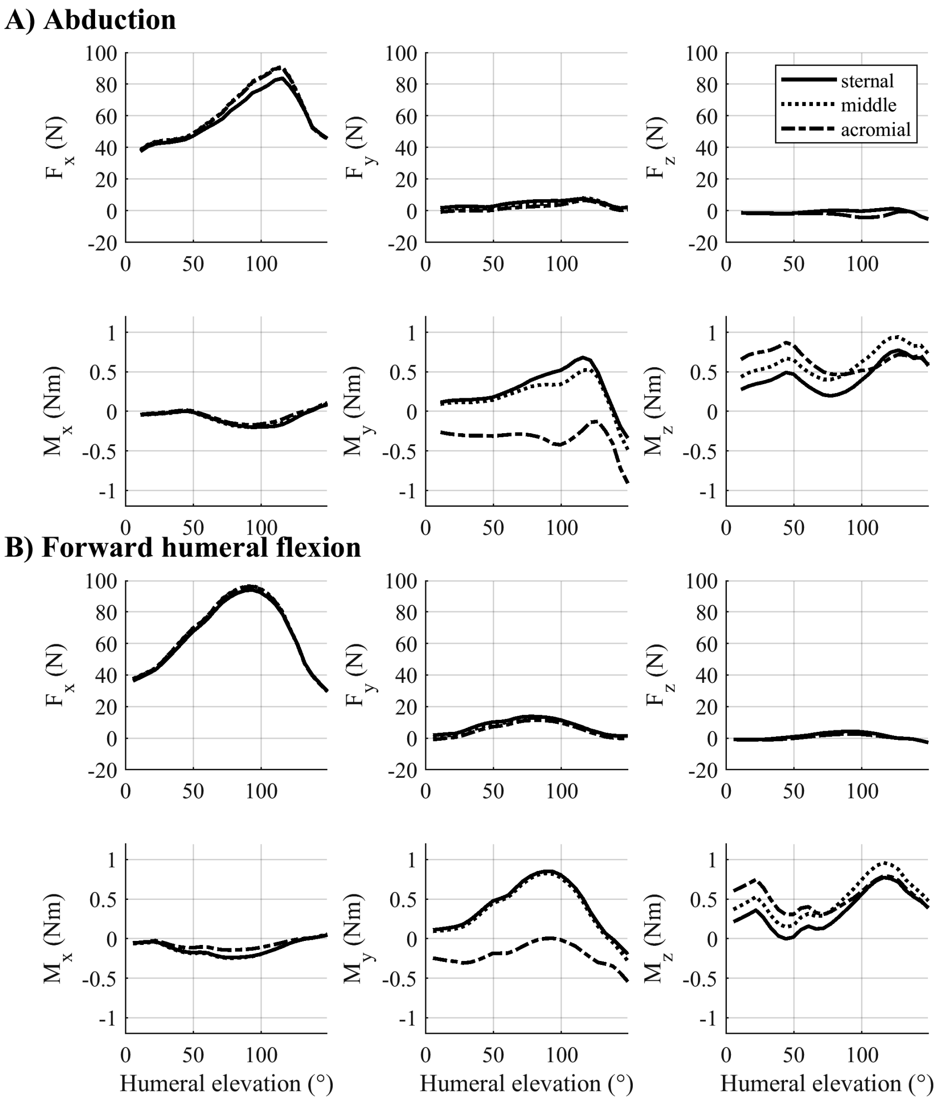

Figure 10.5. Forces (top row) and moments (bottom row) acting on the clavicle at the planes of interest as a function of humeral elevation for **(A)** abduction and **(B)** forward humeral flexion. Traces are shown for forces and moments acting on the sternal (solid line), middle (dotted line) and acromial (dash-dotted line) side of the middle third of the clavicle.

of abduction. Furthermore, a maximum tensile load of -5.2 N (SD 8.0) was found. Our findings for 90 degrees of humeral abduction yielded a maximum compressive force almost 3 times higher and showed no tensile loading along the x-axis. Part of this difference may be explained by the different methods used to estimate the forces

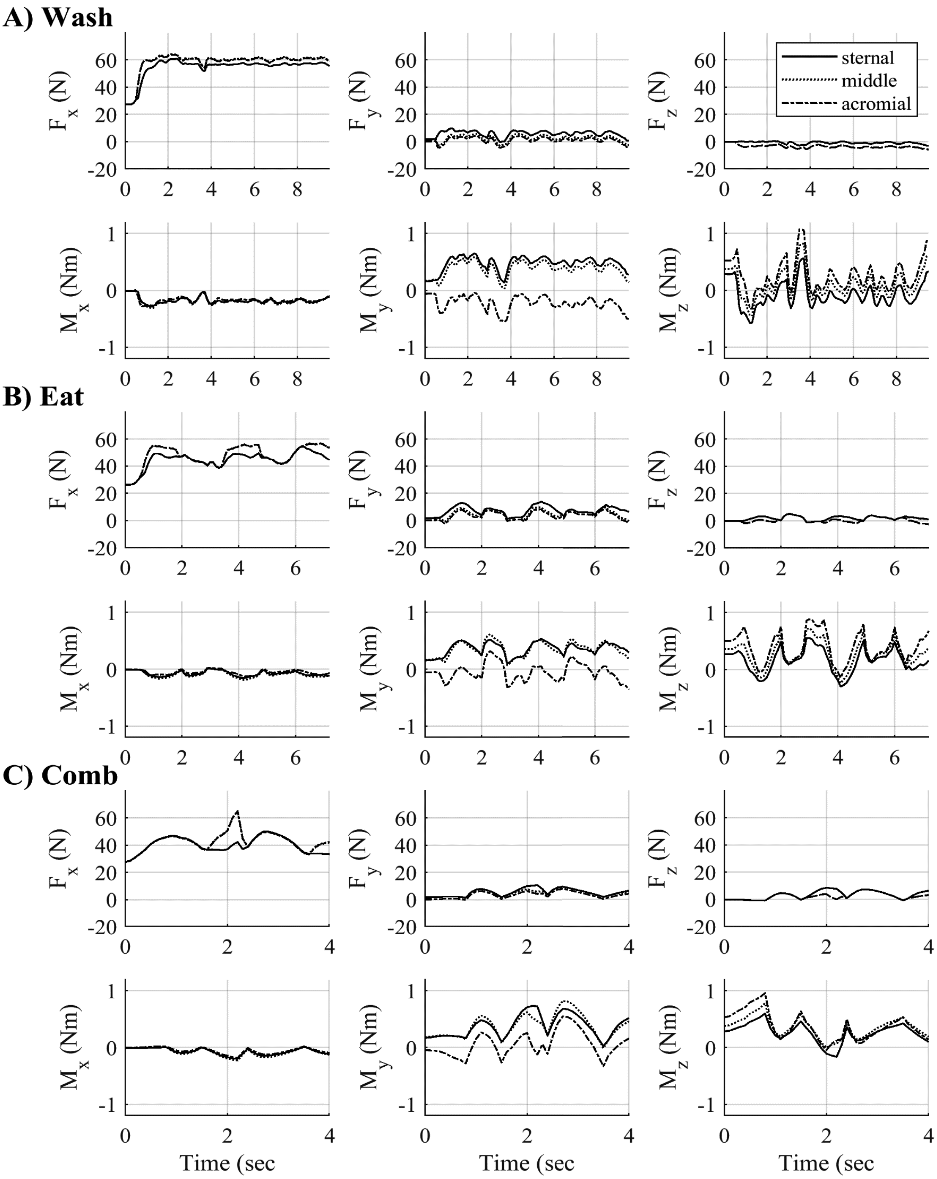

Figure 10.6. Forces (top row) and moments (bottom row) acting on the clavicle at the planes of interest as a function of time during **(A)** Washing axilla **(B)** Eating and **(C)** Combing hair. Traces are shown for forces and moments acting on the sternal (solid line), middle (dotted line) and acromial (dash-dotted line) side of the middle third of the clavicle.

(experimental vs simulation). Additionally, Iannolo et al. established a static balance situation by applying weights to the shoulder cuff muscles and ligaments and used this as a zero-reference before starting the dynamic movement measurements. Therefore, it is to be expected that our findings yield higher results.

Comparing the peak torsion; Iannolo et al. measured the torsion around the x-axis to be 0.4 Nm, whereas we calculated a force around the x-axis during abduction of 0.1 Nm. Other than observe the fact that these results seem similar and seem to confirm the validity of the DSEM, no definitive conclusions can be drawn. Moments around the y-axis were found to be the largest in all simulated movements especially during abduction and forward humeral elevation indicating that bending moments perpendicular to the longitudinal axis in a grossly superior-inferior direction were dominant. This reflects the probable clinical mechanism for failure of fixation devices and serves as another verification of the simulation generated by the DSEM.

Interestingly we identified that rotational forces around the longitudinal axis of the clavicle were the smallest which, theoretically is to be expected due to the short lever arm but is feared by clinicians since this is thought to be one of the reasons for failure of plate fixation.

A decrease in forces across the clavicle was simulated during abduction and forward humeral elevation in the 90-120 degrees interval. Most physical therapy (PT) protocols initially limit motion above 90 degrees of abduction/ forward humeral elevation. This finding raises questions about the necessity of this restriction. However, the moments around the z-axis continue to increase in this interval. Furthermore, GH-joint contact forces and thus possibly the forces across the clavicle estimated by the DSEM are well validated for movements up to 90 degrees of humeral elevation, but for movements above the shoulder line the model underpredicted the measured force by, on average, 31%.[22, 23] Further research on the forces and moments above 90 degrees of abduction and elevation to evaluate possible implications for rehabilitation protocols needs to be initiated.

Evaluating the forces on the middle section of the clavicle during washing the axilla, combing hair and eating, comparable forces and moments were simulated in all three planes with a maximum of 65 N and 1.6 Nm. All forces were lower than those during isolated abduction and forward humeral elevation. Minimum and maximum forces and moments occur at different locations during different movements; this is important to realize when developing future clavicular fixation devices.

Another interesting finding is that the simulations showed that forces act in opposing directions along the y-axis on either side of the conoid ligament at the acromial end of the clavicle. Due to the muscle insertions medial of the conoid ligament and the weight of the arm on the lateral side, this may not be a surprising finding in itself. However, to the authors' knowledge this is the first study to quantify these forces at this location. Failure of fixation in lateral clavicle fractures is a known complication and is attributed to lack of cortical surface for screw placement and cranially directed forces of the medial end. The findings of the DSEM simulations may contribute to a better understanding of the failure of fixation.

One of the limitations of this study includes the validity of the predictions of the DSEM, and the assumptions made during the calculations. The forces acting on the clavicle may have been underestimated by the inability to account for muscle co-contraction using the inverse dynamic modelling approach used here, and by not including the external forces which are exerted on the hand during the ADL tasks (e.g. the hand pushing into the axilla for washing). These introduce an unknown margin of error in the results; however currently it is one of the best simulation models available and the outcomes seem comparable and realistic with direct measurements on physical models. Another limitation is that we did not simulate internal and external rotations. We do not expect the exclusion of these movements to have influenced the main findings significantly, since the majority of the forces during rotation will act at the level of the glenohumeral joint and not the clavicle itself. The fact that the DSEM is originally a shoulder-oriented model is the cause of the third limitation being that the sternocleidomastoid muscle was not included in the simulation which could influence the results. A fourth limitation is that we only evaluated the forces and moments across the clavicle in a non-weightbearing state. It is of interest to conduct further research on if and how weightbearing would influence the results. However, the forces and moments on the clavicle are clinically most relevant in the early stages of rehabilitation after surgical treatment of midshaft clavicle fractures, as rehabilitation generally consists of rest, and passive range of motion exercises for several weeks followed by non-weight bearing active range of motion exercises until fracture union has occurred. This initial timeframe is of particular interest because the forces that occur in this phase could lead to loss of fixation or hardware failure. Once united, the osseous parts of the clavicle, and not the fixation device, will bear most of the load. One of the strengths of this study is that it is the first to simulate and quantify the forces and moments across the clavicle during forward humeral elevation and activities of daily living. Another strength is the inclusion of all but one of the muscle groups and ligaments involved in the motion of the clavicle.

CONCLUSION

The largest resultant force and moment simulated across the clavicle was 126 N during abduction and 2.4 Nm during both forward humeral elevation and abduction, respectively. Minimum and maximum forces occurred at different locations on the middle third of the clavicle during different movements. The results create an understanding of the forces across the clavicle during shoulder abduction, forward humeral elevation and activities of daily living.

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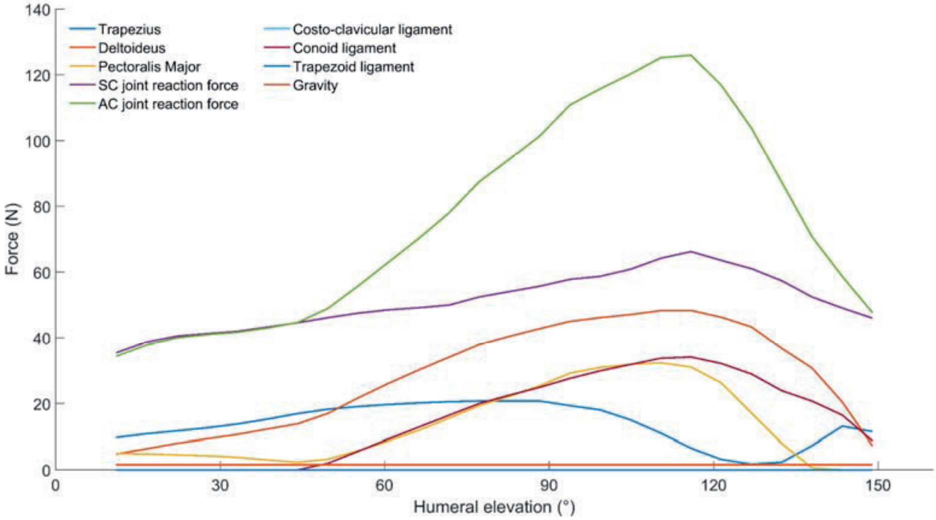
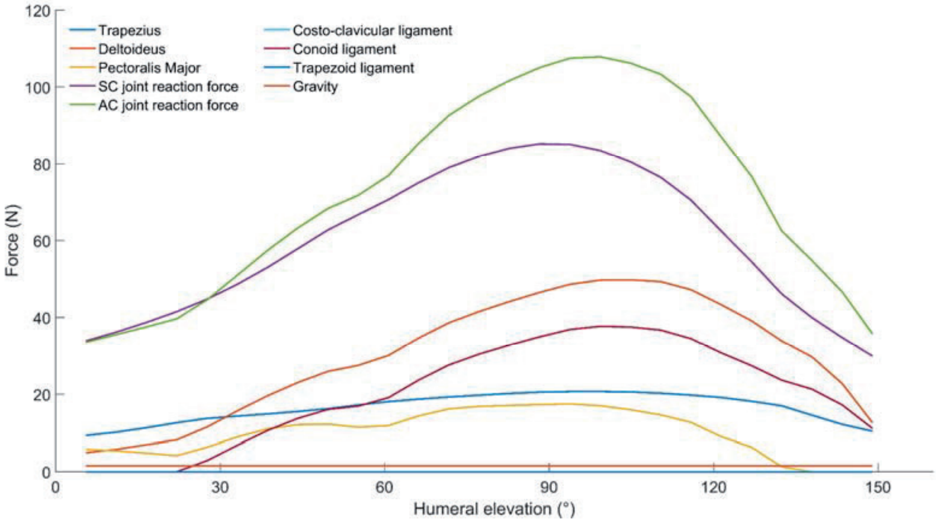
SUPPLEMENTARY MATERIAL

a



b



Supplementary Figure S10.1. (a) Shoulder abduction. **(b)** Forward humeral flexion.

11

Functional outcomes, union rate and complications of the Anser Clavicle Pin at 1 year: A novel intramedullary device in managing midshaft clavicle fractures

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ABSTRACT

Purpose: Surgical management of displaced midshaft clavicle fractures in adults leads to better union rates, improved early functional outcomes, and increased patient satisfaction compared to nonoperative treatment. However, both intramedullary fixation and plate osteosynthesis are subject to a specific array of disadvantages and complications. The Anser Clavicle Pin is a novel intramedullary device designed to address these disadvantages and complications. The aims of this study were to evaluate the union rate, functional outcomes and complications of the Anser Clavicle Pin at 1-year follow up.

Methods: A prospective explorative case series including twenty patients with displaced midshaft clavicle fractures was performed in two hospitals. Primary outcomes were union rates, functional outcomes (Constant-Murley score and Disabilities of Arm, Shoulder and Hand score) and complications. Secondary outcomes were closed reduction rate, operative time, image-intensifier time, hospital stay, incision length, time to radiological union, post-operative pain reduction, re-operation rates, health related quality of life scores and patient satisfaction.

Results: There was a 100% union rate. The Constant-Murley score at 1-year was 96.7 (SD 5). The Disabilities of Arm, Shoulder and Hand score was 5.1 (SD 10). There were no infections, neuropathy of the supraclavicular nerve or hardware irritation requiring removal of hardware. Three device-related complications (15%) occurred including plastic deformation, protrusion and hardware failure. VAS satisfaction was 8.9 (SD 1) at the 1-year follow up.

Conclusion: Managing displaced midshaft clavicle fractures with the Anser Clavicle Pin results in a 100% union rate, excellent functional outcomes and patient satisfaction. It has a low non-device related complication rate and the device-related complications that occurred in this series may be prevented in the future.

Level of evidence: 4.

Keywords: clavicle; fracture; intramedullary; fixation; functional outcomes; complications

INTRODUCTION

Midshaft clavicle fractures are common fractures with an incidence of 59.3 per 100,000 person years, comprising up to 5% of all fractures in adults.[1,2] In recent years the incidence of clavicle fractures has increased and the operative treatment of these fractures has risen disproportionately.[3,4] Reasons for the increase in operative management may be multiple reports stating that surgical treatment in adults leads to better union rates, improved early functional outcomes, and increased patient satisfaction.[3,5-12]

Currently, the gold standard of surgical management of the mid-shaft clavicle fracture is Open Reduction Internal Fixation (ORIF) by means of plates and screws. A plethora of different plate types (DCP, LC-DCP, LCP, pre-contoured, reconstruction) and locations (superior, anterior) has been described. Some of the advantages of ORIF with a plate and screw construct include the restoration of the anatomy and thus length of the clavicle, improved union rates, as well as early pain reduction and start of rehabilitation.[3,8,11-15] Disadvantages include large incisions, risk of infection, hardware failure, nerve damage of the supraclavicular nerve and hardware irritation requiring removal during a secondary intervention.[3,5,8,11,12,15,16]

Other techniques manage these fractures by means of an intramedullary device such as the Sonoma Crx, Rockwood Pin, Hagie Pin and Knowles Pin or Titanium Elastic Nails (TENs). The advantages of these devices are that they are minimally invasive, have low rates of infection and good union rates. However, these devices also have their specific array of disadvantages such as hardware prominence, protrusion, telescoping, migration, wound breakdown and, in case of TENs, an almost 100% need for removal during a secondary intervention.[17-27]

11

The Anser Clavicle Pin is a novel intramedullary device aiming to result in excellent functional outcomes, union rates and patient satisfaction in surgically managed patients with midshaft clavicle fractures. It is designed to address the disadvantages of the current techniques with the goal to lower healthcare costs and societal burden by reducing the need for secondary interventions, such as hardware removal.

The aims of the current first-in-man study were to evaluate the union rate, functional outcomes and complications of the Anser Clavicle Pin.

MATERIALS AND METHODS

A prospective explorative case series was performed in two Dutch hospitals (Radboud university medical center (RUMC) Nijmegen and Rijnstate Arnhem (RA)). This study was approved by the institutional review board (CMO Arnhem-Nijmegen; 2016-2428) and the Dutch healthcare inspectorate (Inspectie voor de Gezondheidszorg IGZ;

VGR1014867). A maximum of 20 patients was allowed to participate. The research protocol was registered before the start of the study in the Netherlands Trial Registry (NTR NL 6097). Written informed consent was obtained from all participants. This study was monitored by an independent monitor.

Inclusion criteria were: 1) midshaft clavicle fracture types 2A2 or 2B1 according to the Robinson Classification, 2) age ≥18 years and ≤65 years, and 3) surgery ≤10 days after trauma. Exclusion criteria were: 1) all patients deemed not fit for surgery by the anesthesiologist, 2) all patients with nonunion or previous malunion, 3) patients <18 years or >65 years, 4) possible noncompliant patients (e.g., alcohol and drug addiction, dementia), 5) additional neurovascular injury, and 6) pathologic fractures.

The authors and treating physicians were not involved in data collection. All pre- and post-operative data were collected by designated independent reviewers in both hospitals and stored in an electronic data capture system (Castor EDC, Amsterdam, The Netherlands).[28] Pre-operative characteristics of the participating patients were collected including age, sex, body mass index (BMI), past medical history, medications, American Society of Anesthesiologists (ASA) classification, dominant side, occupation, trauma mechanism, smoking status, health related quality of life questionnaire (Short Form 36), participation and level of sports, and fracture classification according to the Robinson Classification.

Primary outcomes included union rate, functional outcome as measured by the Constant-Murley (CMS) score and Disabilities of Arm, Shoulder and Hand (DASH) score and complications at 1-year follow up. Union was defined as a 2/3rd circumferential cortical bridging between medial and lateral fragments on both the AP and 15 degrees caudo-cranial radiographs as determined by three independent radiologists. Complications were defined as any general or implant-related intra- or post-operative adverse events that occurred during follow up. Explicit inquiries were made regarding infection, hardware irritation and neuropathy of the supraclavicular nerve.

Secondary outcomes recorded were the closed reduction rate, operative time (minutes), image-intensifier time, length of hospital stay, incision length, time to radiological union, post-operative pain reduction (visual analogue scale, VAS 0-10), re-operation rates, Short Form 36 (SF-36) questionnaire, and patient satisfaction (VAS 0-10).

Follow-up was scheduled at 1, 3 and 6 weeks, 3, 6 and 12 months in the outpatient clinic. All visits included a standardized clinical evaluation and registration of complications. Radiographs were taken immediately after surgery, and at 1, 3 and 6 weeks until radiographic union had occurred. The CMS and DASH scores were recorded during the 6 weeks, 3 and 6 months and 1-year postoperative visits. Patient satisfaction was recorded during the 6 weeks, 3 and 6 months, and 1-year visits. At 6 months and 1 year the patients were asked to complete the SF-36 questionnaire. Descriptive statistics were used to summarize the data. For the analysis of the CMS, DASH and SF-36 scores over time linear mixed models were used. Statistical analyses were performed using R version 3.6.0 (R Foundation for Statistical Computing, Vienna, Austria).

Surgical Technique and Rehabilitation Protocol

The Anser Clavicle Pin is based on the premise that midshaft clavicle fractures do not need absolute stability, but do need to be realigned and kept at length until union has occurred. It is flexible so it can follow the bi-planar sigmoid-shaped intramedullary canal of the clavicle and rigid enough to withstand the forces across the clavicle. It is anchored on both sides of the fracture maintaining the reduction and preventing implant migration and secondary shortening. To prevent loss of fixation and hardware failure the technology allows for rotational freedom of the fracture elements within its design. A rendering of the Anser Clavicle Pin and instruments used is shown in Figure 11.1.

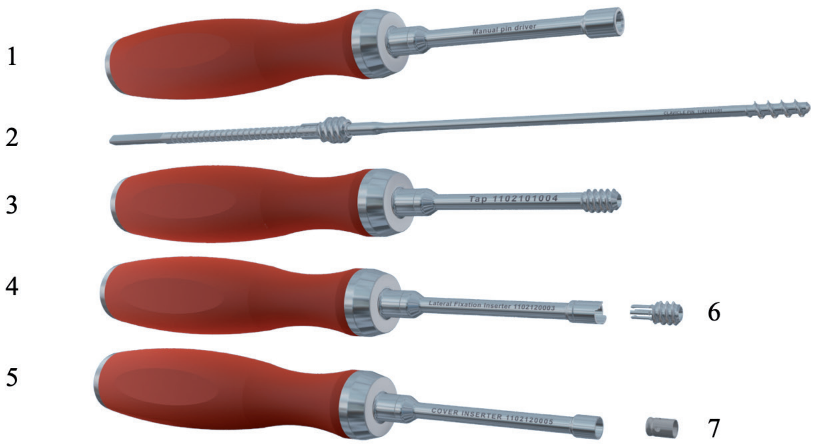

Figure 11.1. The Anser Clavicle Pin and instruments. 1 = Anser Manual Pin Driver, 2 = Anser Clavicle Pin (including the Anser Lateral Fixation Device), 3 = Anser Tap, 4 = Anser Lateral Fixation Device Inserter, 5 = Anser Endcap Inserter, 6 = Anser Lateral Fixation Device, 7 = Anser Endcap.

All surgeons were trained during a cadaveric instructional course or by the surgeon (PK) with the most experience using the Anser Clavicle Pin.

A detailed surgical technique can be found in Supplementary Material 11.1. In short, after the induction of general anesthesia and the administration of prophylactic antibiotics, the patient was positioned in a beach-chair configuration and prepped and draped with the arm free. Anatomic landmarks of the shoulder were identified and marked. The image-intensifier was positioned so adequate views of the clavicle in two directions could be obtained. The posterolateral entry point at the posterior conoid tubercle was identified and an incision through skin and subcutaneous tissue was made. After visual identification of the posterior conoid tubercle the intramedullary canal was opened using a 4.0 mm drill and the Anser Clavicle Pin was advanced into the lateral fragment using the Universal Pin Driver or Anser Manual Pin Driver until it reached the fracture site. Closed reduction was attempted using percutaneous large pointed reduction clamps. If this was not possible a small incision over the fracture site was made to facilitate direct reduction and visual confirmation. The Anser Clavicle Pin was then advanced into the medial fragment in an oscillating manner. The last centimeters towards the sternoclavicular joint and subchondral plate the Anser Manual Pin Driver was used until adequate grip and fixation was obtained. With a cannulated Anser Tap the lateral cortex was prepared and the Anser Lateral Fixation Device was placed. Reduction and length of the clavicle was once more checked and then secured by placing the Anser Endcap. The Anser Clavicle Pin was then cut flush to the Anser Endcap. The wound(s) were irrigated and closed. After dressing the wound the arm was placed in a sling for comfort.

Postoperatively, patients were encouraged to start with pain-dependent mobilization after 1 week and to discard the sling as soon as possible thereafter. Load bearing was not recommended until osseous consolidation had occurred. After 2 weeks passive guided exercises by a physical therapist were initiated.

RESULTS

Between May 2017 and April 2018 20 patients (18 male, 2 female) were enrolled in this prospective case series. Table 11.1 provides an overview of included patient characteristics.

The mean age at the time of surgery was 42.2 years (SD 13.1). Mean recorded BMI was 25 (SD 2.5). There were 15 Robinson type 2B1 fractures included of which 9 included a butterfly fragment (Figure 11.2). Four fractures were classified as Robinson type 2B1 fractures during enrollment but intra-operatively a comminuted zone was observed and thus were retrospectively classified as a Robinson type 2B2 fracture (Figure 11.3). One Robinson 2A2 fracture was included. Eighteen clavicle fractures were vertically displaced more than 100% of the shafts width, one was vertically displaced 50-100% and one fracture was vertically displaced 0-50%. The majority of the patients participated in cycling and gym work-outs on an amateur level. Almost half of the patients had high physical demand occupations for their upper extremities including 3 active military, a bus driver, a carpenter, a sculptor, a mechanic and a furniture maker. Nineteen patients were classified as ASA 1. One patient stated to use tobacco.

Table 11.1. Patient data and baseline characteristics

Patient	Sex	Age	Height	Weight	BMI	Dominant side	Injured side	Trauma mechanism	Robinson classification	Sports	Occupation	ASA	Smoking
1	M	34	177	76	24	Right	Left	Direct	2B1‡	Gym	Accountant	1	No
2	M	60	190	80	22	Left	Right	FOOSH	2B1‡	-	Carpenter	1	No
3	M	47	180	82	25	Right	Right	FOOSH	2B1‡	Gym	Active military	1	No
4	F	60	170	77	27	Right	Right	FOOSH	2B2	Cycling	Secretary	1	No
5	M	49	182	87	26	Right	Left	Direct	2B1‡	Gym	Manager	1	No
6	M	48	188	90	25	Right	Right	FOOSH	2A2	Cross Fit *	Active military	1	No
7	M	35	176	72	23	Right	Right	FOOSH	2B2	ATB	Designer	1	Yes
8	F	20	166	75	27	Right	Right	FOOSH	2B1	-	Student	1	No
9	M	55	179	87	27	Right	Left	Direct	2B1	Gym	Bus driver	1	No
10	M	56	178	103	33	Left	Left	Direct	2B1‡	Cycling	Teacher	2	No
11	M	43	178	80	25	Right	Left	Direct	2B2	Motorcross	Mechanic	1	No
12	M	44	196	91	24	Right	Right	FOOSH	2B1‡	Cycling	Manager	1	No
13	M	26	182	75	23	Right	Left	FOOSH	2B1‡	Soccer	Therapist	1	No
14	M	23	173	63	21	Right	Left	Direct	2B1	Triathlon	Student	1	No
15	M	51	190	95	26	Right	Left	Direct	2B2	Cycling	Engineer	1	No
16	M	62	190	90	25	Right	Left	Direct	2B1	Cycling	Entrepeneur	1	No
17	M	31	186	88	25	Right	Right	Direct	2B1	Rugby	Active military	1	No
18	M	51	180	80	25	Right	Right	FOOSH	2B1‡	Equestrianism	Sculpturer	1	No
19	M	37	180	70	22	Right	Right	FOOSH	2B1	ATB	Administrator	1	No
20	M	25	183	80	24	Right	Right	FOOSH	2B1‡	Running	Furniture maker	1	No

Height in centimetres. Weight in Kilograms. M, Male; F, Female. BMI, Body Mass Index; FOOSH, Fall On Outstretched Hand; ASA, American Society of Anaesthesiologists Classification; ATB, All terrain bike. ‡ With Butterfly Fragment. * Semi-professional.

Figure 11.2. An example of a Robinson type 2B1 fracture managed with the Anser Clavicle Pin. Bottom 2 images at 3 months follow up.

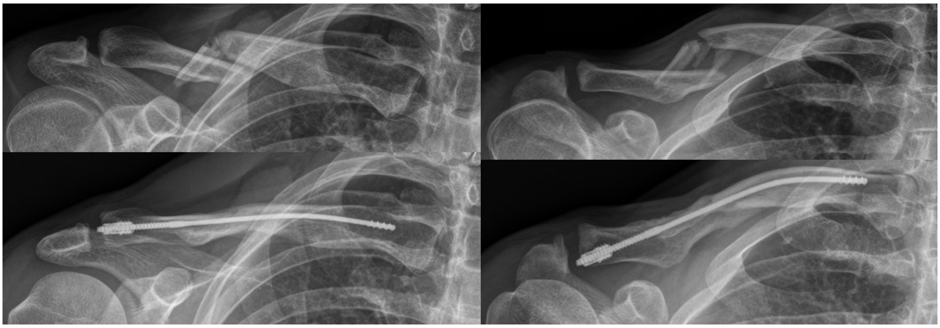

Figure 11.3. An example of a Robinson type 2B2 fracture managed with the Anser Clavicle Pin. Bottom 2 images at 3 months follow up.

Primary outcomes

A 100% union rate was found at the 1-year follow up. Adequate callus formation was seen in all but one of the cases at 6 weeks, as was radiographic consolidation at the 3 months follow up evaluation. The remaining fracture consolidated between 3 and 6 months postoperatively. The Constant-Murley score increased from 81.0 (SD 14, range 55-100) at 6 weeks to a mean of 96.7 (SD 5, range 83-100) at the 1-year follow up (Figure 11.4). The Disabilities of Arm, Shoulder and Hand score improved from 17.9 (SD 16, range 2-49) at 6 weeks to a mean of 5.1 (SD 10, range 0-29) at the 1-year follow up (Figure 11.4).

No infections or neuropathy of the supraclavicular nerve were recorded during follow up. One out of 18 patients with the Anser Clavicle Pin in situ at 1-year follow up reported minimal hardware irritation at the posterolateral entry point not requiring removal of hardware. One non-device related adverse event was recorded; a thrombo-embolic

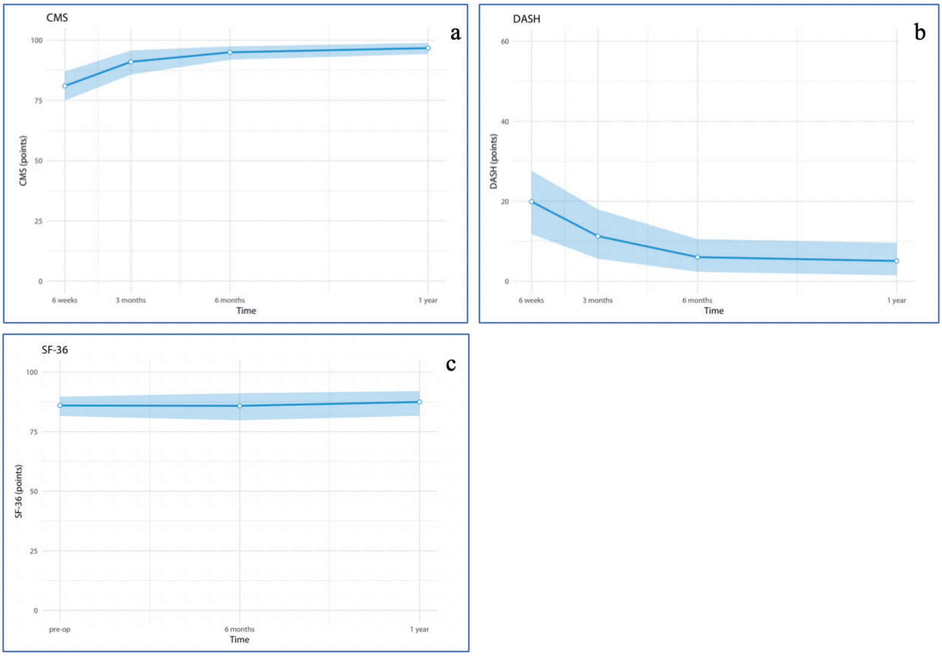

Figure 11.4. (a) The mean Constant-Murley score (CMS)with 95% Confidence Intervals at the different follow up moments. (n=18 at 6 weeks, n=18 at 3 months, n=17 at 6 months, n=17 at 1 year). **(b)** The mean Disabilities of Arm, Shoulder and Hand (DASH) score with 95% Confidence Intervals at the different follow up moments. (n=17 at 6 weeks, n=18 at 3 months, n=15 at 6 months, n=17 at 1 year). **(c)** The mean Short-From 36 (SF-36) scores with 95% Confidence Intervals pre-operatively and at 6 months and 1-year follow up. (n=19 pre-operatively, n=15 at 6 months, n=18 at 1 year).

process of the subclavian vessels for which temporary anti-coagulant therapy with Apaxiban was initiated. At the 1-year follow up a CMS of 96.0 points, a DASH score of 1.6 points and a VAS satisfaction of 8 points was recorded for this particular patient. Three device-related complications occurred in the present series. One pin was not advanced far enough in the medial fragment leading to a plastic deformation of the pin. The patient declined the possibility of revision since it did not bother him and the fracture united without complications and resulted in a CMS of 100 points, a DASH score of 0 points and a VAS satisfaction of 10 points at the 3 months and 1 year postoperative follow up. One pin was not adequately fixed into the posterolateral cortex, therefore allowing secondary shortening and causing hardware irritation requiring hardware removal. At the 1-year follow up the patient reported a CSM of 99.0 points and a VAS satisfaction of 10. The third device-related complication was a hardware failure at 4 weeks which required revision surgery. A superiorly located plate was placed and the fracture went to unite without any complications. This patient was excluded from further analysis. Both of the removal of hardware procedures were uncomplicated.

Table 11.2. (Secondary) outcome measures Anser Clavicle Pin

Patient	Days to surgery	OR time (minutes)	Fluoroscopy time (seconds)	Closed reduction	Incision length* (centimetres)	Complication	Union	Neuropathy Suprascapular Nerve at 12 months	Hardware Irritation at 12 months
1	11	38	43	No	5		Yes	No	Minimal
2	12	49	34	No	8		Yes	No	No
3	12	45	34	No	7		Yes	No	No
4	8	45	19	No	7		Yes	No	No
5	9	30	13	No	8		Yes	No	No
6	3	40	27	No	9		Yes	No	No
7	5	45	61	No	7		Yes	No	No
8	3	61	66	No	7		Yes	No	No
9	6	35	33	No	7		Yes	No	No
10	5	45	25	No	6		Yes	No	No
11	9	42	36	No	-		Yes	No	No
12	8	30	34	No	6	Plastic deformation Anser Clavicle Pin	Yes	No	No
13	5	50	25	No	8	Thromboembolism Subclavian vessels	Yes	No	No
14	5	37	17	No	6		Yes	No	No
15	6	35	58	No	5		Yes	No	No
16	7	67	83	No	6		Yes	No	No
17	3	80	48	No	6		Yes	-	-
18	6	27	15	No	6		Yes	No	No
19	6	30	15	No	9	Inadequate lateral fixation†	Yes	No	N/A
20	3	29	14	No	-	Hardware failure†	Yes§	N/A	N/A

* Combined posterolateral and anterior incisions. † Requiring removal of hardware. § After ORIF with plate.

Secondary outcomes

Secondary outcomes are shown in Table 11.2.

The mean time to surgery was 6.6 days (SD 2.9, range 2-12). The mean surgical time was 43.0 minutes (SD 13.6, range 27-80). The mean fluoroscopy time was 35 seconds (SD 19.6, range 13-83). All but one patient stayed in hospital for 1 day. The remaining patient was admitted for 3 days for unrelated medical reasons. All patients had a small accessory incision made over the fracture site to aid in reduction and adequate advancement of the Anser Clavicle Pin. The mean length of the two incisions combined was 6.8 cm (SD 1.2, range 5-9 cm). Post-operatively, the Anser Clavicle Pin led to a quick reduction in pain from 3.0 (SD 2.3, range 0-8) at 1 week to 2.0 (2.3, range 0-7) at 6 weeks (Figure 11.5). VAS satisfaction increased from 7.3 (SD 2, range 2-10, n=19) at 6 weeks to 8.9 (SD 1, range 4-10, n=18) at the 1-year follow up (Figure 11.5).

At 6 weeks, 15 patients had returned to work. At the 1-year follow up, one patient had not returned to work which was not a sequela of the clavicle fracture or its treatment. The health-related quality of life assessment using the SF 36 showed a return to pre-operative baseline scores (86, 95% CI 81-91) at both 6 month (86, 95% CI 81-91) and 1-year follow up (88, 95% CI 82-93) (Figure 11.4).

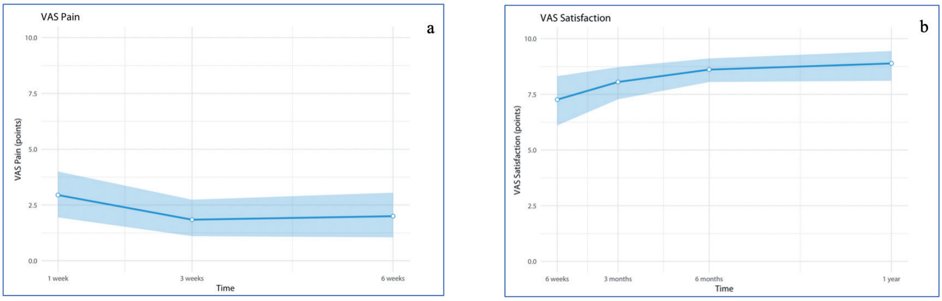

Figure 11.5. (a) The mean Visual Analogue Scale-Pain with 95% Confidence Intervals at 1 (n=19), 3(n=19) and 6 (n=19) weeks post-operatively. **(b)** The mean Visual Analogue Scale-Satisfaction with 95% Confidence Intervals at the different follow up moments (n=19 at 6 weeks, n=18 at 3 months, n=18 at 6 months, n=18 at 1 year).

DISCUSSION

In the present study, we aimed to evaluate the union rate, functional outcomes and complications of the Anser Clavicle Pin. We found a 100% union rate and excellent functional outcome scores as measured by the Constant-Murley and DASH scores. Union rates of displaced midshaft clavicle fractures are reported between 90-100% when managed surgically with either plate or intramedullary fixation.[16] The mean Constant-Murley score when using the Anser Clavicle Pin is in line with the scores reported in a systematic review by Zhu et al. who described a CMS of 93.8 points at 1-year follow up using intramedullary fixation and 89.3 points when using plate fixation.[29] Xiao et al reported a CMS of 92.6 points at 6 months follow up using intramedullary fixation and 87.2 points when using plate fixation.[30] These scores fall well within the minimally important clinical difference (MCID) of 10 points and should be regarded as similar.[31] Chen et al. reported on a DASH score at 6 months follow up of 6.6 points when using the intramedullary TEN and a score of 15 points when using plate fixation.[32] The DASH score after management with the Anser Clavicle Pin at 6 months follow up was similar at 6.1 points (SD 8) further improving to 5.1 (SD 10) at 1-year follow up.

Infection rates for plate and intramedullary fixation range from 0-36% and occur significantly more often when using plate fixation.[16] No infections were recorded when using the Anser Clavicle Pin. Neuropathy of the supraclavicular nerve may be one of the most commonly underreported complications associated with plate fixation of the displaced midshaft clavicle fracture. Since there was the possibility of an accessory incision over the fracture site using the present device it was decided before the start of the study to actively record the occurrence of this specific complication. No sensory deficits of the supraclavicular nerve were recorded when using the Anser Clavicle Pin at 1-year follow up. One out of 18 patients with the Anser Clavicle Pin in situ at the 1-year follow up reported minimal hardware irritation at the posterolateral entry point not requiring removal. This seems to be lower than the hardware irritation caused by the TEN which is often reported to be higher than 20% and up to 61%.[16-18, 27, 33-42] The reduction in hardware irritation is likely inherent to the design of the Anser Clavicle Pin allowing it to be placed in a retrograde fashion from the posterolateral clavicle where it is minimally prominent and covered by more soft tissues than a TEN that is placed in an antegrade fashion just lateral of the sternoclavicular joint.

Three device related complications were reported. In one occasion the Anser Clavicle Pin was plastically deformed. This is most likely caused by insufficient advancement of the pin into the medial fragment resulting in a less stable fracture and longer lever arm of the medial fragment on the pin. This complication may be prevented in the future by advancing the Anser Clavicle Pin far enough into the medial fragment. The second complication was hardware irritation at the posterolateral clavicle due to inadequate placement and thus fixation of the lateral fixation device into the cortex of the posterior conoid process. This allowed for secondary shortening and hardware irritation necessitating removal of hardware. This complication may be prevented in the future by adequately securing the lateral fixation device into the cortex. This one case of hardware irritation requiring hardware removal is substantially lower than those reported for plate osteosynthesis (38%) and intramedullary fixation (73%)[16] and would theoretically lead to a more cost-effective approach to the surgical management of midshaft clavicle fractures. The last complication consisted of hardware failure of the Anser Clavicle Pin. After reviewing the available radiographs for this patient, it seems that the fracture was reduced and fixed in a distracted position. This would have increased the forces on the device resulting in its failure. This complication may be prevented in the future by ascertaining oneself that the clavicle is not lengthened during the procedure. Furthermore, the rehabilitation protocol for the present study allowed for early mobilization. When in doubt, a transition to a more restricted rehabilitation protocol could be considered in order to prevent hardware failure. According to Hussain et al.,[43] intramedullary fixation is 20.2 minutes faster than plate osteosynthesis. The studies reporting on intramedullary fixation used for this comparison report a mean OR time between 35.6 minutes (SD 5.5)[44] and 53.2 minutes (SD 25.8).[17] In the present study a mean OR time of 43.0 minutes (SD 13.6) was recorded. This time could be reduced further with increased experience and by lowering the threshold for making the accessory incision over the fracture site. In the present study the accessory incision does not seem to influence the union rate or cause neuropathy of the supraclavicular nerve. The added benefit of the accessory incision is that it allows for direct visualization of the fracture site and therefore safe pin advancement. Furthermore, it maybe cosmetically more pleasing than 4 stab incisions, that are not in line, used for percutaneous reduction maneuvers.[45] During our series it was noted that, most likely due to the delay until intervention, adequate closed reduction and advancement of the Anser Clavicle Pin was difficult. This could possibly be improved by earlier intervention (<3 days after trauma). This case series confirms that the Anser Clavicle Pin allows for early and adequate pain reduction and thus early rehabilitation as well as return to baseline health-related quality of life at 6 months follow up.

A potential limitation is that one of the authors is involved in the development and commercialization of the Anser Clavicle Pin. The fact that this prospective case series has a registered protocol which has been adhered to reduces the risk of reporting bias. This potential limitation is further mitigated by the data collection by designated independent reviewers and independent study monitoring. Another potential limitation of this study includes the small sample size. It was not permitted to include more patients by the institutional review board and the Dutch healthcare inspectorate IGZ.

In summary, in this first in man prospective case series of 20 patients, the Anser Clavicle Pin has an excellent union rate, functional outcomes and patient satisfaction when used in the management of displaced midshaft clavicle fractures. It has a low non-device related complication rate and the device-related complications that occurred in this series may be prevented in the future. The low rate of re-interventions and absence of hardware removal due to hardware irritation could positively impact the associated morbidity and economic and societal burden.

In order to confirm the present findings a larger case series is necessary, followed by a comparison to other intramedullary fixation devices and/or plate osteosynthesis in a randomized controlled trial which includes a cost-effectiveness analysis.

CONCLUSION

Managing displaced midshaft clavicle fractures with the Anser Clavicle Pin results in an excellent union rate, functional outcomes and patient satisfaction. It has a low non-device related complication rate and the device-related complications that occurred in this series can be prevented in the future.

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SUPPLEMENTARY MATERIAL 11.1

Detailed surgical procedure Anser Clavicle Pin

1. Prophylactic antibiotics are given: cephalosporine, e.g. KEFZOL®. (Sterile natrium-cefazoline), 2 g i.v.
2. The patient is positioned in beach chair position on a radiolucent table or table which allows for removal of the shoulder/flank part on the ipsilateral side. (in case the table only allows for removal of the shoulder part it may cause inability to properly use the fluoroscopy in two directions which may lead to opening the skin over the fracture to reduce the fracture and advance the Anser Clavicle Pin).
3. Identification and marking of the anatomic landmarks. Clavicle, AC joint, scapular spine, posterior conoid tubercle, acromion.
4. Positioning of the fluoroscopy.
5. Determine and mark the entry position and exact location for skin incision: Palpate the trapezoid muscle and posterior side of the distal clavicle at the location of the posterior conoid tubercle. The skin incision should be made at the level of the AC joint progressing medially in order to create enough room for the approach of the Anser Clavicle Pin.
6. Disinfection and sterile draping.
7. Make a 2-3 cm incision of the skin and subcutis at the previously determined position. Make the incision of the subcutis aiming medially towards the posterior conoid tubercle. Do not open the AC joint. Palpate the posterior conoid tubercle and the fascia of the trapezoid muscle.
8. Open the fascia to have direct access to the posterior conoid tubercle.
9. Place small rasparatorium or a small Hohmann retractor caudal of the posterior conoid tubercle to identify the caudal border and direction of the medullary canal of the lateral fragment.
10. Use the 4 mm spiral drill with tissue-protector to open the cortex into the medullary canal of the lateral fracture element. Make sure the opening is done in the middle or slightly under the equator of the posterior conoid tubercle. Start perpendicular to the primary cortex and slowly angle the drill in the direction of the medullary canal.
11. Remove the drill but keep the tissue-protector in place in order to adequately maintain position and direction at the entry point.

12. Use the universal pin driver to place the flexible Anser Clavicle Pin into the lateral fracture element.
13. Check position of the Anser Clavicle Pin using fluoroscopy in two planes.
14. Advance the Anser Clavicle Pin until the fracture site.
15. Reposition the fracture elements and align them percutaneously using the reduction clamps and reduction maneuvers. If not possible, make an accessory 2-3 cm incision over the fracture site.

WARNING: Do not use the Anser Clavicle Pin as a lever or “joystick” during reduction. It may deform or break.

16. Slowly drive the Anser Clavicle Pin into medial bone fragment in an oscillating fashion to prevent damage to the soft tissues around the fracture site.
17. Check the position of the Anser Clavicle Pin by using fluoroscopy in two planes.
18. If closed reduction fails make a small incision over the fracture site and slowly drive the Anser Clavicle Pin into medial bone fragment under visual control. (Tip: identify both sides of the fracture and manipulate the Anser Clavicle Pin against the cranial cortex of the medial fragment using the small rasparatorium).
19. Manually drive the Anser Clavicle Pin towards the SC joint using the manual base pin driver until good grip is acquired.
20. Check the position of the base pin by using fluoroscopy in two planes.
21. Prepare the lateral fragment for the Anser lateral fixation device using the cannulated tap. (Sometimes a bit of pressure needs to be asserted in order to start the tap since it approaches at an angle).
22. Insert the Anser lateral fixation device over the Anser Clavicle Pin using the Anser lateral fixation device inserter. Ascertain the Anser lateral fixation device has positioned itself in one of the indentations of the Anser Clavicle Pin. (If this is not the case it is not possible to place the Anser Endcap; Manipulate either the Anser Clavicle Pin or Anser lateral fixation device to position the Anser lateral fixation device in one of the indentations on the Anser Clavicle pin)
23. Check the reposition of the fracture elements and when ascertained of the correct position place the Anser Endcap.
24. Advance the Anser endcap until a click is felt and/or heard. (When the Anser lateral fixation device is placed relatively deep into the lateral cortex, the Anser Endcap inserter may be blocked by the cortex. When this is the case advance the Anser

Endcap as much as possible and then simply push the Anser Endcap in position using forceps)

Warning: The Anser Endcap should be placed smoothly over the Anser lateral fixation device. If this does not happen there may be debris interfering or the Anser lateral fixation device has **NOT** positioned itself in one of the indentations of the Anser Clavicle Pin. Clean and/or manipulate either the Anser Clavicle Pin or Anser lateral fixation device to position the Anser lateral fixation device in one of the indentations on the Anser Clavicle Pin. **Do not push with force.** This may deform or damage the Anser lateral fixation device.

25. Placing the Anser Endcap secures the repositioned fracture elements and the appropriate length. To prevent friction and loss of reduction the lateral fixation and Anser Endcap can freely rotate along the Answer Clavicle Pin.
26. Cut the Anser Clavicle Pin just above the endcap using the Anser Clavicle Pin cutter.
27. Irrigate the surgical field and close the wound(s).
28. Obtain final images of the Anser Clavicle Pin in two directions.

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Summary & Discussion

The main body of this thesis consists of two parts aiming to improve the radiographic evaluation (part A) and the results of managing midshaft clavicle fractures (part B).

In **chapter 2** the available literature and current concepts in the management of midshaft clavicle fractures is reviewed. It describes that operative management leads to improved short-term functional outcomes, increased patient satisfaction, an earlier return to sports and lower rates of non-union compared with conservative treatment. However, it also describes that operative treatment is associated with an increased risk of complications and re-operations. This chapter identifies the lack of a uniform radiographic evaluation of the midshaft clavicle fracture and the opportunity to improve upon the disadvantages of the currently available operative techniques. In spite of ample reports on the topic from around the globe, it remains challenging to discern which patients would benefit from surgical management and for which ones a non-operative treatment would be advantageous. Shortening and vertical displacement are proposed factors that could potentially be helpful in answering this question.

PART A: OPTIMIZING RADIOGRAPHIC EVALUATION OF MIDSHAFT CLAVICLE FRACTURES

In **chapter 3** a systematic review was conducted in which the reliability and reproducibility of measurements of shortening in displaced midshaft clavicle fractures was evaluated. The results demonstrate that the literature on this topic is sparse and did only yield 3 fair and 1 poor quality studies. Despite the lack of high-quality studies, the available knowledge gained should not be discarded. The most commonly used radiographic projections in daily clinical practice are the AP and 15°-30° caudo-cranial projections. Surprisingly, compared to CT scans, it is the 15° caudo-cranial radiograph of the clavicle that is found to be the least accurate, the AP projection of the fractured clavicle that is not reliable in the prediction of the shortening and both projections display weak to no inter- and intra-observer agreement. Two out of four studies used the assumption of physiological side-to-side symmetry which potentially further compromised reliability. It was made abundantly clear that there is an opportunity to improve the radiographic evaluation of midshaft clavicle fractures. Both Jones et al.[1] and Silva et al.[2] proposed a standardized method of measuring shortening in displaced midshaft clavicle fractures by means of quantifying the overlap between fracture elements. They did not find a difference in standardized measurements or method of choice and only moderate inter- and intra-observer agreement. More recent studies, however, found both a moderate and excellent interobserver agreement using a standardized method of measuring[3,4] The results of this study support the need for further research aiming to identify an evidence based and reliable standardized method of imaging and measuring the fractured midshaft clavicle.

In **chapter 4** one of the more commonly used methods of determining the amount of shortening of the fractured clavicle by comparing the length of the fractured side to the length of contralateral unfractured clavicle was evaluated. This was done because a pre-existing natural asymmetry can make quantification of shortening using this method unreliable. The goal of this study was to assess the side-to-side variation in clavicle length in 100 uninjured, skeletally mature adults. It was found that 30% of the studied population, without any previous clavicular trauma, had a physiological asymmetry between the right and left clavicle of 5 mm or more and that 2% had an asymmetry of more than 10 mm. The results of this study confirm those of Cunningham et al.[5] and strengthen the conclusion that assuming symmetry is unreliable. Furthermore, this study is the first to describe the statistically significant association between clavicle length and dominant side and sex ($p<0.001$). The negative association between hand size and dominant side found by Manning et al.[6] seems also to be true for clavicle length and dominance and may further influence the quantification of shortening in midshaft clavicle fractures when comparing it to the contralateral side. Given its large potential for error that could lead over- or under-treatment of the fractured clavicle it would not be recommended to use this technique in quantifying shortening.

Midshaft clavicle fractures are often associated with a certain degree of shortening. In **chapter 5** a more in-depth evaluation of the influence of projection on measurements of the fractured clavicle is performed. The aim was to identify and quantify differences in measurements of shortening and length of fracture elements using a standardized measuring method and to evaluate inter- and intra-observer agreement. Digitally Reconstructed Radiographs (DRR) were created for 40 CT data sets in AP, 15° and 30° cranio-caudal, 15° and 30° caudo-cranial views. Both the intra-and interobserver agreements in all 5 views were excellent supporting the notion that a standardized method would be beneficial in the evaluation of shortening. It also indicates that the direction of the X ray view itself is not influencing reliability therefore clearing the path for any view that would be identified as most accurate. A difference in median absolute shortening between the commonly used 30° caudo-cranial and AP view of 5.8 mm was found. It is important to realize this difference is present and that the choice on which projection to measure shortening could theoretically alter the choice of treatment.

Similar to the results from Axelrod et al.[8] this study identified the increase in measured absolute lengths from caudal-cranial to cranial-caudal views. Contrary to the use in current clinical practice, a more cranial view results in a larger measurement therefore would be approximating reality the best and supports the notion it should be included in the standard evaluation over the caudo-cranial views.

The influence of radiographic projection on measurements of vertical displacement is described in **chapter 6**. Besides quantifying the difference in measurements of vertical displacement in an absolute, relative and categorical manner between 5 different projections, it assesses the association between categorical and continuous descriptions of vertical displacement. Since so far in the current body of literature only categorical descriptions of vertical displacement has been reported it was deemed important to evaluate how reliable this actually is or whether it would be more beneficial to quantify vertical displacement in an absolute manner. A clinical measurement study was conducted on 31 sets of digitally reconstructed radiographs (DRRs) in 5 different projections (15° and 30° caudo-cranial, AP, 15° and 30° cranio-caudal views). Unlike for shortening, absolute and relative vertical displacement of the midshaft clavicle fracture was not significantly influenced by radiographic projection. We found that the proposed novel standardized method to measure vertical displacement is reproducible and could be used for future research purposes. However, due to the very strong correlation between categorical and continuous measurements this may not be necessary for clinical use.

It is unclear whether the differences in measured shortening found between projections in **chapter 5** equate to clinically relevant differences in the treatment algorithm. Therefore, in **chapter 7** it was investigated whether two different projections of the same midshaft clavicle fracture would lead to a difference in choice amongst 23 orthopedic trauma or upper extremity surgeons for necessitating either conservative or operative treatment. It was shown that on average the decision changed in 33.9% of the cases, solely based on the projection of the fractured clavicle. Interestingly, we found an increased tendency to treat a midshaft clavicle fracture operatively when using the 15° caudo-cranial projection. Since it the cranio-caudal views are more accurate projections and that the caudo-cranial views show a low agreement with CT measurements, one would expect an increased amount of shortening and thus increased choice for surgical treatment with the 15° cranio-caudal projection. It may be the projected displacement that causes this difference. This, however, is not in line with the findings in chapter 6 or those of Wright et al.[9] who reported an underestimation of actual displacement on 20° caudo-cranial x-rays compared to the shortening measured on CT-scans. A possible explanation for this finding may be identified in **chapter 8**.

In the last section of part A, **chapter 8**, a prospective clinical measurement study quantifying the influence of both radiographic projection and patient positioning on the measurement of shortening and vertical displacement in 22 acute Robinson type 2B1 clavicle fractures was conducted. A statistically significant difference in average measurements of absolute shortening (4.5 mm), relative shortening (3.2%) and vertical displacement (odds 4.7) between the supine and upright views when keeping all other variables constant was found. Differences in orientation of the arm during imaging did not result in differences in measured shortening or vertical displacement and therefore may be of no clinical relevance. No statistically significant differences between the average absolute and relative shortening when evaluating the 15° caudo-cranial and

15° cranio-caudal projections were identified. This is a different result than those from **chapter 5** and could be caused by inherent differences between DRRs and the use of proper X-ray projections. The different projections are well controlled in DRRs which may not be the case for proper X-rays. It is possible that by using larger angulations of projections (i.e. 30° caudo-cranial and 30° cranio-caudal views) a statistically significant and possibly clinically relevant difference could be identified. Further research is needed to further evaluate this.

A statistically significant difference was found when evaluating the caudo-cranial to cranio-caudal projections for vertical displacement. A proportional odds ratio of 5.9 (95% CI 2.8-12.6) was calculated for an increase in category. Caudo-cranial projections were scored in a higher category of vertical displacement more often. Even though in **chapter 6** no statistically significant differences in vertical displacement between projections were found, the differences found in this study are in line with the findings in **chapter 7** and could explain increased choice for surgical management for the caudo-cranial projection of the same fractured clavicle compared to its cranio-caudal projection.

PART B: INNOVATIONS IN SURGICAL MANAGEMENT OF MIDSHAFT CLAVICLE FRACTURES

Chapter 9 describes a first in its kind systematic review that aims to generate an overview of functional outcomes and complications in the management of displaced midshaft clavicle fractures per available intramedullary device. This was deemed important since these devices differ considerably in their specifications and characteristics and the profile and distribution of complications may vary. In this study good functional results and union rates irrespective of the type of device were found in the reviewed literature. The most common reported complications after intramedullary fixation are implant-related and implant-specific. For the TEN, hardware irritation and protrusion, telescoping or migration, with a reported pooled incidence of 20% (95% CI 14-27) and 13% (95% CI 9-20), are major contributors to the total complication rate. The explanation for this finding may be that the TEN re-aligns but does not fixate in either fracture element of the clavicle. These TEN-specific complications lead to infection, soft-tissue problems, pain, early re-interventions (removal or additional cutting of the nail) and loss of reduction with subsequent secondary shortening. For the Rockwood/Hagie Pin, hardware irritation is identified as the most common complication with 21% (95% CI 11-35). This may be explained by the two bulky nuts at the posterolateral aspect of the clavicle where the pin is inserted and is has been reported to be an important disadvantage of the implant.[10-12] The most common complication for the Sonoma CRx was cosmetic dissatisfaction in 7% (95% CI 2-22) of cases. Meta-analysis shows no statistically significant differences in hardware failure between the types of implant. The pooled incidence for nonunion using the Rockwood/Hagie pin was 6% (95% CI 3-13) compared to 3% (95% CI 2-7) and 2% (95% CI 1-11) with the use of the TEN or Sonoma CRx respectively. Another finding during this study was that most studies do not clearly report causes for implant failure, measures taken with occurrence of infection or information concerning implant migration or secondary shortening. Only few specifically report on the presence or absence of certain relevant complications such as secondary shortening, neuropathy of the supraclavicular nerve, delayed union and persistent pain. This information should be fully reported in future studies. This systematic review identified several limitations one could improve upon per intramedullary device. It is interesting to take these into account in order to optimize future designs.

When designing a new medical device for the management of midshaft clavicle fractures it is imperative to have knowledge of the forces that act on the clavicle during shoulder movements and activities of daily living. In **chapter 10** one of the most detailed and well-validated biomechanical computer models of the human upper limb (the Delft Shoulder and Elbow Model (DSEM) was used to calculate these forces. Maximum compressive forces along the x-axis of 97 N during abduction and 91 N during forward humeral elevation were identified. No tensile forces along the x-axis were calculated during these motions signifying a continuous compressive force. All of the maximum moments occurred outside the middle third. Interestingly, it was found that rotational forces around the longitudinal axis of the clavicle were the smallest which, theoretically is to be expected due to the short lever arm but is feared by clinicians since this is thought to be one of the reasons for failure of plate fixation. A decrease in forces across the clavicle was simulated during abduction and forward humeral elevation in the 90-120 degrees interval. Most physical therapy (PT) protocols initially limit motion above 90 degrees of abduction/ forward humeral elevation. This finding raises questions about the necessity of this restriction.

One of the limitations of this study includes the validity of the predictions of the DSEM, and the assumptions made during the calculations. The forces acting on the clavicle may have been underestimated by the inability to account for muscle co-contraction using the inverse dynamic modelling approach used here, and by not including the external forces which are exerted on the hand during the ADL tasks (e.g. the hand pushing into the axilla for washing). These introduce an unknown margin of error in the results; however currently it is one of the best simulation models available and the outcomes seem comparable and realistic with direct measurements on physical models.

The results of this study create an understanding of the forces and their distribution across the clavicle during activities of daily living and these data may be helpful in the development of clavicular fixation devices.

The results from the study in **chapter 10** were used during the design and development of the Anser Clavicle Pin. As stated in the introduction, it may require not just an adaptation of current devices, but possibly the introduction of an entirely new concept to reduce the complications profile of surgical management of the fractured clavicle. **Chapter 11** describes the concept behind the Anser Clavicle Pin which includes the reduction the fractured clavicle and maintenance of its length in an intramedullary fashion whilst allowing rotation along the longitudinal axis to occur. It aimed to evaluate the union rate, functional outcomes and complications of the Anser Clavicle Pin. A 100% union rate and excellent functional outcome scores as measured by the Constant-Murley and DASH scores were found. No infections were recorded when using the Anser Clavicle Pin. Neuropathy of the supraclavicular nerve, as mentioned before, may be one of the most commonly underreported complications associated with plate fixation of the displaced midshaft clavicle fracture. No sensory deficits of the supraclavicular nerve were recorded when using the Anser Clavicle Pin at 1-year follow up. One out of 18 patients with the Anser Clavicle Pin in situ at the 1-year follow up reported minimal hardware irritation at the posterolateral entry point not requiring removal. The low rate of hardware irritation is likely inherent to the design of the Anser Clavicle Pin allowing it to be placed in a retrograde fashion from the posterolateral clavicle where it is minimally prominent and covered by more soft tissues than a TEN that is placed in an antegrade fashion just lateral of the sternoclavicular joint.

Three device related complications were reported and its root causes were most likely identified allowing for them to be prevented in the future. A mean OR time of 43.0 minutes (SD 13.6) was recorded. This time could be reduced further with increased experience and by lowering the threshold for making the accessory incision over the fracture site. In the present study the accessory incision does not seem to influence the union rate or cause neuropathy of the supraclavicular nerve. The added benefit of the accessory incision is that it allows for direct visualization of the fracture site and therefore safe pin advancement. Closed reduction rates could possibly be improved by earlier intervention (<3 days after trauma). The Anser Clavicle Pin allows for early and adequate pain reduction and thus early rehabilitation as well as return to baseline health-related quality of life at 6 months follow up.

It was concluded that managing displaced midshaft clavicle fractures with the Anser Clavicle Pin resulted in an excellent union rate, functional outcomes and patient satisfaction. It had a low non-device related complication rate and the device-related complications that occurred in this series may be prevented in the future.

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Conclusions & Future directions

To date, there has been no uniformity in quantifying shortening and vertical displacement of midshaft clavicle fractures. Therefore, the reporting of these parameters in clavicle-related studies may not be interchangeable or reliable. However, we believe these parameters should not be discarded in the treatment algorithm yet. Instead, with the knowledge gained from this thesis, we propose standardization in order to optimize its reporting in future studies and the realization of comparable results.

When considering the most safe, accurate, reliable and cost-efficient method of imaging and measuring the fractured clavicle one should consider multiple influences such as imaging modality, radiation exposure, cost, radiographic projection, magnification, patient positioning and the method for quantifying shortening and displacement.

As for imaging modality; CT scans and PA thorax radiographs may be the most accurate but the first is expensive and both expose the patient to a much higher radiation dose than AP views. Furthermore, unlike radiographic imaging, a CT scanner may be a resource that is not available everywhere. It is known that additional projections of the fractured clavicle can influence the surgeon's treatment decision. In order to keep cost and radiation exposure to a minimum the number of images during the radiographic evaluation should be kept limited. The results from this thesis consistently show that cranio-caudal views are more accurate in measuring shortening and length of the fracture elements. Caudo-cranial views possibly convey a more accurate vertical displacement. Straight AP views offer no added benefit in the evaluation of either shortening or vertical displacement and could therefore be discarded. Intra- and interobserver reliability is excellent irrespective of projection for both shortening and vertical displacement when using a standardized method for quantification.

There are uniform reports, from both this thesis and the body of literature, that supine patient positioning leads to an underestimation of shortening and vertical displacement. Positioning of the arm does not influence measurements of shortening and displacement. Calibrated views will prevent magnification errors. Although not necessarily proven superior, it would be advised to quantify shortening and displacement in a standardized manner quantifying the overlap between fragments. It is not advised to use the contralateral side for comparison given the large margin for error.

The coalescence of the findings above in conjunction with the evidence available in the body of literature would result in the following recommendations:

Radiographic evaluation of midshaft clavicle fractures should consist of 2 calibrated anterior-to-posterior directed images with the patient in upright position irrespective of the position of the arm:

1) a 15° caudo-cranial view to most adequately evaluate vertical displacement.
2) a 15° cranio-caudal view to most adequately evaluate shortening.

As for the quantification of shortening and vertical displacement:

1. Use a standardized method for quantifying shortening measuring the overlap between fragments as proposed by Silva et al. instead of comparing to the contralateral side.
2. Though reproducible and possibly useful for research purposes, the proposed novel standardized measurements of vertical displacement in this thesis may be obsolete for clinical use since the correlation between categorical and continuous measurements is very strong.
3. In clavicle-related manuscripts it should be stated which projection was used for which measurements when reporting on shortening and vertical displacement.
4. In clavicle-related manuscripts it should be stated both absolute and relative measurements of shortening.

There are still many questions that remain to be answered. Some are specific to the radiographic evaluation such as assessing whether larger angulations of projections (30° caudo-cranial and 30° cranio-caudal views) would be beneficial in more adequately evaluating vertical displacement. Another is whether this proposal for a uniform radiographic evaluation will be accepted by those involved in the treatment of midshaft clavicle fractures and applied in daily practice and to future research. To achieve this an awareness needs to be created in both the realms of (Orthopedic) Surgery and Radiology. Continued efforts to present the recommended imaging protocol at conferences, in peer-reviewed medical journals and symposia are necessary with the goal of having them evaluated and implemented by the involved professional associations in guidelines and protocols.

This thesis does not answer the question if shortening and displacement can be used as indicators for surgery; it merely creates the foundation to do so. Only when sufficient researchers adopt the proposed imaging protocol one can answer these questions once sufficient and reproducible radiographic and clinical data are available to discern an association between radiographic parameters, management strategy and outcomes.

It is clear that the disadvantages of the current devices are inherent to its design. In other words, an optimization of patient selection or surgical technique will unlikely result in a significant decrease of the implant-specific complications. In order to improve upon these disadvantages a new concept and design in the form of the Anser Clavicle Pin has been proposed. Its specifications are partially based on the findings of the magnitude of forces acting on the clavicle calculated by the DSEM in chapter 10. An interesting finding in this chapter was the decrease in forces across the clavicle during abduction and forward humeral elevation in the 90 to 120 degrees interval. Most physical therapy protocols initially limit motion above 90 degrees of abduction and forward humeral elevation. This finding raises questions about the necessity of this restriction. By optimizing the DSEM through the addition of the sternocleidomastoid muscle, more focused research on the forces in the beforementioned range of motion will be possible. This, as well as the influence of weightbearing would be interesting pathways in assessing whether the results in chapter 10 indeed should have implications for rehabilitation protocols in the future. Once a theoretical and biomechanical basis for this assumption is established, further clinical evaluation is indicated.

The development of a new medical device is an adventure in itself. It is not only exciting and rewarding to complete different milestones throughout the endeavor, such as designing and testing different prototypes, securing funding, obtaining regulatory approval and clinically evaluating the medical device. It is more than merely designing and testing a concept in collaboration with medical engineers. It is also something no medical graduate has been trained for and it is a personal excercise in patience, perserverance and coping with frustration and uncertainty. The Anser Clavicle Pin would not have been developed if it was not for the available knowledge and resources at the Radboud University Medical Center and its connections to the medical engineering company BAAT Medical. Important was the support from the Orthopedic Surgery department, the Orthopedic Research Lab, Radboud Technology Center and Valoristation department. All departments involved have been very helpful during the initiation of clinical research under the surveillance of the Inspectie van de Gezondheidszorg. It is imperative to have this type of infrastructure available when embarking on a similar journey. This is an excellent characteristic of the situation in the Netherlands as compared to the situation in the USA where the initiation of clinical research under an investigational device exemption (IDE) is expensive and the barriers for innovation are therefore possibly larger than those in the European Union. It may be worth to include some of the basic knowledge needed for medical innovation into the medical training curriculum. This way, not only would medical students learn about some pearls and pitfalls of medical innovation, it would also direct them to those who would guide them through the proces and most importantly, it would make them aware of the fact innovation is an ongoing process and possibly trigger them to have a mindset geared towards the creation of new concepts. In the case of the Anser Clavicle Pin specifically, obstacles in the development have been the changing regulatory landscape from MEDDEV towards MDR. This has resulted in a notified body that was difficult if not nearly impossible to communicate with, which has slowed down the process tremendeously. Another obstacle during this experience is that early stage (seed) funding is relatively well obtainable from multiple governmental agencies in both the Netherlands and the USA. However, it is noteworthy there is still a dearth in securing further pre-revenue funding. Many investors, venture capitalists and even governmental investment agencies are either looking to invest very early on or when the concept has been proven. During the phase in between it is challenging to secure additional financial support. This may be something worth addressing to academic hospitals and involved governmental agencies in order to continu to allow knowledge and innovation to reach market.

More research is needed to evaluate whether the Anser Clavicle Pin is indeed a viable option and an improvement compared to the currently available treatment options. This would initially entail a larger case series using a similar protocol as the study presented in chapter 11 to ensure improved patient-related outcomes. Once this study would confirm the efficacy and safety of the Anser Clavicle Pin, an RCT is necessary to compare it to the current gold standard of plate osteosynthesis and possibly even non-operative management. In the light of ever-growing healthcare costs and societal burden, it is paramount to include a cost-effectiveness analysis. Care should be taken to include not only the direct hospital costs related to each management strategy, but also the indirect costs such as time of work due to disability, and direct costs in the outpatient setting such as physical therapy.

The work described in this thesis covers the first steps taken to further advance both the radiographic evaluation and surgical management of midshaft clavicle fractures. Continued efforts are necessary to evaluate whether the knowledge established in this thesis will help further discern which patients would benefit from surgical management in the setting of displaced midshaft clavicle fractures.

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Summary & Discussion in Dutch / Nederlandse samenvatting & Discussie

Dit proefschrift bestaat uit twee delen welke gericht zijn op 1) het optimaliseren van de radiologische evaluatie (deel A) en 2) het verbeteren van de operatieve behandeling van midschacht claviculafracturen (deel B).

In **hoofdstuk 2** worden de beschikbare literatuur en huidige concepten omtrent de behandeling van midschacht claviculafracturen besproken. Operatieve behandeling leidt veelal tot verbeterde functionele resultaten op de korte termijn, een hogere patiënttevredenheid, een eerdere terugkeer naar sport en lager percentage van non-union in vergelijking met de conservatieve behandeling. Echter, operatieve behandeling gaat ook gepaard met een verhoogd risico op complicaties en re-operaties. Verder blijkt uit dit hoofdstuk dat een uniforme radiologische evaluatie van midschacht claviculafracturen ontbreekt en dat er ruimte is om de momenteel beschikbare operatietechnieken verder te verbeteren.

Ondanks een overvloed aan gepubliceerde onderzoeksresultaten, blijft het een uitdaging om te bepalen welke patiënten baat zouden hebben bij een chirurgische behandeling en voor welke patiënten juist een niet-operatieve behandeling beter zou zijn. De mate van verkorting en verticale verplaatsing van de fractuurdelen van de clavicula zijn factoren die mogelijk nuttig kunnen zijn bij het beantwoorden van deze vraag.

DEEL A: OPTIMALISATIE VAN DE RADIOLOGISCHE EVALUATIE VAN MIDSCHACHT CLAVICULAFRACTUREN

In **hoofdstuk 3** werd een systematische review uitgevoerd waarin de betrouwbaarheid en reproduceerbaarheid van metingen betreffende verkorting van verplaatste midschacht claviculafracturen werd geëvalueerd. De resultaten laten zien dat de literatuur over dit onderwerp schaars is en de systematische review slechts 3 studies van redelijke en 1 studie van slechte kwaliteit opleverde. Ondanks het ontbreken van studies van hoge kwaliteit mag de opgedane kennis uit de beschikbare studies niet worden genegeerd. De meest gebruikte radiologische projecties in de dagelijkse klinische praktijk zijn de AP en 15°-30° caudo-craniale projecties. Een verrassende bevinding was echter, dat in vergelijking met CT-scans, de 15° caudo-craniale röntgenfoto van de clavicula de minst nauwkeurige is als het gaat om het kwantificeren van verkorting, dat de AP-projectie van de gebroken clavicula ook niet betrouwbaar is in het meten van verkorting en dat metingen gebruikmakende van deze twee projecties een afwezige of een zwakke inter- en intra-observer agreement heeft. Twee van de vier gevonden studies gebruikten de veronderstelling dat er een fysiologische symmetrie tussen beide claviculae bestaat. Daar dit niet het geval is zou deze methode de betrouwbaarheid van de metingen mogelijk verder aantasten.

Dit hoofdstuk maakt het overduidelijk dat er een mogelijkheid is om de radiologische evaluatie van midschacht claviculafracturen te verbeteren.

Er zijn studies die het gebruik van een gestandaardiseerde methode om de verkorting in verplaatste midschacht claviculafracturen te meten. Zij doen dit door middel van het kwantificeren van de overlap tussen de breukelementen. Deze studies vonden geen verschil tussen de gestandaardiseerde metingen en die van een methode naar keuze van diegenen die de metingen verrichtten en tevens werd er slechts een matige inter- en intra-observerovereenstemming gevonden. Recentere studies beschrijven echter een betere inter-observerovereenkomst als er een gestandaardiseerde meetmethode werd gebruikt. De resultaten van deze studie ondersteunen de behoefte aan verder onderzoek gericht op het identificeren van een evidence-based, accurate, reproduceerbare en gestandaardiseerde meetmethode van midschacht claviculafracturen.

In **hoofdstuk 4** werd een van de meest gebruikte methoden voor het bepalen van de verkorting van de gebroken midschacht clavicula geëvalueerd door de lengte van de gebroken zijde te vergelijken met de lengte van het contralaterale niet-gebroken zijde. Dit is relevant omdat als er sprake is van een natuurlijke asymmetrie, de kwantificering van verkorting middels deze methode onbetrouwbaar is. Het doel van deze studie was om de variatie in lengte tussen de linker en rechter clavicula te bepalen in 100 volwassenen. Het bleek dat er in 30% van de onderzochte populatie een natuurlijke asymmetrie tussen beide claviculae van 5 mm of meer bestaat. In 2% was er sprake van een asymmetrie van meer dan 10 mm. De resultaten van deze studie leiden tot de conclusie dat meten van verkorting op basis van symmetrie onbetrouwbaar is. Verder is deze studie de eerste die een statistisch significante associatie tussen lengte van de clavicula en dominante zijde en geslacht beschrijft. De negatieve associatie tussen handgrootte en dominante zijde gevonden door Manning et al. lijkt dus ook waar te zijn voor de lengte van de clavicula. Ook deze associatie kan de kwantificering van verkorting in midschacht claviculafracturen verder beïnvloeden. Gezien het grote potentieel voor een foutieve meetuitkomst die kan leiden tot over- of onderbehandeling van de gebroken clavicula, wordt het niet aanbevolen om de techniek gebaseerd op veronderstelde symmetrie te gebruiken bij het kwantificeren van verkorting.

Midschacht claviculafracturen zullen in een groot deel van de gevallen leiden tot een zekere mate van verkorting. In **hoofdstuk 5** wordt een meer diepgaande evaluatie verricht met betrekking tot de invloed van radiologische projectie op de meetresultaten van verkorting. Het doel was om verschillen in meetresultaten van verkorting en lengte van de breukelementen te identificeren en te kwantificeren met behulp van een gestandaardiseerde meetmethode. Een ander doel van de studie was om de intra- en interobserver agreement per projectie te bepalen. Digitaal gereconstrueerde röntgenfoto's werden gecreeërd in AP, 15° en 30° cranio-caudale, 15° en 30° caudo-craniale projecties op basis van CT-scans van 40 patiënten. Zowel de intra- als de interobserver agreement was in alle 5 de projecties uitstekend. Dit ondersteunt het idee dat een gestandaardiseerde meetmethode reproduceerbaar is in de evaluatie van verkorting. Het geeft ook aan dat de richting van de röntgenfoto zelf de reproduceerbaarheid van de meting niet beïnvloedt. Hierdoor is dit geen barrière om de meest nauwkeurige projectie te kiezen. Een verschil in mediane absolute verkorting tussen de algemeen gebruikte caudo-craniale 30° en AP-weergave van 5,8 mm werd gevonden. Het is belangrijk om te beseffen dat dit verschil aanwezig is en dat dus het meten van verkorting op verschillende projecties in theorie de keuze van de behandeling zou kunnen beïnvloeden.

Deze studie vond dat de absolute lengte van caudale-craniale naar craniale-caudale stapsgewijs toenam. In tegenstelling tot het gebruik in de huidige klinische praktijk, zouden meer cranio-caudale projecties dus resulteren in een groter meetresultaat van fractuurdelen en verkorting. Omdat deze projecties de realiteit het beste lijken te benaderen zou het aan te raden zijn om deze op te nemen in de standaardevaluatie van de gebroken clavicula.

De invloed van radiologische projectie op de meetresultaten betreffende verticale verplaatsing wordt beschreven in **hoofdstuk 6**. Naast het kwantificeren van het verschil in metingen van verticale verplaatsing op een absolute, relatieve en categorische manier tussen 5 verschillende projecties, wordt ook de associatie tussen categorische en continue uitkomsten van verticale verplaatsing geëvalueerd. Omdat in de huidige literatuur tot nu toe de verticale verplaatsing alleen op categorische wijze wordt gerapporteerd, werd het belangrijk geacht om te evalueren hoe betrouwbaar dit nu eigenlijk is en of het niet beter zou zijn om verticale verplaatsing als een absolute maat te kwantificeren. Een klinisch meetonderzoek werd uitgevoerd op 31 sets van digitaal gereconstrueerde röntgenfoto's in 5 verschillende projecties. Anders dan bij verkorting werd de absolute en relatieve verticale verplaatsing van de sleutelbeenbreuk niet significant beïnvloed door de radiologische projectie. Verder werd er vastgesteld dat de voorgestelde nieuwe gestandaardiseerde methode om verticale verplaatsing te meten reproduceerbaar is en kan worden gebruikt voor toekomstige onderzoeksdoeleinden. Vanwege de zeer sterke correlatie tussen categorische en continue uitkomsten is dit echter niet noodzakelijk voor klinisch gebruik.

Het is onduidelijk of de verschillen in gemeten verkorting gevonden tussen projecties in **hoofdstuk 5** ook daadwerkelijk voor klinisch relevante verschillen in het behandelingsalgoritme zorgen. Daarom werd in **hoofdstuk 7** onderzocht of twee verschillende projecties van dezelfde midschacht claviculafractuur zou leiden tot een verschil in keuze tussen een conservatieve of operatieve behandeling. Drieëntwintig trauma orthopeden, traumachirurgen of chirurgen gespecialiseerd in de bovenste extremiteit namen deel. Er werd aangetoond dat de beslissing gemiddeld in 33,9% van de gevallen veranderde tussen de twee behandelopties, uitsluitend op basis van de projectie van de gebroken clavicula. Interessant is dat de keuze vaker viel op een operatieve behandeling van de midschacht claviculafractuur bij gebruik van de 15° caudo-craniale projectie. Omdat uit eerdere studies juist bleek dat de cranio-caudale projecties resulteren in een meer accurate representatie van de werkelijkheid, zou men een verhoogde hoeveelheid verkorting en dus een grotere keuze voor chirurgische behandeling met de 15° cranio-caudale projectie verwachten. Mogelijk is het de geprojecteerde verticale verplaatsing die dit verschil veroorzaakt. Dit komt niet echter overeen met de bevindingen in **hoofdstuk 6** of die van andere studies die een onderschatting van de werkelijke verticale verplaatsing op een 20° caudo-craniale röntgenfoto's vonden in vergelijking met de verkorting gemeten op CT-scans. Een mogelijke verklaring voor deze discrepantie is te vinden in **hoofdstuk 8**.

In de laatste sectie van deel A, **hoofdstuk 8**, werd een prospectieve klinische meetstudie uitgevoerd die de invloed van zowel radiologische projectie als positionering van de patiënt op de meetresultaten van verkorting en verticale verplaatsing verrichtte. Dit werd gedaan bij 22 acute midschacht Robinson type 2B1 claviculafracturen . Een statistisch significant verschil in absolute verkorting (4,5 mm), relatieve verkorting (3,2%) en verticale verplaatsing (odds ratio 4,7) tussen de liggende en staande projecties werd gevonden. Verschillen in oriëntatie van de arm tijdens de beeldvorming resulteerden niet in verschillen in gemeten verkorting of verticale verplaatsing en zijn daarom mogelijk minder klinisch relevant. Er werden ook geen statistisch significante verschillen tussen de 15° caudo-craniale en 15° cranio-caudale projecties gevonden met betrekking tot de verkorting en verticale verplaatsing. Dit is in tegenstrijd met de resultaten gevonden in **hoofdstuk 5**. Deze verschillen kunnen worden veroorzaakt door inherente verschillen tussen digitale reconstructies van CT-scans en het gebruik van de daadwerkelijke röntgenfoto's. Een andere verklaring is dat digitale reconstructies een statische representatie is van de claviculafractuur terwijl dit mogelijk niet het geval is tijdens het gebruik van daadwerkelijke röntgenfoto's. Het is mogelijk dat er bij het gebruik van grotere projectiehoeken (dat wil zeggen 30° caudo-craniale en 30° cranio-caudale projecties) er wel een statistisch significant en mogelijk klinisch relevant verschil kan worden geïdentificeerd. Verder onderzoek is nodig om dit verder te evalueren.

Wel werd er een odds ratio van 5,9 gevonden dat caudo-craniale projecties vaker in een hogere categorie van verticale verplaatsing werd gescoord. Hoewel er in **hoofdstuk 6** geen statistisch significante verschillen in verticale verplaatsing tussen verscheidene projecties werden gevonden, zijn de in dit onderzoek gevonden verschillen in overeenstemming met de bevindingen in hoofdstuk 7. Deze zouden dus de grotere keuze voor chirurgische behandeling op de caudo-craniale projectie van dezelfde fractuur kunnen verklaren.

DEEL B: INNOVATIES IN DE OPERATIEVE BEHANDELING VAN MIDSCHACHT CLAVICULAFRACTUREN.

Hoofdstuk 9 beschrijft een eerste systematische review in zijn soort die tot doel heeft een overzicht te creëren van de functionele uitkomsten en complicaties per beschikbaar intramedullair implantaat in de behandeling van midschacht claviculafracturen. Dit werd belangrijk geacht omdat de implantaten aanzienlijk verschillen in hun specificaties en kenmerken waardoor het complicatieprofiel dus ook zou kunnen variëren. In deze studie werden goede functionele resultaten en union rates gevonden, ongeacht het type implantaat. De meest voorkomende complicaties na intramedullaire fixatie zijn implantaat-gerelateerd en implantaat-specifiek. Voor de TEN zijn dit hardware irritatie en protrusie/migratie, met een respectievelijke gerapporteerde gepoolde incidentie van 20% en 13%. De verklaring voor deze bevinding kan zijn dat de TEN de midschacht claviculafractuur in lijn kan brengen maar zich niet fixeert in de breukelementen. Deze TEN-specifieke complicaties leiden tot infectie, weke delen problemen, pijn, re-interventies (verwijdering of extra inkorting) en verlies van repositie met de daaropvolgende secundaire verkorting. Voor de Rockwood/Hagie Pin bleek dat hardware-irritatie de meest voorkomende complicatie is met 21%. Dit kan worden verklaard door de twee moeren die worden geplaatst aan de buitenzijde van de posterolaterale cortex. De meest voorkomende complicatie voor de Sonoma CRx was cosmetische ontevredenheid in 7% van de gevallen. Er lijken geen klinisch relevante verschillen in hardware falen tussen de soorten implantaten te bestaan. De gepoolde incidentie voor non-union met behulp van de Rockwood / Hagie-pin was 6% vergeleken met respectievelijk 3% en 2% voor TEN en Sonoma CRx. Wat verder opviel tijdens het analyseren van de beaschikbare data was dat de meeste publicaties geen duidelijke oorzaken voor implantaat falen geven en geen verslag doen van de maatregelen die zijn getroffen bij het optreden van een infectie. Tevens wordt er vaak ook helemaal geen informatie over implantaatmigratie of secundaire verkorting gegeven. Tot slot rapporteren slechts weinigen specifiek de aanwezigheid of afwezigheid van bepaalde relevante complicaties zoals de eerder genoemde secundaire verkorting, neuropathie van de n.supraclavicularis, delayed union en aanhoudende pijn. Deze informatie zou volledig moeten worden gerapporteerd in toekomstige studies. Deze systematische review identificeerde het voorkomen van de verschillende nadelen en complicaties per intramedullair implantaat. Het is aan te bevelen om hier rekening mee te houden tijdens het ontwerpen van toekomstige implantaten.

Bij het ontwerpen van een nieuw medisch hulpmiddel voor de behandeling van mid-schacht claviculafracturen is het noodzakelijk om kennis te hebben van de krachten die op de clavicula werken tijdens de bewegingen van de schouder gedurende dagelijkse activiteiten. In **hoofdstuk 10** werd één van de meest gedetailleerde en gevalideerde biomechanische computermodellen van het de bovenste extremiteit (het Delft

Shoulder and Elbow Model (DSEM)) gebruikt om deze krachten te berekenen. Maximale compressiekrachten langs de x-as van 97 N tijdens abductie en 91 N tijdens elevatie werden berekend. Er werden geen distractiekrachten langs de x-as gesimuleerd. Alle maximale momenten traden op buiten het middelste derde deel. De rotatiekrachten rond de lengteas van de clavicula waren het kleinst, iets wat theoretisch te verwachten is vanwege de korte hefboomarm, maar wat wordt gevreesd door clinici, omdat dit een van de redenen is voor het falen van plaatfixatie. Verder werd gevonden dat tijdens abductie en elevatie in het interval van 90-120 graden de gesimuleerde krachten in de clavicula afnamen. De meeste fysiotherapie protocollen beperken aanvankelijk beweging boven de 90 graden. De bevindingen van deze studie roept vragen op over de noodzaak van deze beperking.

Een van de beperkingen van dit onderzoek is de validiteit van de voorspellingen van de DSEM en de aannames die tijdens de berekeningen zijn gemaakt. De krachten die op de clavicula inwerken, zijn mogelijk onderschat door het onvermogen om spier co-contracties te verwerken in de inverse dynamische modelleringsbenadering die hier wordt gebruikt en door de externe krachten die op de hand worden uitgeoefend tijdens de ADL-taken. Deze limitaties introduceren een onbekende foutenmarge in de resultaten. Echter is de DSEM één van de beste simulatiemodellen die beschikbaar is en lijken de resultaten vergelijkbaar en realistisch met de directe biomechanische kadaver metingen bekend in de literatuur.

De resultaten van deze studie creëren een inzicht in de krachten en hun verdeling over de clavicula tijdens activiteiten van het dagelijks leven. Deze informatie kunnen van nut zijn bij de ontwikkeling van nieuwe fixatiemethoden voor claviculafracturen.

De resultaten van de studie in **hoofdstuk 10** zijn gebruikt tijdens het ontwerp en de ontwikkeling van de Anser Clavicle Pin. Zoals vermeld in de inleiding, kan een verbetering in de operatieve behandeling niet alleen een aanpassing van de huidige technieken vereisen, maar mogelijk de introductie van een geheel nieuw concept. **Hoofdstuk 11** beschrijft het concept achter de Anser Clavicle Pin. De Anser Clavicle Pin zorgt voor de repositie van de breukdelen en het behoud van de lengte op een intramedullaire wijze, terwijl rotatie om de lengte-as kan blijven plaatsvinden. Het doel van de studie beschreven in dit hoofdstuk was om de union rate, functionele uitkomsten en complicaties van de Anser Clavicle Pin te evalueren. Een union rate van 100% en uitstekende functionele uitkomsten, gemeten met de Constant Murley- en DASH-scores, werden gevonden. Er werden geen infecties gezien. Neuropathie van de n.supraclavicularis is één van de meest ondergeregistreerde complicaties met betrekking tot de operatieve behandeling van midschacht claviculafracturen. Er werd in deze studie geen neuropathie van de supraclaviculaire zenuw waargenomen na 1 jaar follow-up. Eén van de 18 patiënten met de Anser Clavicle Pin in situ bij de 1-jaars follow-up rapporteerde minimale hardware-irritatie, welke geen verwijdering behoefde.

Het weinige voorkomen van hardware-irritatie wordt waarschijnlijk gerealiseerd door het ontwerp van de Anser Clavicle Pin. Door de specifieke manier van plaatsen via de posterolaterale zijde is het minimaal prominent en bedekt is met meer weefsels dan bijvoorbeeld een TEN of plaat.

Drie implantaat-gerelateerde complicaties werden gerapporteerd en de onderliggende oorzaken hiervoor zijn hoogstwaarschijnlijk geïdentificeerd waardoor ze in de toekomst voorkomen kunnen worden. Een gemiddelde operatietijd van 43,0 minuten werd geregistreerd. Deze tijd kan waarschijnlijk verder worden verkort met meer ervaring en door het maken van een extra incisie over de fractuur. Uit de huidige studie blijkt namelijk dat deze tweede incisie de union rate niet beïnvloedt en geen neuropathie van de n.supraclavicularis veroorzaakt. Het extra voordeel van de accessoire incisie is dat deze een directe visualisatie van de fractuurdelen mogelijk maakt waardoor het opvoeren van de Anser Clavicle Pin gemakkelijk en veilig kan gebeuren. Gesloten repositie kan mogelijk worden verbeterd door een vroegere interventie (<3 dagen na trauma).

De Anser Clavicle Pin zorgt voor vroege en adequate pijnreductie en laat een vroege revalidatie toe. Er werd een terugkeer naar de pre-operatieve gezondheids-gerelateerde kwaliteit van leven na 6 maanden follow-up gevonden.

De Anser Clavicle Pin resulteerde in een uitstekende union rate, functionele uitkomsten en patiënttevredenheid. Het had weinig niet-implantaat-gerelateerde complicaties en de implantaat-gerelateerde complicaties die zich in deze serie hebben voorgedaan kunnen met de kennis uit deze studie in de toekomst worden voorkomen.

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Research data management

The data used in this thesis was managed according to the FAIR principles, as first published by Wilkinson et al. (2016) in Nature, in order to enhance and improve Findability, Accessibility, Interoperability and Reuse of research data.

The data obtained for **chapters 2, 3 and 9** are extracted from the current body of literature and can be accessed by using the search strategy as specified in the corresponding appendices.

All data used for **chapters 4, 5, 6 and 7** were extracted from readily available CT scans in our hospital's PACS system. The medical and ethical review board Committee on Research Involving Human Subjects Region Arnhem-Nijmegen, Nijmegen, the Netherlands has given approval to conduct these studies. Informed consent was obtained for participants in chapters 4 and 5. Data were stored in Castor EDC and in the Digital Research Environment (DRE), a cloud-based globally available research environment where data is stored and organized securely. De-identified data from these databases were used to conduct the studies in **chapters 6 and 7**. These datasets can be made available from the corresponding author upon reasonable request.

The three-dimensional kinematic data of the forearm, humerus, scapula, clavicula and thorax used in **chapter 10** were obtained from the publicly available Shoulder Movements Database.

The data obtained for the studies involving human participants, **chapters 8 and 11**, were conducted in accordance with the principles of the Declaration of Helsinki. The medical and ethical review board Committee on Research Involving Human Subjects Region Arnhem-Nijmegen, Nijmegen, the Netherlands has given approval to conduct these studies.

All paper data-gathering forms in these studies were scanned and saved to the Digital Research Environment (DRE). All other data were stored in Castor EDC. All radiographic data were stored in the hospital's PACS system. Monitoring was performed by the Radboud Technology Center. The privacy of the participants was ensured by use of unique individual subject codes. The code master key was stored separately from the study data. The data will be saved for 15 years after termination of the study (chapter 8: 2018, chapter 11: 2019). Using these patient data in future research is only possible after a renewed permission by the patient. The datasets analyzed during these studies are available from the corresponding author on reasonable request.

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- Acknowledgements / Dankwoord
- List of publications and presentations
- Curriculum vitae

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Presentations

Hoogervorst P, Konings P, Hannink G, Holla M, Schreurs BW, Verdonschot N, van Kampen A. Functional Outcomes, Union Rate and Complications of the Anser Clavicle Pin at 1 year: A novel intramedullary device in managing midshaft clavicle fractures. European Federation of National Associations for Orthopaedics and Traumatology (EFORT) Annual Meeting 2020, E-Poster Presentation.

European Society for Surgery of the Shoulder and the Elbow (SECEC-ESSSE) Annual Meeting 2020, E-Poster Presentation.

Nederlandse Vereniging voor Traumachirurgie Traumadagen 2019, Amsterdam, the Netherlands, Podium Presentation.

Hoogervorst P, Appalsamy A, Meijer D, Doornberg JN, van Kampen A, Hannink G. *Does altering projection of the fractured clavicle change treatment strategy?* Orthopedic Trauma Association (OTA) Annual Meeting 2018, Orlando, USA, Poster Presentation.

Working ZM, El Naga AN, Hoogervorst P, Knox R, Marmor M. *Identification of Subtle Residual Sacroiliac Joint Flexion in AO/OTA 61-C1.2 (APC3) Pelvic Injuries After Anterior Fixation*. Orthopedic Trauma Association (OTA*)* Annual Meeting 2018, Orlando, USA, Poster Presentation.

CURRICULUM VITAE

Paul Hoogervorst was born April 23rd 1981 in Lelystad, the Netherlands. After finishing secondary school (VWO) in 1998 at O.S.G. De Rietlanden in Lelystad, he obtained his propedeuse in Medical Biology in 1999 before commencing his medical training at the Vrije Universiteit, Amsterdam. After graduating medical school in 2006 he gained clinical experience as a non-training resident in Ziekenhuis Amstelland Amstelveen, Westfriesgasthuis (now Dijklander Ziekenhuis) Hoorn, Sint Lucas Andreas Ziekenhuis (now OLVG West) Amsterdam and Radboud UMC Nijmegen. The General Surgery portion of his residencies he completed at the OLVG East Amsterdam (2010-2011). During his Orthopedic Surgery residencies, he rotated through the Radboud UMC Nijmegen, Sint Maartenskliniek Nijmegen, Rijnstate Ziekenhuis Arnhem and returned to the OLVG East Amsterdam for a differentiation in upper extremity pathology (2012-2016). During his residencies he formulated the concept behind the Anser Clavicle Pin which was subsequently patented, developed in conjunction with the Radboud UMC and BAAT Medical BV. This partnership was able to secure multiple grants to finance these endeavors which led to a medical device that is now CE certified and FDA approved. The interest in clavicular pathology and the desire to further develop his scholarly capabilities led to his pursuit to complete this thesis and obtain his PhD degree. Simultaneously to these activities he successfully completed all steps of the United States Medical Licensing Examination (USMLE) and in 2017 he moved with his family to San Francisco, CA, the birthplace of his wife Joanna Mednick. In the US he completed a Trauma/Research Fellowship at UCSF, San Francisco, CA, a Sports Orthopedics Fellowship at SOAR, San Francisco, CA and an Arthroplasty Fellowship at the University of Minnesota, Minneapolis, MN. In 2020 he will continue his career at the University of Minnesota, Minneapolis, MN as an attending orthopedic surgeon.

Paul is the proud father of his son Liam, daughter Quinn and dog Ella.