Outcome after plate and intramedullary fixation of displaced midshaft clavicle fractures; a search for the optimal surgical treatment

Olivier A.J. van der Meijden

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Outcome after plate and intramedullary fixation of displaced midshaft clavicle fractures; a search for the optimal surgical treatment

Uitkomsten van plaat en intramedullaire fixatie van gedisloceerde midschacht clavicula fracturen; op zoek naar de optimale chirurgische behandeling

(met een samenvatting in het Nederlands)

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CHAPTER I

General introduction, aims and outline

INTRODUCTION

The clavicle or collar bone is an S-shaped long bone which, by its horizontal orientation, forms a strut between the sternum and the scapula. The name originates from the Latin word *clavis* which means *key*. Clavicula is a diminutive of *clavis* and means *small key*, referring to its size and the fact that the clavicle is able to rotate around its axis enabling full range of motion of the shoulder girdle. This introduction highlights key elements of clavicle fractures and treatment thereof. All these will be further explored in this thesis.

Fractures of the clavicle; classification and history

Studies indicate that 29 – 64 per 100.000 adolescents and adults suffer from a clavicle fracture each year and that clavicle fractures account for 2–5% of all fractures in adults.[1] In the late 1960's Allman was the first to propose a classification of clavicle fractures based on the anatomic location of the fracture site; fractures of the medial (5%), middle (80%) and lateral third (12-15%) of the clavicle.[2-4] Since then several other classification systems have evolved. The Robinson classification is currently the most widely used classification system.[5] Although still based on the anatomic location of the fracture site, the degree of fracture dislocation has been added. This classification system has proven to be highly predictive of patient outcome in relation to both nonoperative and operative treatment.[6]

Clavicle fractures have been an ongoing topic of debate and recordings on treatment strategies date far back. As early as 3550 BC the earliest description of reducing a clavicle fracture was noted by an unknown Egyptian surgeon; 'thou shouldst place him prostrate on his back with something folded between his shoulder blades, thou shouldst spread out with his two shoulders in order to stretch apart his collar bone until break falls into place'.[7] In 400BC, Hippocrates had already recorded that a fracture is almost impossible to maintain reduced without surgical fixation,[8,9] confirmed by many in the years to follow. By 1927, Kreisenger had found writings on 200 devices to aid in the treatment of clavicle fractures. Additional 'historical merits' include the death of William III, Prince of Orange, in 1702 and of Sir Robert Peel, Prime Minister of the United Kingdom, in 1850 following horse riding accidents. Both men died of the complications after suffering from a clavicle fracture.[10]

Benefits of surgery

Historically, general consensus was that the vast majority of clavicle fractures heal well without operative intervention. Other than 'traditional' indications for surgical intervention such as neurovascular compromise and open fractures, operative management remained somewhat controversial and quite often it still forms an ongoing topic of debate.[11]

More recent studies, however, point

out that an exception should be made for the subgroup of patients with displaced fractures of the middle third of the clavicle, from hereon called displaced midshaft clavicle fractures (DMCF). Reported patient outcomes improve following operative reduction and fixation and the risk of mal- and nonunions is significantly reduced.[12-14] In addition, due to fracture fixation patients are usually able to return to daily activities quickly following surgery. Athletes, for instance, therefore suffer only a short leave of absence from competition. An incredible example of this is the MotoGP World Champion of 2012, Jorge Lorenzo. The Spanish motor cycle road racer suffered from a DMCF after falling of his bike in a practice session for the Dutch TT in 2013. He then underwent surgical plate fixation of his fracture and finished 5th in the Grand Prix within 24 hours after surgery.

How to operate; that's the question!

This subgroup of patients, who suffer a DMCF, forms the leading object of this thesis. Open reduction and internal plate fixation (PF) is considered to be the golden standard when it comes to operative intervention. However, there is also a considerable amount of surgeons that favor (closed) reduction and intramedullary fixation (IMF) using a nail or pin. To date, study results do not clearly support one or the other technique. The main objective of this thesis is to directly compare these surgical techniques.

Reporting on treatment outcome

The development of a shoulder disability questionnaire dates back to the late 1980's.[15] Initially focusing on objective outcome scores, the use of subjective results is increasing in current daily practice.[16] The most extensively studied and used tool to assess shoulder function is the Disability of the Arm, Shoulder, and Hand scale (DASH).[17,18] It was originally developed to quantify disability in patients with upper extremity musculoskeletal conditions and meanwhile its usefulness across the whole extremity has been confirmed.[19] The Surgical Therapeutic Index (STI) is an alternative way to present the benefits and risks of surgical treatment, and provides an additional tool in deciding on optimal surgical treatment. Derived from the therapeutic index in pharmacology and first applied in incontinence surgery, the STI is yet to make its introduction in trauma surgery. The STI is defined by dividing a procedure's cure rate by its complication rate. The index should be interpreted as expressing a certain level of safety; the higher a procedure's STI, the higher the benefit/risk balance of that procedure.[20]

Biomechanical aspects of clavicle fracture fixation

The goals of fracture fixation include early mobilization and prevention of nonunion. The choice of implant affects the strength of the repair construct which in turn might influence progress of rehabilitation and perhaps also the rate of recovery. The past decade has shed increasing light on the biomechanical properties of various repair constructs which can possibly be translated into clinical practice. A recently identified possible complicating factor of clavicle fractures is that shortening of the clavicle after sustaining a fracture might contribute to altered scapulothoracic kinematics, leading to shoulder discomfort and pain.[21] Though restoration of physiological kinematics is a goal itself in many fields of (orthopaedic) surgery,[22] there is a paucity in data on the biomechanical influences of surgical procedures on scapulothoracic kinematics following clavicle fractures.

OUTLINE

Following this introduction and outline a general overview of clavicle fractures is provided in **Chapter II**. The results of systematic searches of complications occurring after operative fixation of DMCF are displayed in the next two chapters; complications after PF in **Chapter III** and after IMF in **Chapter IV**. The literature review of this thesis is concluded with **Chapter V** which provides an overview of current biomechanical qualities of both PF and IMF.

Chapter VI reports on the current status of clavicle fracture treatment by trauma and orthopaedic surgeons in the Netherlands. The main clinical component of this thesis commences with **Chapter VII** which depicts both objective and subjective results of a randomized controlled clinical trial of Plate Or Pin fixation of DCMF (the POP-study). The Surgical Therapeutic Index is introduced and applied on operative treatment of DMCF in **Chapter VIII**. Finally, the results of an experiment on scapulothoracic kinematics following either surgical fixation technique of DMCF are reported in **Chapter IX**.

AIMS

This thesis focuses on the operative treatment of displaced midshaft clavicle fractures (DMCF) and its' sequels. The aims of this thesis are;

1. To provide a general overview of clavicle fractures followed by a systematic report of current data on surgical complications of the most commonly used fracture fixation techniques and a comprehensive summary of the biomechanical characteristics of these techniques.

2. To reproduce the daily practice of management of displaced midshaft clavicle fractures among surgeons in The Netherlands.

3. To report objective and subjective results of a clinical trial comparing plate fixation and intramedullary fixation of DMCF and introduce the Surgical Therapeutic Index as an indicator of benefits and risks of surgical trauma care.

4. To study the scapulothoracic kinematics of patients after surgical fixation of DMCF in an experimental setting.

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CHAPTER II

Treatment of Clavicle Fractures; Current Concepts Review

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Olivier A.J. van der Meijden, MD[1]
Trevor R. Gaskill, MD[1,2]
Peter J. Millett, MD, MSc[1,2]

[1]The Steadman Philippon Research Institute, Vail, CO, USA
[2]The Steadman Clinic, Vail, CO, USA

ABSTRACT

Clavicle fractures are common in adults and children. Most commonly these fractures occur within the middle third of the clavicle and exhibit some degree of displacement. While many midshaft clavicle fractures can be treated non-surgically, recent evidence suggests that more Although the indications for surgical fixation of midshaft clavicle fractures remain controversial, they appear to be broadening.
Most fractures of the medial or lateral end of the clavicle can be treated non-surgically if fracture fragments remain stable. Surgical intervention may be required in cases of neurovascular compromise or significant fracture displacement. In children and adolescents these injuries mostly consist of physeal separations, which have a large healing potential and can therefore be managed conservatively. Current concepts of clavicle fracture management are discussed including surgical indications, techniques, and results.

INTRODUCTION

Approximately 2 – 5% of all fractures in adults and 10 – 15% in children involve the clavicle.[1-3] The incidence of this type of fracture in the adolescent and adult population is reportedly 29 - 64 per 100.000 annually.[2-4] Fractures of the clavicle also demonstrate a bimodal age distribution. Young males who are less than 30 years old and elderly patients over the age of 70 appear to be two distinct age groups at higher risk for clavicle fractures.[5]
In adults, more than two-thirds of these injuries occur at the diaphysis of the clavicle and are more likely to be displaced as compared to medial and lateral third fractures. In children, up to 90% of clavicle fractures are midshaft fractures.[2,6] Lateral third fractures are less common, accounting for approximately 25% of all clavicle fractures and are less likely to be displaced than those occurring in the midshaft. Medial third fractures comprise the remaining 2 – 3% of these injuries.[2-5,7,8]
Traditionally, nonsurgical management has been favored as the initial treatment modality for most clavicle fractures because of the high nonunion rates reported following operative treatment.[9,10] Although nonsurgical management may be optimal for many clavicle fractures, good outcomes of nonsurgically treated fractures are not universal.[11-14] Recent evidence suggests that specific subsets of patients may be at high risk for non-union, shoulder dysfunction, or residual pain after nonsurgical management.[15] In this subset of patients, acute surgical intervention may minimize suboptimal outcomes. Therefore, specific treatment of clavicle fractures should not be broadly applied, but rather individualized based on fracture characteristics and patient expectations.

The purpose of this review is to provide an overview of the current treatment strategies for clavicle fractures based on their anatomic location and stability. In addition, a necessary distinction is made between fractures in adults and the skeletally immature.

CLASSIFICATION OF CLAVICLE FRACTURES

A number of classification systems have been proposed to aid in the description of clavicle fracture patterns for clinical and research purposes.[1,2,4,7,16] To date, most modern clavicle fracture classification systems are primarily descriptive and not predictive of outcome. The first widely accepted classification system for clavicle fractures was described by Allman in 1967.[7] Fractures were classified based on the anatomic location of the fracture in descending order of fracture incidence. Type I fractures occur within the middle third of the clavicle, whereas Type II and Type III fractures represent involvement of the lateral and medial thirds respectively.

Fractures of the lateral third of the clavicle were further sub-classified by Neer, recognizing the importance of the coracoclavicular (CC) ligaments to the stability of the medial fracture segment.[1] A type I lateral clavicle fracture occurs distal to the CC ligaments resulting in a minimally displaced fracture that is typically stable. Type II injuries are characterized by a medial fragment that is discontinuous with the CC ligaments. In these cases the medial fragment often exhibits vertical instability after loss of the ligamentous stability provided by the CC ligaments. Type III injuries were characterized by an intra-articular fracture of the acromioclavicular joint with intact coracoclavicular ligaments. Though these fractures are typically stable injuries, they may ultimately result in traumatic arthrosis of the acromioclavicular joint. More subtle fractures may require special radiographic views for identification and may be mistaken for a first-degree acromioclavicular joint injury.

A more detailed classification system (Edinburgh Classification) was proposed by Robinson.[4] Similar to earlier descriptions, the primary classification is anatomically divided into medial (Type I), middle (Type II) and lateral (Type III) thirds. Each of these types is then subdivided based on the magnitude of fracture fragment displacement. Fracture displacement less than 100% characterizes subgroup A whereas those displaced more than 100% account for subgroup B. Type I (medial) and III (lateral) fractures are further subdivided based on articular involvement. Subgroup 1 represents no articular involvement and subgroup 2 is characterized by inter-articular extension. Similarly, Type II (middle) fractures are subcategorized by the degree of fracture comminution. Simple or wedge type fracture patterns make up subgroup 1 and comminuted or segmental fracture patterns represent subgroup 2.

Craig further modified Neer Type II lateral clavicle fractures by stressing the importance of the conoid ligament and separately classifying intra-articular and pediatric clavicle fractures.[16] A recent comparison of these classification systems revealed that Craig's classification was most prognostic when predicting delayed or non-union of lateral third fractures and Robinson's classification had the greatest prognostic value for middle third fractures.[8,16]

MEDIAL THIRD FRACTURES

Non-operative management

Fractures of the medial third of the clavicle (Edinburgh Type I) are nearly always treated nonoperatively. These clavicle fractures are uncommon, frequently non- or minimally displaced, and rarely involve the sternoclavicular joint.[2,4,14] In general, a sling or figure-of-eight brace is provided for comfort and, as pain allows, early range of motion is encouraged. Patient comfort plays a key role in the total duration of immobilization which generally varies between 2 and 6 weeks. A structured rehabilitation ensures a satisfactory outcome for most patients. In order to protect the healing clavicle it is important to avoid contact sports for a minimum of 4 – 5 months.

Surgical management

Surgical treatment of medial end clavicle fractures is indicated if mediastinal structures are at risk due to fracture displacement, in case of soft tissue compromise, or multiple trauma and/or floating shoulder injuries. Closed or open reduction should be performed to reduce the displaced fragment in an emergent fashion.[17,18]

When open reduction is necessary, several techniques have been described for internal fixation of fracture fragments. These include wire or plate fixation and interosseus sutures.[17-19] In general, Kirschner wire fixation has proven unsafe due to breakage and migration. By contrast, use of interosseus wires or suture and modified hooked Balser plate fixation appear more successful, but require a second operation for hardware removal.[17-19]

Children / Adolescents

Most injuries in children and adolescents involving the medial end of the clavicle consist of physeal separations. This is due to the fact that the medial epiphysis of the clavicle does not ossify until age 20 and ossification centers rarely fuse before age 25.[20] It is important, however, to differentiate physeal separations from true sternoclavicular (SC) joint dislocations because of the remodeling potential and treatment of these two diagnoses can differ greatly. A computed tomography (CT) scan can be helpful to distinguish these entities.[17,20]

Results

The results of nonsurgical treatment of fractures of the medial end of the clavicle are in general satisfactory, although the low prevalence of these fractures precludes detailed analysis.[4] Nonunion rates are reported between 4 and 8%, however, an increased risk of nonunion accompanies cases of complete fracture fragment displacement.[4,14] Reports detailing the surgical treatment of medial clavicle fractures are also small, providing only anecdotal experiences with surgical management.[17-19,21]

Authors' preferred treatment
Nonsurgical treatment should be the first treatment of choice in the vast majority of patients. However, considering the increased risk for fracture nonunion in case of complete fracture displacement, open reduction and internal plate fixation should be considered in these cases.

MIDDLE THIRD FRACTURES

Non-operative Management
The goal of clavicle fracture treatment is to achieve bony union while minimizing dysfunction, morbidity and cosmetic deformity. Historically the vast majority of clavicle fractures have been treated nonoperatively in the acute setting. This is largely due to reported nonunion rates of less than 1% and separate reports by Neer and Rowe in the 1960's suggesting operative intervention resulted in a more than three-fold increase in nonunion rate.[1,10] In addition, several studies reported high rates of patient satisfaction following nonoperative treatment.[12,21,22]
Nonoperative management remains the treatment of choice for nondisplaced midshaft clavicle fractures (Edinburgh Type IIA). Meta-analyses of 1145 non-operatively treated midshaft fractures, 986 of which were nondisplaced, demonstrated a nonunion rate of only 5.9%.[15] The nonunion rate for displaced fractures, however, was 15.1% when treated non-operatively. The nonoperative management is identical to that of fractures of the medial third.

Surgical Management
Definitive indications for acute surgical intervention include skin tenting, open fractures, the presence of neurovascular compromise, multiple trauma or 'floating shoulder'. Outside of these indications, the management of displaced fractures of the midshaft (Edinburgh Type IIB) remains somewhat controversial. Recent literature is challenging the traditional belief that midshaft clavicle fractures uniformly heal without functional deficit. This paradigm shift is supported by several (prospective) studies by (members of) the Canadian Orthopaedic Trauma Society who reported higher nonunion rates and functional deficits following nonsurgical treatment of midshaft clavicle fractures when compared to internal fixation.[23-25]
Others suggest that specific clavicle fracture types are at higher risk for poor patient reported outcomes.[15] To this end, a retrospective series of 52 nonoperatively treated patients revealed that displaced fractures with shortening of 2cm or more is predictive of higher nonunion or symptomatic malunion

rates.[11] Others have shown that nonunion rates may be as high as 20% in displaced and comminuted fractures after nonsurgical treatment and that strength and endurance deficits are more common in these cases.[4,24] These reports, in combination with a more prognostic classification system, have led many authors to recommend acute surgical fixation for these fracture subtypes.[14]

Therefore relative indications for acute surgical treatment may include younger, active patients with clavicle shortening greater than 1.5 – 2cm, significant cosmetic deformity, or multi trauma situations. Under these auspices surgical fixation may provide more optimal outcomes and earlier return to sport. Adequate counseling regarding the risks, benefits, and likely results of treatment should occur in these circumstances. Late intervention should be considered for persistently symptomatic nonunions, malunions or if acromioclavicular arthritic changes occur.

Open reduction and internal fixation of clavicle fractures can be performed using either plate or intramedullary pin fixation. Plate fixation can provide immediate rigid fixation, helping to facilitate early mobilization.[1,11,26,27] However, it is thought that superior clavicle plating may result in a greater risk to underlying neurovascular structures and may be more prominent than anterior plating or intramedullary pin fixation.[15,28] A study by Bostman reported that complication and reoperation rates may be as high as 43% and 14% respectively if hardware removal is considered.[29] Other reported complications include infection, hardware failure, and hypertrophic scarring.[29,30] The recent introduction of anatomically contoured clavicle plates may reduce the need for hardware removal.[23,31]

Antegrade or retrograde intramedullary pin fixation is typically a more cosmetic technique, requiring a smaller incision and less stripping of the clavicle compared to plate fixation. Intramedullary pins frequently cannot be statically locked, thereby providing less rotational and length stability compared to other fixation techniques.[10,32-34] The intramedullary pin also requires routine removal after clinical and radiographic evidence of healing. Reported complications for this specific technique include implant breakage, skin breakdown and temporary brachial plexus palsy.[35-37] A recent study reported major complications requiring revision surgery in 5 out of 58 analyzed patients. All revisions were done for fracture nonunion.[35]

Children / Adolescents

The treatment of choice in children and adolescents with midshaft clavicle fractures is less controversial than that of adults. Due to the remodeling capabilities of clavicle fractures in this age group, almost all fractures can be treated nonoperatively with a very low incidence of complications.[38-40] Those patients exhibiting skin perforation or neurovascular compromise may still benefit from operative intervention.[41] In addition, as in adults, the degrees of fracture shortening and displacement have recently been reported to predispose to malunion of clavicle fractures in adolescents. For these types of fractures, plate fixation proved a relatively safe and successful treatment to restore anatomy and shorten time to union.[42]

Supportive treatment in a sling or figure-of-eight brace is used for comfort. Sport participation should be avoided until radiographic evidence of healing which is typically a minimum of 6 to 8 weeks. Andersen et al[22] evaluated sling and figure-of-eight brace immobilization and reported no differences in overall alignment or union rates between the immobilization techniques. In this series, however, the sling was better tolerated by patients as compared to the figure-of-eight brace. Fracture healing is usually accompanied by a bump that will remodel over a number of months.[41,43]

Results

Reported outcomes of surgical treatment of midshaft clavicle fractures have become more favorable over the past two decades. A meta-analysis of current data on nondisplaced fractures suggested a relative risk reduction of 72% and 57% for nonunion as compared to nonoperative treatment using intramedullary or plate fixation respectively. For displaced fractures the relative risk reduction increased to 87% and 86% respectively.[15]

Patient-reported satisfaction scores may also be superior with early surgical management in some circumstances. A multicenter trial reported better functional outcomes, lower malunion and nonunion rates and shorter overall time to union in operatively treated clavicle fractures after plate fixation.[23] A significant improvement in functional outcome scores was also reported when operatively and nonoperatively treated fractures were compared. The authors note, however, that functional benefits are less clear when healed nonoperatively treated fractures and surgically treated injuries are evaluated. The most recently published trials comparing intramedullary pin and plate fixation reported high union rates and good functional outcome scores in both groups. Additionally, no significant difference in complications rates were found between the two techniques.[44,45]

Authors' preferred treatment

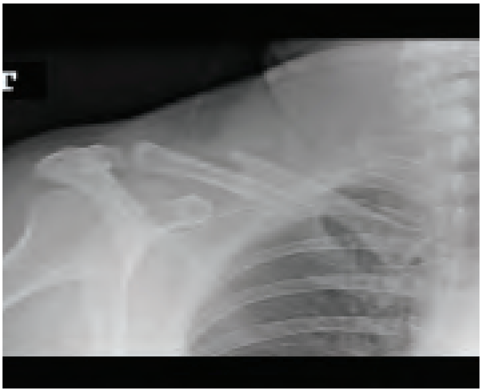
The management of midshaft clavicle fractures should be individualized to the patient's goals and activity level. We generally recommend acute intervention in active patients where displacement of the fracture fragments is greater than 100%, greater than 1.5 - 2 cm of shortening exists, or significant comminution is present. For most midshaft fractures that do not have excessive comminution or obliquity to the fracture planes, it is our preference to utilize intramedullary pin fixation to minimize fragment stripping, avoid supraclavicluar nerves compromize, achieve relative stability and to improve cosmesis (Figure IA-B).

In more comminuted fracture patterns, segmental fractures, or fractures with a large amount of obliquity, plate fixation is utilized. In the case of nonunions, the treatment of choice is usually open reduction and plate fixation (Figure IIA-B, video) with autogenous bone grafting. We use local bone graft in hypertrophic non-unions and iliac crest bone graft in atrophic nonunions.

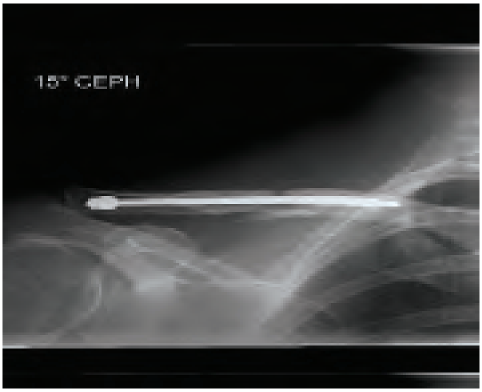
LATERAL THIRD FRACTURES

Non-operative Management

Because the majority of fractures of the lateral third of the clavicle are non- or minimally displaced and extra-articular, nonoperative treatment is typically the treatment of choice.[4,46] The rehabilitation and treatment modalities available are similar to those for nonoperative management of midshaft and medial end fractures.

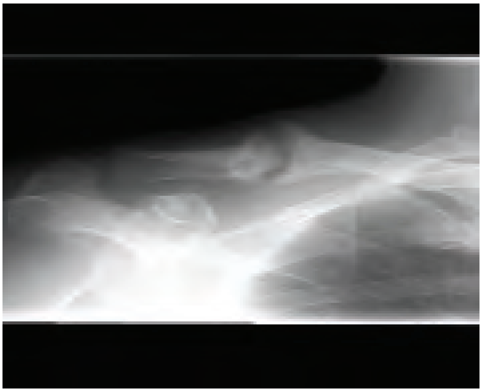


I. A

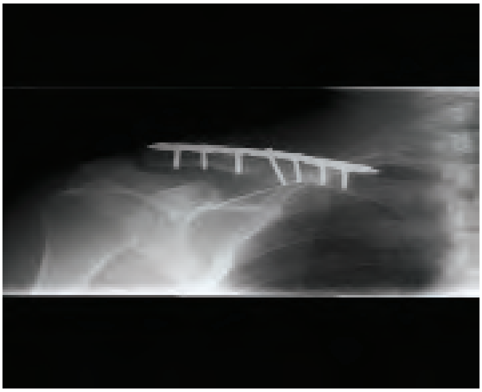


I. B

Figure I. Preoperative radiograph of right-sided, acute, displaced, midshaft clavicle fracture (A) and corresponding postoperative radiograph after intramedullary pin fixation (B).



II. A



II. B

Figure II. Nonunion of midshaft clavicle fracture (A) requiring open reduction and internal plate fixation (B).

Surgical Management

The indication for surgical treatment of lateral third clavicle fractures is based on the stability of the fracture segments, displacement and patient age. The integrity of the coracoclavicular ligaments plays a key role in providing stability to the medial fracture fragment. Displacement of the medial clavicle is seen when the coracoclavicular ligaments are disrupted (Edinburgh Type IIIB). It is established that this fracture configuration leads to nonunion rates as high as 28%.[1,4] Others have reported the risk of nonunion increases with advancing age and displacement.[14,47,48] Again, the presence of soft tissue compromise, multiple trauma and 'floating shoulder' are also indications for operative treatment.

Many surgical techniques have been proposed for fixation of lateral end fractures. These include Kirschner wire fixation,[49] coracoclavicular screws,[50] plate or hook-plate fixation[51,52] and suture and sling techniques.[52-55] However, reported complication rates limit their utility. For example, migration rates of up to 50% and failure of Kirschner wire fixation has led several authors to recommend it not be utilized as a primary fixation technique.[48,56,57]

Furthermore, the use of coracoclavicular screw fixation is limited by the fracture location and extent of comminution. In addition, screws must be routinely removed as they can limit shoulder girdle motion. Some failures noted in patients treated with coracoclavicular screw fixation are likely due to the combination of rigid (screw) fixation and the motion normally present at this location.

Plate fixation can also be utilized in circumstances where the distal fragment allows sufficient fixation.[47] A hook plate might be indicated if the distal fragment is inadequate for screw placement. This is performed in a fashion similar to standard plate fixation with the exception that distal fixation is achieved by placing the "hooked" end of the implant under the acromion to maintain a satisfactory reduction.

Finally, suture and graft sling techniques can be used to reconstruct coracoclavicular ligaments in a manner similar to anatomical acromioclavicular joint reconstruction. These techniques can be used to reinforce other fixation techniques or as the primary mode of reconstruction.[52-55]

Children / Adolescents

The physis of the lateral clavicle fuses around the age of 25. Therefore, most injuries to the lateral end of the clavicle result in physeal separation rather than fracture, since the acromioclavicular and coracoclavicular ligaments are biomechanically more robust than the physis. Because of the physeal injury, a large potential for healing and remodeling exists.[41] The majority of these injuries can therefore be treated with a period of immobilization. Indications for surgical intervention are infrequent, but include considerable displacement, soft tissue interposition, open injuries or risk to soft tissue structures in older adolescents.[58]

Results
Nonoperative management of lateral clavicle fractures results in a good outcome in up to 98% of minimally or non-displaced fractures.[14] Nonunion rates, however, are much greater for displaced fractures (Neer type II and Edinburgh type IIIB) and are reported as high as 33 % if treated nonsurgically.[1,2,4]
The timing of surgery for lateral end fractures seems more important for patient outcome when compared to medial third fractures.[47,49] Although the union rate does not seem to be influenced by acute or delayed treatment, the complication rate may be higher when the surgical treatment is delayed (7% vs. 36%).[47] Lateral clavicle fractures that exhibit intra-articular extension may result in an increased risk of acromioclavicular joint degeneration. If acromioclavicular arthrosis occurs, the patient may require a late distal clavicle excision.
Despite the limitations of coracoclavicular screw fixation, results of fracture healing and restoration of shoulder function are mostly favorable though only small cohorts have been reported.[60,61] Plates have also been used successfully, but complications such as peri-implant fracture, non-union, stiffness and arthritic progression are of concern in up to 15% of patients.[47,56,62] Finally, acceptable functional results and high union rates have been reported using suture or graft sling techniques to reconstruct coracoclavicular ligaments.[52-55]

Authors' preferred treatment
Nonoperative treatment is typically successful in cases where minimal to no displacement of the fracture fragments exist. However, when coracoclavicular ligament injury is present and fracture displacement exists, surgical fixation is typically recommended. If sufficient bone is available laterally for screw purchase, our preference is plate fixation. In cases where this is not possible we prefer to perform coracoclavicular ligament fixation to hold the fracture fragments in place while healing occurs. This is typically performed using a coracoclavicular fixation device with cortical buttons (Tightrope, Arthrex, Naples, FL, USA) or suture fixation device. Alternatively a hook plate can be used, but this requires removal and may increase the risk of traumatic arthrosis of the acromioclavicular joint.

CONCLUSION

Most medial and lateral ended fractures can be treated nonsurgically if fracture fragments remain stable. Surgical intervention may be required in cases of neurovascular compromise or significant fracture displacement. In children and adolescents these injuries mostly consist of physeal separations, which have a large healing potential and can therefore be managed conservatively.

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CHAPTER III

Systematic review of the complications of plate fixation of clavicle fractures

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Frans-Jasper G. Wijdicks, PhD[1]
Olivier A.J. Van der Meijden, MD[1,2]
Peter J. Millett, MD, MSc[2,3]
Egbert J.J.M. Verleisdonk, MD, PhD[1]
R. Marijn Houwert, MD, PhD[1]

[1]Department of Surgery, Diakonessenhuis, Utrecht, The Netherlands
[2]Steadman Philippon Research Institute, Vail, CO, USA
[3]The Steadman Clinic, Vail, CO, USA

ABSTRACT

Background

The number of displaced midshaft clavicle fractures (DMCF) treated surgically is increasing and plate fixation (PF) is often the treatment modality of choice. The study quality and scientific levels of evidence at which possible complications of this treatment are presented vary greatly in literature.

Purpose

The purpose of this systematic review is to assess the prevalence of complications concerning PF of dislocated midshaft clavicle fractures.

Methods

A computer based search was carried out using EMBASE and PubMed/MEDLINE. Studies included for review reported complications after PF alone or in comparison to either treatment with intramedullary fixation and / or nonoperative treatment. Two quality assessment tools were used to assess the methodological quality of the studies. Included studies were ranked according to their levels of evidence.

Results

After study selection and reading of the full texts, 11 studies were eligible for final quality assessment. Nonunion and malunion rates were less than 10% in all analysed studies but one. The vast majority of complications seem to be implant related, with irritation or failure of the plate being consistently reported on in almost every study, on average ranging from 9% - 64%.

Conclusion

The quantity of relevant high evidence studies is low. With low nonunion and malunion rates PF can be a safe treatment option for acute dislocated midshaft clavicle fractures, but complications related to the implant material requiring a second operation are frequent. Future prospective trials are needed to analyse the influence of various plate types and plate position on implant related complications.

INTRODUCTION

Clavicle fractures in adults occur quite frequently; approximately 5% of all fractures concern the clavicle. The vast majority of fractures, approximately 80%, is located in the midshaft of the clavicle and half of these fractures are displaced.[1,2] In the past, treatment of choice for most midshaft clavicle fractures was nonoperative with a sling or figure-of-eight bandage.[3,4] Reported nonunion rates following surgical fixation of clavicle fractures were initially higher than those reported following nonoperative treatment.[3,4] More recent studies, however, suggest higher complication and nonunion rates of up to 15% following nonoperative treatment, in particular for patients with displaced midshaft clavicle fractures (DMCF).[5-9] In addition, these patients are at high risk of residual pain, disappointing cosmesis and shoulder dysfunction.[5,6,8,10]

A regularly used surgical treatment option for DMCF is plate fixation (PF). An advantage of PF is the immediate stability it provides which enables early postoperative mobilization.[3,11,12] Several types of plates and fixation methods have been previously described; these include (precontoured) dynamic compression plates (DCP), tubular plates or reconstruction plates.[11,12] Although high success rates of PF of displaced clavicle fractures have been shown, reported complications of PF include implant failure, (deep) infections, implant prominence, poor cosmesis, nonunions and refracture as a result of removal of the plate.[13-15] The study quality and scientific levels of evidence at which complications are presented, however, vary greatly in literature. Different reviews are performed on clavicle fractures, but none of these reviews specifically address the complications of PF for DMCF.

This systematic review therefore aims at answering the following questions;

1. What is the incidence of minor and major complications after surgical PF of acute DMCF?
2. What is the value of reported complications in terms of the scientific level of evidence at which they are presented?
3. What are the frequency and severity of the long-term consequences of major complications after PF?
4. What conclusions may be drawn from these findings and how may it influence treatment of midshaft clavicle fractures?

METHODS

Search strategy

On April 4th 2011, a computer aided search using EMBASE and PubMed/MEDLINE was conducted using the first two phases of the optimal search strategy from the Cochrane Handbook (www.cochrane-handbook.com). This strategy was combined with a subject specific search (Appendix I). Reference and citation tracking was used to complete the search database.

Inclusion criteria

Studies included for review reported complications after acute, displaced, midshaft clavicle fractures treated with PF alone or in comparison to either treatment with intramedullary fixation and / or nonoperative treatment. (Degree of) fracture displacement had to be noted in the material and methods section for studies to be enrolled for further analysis. Studies in English, Dutch, German or French were assessed for inclusion. Case reports, biomechanical studies, papers describing a surgical technique and reviews were excluded from the database. Studies reporting on complications of the operative treatment of clavicle malunions, nonunions, open fractures, multiple fractures to the shoulder girdle, pathologic fractures, additional morbidity (i.e. floating shoulder) or fractures that had initial nonoperative treatment as starting point were also excluded.

Selection of studies
After the initial search strategy was performed, the remaining studies were screened for inclusion criteria based on their title / abstract by two researchers (F.J.G.W., O.A.J.v.d.M.). Studies eligible for inclusion, were additionally read completely for final inclusion. Finally, (prospective) trials without any notice of ethics committee consultation or approval were excluded from further assessment. Disagreement between the reviewers was resolved by discussion with another independent reviewer (R.M.H.).

Quality assessment
Two quality assessment tools were used to assess the methodological quality of the final selection of studies. Assessment was performed without masking the source or authorship of trial reports. The two tools used were the Level of Evidence (LoE) rating according to the Oxford Centre of Evidence Based Medicine (www.cebm.net) and the modified version of the Cochrane Bone, Joint and Muscle Trauma Group's former quality assessment tool (QAT, www.cochrane-handbook.com). Studies were first labelled according to their LoE (Level I; high evidence, Level II: moderate evidence, Level III: low evidence, Level IV: very low evidence). Secondly, the QAT was used to assess the research quality into more detail. The QAT is a tool that scores an article on 11 items: 7 items on internal validity and 4 items on external validity. The higher the QAT score, the better the methodological study quality with a maximum of 24. Disagreement between the reviewers about the quality assessment was again resolved by discussion with another independent reviewer (R.M.H.).

Data extraction and analysis
Included studies were ranked according to their levels of evidence. The study characteristics, including design, type and position of plate used for fixation and follow-up time were also taken into account. Complications following the PF of DMCF were identified and broken down into the following categories, if possible; bone-healing problems (nonunion and symptomatic malunion), infection (deep or wound), implant related problems (breakage, mechanical failure, irritation, angulation), plate debridement, removal or revision,

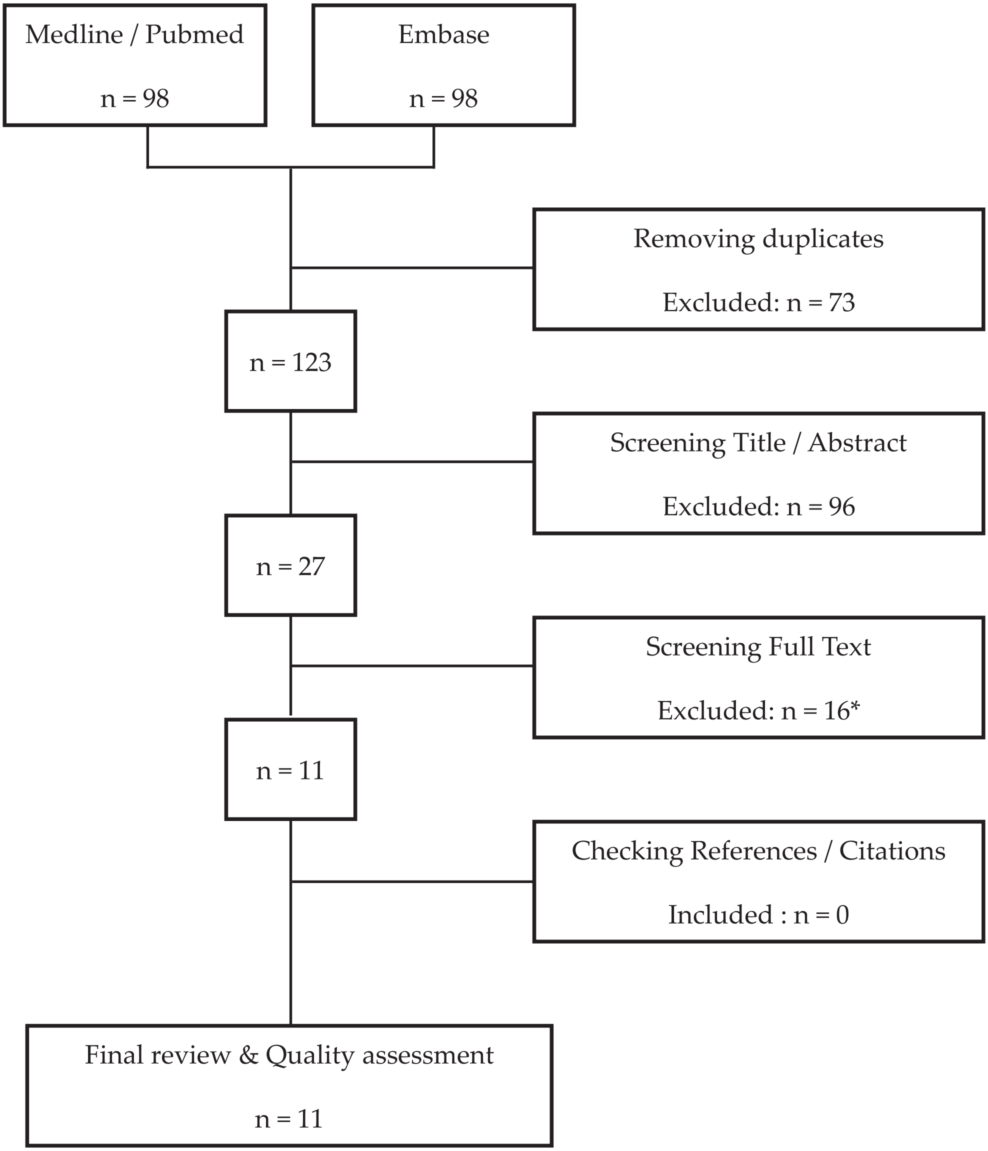

Figure I. Flowchart demonstrating the article search and appraisal process. Search was conducted on April 6th 2011.

* Excluded were one case report[29] and two studies in which there was no clear distinction made between postoperative complications after acute fractures and nonunions.[9,14] Seven studies included complicated fractures and made no distinction with uncomplicated fractures when describing complications.[3,8,15,18-20,32] One study was a surgical technique paper,[2] one study only reported outcomes and no complications,[28] 2 studies had no clear definition of indication for surgery[1,38] and, finally, two studies included different kinds of clavicle fractures (pathological, distal and nonunions).[11,26]

neurovascular problems (transient or persistent brachial plexus symptoms, regional pain syndrome), refracture after plate removal and other complications. These categories were further subcategorized into two groups; major and minor complications. Major complications are characterized as a complication that needs another surgery to either remove or revise the plate as a result of the complication presented. Major complications included:

Table I. Studies graded Level of Evidence I according to the Oxford Centre of Evidence Based Medicine (www.cebm.net).

Study Characteristics	**COTS[16]**	**Ferran et al.[17]**	**Shen et al.[18]**
Design	RCT; plating vs. non-operative treatment	RCT plating vs. pin fixation	RCT 'normal' plating vs. 3D aided plating
Number of plate fixations	n = 62	n = 15	n = 133
Type of plate (times used)	LCDCP (44) Reconstruction plate (15) Precontoured plate (4) Other (4)	LCDCP (15)	Reconstruction plate: 'Normal' (66) '3D-aided' (67)
Plate positioning	Superior	Superior	Superior
Mean follow up in months (range)	12	12 (5 - 28)	12
Complication rate			
Bone-healing problem;			
Nonunion	2 (3%)	0 (0%)	8 (12%) vs 1 (1%)
(Symptomatic) Malunion	0	n/a	n/a
Infection;			
Wound	3 (5%)	3 (20%)	12 (19%) vs 2 (3%)
Deep	n/a	n/a	n/a
Implant failure/irritation;			
Irritation	6 (10%)	3 (20%)	n/a
Mechanical failure	n/a	n/a	n/a
Plate debridement/removal/revision	6 (10%)	8 (53%)*	n/a
Neurovascular problems;			
Brachial Plexus symptoms	8 (13%)	1 (7%)	n/a
Regional Pain Syndrome	0	1 (7%)	n/a
Refracture after plate removal	0	n/a	n/a
Other	4 (6%)	n/a	0

RCT = Randomized Controlled Trial
3D = 3-dimensional
LCDCP = Limited Contact Dynamic Compression Plate
n/a = not applicable (complication not mentioned in study)
**One plate was removed because the patient was a high level athlete*

nonunions, symptomatic malunion, deep infections, mechanical failure, irritation, breakage of the implant, angulation and refracture after plate removal. Minor complications are characterized as a complication that does not need another surgery and where a small intervention (i.e. oral antibiotics) may suffice. Minor complications are: wound infection and neurovascular problems. To avoid misinterpretation, the definitions of various complications

Table II. Studies graded Level of Evidence II according to the Oxford Centre of Evidence Based Medicine (www.cebm.net).

Study Characteristics	**Kuhlshrestha et al.**[33]
Design	Prospective cohort; plating vs. non-operative treatment
Number of plate fixations	n = 45
Type of plate (times used)	Reconstruction plate (45)
Plate positioning	Superior (15) / Anterior-inferior (30)
Mean follow up in months (range)	12
Complication rate	
Bone-healing problem;	
Nonunion	2 (4%)
(Symptomatic) Malunion	n/a
Infection;	
Wound	4 (9%)
Deep	n/a
Implant failure/irritation;	
Irritation	n/a
Mechanical failure	n/a
Plate debridement/removal/revision	0
Neurovascular problems;	
Brachial Plexus symptoms	8 (13%)
Regional Pain Syndrome	0
Refracture after plate removal	0
Other	4 (6%)

n/a = not applicable (complication not mentioned in study)

Table III. Studies graded Level of Evidence III according to the Oxford Centre of Evidence Based Medicine (www.cebm.net).

Study Characteristics	**Vanbeek et al.[37]**	**Cho et al.[34]**
Design	Retrospective cohort study; Noncontoured plating vs. Contoured plating	Retrospective cohort study; Reconstruction plating vs. Reconstruction Locking plating
Number of plate fixations	n = 42	n = 41
Type of plate (times used)	Noncontoured (14); DCP (4) LCP (2) LCDCP (4) Reconstruction plate (4) Precontoured (28); Locking Clavicle Plate (28)	Precontoured; Reconstruction plate (19) Reconstruction LCP (22)
Plate positioning	Superior	Superior
Mean follow up in months (range)	12	13 (7 - 35) vs. 12 (7 -24)
Complication rate		
Bone-healing problem;		
Nonunion	0 vs 1 (4%)	0
(Symptomatic) Malunion	n/a	0
Infection;		
Wound	0 vs 1 (4%)	0
Deep	n/a	0
Implant failure/irritation;		
Irritation	9 (64%)* vs 9 (32%)	0
Mechanical failure	n/a	0
Plate debridement/removal/revision	3 (21%) vs 3 (11%)	n/a
Neurovascular problems;		
Brachial Plexus symptoms	n/a	n/a
Regional Pain Syndrome	n/a	2 (11%) vs 1 (5%)
Refracture after plate removal	0 vs 1 (4%)	0
Other	0 vs 2 (7%)	7 (39%) vs 5 (23%)

LCDCP = Limited Contact Dynamic Compression Plate
Reconstruction LCP = Reconstruction Locking Clavicle Plate
**Removed non-contoured plates included DCP (1), LCDCP (1) and Reconstruction Plate (1)*

Table III. Continued

Study Characteristics	**Liu et al.[35]**	**Thyagarajan et al.[36]**
Design	Retrospective cohort study; Plating vs. Pin fixation	Retrospective cohort study; Plating vs. Pin fixation vs. Non-operative treatment
Number of plate fixations	n = 59	n = 16
Type of plate (times used)	Reconstruction LCP (59)	LCDCP (16)
Plate positioning	Superior	Superior
Mean follow up in months (range)	12	6 (4 - 11)
Complication rate		
Bone-healing problem;		
Nonunion	6 (10%)	1 (6%)
(Symptomatic) Malunion	2 (3%)	n/a
Infection;		
Wound	6 (10%)	1 (6%)
Deep		1 (6%)
Implant failure/irritation;		
Irritation	12 (20%)	2 (13%)
Mechanical failure	4 (8%)	n/a
Plate debridement/removal/revision	14 (24%)	2 (13%)
Neurovascular problems;		
Brachial Plexus symptoms	n/a	4 (25%)
Regional Pain Syndrome	n/a	6 (38%)
Refracture after plate removal	n/a	n/a
Other	n/a	1 (6%)

stated in the reviewed studies were used in our analysis as much as possible.

RESULTS

A total of 196 articles were identified, of which 27 were potentially relevant after screening the title and abstract and excluding doubles (Figure I). Full text screening resulted in 11 studies eligible for final quality assessment. There was no disagreement between the reviewers about the selection of the 11 final articles.

Level of Evidence

Three studies were designed as randomized controlled trials and marked with the highest LoE (Table I).[16-18] All three studies report considerable wound infection rates (5% - 22%).[16-18] In addition, Shen et al.[18] report high non-union rates of 13% in comparison to Ferran et al.[17] and the COTS,[16] 0% and 3% respectively. They, on the other hand, reported significant rates of implant related problems requiring plate debridement, removal or even revision fixation, 10% and 53%.[16,17]

One study was graded LoE II, being designed as prospective cohort study and reported complications were mainly implant related (Table II).[33] A total of 4 studies were designed as retrospective cohort studies and therefore labelled as LoE III.[34-37] Again the main complications reported in these four studies were implant related problems (Table III). Finally, 3 studies were assigned to LoE IV, all of them being retrospective case series.[13,38,39] The majority of complications again concerned the used implants (Table IV).

A total of 10 of the 11 assessed studies reported usage of superior position for PF.[13,16,17,18,33-38] Anterior or anterior inferior plate positioning was analyzed in three studies.[13,33,39] The reconstruction plate and the low contact dynamic compression plate (LCDCP) were the two most commonly used types for PF.

Quality Assessment

The majority of studies had well defined in- and exclusion criteria, interventions and outcome measures. Adequate duration of follow up was considered a minimum of 1 year which applied to most studies (Table V). The study by the Canadian Orthopedic Trauma Society[16] was graded the strongest of selected studies and of highest scientific quality.

DISCUSSION

The goal of this systematic review was to document the (prevalence of) complications after PF of DMCF. To obtain the best available evidence, relevant studies were scored on scientific methodology and the level of evidence they provide. We attempted to find an answer to the following questions; (1) what is the incidence of minor and major complications after surgical PF of acute DMCF? (2) What is the value of reported complications in terms of the scientific level of evidence at which they are presented? (3) What are the frequency and severity of the long-term consequences of major complications after PF? And (4) what conclusions may be drawn from these findings and how may it influence treatment of midshaft clavicle fractures? In response to our second question we found that only three of the eligible studies provided the highest level of evidence.[16-18] Two of these studies included a sample-size calculation.[16,17] One study was a prospective cohort study but scored very well on quality assessment.[33] Based on their quality of methodology, we believe the studies by the COTS[16] and Kulshrestha et al.[33] to provide the best

Table IV. Studies graded Level of Evidence IV according to the Oxford Centre of Evidence Based Medicine (www.cebm.net).

Study Characteristics	**Russo et al.[38]**	**Verborgt et al.[39]**	**Bostman et al.[13]**
Design	Retrospective Case series	Retrospective Case series	Retrospective Case series
Number of plate fixations	n = 43	n = 39	n = 103
Type of plate (times used)	Mennen-plate	Precontoured; Reconstruction Plate (?) LCDCP (?)	DCP (57) Reconstruction Plate (46)
Plate positioning	Superior	Anterior	Anterior (57) Superior (46)
Mean follow up in months (range)	12	3	23 (6 - 53)
Complication rate			
Bone-healing problem;			
Nonunion	2 (5%)	2 (5%)	3 (3%)
(Symptomatic) Malunion	n/a	n/a	12 (12%)
Infection;			
Wound	0	4 (10%)	3 (3%)
Deep	0	3 (8%)	5 (5%)
Implant failure/irritation;			
Irritation	0	n/a	n/a
Mechanical failure	0	2 (5%)	16 (16%)
Plate debridement/removal/revision	13 (30%)*	7 (18%)	14 (14%) + 54 (52%)**
Neurovascular problems;			
Brachial Plexus symptoms	10 (23%)	3 (8%)	2 (2%)
Regional Pain Syndrome	n/a	n/a	n/a
Refracture after plate removal	n/a	2 (5%)***	1 (1%)
Other	2 (5%)	n/a	n/a

LCDCP = Low Contact Dynamic Compression Plate, DCP = Dynamic Compression Plate
n/a = not applicable (complication not mentioned in study)
**11 patients requested removal of the plate for cosmetic reasons / **54 patients underwent routine plate removal*
****Refractures both after fixatiion with LCDCP*

Table V. Quality assessment outcome of all analyzed studies according to the modified version of the Cochrane Bone, Joint and Muscle Trauma Group's former Quality Assessment Tool (QAT, www.cochrane-handbook.com).

Study	COTS[16]	Ferran et al.[17]	Kuhlshrestha et al.[33]	Shen et al.[18]	Liu et al.[35]	Cho et al.[34]
Allocation concealment	2	2	2	2	0	0
Intention-to-treat analysis	2	2	2	2	0	0
Assessor blinding	0	0	0	2	0	0
Comparable baseline characteristics	2	2	2	2	2	1
Participant blinding	0	0	0	2	0	0
Treatment provider blinding	0	0	0	0	0	0
Care program comparability	2	2	2	0	2	2
Defined in- and exclusion criteria	2	2	2	1	2	1
Well defined interventions	2	2	2	2	2	2
Well defined outcome measures	2	2	2	0	2	2
Clinically useful diagnostic tests	2	1	1	0	2	2
Adequate duration of follow-up	2	2	2	2	2	1
QAT Score	**18**	**17**	**17**	**15**	**14**	**11**

Study	Vanbeek et al.[37]	Russo et al.[38]	Bostman et al.[13]	Thyagarajan et al.[36]	Verborgt et al.[39]
Allocation concealment	0	0	0	0	0
Intention-to-treat analysis	0	0	0	0	0
Assessor blinding	0	0	0	0	0
Comparable baseline characteristics	2	0	0	2	0
Participant blinding	0	0	0	0	0
Treatment provider blinding	0	0	0	0	0
Care program comparability	2	0	0	0	0
Defined in- and exclusion criteria	2	1	2	2	1
Well defined interventions	1	2	2	1	1
Well defined outcome measures	2	2	2	2	2
Clinically useful diagnostic tests	2	2	1	0	1
Adequate duration of follow-up	0	2	1	0	2
QAT Score	**11**	**9**	**8**	**7**	**7**

available evidence.

In search of an answer to our first question we found nonunion rates were no higher than 10% in all analyzed studies but one.[13,16-18,33-38] If reported on, infection rates, both wound and deep infections, were also below 10% in all but two studies.[13,16-18,33-38] The vast majority of these infections were wound infections, reportedly treated successfully with oral antibiotics. Neurovascular complications included brachial plexus symptoms and regional pain syndromes and ranged in prevalence from 0% - 38%, all reportedly were transient.[13,16,17,34,36,38,39] Based on these figures the incidence of minor complications (wound infections and neurovascular problems) is low.

Regardless of the Level of Evidence provided, the vast majority of complications seem to be implant related, with irritation or failure of the plate being consistently reported on in almost every study, on average ranging from 9% - 64%.[16-18,33,35,37] This is a point of concern, considering that, even in the better designed studies, a second operation with plate debridement, removal or revision was required at best in 1 out of every 10 patients treated, in some studies even up to 1 out of every 2 patients.[13,16,17,33,35-38] There is a relatively small risk of refracture after plate removal, between 1% and 5%.[13,37,38] However, it must be noted that only 3 of the 11 analyzed studies report on these numbers. In one study two refractures after plate removal were reported.[38]

This study compared LCDCP plates and reconstruction plates, both refractures occurred after removal of LCDCP plates. Another study had a refracture after removal of a precountoured plate; the Locking Clavicle Plate.[18] The last refracture was reported after removal of an eight-screw dynamic compression plate.[13] The numbers presented above provide us with an answer to our third question. We conclude, based on the figures of plate debridement, removal or revision, that the incidence of major complications is high, ranging up to 64%. Major complications do require another surgery, but this surgery does treat the condition and complication and no long-term consequences are expected portraying low severity.

In light of our last question this review points out that implant related problems occur frequently. It is possible that the positioning of the plate anteriorly can decrease the number of complications. However, only one study mentioned that they felt that plate position initially influenced the outcome and complications of their treatment.[33] Additionally, plate type and pre-contouring to the anatomic shape of the clavicle may be of influence. However, the current numbers available are too small and study designs to different to make any assumptions.

Although not optimal with regards to methodological qualities, we included retrospective case series in our analysis. In some studies the complications were well documented and the reported complication rates were too high to ignore. In particular in the studies by Russo et al.[38] and Bostman et al.[13], the authors gave detailed descriptions of encountered complications and the complication rates are high.

There are some limitations to this review. Proceedings from annual meetings (conferences) were not included in this review. Only PubMed/EMBASE and the Cochrane databases were used for search. Therefore some valuable information might be lost. However, at proceedings mostly interim analyses are reported and these results might differ from the final results. PubMed and EMBASE are the largest medical databases. We thoroughly screened the studies and submitted them to a quality assessment which results in an evidence-based conclusion to what extend complications can be attributed to PF. Because of the different study-designs and characteristics, data could not be pooled and the data were summarized separately per study. We used the definitions of complications set forth in the analyzed studies to divide the complications in to six main categories. However, different authors may have used different definitions for complications i.e. deep, superficial and wound infections. In the future, improvements can be made concerning definitions of complications. Actual complication rates might be higher than many authors report, based on distinctions made between minor and major complications and overlap in definitions (e.g. failure or infection may result in removal, debridement or revision).

Based on the overall low numbers of reported nonunion and symptomatic malunion we conclude and answer our final question that PF is a safe treatment option for DMCF. However, this review also points out that complications related to the implant material are frequent, often requiring removal, revision or debridement of the plate. The quantity of high level of evidence studies to support this is limited. More prospective trials with well-defined complications as outcome measurements are needed to make more specific recommendations with regard to optimum plate position, the type of plate and possible postoperative complications regarding PF for DMCF.

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Appendix I.

PubMed/MEDLINE search string

((((((((midshaft[Title/Abstract]) OR shaft[Title/Abstract]) OR shafts[Title/Abstract]) OR mid[Title/Abstract]) OR midclavicle[Title/Abstract]) OR middle[Title/Abstract]) OR mid-third[Title/Abstract]) OR diaphysis[Title/Abstract]) OR diaphyseal[Title/Abstract])

AND

(((((((clavicular[Title/Abstract]) OR clavicula[Title/Abstract]) OR claviculae[Title/Abstract]) OR clavicle[Title/Abstract]) OR clavicles[Title/Abstract]) OR collarbone[Title/Abstract]) OR collarbones[Title/Abstract])

AND

(((((plating[Title/Abstract])OR plate[Title/Abstract]) OR plate-osteosynthesis[Title/Abstract]) OR plates[Title/Abstract]) OR plate-fixation[Title/Abstract])

AND

(((fractures[Title/Abstract]) OR fracture[Title/Abstract]) OR fractured[Title/Abstract])

Embase search string

midshaft:ab,ti OR shaft:ab,ti OR shafts:ab,ti OR mid:ab,ti ORmidclavicle:ab,ti OR middle:ab,ti OR third:ab,ti OR diaphysis:ab,ti OR diaphysial;ab,ti AND (clavicular:ab,ti OR clavicula:ab,ti OR claviculae:ab,ti OR clavicle:ab,ti OR clavicles:ab,ti OR collarbone:ab,ti OR collarbones:ab,ti) AND (plating;ab,ti OR plate:ab,ti OR plate-osteosynthesis:ab,ti OR plates:ab,ti OR plate-fixation:ab,ti) AND (fractures:ab,ti OR fracture:ab,ti OR fractured:ab,ti) AND [embase]/lim

CHAPTER IV

Systematic review of complications after intramedullary fixation for displaced midshaft clavicle fractures

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Frans-Jasper G. Wijdicks, PhD[1]
R. Marijn Houwert, MD, PhD[1]
Peter J. Millett, MD, MSc[2,3]
Egbert J.J.M. Verleisdonk, MD, PhD[1]
Olivier A.J. Van der Meijden, MD[1,2]

[1]*Department of Surgery, Diakonessenhuis, Utrecht, The Netherlands*
[2]*Steadman Philippon Research Institute, Vail, CO, USA*
[3]*The Steadman Clinic, Vail, CO, USA*

ABSTRACT

Background

The number of displaced midshaft clavicle fractures treated surgically is increasing and (closed) reduction and intramedullary fixation (IMF) is an upcoming surgical treatment option. The study quality and scientific levels of evidence at which possible complications of this treatment are presented vary greatly in literature.

Methods

Systematic computer based searches using online databases EMBASE and PubMed/MEDLINE were carried out. Studies included for review reported complications after IMF alone or in comparison to either treatment with plate fixation and / or nonoperative treatment. The Level of Evidence rating and Quality Assessment Tool were used to assess the methodological quality of the studies. Included studies were ranked according to their levels of evidence.

Results

A total of 6 articles were eligible for inclusion and final quality assessment after study selection and reading of the full texts. Three studies were graded the highest Level of Evidence. Major complications like bone-healing problems and deep infections requiring implant removal were reported no higher than 7%. Reported rates for minor complications, such as wound infection and implant irritation that could be resolved without further surgery, were as high as 31%.

Conclusion

The noted rates for major complications requiring additional surgery were low, but implant related problems that also require additional surgery might present with high prevalence. Due to routine implant removal, treatment with IMF often requires an additional surgical procedure.

BACKGROUND

Fractures of the clavicle account for 5% of all fractures, and 80% of these fractures are located in the middle third of this S-shaped bone.[1-4] The incidence of surgical treatment for completely displaced midshaft clavicle fractures (DMCF) is rising owing to poor results reported after nonoperative treatment for this specific subset of patients over recent years.[5-10]

Intramedullary fixation (IMF) has emerged as a promising alternative to traditional open reduction and internal plate fixation.[11] Advantages of this minimal invasive treatment option include maintaining the fracture hematoma and keeping the periosteum intact, which positively influences bone formation, and improves cosmetics due to the small incisions used.[11,12] Different techniques and examples of IMF devices have been reported and include the Hagie,[9] Knowles[13] and Rockwood[14] pins and Titanium Elastic Nails (TEN).[15]

A spectrum of possible postoperative complications, including pin migration, implant failure, deep and superficial infections, re-fractures and mal- or nonunions have been reported.[11,16] In the current literature, however, the scientific level of evidence for reported complications from IMF of DMCF and the quality of the studies reporting them varies.

The aim of this systematic review was to answer the following questions;

1. What is the incidence of major and minor complications due to IMF of acute displaced midshaft clavicle fractures?
2. What interventions are available for resolving major or minor complications?
3. What is the value of reported complications in terms of the scientific level of evidence and the quality at which they are presented?

METHODS

Search strategy

A computer-based search for relevant studies was carried out on June 1st, 2011, on EMBASE and PubMed/MEDLINE online databases. We consulted the Cochrane Handbook (www.cochrane-handbook.com) for an optimal search strategy. Using the first 2 phases of this strategy in combination with a subject-specific search, a study database was obtained. To ensure inclusion of all relevant studies, reference and citation tracking were performed.

Inclusion and exclusion criteria

Studies were included for quality assessment if they reported on acute, isolated, DMCF treated with IMF. Comparative studies in which IMF was compared with other treatment modalities were also eligible for inclusion.

Exclusion criteria were studies written in languages other than English, German, Dutch or French. Also, case reports, biomechanical studies, surgical technique studies, review papers and studies involving fewer than 10 patients were excluded. Studies reporting on IMF as a treatment for open fractures, pathological fractures, multitrauma, floating shoulders, nonunions or malunions and without a clear distinction in complication rates between these and isolated DMCF were also excluded.

Selection of studies

After completion of the initial search strategy, 2 researchers (F.J.G.W., O.A.J.v.d.M.) screened the title and abstracts of potential studies against the inclusion criteria. Studies were then thoroughly read to assess them for final eligibility. Disagreement between the reviewers was resolved by discussion with another independent reviewer (R.M.H.).

Quality assessment

Quality assessment was performed by 2 researchers (F.J.G.W., O.A.J.v.d.M.) on the final study selection without masking the source or authorship of trial reports. Studies were first labelled according to their level of evidence (LoE, Oxford Centre of Evidence Based Medicine, www.cebm.net). The LoE rating is divided into 4 levels: level I indicates high-evidence studies, level II moderate, level III low and level IV very low-evidence studies.

To further interpret methodological study quality, we used the modified version of the Cochrane Bone, Joint and Muscle Trauma Group's former quality assessment tool (QAT, www.cochrane-handbook.com). The QAT is a tool with 11 items (7 on internal validity and 4 on external validity) that can be used to score a study on methodological qualities. Scores can range from 0 to 24. Disagreement between the reviewers about the quality assessment was resolved by discussion with another independent reviewer (R.M.H.).

Data extraction and analysis

Studies were ranked according to their LoE. The study characteristics, including design, type of IMF and follow-up time were also noted. Complications of IMF were identified and categorized for each study. The categories included implant-related problems (medial/lateral protrusion, visible or palpable presence of the implant, migration/telescoping, displacement of the IM device with or without displacement of the fracture parts), infection (wound or deep), bone-healingproblems (nonunion, delayed union and symptomatic malunion), mechanical failure (angulation or breaking of IM device and corresponding irritation), refractures, nonroutine IM device removal and other complications. These categories were further subdivided into 2 groups: major and minor complications. Major complications were those requiring additional (nonroutine) surgery to either remove or revise IMF devices as a result of the complication presented. Major complications included nonunions, symptomatic malunions, deep infections requiring implant removal, breakage of the implant, angulation of the implant with persistent symptoms requiring removal and refractures after device removal. Minor complications were those not requiringadditional (non-routine) surgery but requiring nonoperative treatment to resolve (i.e., antibiotics in case of an infection). These included wound infections, deep infections not requiring implant removal or irrigation/debridement, irritation, migration and telescoping, angulation of the implant without persistent symptoms and neurovascular problems.

Irritation, migration and telescoping of the IM device can often be resolved by minimally invasive shortening of the device under local anesthesia.[11] Neurovascular problems have the tendency to be self-limiting over time.[11,17,18] To avoid misinterpretation,

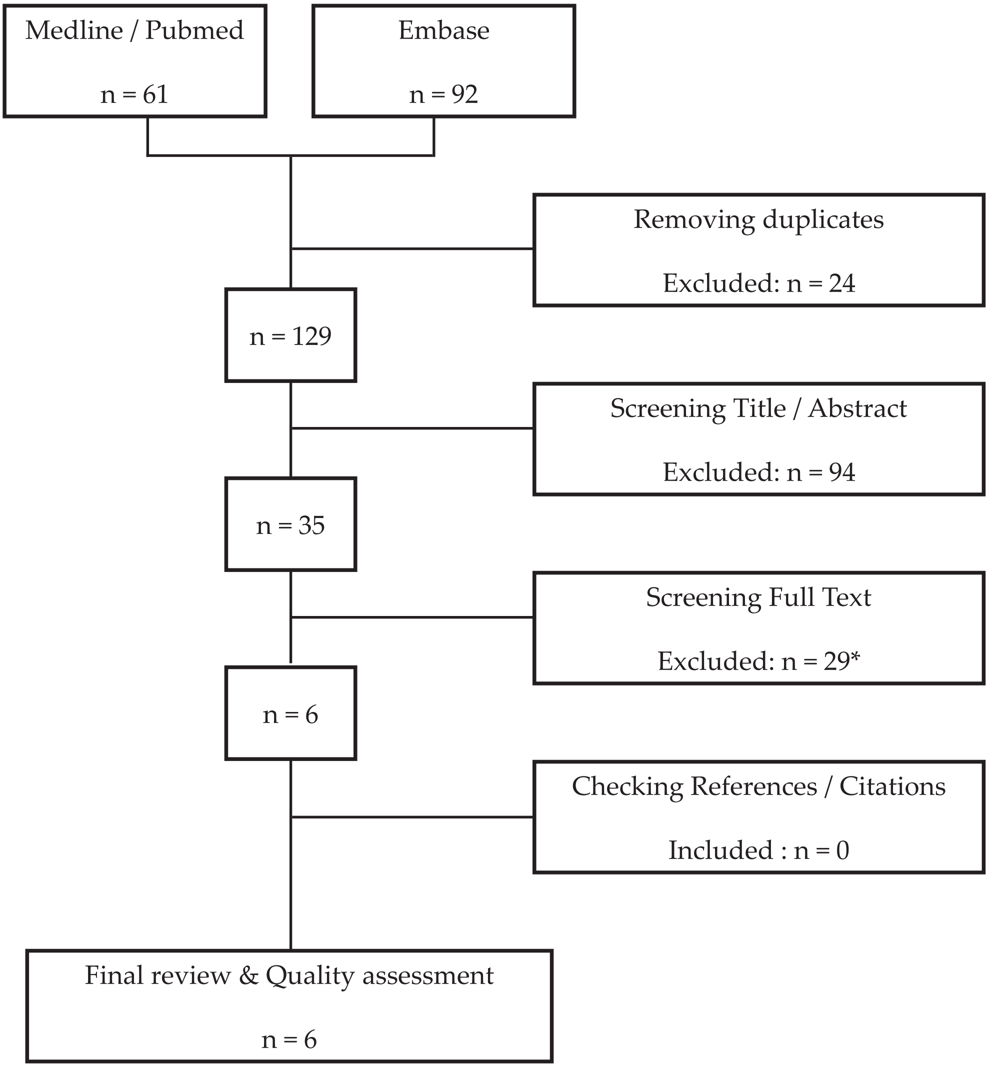

Figure I. Flowchart demonstrating the article search and appraisal process.
Search was conducted on January 7th 2011.
*Excluded were 1 review paper,[19] 4 studies in which there was no clear difference in postoperative complications made between closed and open clavicle fractures[13,20-22] and 11 studies which included additional morbidity (i.e. floating shoulders or ribfractures) but the authors made no distinction between complications after isolated clavicle fractures and fractures with additional injury.[14,23-32] Additionally, 6 studies included treatment of nonunions or delayed unions and did not make a distinction with the treatment of acute fractures when describing the complications,[16,33-37] 2 studies were surgical technique papers,[38,39] 1 study reported on plate fixation,[40] 1 study lacked a definition for dislocation,[41] 1 study did not make a distinction between angulation and communition,[42] one study included less than 10 patients[15] and finally, in 1 study[11] authors reported on a previously reported patient population.[43]

the definitions of various complications stated in the reviewed studies were used in our analysis as much as possible.

RESULTS

The search in PubMed/MEDLINE identified 61 articles; the search in EMBASE identified 92 articles. After checking for double entries, we excluded articles based on title and abstract content; 35 articles remained for full text screening. Finally 6 articles were eligible for inclusion and final quality assessment (Figure I). There was no disagreement between the reviewers about the selection of the 6 final articles.

Level of evidence

Three studies were assigned the highest LoE (Table I).[18,43,44] The rates of major complications like bone-healing problems and refractures were no higher than 7% in these 3 studies.[18,43,44] Judd and colleagues[18] reported 1 nonunion that required open reduction and plate fixation and 1 refracture after pin removal that was treated successfully with nonoperative treatment. Two studies reported a total of 3 delayed unions that all healed without further intervention.[18,43]

Regarding minor complications, Judd and colleagues[18] reported an implant-related irritation rate of 31% resulting in the early removal of 3 IM devices owing to wound infections (10%), but the authors made no mention of further treatment for the remaining 21% of patients. Smekal and colleagues[43] reported a rate of 20% for device protrusion, which was treated with shortening of the IM device under local anesthesia.

The study by Witzel[45] was assigned level II evidence (Table II). There were no major or minor complications reported in that series of 35 patients. One retrospective cohort study was assigned level III evidence (Table III).[17] This study reported 1 nonunion, 2 delayed unions and 4 malunions, but the authors did not describe treatment for these major complications. In addition, a 30% radiographic migration rate of the IMF devices was reported in this study; most patients, however, remained asymptomatic and did not require any additional treatment.[17]

Finally, 1 retrospective case series was assigned level IV evidence (Table IV).[46] In this study, Chen and colleagues[46] reported a rate of 7% for malunions, which did not require additional surgery. Most of the complications encountered were minor and involved a 20% rate of irritation, which was treated by device shortening under local anaesthesia. Finally, in 4 out of the 6 included studies all of the IM devices were routinely removed, according to the standard treatment guidelines in the authors' practices.[17,18,44,45]

Table I. Studies graded Level of Evidence I according to the Oxford Centre of Evidence Based Medicine (www.cebm.net).

Study Characteristics	Smekal et al.[43]	Ferran et al.[44]	Judd et al.[18]
Design	RCT: IMF vs. Nonoperative treatment	RCT: IMF vs. Plate fixation	RCT: IMF vs. Nonoperative treatment
Number of IM fixations	n = 60	n = 17	n = 29
Type of IM fixation	TEN	Rockwood Pin	Hagie Pin
Mean follow up in months (range)	24 (22 - 27)	12 (5 - 28)	3 (1 - 12)
Major complication rates			
Bone-healing problem;			
Nonunion	0	0	1 (3%)
Delayed union	2 (3%)	0	1 (3%)
(Symptomatic) Malunion	0	0	n/a
Infection; Deep	n/a	n/a	2 (7%)
Implant breakage / failure	2 (3%)	1 (6%)	1 (3%)
Refracture after pin removal	1 (2%)	n/a	2 (7%)
Minor Complications rates			
Implant related;			
Irritation	5 (5%)	1 (6%)	9 (31%)
Migration / Telescoping	7 (12%)	n/a	n/a
Medial / Lateral Protrusion	12 (20%)	n/a	n/a
Infection; Wound	1 (2%)	0	4 (14%)
Routine nail removal	n/a	17 (100%)	26 (90%)
Non-routine nail removal	0	0	3 (10%)
Neurovascular problems;			
Brachial plexus symptoms	0	2 (12%)	1 (3%)
Regional Pain Syndrome	0	0	n/a
IMF device shortening	12 (20%)	n/a	n/a

RCT = Randomized Controlled Trial
IMF = IntraMedullary Fixation
TEN = Titanium Elastic Nail
n/a = not applicable (complication not mentioned in study)

IV

Table II. Studies graded Level of Evidence II according to the Oxford Centre of Evidence Based Medicine (www.cebm.net).

Study Characteristics	**Witzel et al.[45]**
Design	RCT: IMF vs. Nonoperative treatment
Number of IM fixations	n = 35
Type of IM fixations	Prévot-Pin
Mean follow up in months (range)	19 (8 - 26)
Major complication rates	
Bone-healing problem;	
Nonunion	0
Delayed union	0
(Symptomatic) Malunion	0
Infection; Deep	0
Implant breakage / failure	0
Refracture after pin removal	0
Minor Complications rates	
Implant related;	
Irritation	0
Migration / Telescoping	0
Medial / Lateral Protrusion	0
Infection; Wound	
Routine nail removal	n/a
Non-routine nail removal	n/a
Neurovascular problems;	
Brachial plexus symptoms	0
Regional Pain Syndrome	0
IMF device shortening	n/a

RCT = Randomized Controlled Trial
IMF = IntraMedullary Fixation
n/a = not applicable (complication not mentioned in study)

Table III. Studies graded Level of Evidence III according to the Oxford Centre of Evidence Based Medicine (www.cebm.net).

Study Characteristics	**Chen et al.[17]**
Design	Retrospective case-control study: IMF vs Plate fixation
Number of IM fixations	n = 57
Type of IM fixation	TEN
Mean follow up in months (range)	24
Major complication rates	
Bone-healing problem;	
Nonunion	1 (2%)
Delayed union	2 (3%)
(Symptomatic) Malunion	4 (7%)
Infection; Deep	n/a
Implant breakage / failure	3 (5%)
Refracture after pin removal	1 (2%)
Minor Complications rates	
Implant related;	
Irritation	4 (7%)
Migration / Telescoping	17 (30%)
Medial / Lateral Protrusion	n/a
Infection; Wound	1 (2%)
Routine nail removal	n/a
Non-routine nail removal	n/a
Neurovascular problems;	
Brachial plexus symptoms	1 (2%)
Regional Pain Syndrome	0
IMF device shortening	n/a

TEN = Titanium Elastic Nail
IMF = IntraMedullary Fixation
n/a = not applicable (complication not mentioned in study)

Table IV. Studies graded Level of Evidence IV according to the Oxford Centre of Evidence Based Medicine (www.cebm.net).

Study Characteristics	**Chen et al.[46]**
Design	Prospective case-series: IMF
Number of IM fixations	n = 41
Type of IM fixation	TEN
Mean follow up in months (range)	15 (7 - 24)
Major complication rates	
Bone-healing problem;	
Nonunion	n/a
Delayed union	n/a
(Symptomatic) Malunion	3 (7%)
Infection; Deep	0
Implant breakage / failure	0
Refracture after pin removal	0
Minor Complications rates	
Implant related;	
Irritation	8 (20%)
Migration / Telescoping	0
Medial / Lateral Protrusion	1 (2%)
Infection; Wound	0
Routine nail removal	41 (100%)
Non-routine nail removal	0
Neurovascular problems;	
Brachial plexus symptoms	2 (5%)
Regional Pain Syndrome	n/a
IMF device shortening	n/a

TEN = Titanium Elastic Nail
IMF = Intramedullary Fixation
n/a = not applicable (complication not mentioned in study)

DISCUSSION

Our systematic review aimed at answering several questions regarding complications after IMF of DMCF. What is the incidence of major and minor complications? What interventions are available for resolving major or minor complications? And, finally, what is the value of reported complications in terms of the scientific LoE and the quality at which they are presented?

Reported rates for major complications like bone healing problems and deep infections requiring implant removal were no higher than 7%.[17,18,43–46] In addition, only 4 refractures after pin removal were reported in a total of 3 studies.[17,18,43] Therefore, overall, the rate of major complications requiring additional surgical treatment was low. Most complications were implant failures, breakages, irritations or implant migrations. Reported rates of minor complications were as high as 31%.

Major complications require an additional surgery (e.g., corrective osteotomy). Minor complications are resolved with antibiotics for wound infections or shortening of the IM device under local anaesthesia. Treatments for minor complications are non- or minimally invasive and therefore easy to resolve. Irritation is one of the main effects of migration, telescoping or protrusion. Three interventions seem to resolve most of these irritation related complications: shortening of the IM device, removal of the device or revision osteosynthesis. Migrating, telescoping or protruding devices may remain asymptomatic without requiring additional treatment, yet most IMF techniques require routine surgical device removal once fracture healing has occurred.[18,44–46] The vast majority of patients require additional surgical interventions, although these interventions are minor. An option for reducing medial protrusion (and thus irritation) might be the use of medial end caps. Frigg and colleagues[47] reported a reduction in medial protrusion rates by using an end cap for TENs.

The LoE and quality assessment tools were used to assess studies on methodological quality. Only 6 studies met our inclusion criteria, 3 of which provided the highest possible LoE. Therefore, studies on this specific subject with high-level evidence are scarce.

The optimal surgical technique to accomplish IMF is anecdotally harder to master than more traditional surgical fixation techniques. Reported operative outcome may be influenced by learning curves of the involved surgeons. Only 1 study included in our review mentioned the involved surgeon's experience with IMF.[45] In addition, depending on the IM device used, the degree of open fracture reduction varies. Theoretically, this may negatively affect infection rates due to increased exposure, cosmetic outcome due to an increase in incision length and fracture healing due to disruption of the periosteum and fracture hematoma. For instance, fixation with the Rockwood pin, requires open reduction,[44] whereas TEN fixation reportedly allows for closed reduction in 60%–85% of cases. In addition, the type of IM device may influence the rate of complications. Unfortunately, the current numbers available are too small and study designs too different to permit a thorough analysis.

Discussion of whether more complex fractures should then be treated with IMF may arise. The included studies did not answer that question. However, other studies that did not meet our inclusion criteria indicated that IMF might also be suitable for fixation of more complex fractures.[11,24,32]

In 3 of the studies included in our review, the IM devices were routinely removed upon fracture healing.[18,44,46] Device removal requires additional surgery with corresponding risks and complications (e.g., infection or refracture). However, it should be noted that these additional surgical procedures only require small incisions and have short durations.[17,44]

Limitations

The study design carries the risk of certain limitations. Only the PubMed/MEDLINE and EMBASE databases were used for our search. Proceedings of annual meetings were not taken into the account; therefore, valuable information might have been lost. However, usually only preliminary results are presented at (annual) meetings and they may differ from the final study results.

Owing to the different study designs and characteristics, data could not be pooled and were summarized separately per study. Available studies were only included if they reported on the treatment of isolated clavicle fractures. This strict inclusion criterion was chosen to avoid the possible influence of comorbidities on reported outcomes and complications. It has to be noted that studies reporting on a combination of clavicle fractures and lower extremity or rib pathology[35,36] were accordingly excluded, although the impact of the mentioned comorbidities on the outcome of the clavicle fracture treatment may not be severe.

Several different complication groups were defined for analysis of the selected studies. However, there are differences in definitions of complications among the studies (e.g., deep, superficial

Table V. Quality assessment outcome of all analyzed studies according to the modified version of the Cochrane Bone, Joint and Muscle Trauma Group's former Quality Assessment Tool (QAT, www.cochrane-handbook.com).

Study	**Smekal et al.[43]**	**Ferran et al.[44]**	**Witzel et al.[45]**	**Judd et al.[18]**	**Chen et al.[17]**	**Chen et al.[46]**
Allocation concealment	2	2	2	2	0	0
Intention-to-treat analysis	2	2	0	0	0	0
Assessor blinding	0	0	0	0	0	0
Comparable baseline characteristics	2	2	2	2	2	2
Participant blinding	0	0	0	0	0	0
Treatment provider blinding	0	0	0	0	0	0
Care program comparability	2	2	2	2	0	1
Defined in- and exclusion criteria	2	2	2	2	2	2
Well defined interventions	2	2	2	2	2	0
Well defined outcome measures	2	2	2	2	2	2
Clinically useful diagnostic tests	2	2	2	2	2	2
Adequate duration of follow-up	2	2	2	2	2	2
QAT Score	**18**	**18**	**16**	**16**	**12**	**11**

and wound infections may have been present). Future studies would benefit from improvements in defining complications when determining outcome parameters. Furthermore, our review focused solely on the spectrum of complications of IMF; therefore, no comparisons with complications after open reduction and internal plate fixation or nonoperative treatment were made.

Finally, the applicability of the quality assessment tools used should be addressed. With regards to the levels of evidence, a "high" LoE referred to the manner in which different treatment options were compared, but not necessarily to the way in which data were collected. In general, prospectively collected data are more reliable than retrospective data. However, when drawing conclusions on the incidence and consequences of adverse events of a single therapeutic intervention, data can be extracted from both case series and comparative studies. It is uncertain that the LoE of data from comparative studies is greater than that of data from prospective case series. Therefore, the quality assessment tool was added and used to strengthen the quality assessment of different studies included in our review.

CONCLUSION

Reported rates of major complications requiring additional surgery (e.g., corrective osteotomy) after IMF were low, but implant-related problems that also required additional surgery might present with high prevalence. Owing to (routine) implant removal, treatment with IMF often requires an additional surgical procedure.

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CHAPTER V

Surgical fixation of midshaft clavicle fractures: a comprehensive review of biomechanical data

Submitted

Olivier A.J. van der Meijden, MD [1,2,3]
R. Marijn Houwert, MD, PhD[1]
Martijn H.J. Hulsmans[1]
Bart J. Burger, MD, PhD[2,3]
Egbert J.M.M. Verleisdonk, MD, PhD[1]
Dirk Jan Veeger, PhD[4]

[1]*Department of Surgery, Diakonessenhuis, Utrecht, The Netherlands*
[2]*Department of Orthopaedic Surgery, Medical Centre Alkmaar, Alkmaar, The Netherlands*
[3]*Centre for Orthopaedic Research Alkmaar (CORAL), Alkmaar, The Netherlands*
[4]*MOVE Research Institute, Faculty of Human Movement Sciences, VU University Amsterdam, Amsterdam, The Netherlands*

ABSTRACT

The optimal surgical fixation technique for displaced midshaft clavicle fractures from a clinical perspective is still unknown and currently under investigation. The goal of this review was to provide an overview of studies comparing the biomechanical properties of surgical plate fixation (PF) with intramedullary fixation (IMF) of midshaft clavicle fractures and translate these biomechanical results into clinical practice.

The exact implications of fracture fixation on direct postoperative rehabilitation in terms of activities in daily living could not be answered. There seems to be a lack of solid physiologic data and included studies displayed a large variation in testing set up. However, the presence of a cortical defect after fracture fixation does directly influence the fixation stability. Both compression plates as well as reconstruction plates seem to form a more robust construct than the 'traditional' IM devices in terms of stiffness and failure loading, yet a novel IM implant seems a promising alternative. In turn, compression plates are significantly stronger than reconstruction plates. A benefit of IM devices is that after removal following fracture union, the remaining clavicle is stronger than after plate removal. It would be beneficial for future biomechanical studies to focus on specific activities of daily living. This kind of information might enable clinicians to specifically inform patients on their *do's* and *don'ts* in the rehabilitation process.

INTRODUCTION

The optimal treatment strategy of midshaft clavicle fractures is an ongoing topic of debate,[1-3] yet it seems that the frequency of operative fixations of fractures with complete fragment displacement has increased over the past years. Not only the type of treatment is subject to discussion, but in case of operative fixation, there also seems to be a void in the knowledge on the optimal surgical fixation technique.[4]

Goals of fracture fixation are early mobilization and prevention of nonunion. In order to do so, repair constructs should hold fracture parts reduced and require sufficient stiffness and rotational stability to facilitate fracture healing while being strong enough to endure peak forces. Additionally, after implant removal the healed clavicle should be able to withstand similar forces. Fixations with plate and screws or with intramedullary implants are the most frequently used techniques (Figure I). The choice of implant affects the strength of the repair construct which in turn might influence progress of rehabilitation and maybe also rate of recovery. Residual clavicle bone strength following implant removal may also be affected by implant characteristics and the principles of the fixation method in question due to

Figure I. Example of a Locking Compression Plate for a left clavicle (Depuy Synthes, Amersfoort, The Netherlands) and a 3.0mm Titanium Elastic Nail (TEN, Depuy Synthes, Amersfoort, The Netherlands). Note that the plate has both locking and nonlocking options. The TEN is placed in an antegrade fashion and allows for closed fracture reduction.

for instance stress shielding and bone remodelling.[5,6]

Reported forces endured by the native clavicle vary in the literature depending on tasks performed and *in vitro* or *in vivo* measurements.[7,8] *In vitro*, physiological axial compressive forces are greatest during glenohumeral abduction (34N)[7] yet peak joint reaction forces measured in vivo around the sternoclavicular and acromioclavicular joints during lifting exercises are as high as 228N.[8] Average impact forces in an anterior to posterior direction leading to a clavicle fracture have been reported varying between 700N and 1000N[9,10] and in a superior to inferior direction between 490 and 640N.[10,11] Axial compression failure loads seem to be slightly higher, averaging around 1500N.[12]

In addition to a current clinical trial aiming to report patient related outcome measures following plate or pin fixation,[4] the past decade has shed increasing light on the biomechanical properties of various repair constructs. The goal of this review was to provide an overview of studies comparing the biomechanical properties of surgical plate fixation (PF) with intramedullary fixation (IMF) of midshaft clavicle fractures and translate these biomechanical results into clinical practice. In particular, this review focuses on the strength of the fixations related to peak loading and the possible implications for post-operative rehabilitation in terms of activities in daily living.

MATERIAL & METHODS

A survey of the PudMed database was performed in November 2013 combining the following search terms: clavicle or clavicula with biomechanics, biomechanical or kinematics. This resulted in 147 articles of which the title and abstract were screened by two reviewers (O.A.J.v.d.M and M.J.H.) for relevance. Eligibility criteria included *in vitro* studies of cadaveric or synthetic clavicles in which operative techniques were compared. Our primary focus was the comparison of PF with IMF. Due to the heterogeneity of performed tests and presented data, studies are summarized narratively. Results were grouped based on the fracture type tested.

Biomechanical testing methodology

We found five articles directly comparing PF with IMF.[11-15] Studies report either the use of cadaveric[11-13] or synthetic bone[14,15] for in vitro testing (Table I). Previous studies into the matter indicated that synthetic bone approaches the characteristics of real bone which makes them an adequate and cheaper alternative.[16,17]

The tests performed differed in direction of forces and the type of strain applied to the bone. These various forms of biomechanical testing are schematically illustrated in figure IIA-E. The most commonly used testing conditions were 3-point bending and cantilever bending. In 3-point bending, both supporting pins are placed inferior to both distal ends of the clavicle in perpendicular fashion and a load cell (third point) is applied along the longitudinal axis of the clavicle. The position of the load cell depends on fracture site and testing direction. When performed in a superior – inferior direction, it simulates the clavicle acting as a fulcrum over the first rib.[11,14] A slightly different test, yet performed in a similar set up is 4-point bending.[13] In this test the load cell consisted of 2 ends which were applied to the clavicle simultaneously, each on either side of the fracture, and the force was applied in an inferior – superior direction.

Cantilever bending was performed by rigidly fixating the medial end of the clavicle and applying a downward bending load on the lateral end of the clavicle.[12,14,15] This form of testing relates to forces endured by the clavicle by the weight of the arm suspended from the lateral aspect of the clavicle with a fixed sternoclavicular joint. Finally, Drosdowech et al. also tested axial torque stiffness at a rate of 2°/minute with a maximum of 1°.[12] Besides failure loading, construct stiffness in different testing settings was reported.

Fixation types

Proubasta et al. and Golish et al. both compared the fixation of simulated transverse fractures[18] (Robinson type IIA1 and IIA2, Figure II) using non-locking plate techniques with an IM implant.[11,13] Implants used were a low contact dynamic compression plate (LCDCP, Synthes, Bettlach, Switzerland)

Table I. Biomechanical studies comparing plate and screw fixation of midshaft clavicle fractures with intramedullary fixation.

Author	Tested clavicle	Fracture simulation	Plate type	Plate position	IM implant	IM technique	Testing method	Testing direction
Proubasta[11]	Cadaver	Transverse fracture	Non-Locking	Superior	Herbert screw	Retrograde	3-point bending	Superior-Inferior
							Non-cyclic loading	
Drosdowech[12]	Cadaver	Transverse fracture	Non-Locking*	Superior	Rockwood pin	Retrograde	Torque load	Superior-Inferior
		± inferior cortical defect	Non-Locking**				Cantilever bending	
			Locking				Non-cyclic loading	
Golish[13]	Cadaver	Transverse fracture	Non-Locking	Superior	Rockwood pin	Retrograde	4-point bending	Inferior-Superior
							Cyclic loading	
Renfree[14]	Synthetic	Transverse fracture	Non-Locking	Superior	Rockwood pin	Retrograde	3-point bending	Superior-Inferior
			Locking				Cantilever bending	
							Non-cyclic loading	
Smith[15]	Synthetic	Inferior Cortical defect	Locking	Superior	Crx	Retrograde	Cantilever bending	Superior-Inferior
							Non-cyclic loading	

*Non-Locking Reconstruction plate **Dynamic Compression plate

IM = Intramedullary

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and a Herbert screw[11] (Zimmer, Warsaw, IN, USA) and a dynamic compression plate (DCP, ACE/Depuy, Warsaw, IN, USA) was evaluated in relation to a Rockwood Pin (Depuy, Warsaw, IN, USA), respectively.[13] In addition, Proubasta et al. tested intact clavicles as control group.[11]

Later, Renfree and colleagues tested both non-locking and locking plate constructs of (Acumed, Hillsboro, OR, USA) with a Rockwood pin (Depuy, Warsaw, IN, USA).[14] Drosdowech et al. also tested the Rockwood pin (Depuy, Warsaw, IN, USA) in comparison to a non-locking and locking plate (DCP and LCP, Synthes, West Chester, PA, USA) and also added a group of reconstruction plates (Synthes, West Chester, PA, USA).[12] In contrast to previous studies, they additionally reported on the influence of preservation of cortical alignment on construct repair strength. This closely resembles simulation of fixation of type IIBI fractures.[18]

The most recently published article by Smith and colleagues introduced several new testing modalities.[15] First off, a different IM implant was tested (Crx, Sonoma Orthopedics, Santa Rosa, CA, USA). During implant positioning it is flexible, but following final placement it offers the possibility to be locked and as a result provides rigidity and axial stability to resist torque and secondary shortening forces. The Crx was compared to a locking plate (Acumed, Hillsboro, OR, USA) and a group of intact clavicles served as internal control group. Secondly, they reported on the bone strength after removal of various fixation devices.

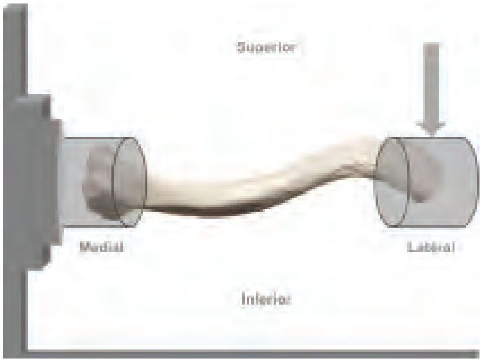
RESULTS

Transverse fractures – intact cortical alignment

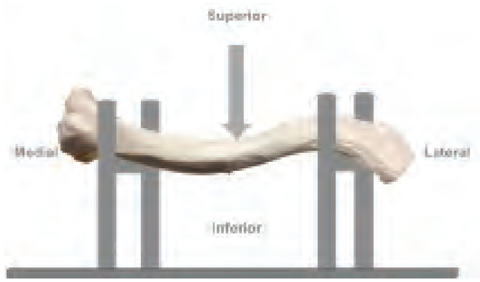
In a 3-point bending-to-failure test in superior-inferior direction the Herbert screw had a mean failure load of 435N, compared to 650N of the non-locking LDCDP and 486N of the intact clavicles.[11] Also, no differences for construct stiffness were reported, 83N/mm and 82N/mm respectively for IMF and PF and 95N/mm for the intact clavicles.

Golish et al. performed a 4-point bending cyclic loading test in inferior-superior direction.[13] Failure was determined as displacement of 10mm or more. They found that the non-locking plate construct showed significantly less displacement at loads varying between 180N and 720N compared to the IM Rockwood pin. At loads of 540N, nearly half of the IM constructs had failed; this was the case for the plate constructs at loads of 720N.

Renfree et al. performed both a cantilever and 3-point bending test.[14] For each test, clavicles were loaded-to-failure in non-cyclic fashion in a superior-inferior direction. During cantilever testing both plate constructs were stiffer (non-locking plate 9N/mm, locking plate 7N/mm) and endured higher maximum loads (non-locking plate 105N, locking plate 97N) than the Rockwood pin (stiffness 2 N/mm, failure load 23N). During 3-point



II. A



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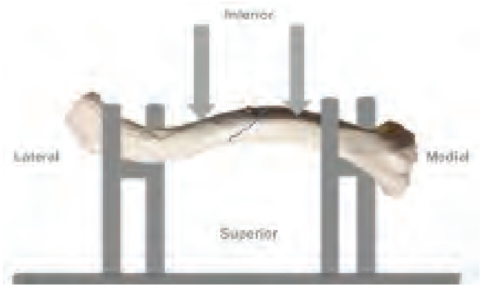

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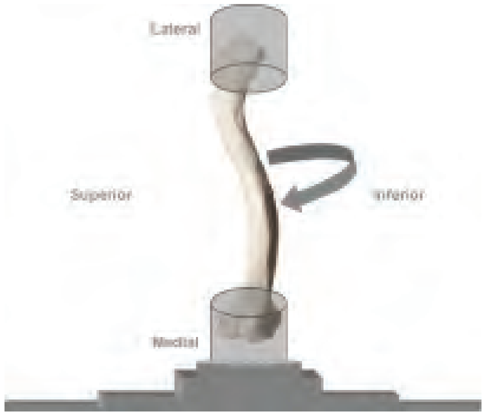

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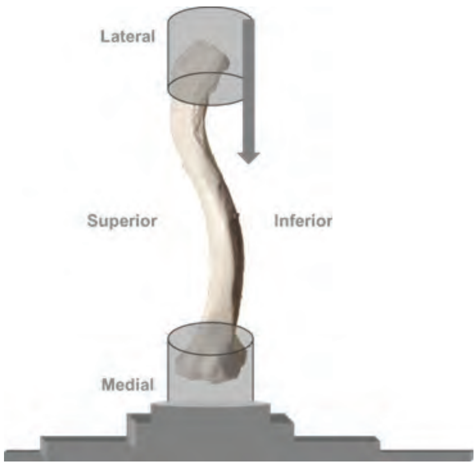

II. E

Figure II. Schematic illustration of various biomechanical testing set ups. The cylinders simulate the potted ends of the clavicle. A left clavicle is fixated on the sternoclavicular end.
A. Cantilever bending
B. 3-point bending
C. 4-point bending
D. Axial torsion testing
E. Axial compression testing

bending, the rotational moment could be better controlled. This resulted in higher loads. Still the plates (non-locking plate 96N/mm, locking plate 98N/mm) were stiffer than the IM implant (30N/mm) yet the Rockwood pin displayed higher maximum loads (350N versus 278N for the non-locking and 284N for the locking plate). In the IMF group, large displacements were noted prior to failing. All implants demonstrated plastic deformation.

Transverse fractures – cortical defect
Drosdowech et al. tested 4 different implants in the absence and presence of an inferior cortical defect.[12] After determining the constructs' bending and torsion stiffness, they were loaded to failure in a cantilever model. Prior to simulating a fracture, the intact clavicles were tested for stiffness to serve as a control, also enabling data of the fixated clavicles to be reported as a percentage of the innate characteristics. Results for the intact clavicle tests were not reported.
For bending and torsion stiffness, the IM group (56% and 50%* of intact clavicle) displayed significantly lower values compared to the plate groups (116% and 96%* for the reconstruction plate, 140% and 100%* for the non-locking compression plate, 135% and 116%* for the locking compression plate). In the presence of a cortical defect, stiffness decreased in all groups with a stiffness of only 33% in comparison to the intact group for the IM group. In addition, the reconstruction plate was significantly less stiff and displayed lower failure loads than the other plates, especially in the presence of an inferior cortical defect (Reconstruction plate 8N/m*, DCP and LCP 22N/m*, Rockwood pin 16N/m*).
Finally, Smith et al. performed superior-inferior cantilever testing in load-to-failure fashion.[15] Similar outcome was reported for torque, even with a trend of higher average failure torques (22Nm versus 18Nm) in the IM group compared to the locking plate group. After implant removal, however, the failure torque for the IM removal group (30Nm) came close to the intact group (37Nm*) and was significantly stronger than the plate removal group (13Nm).
**Estimated values obtained from figures*

DISCUSSION

The purpose of this review was to provide an overview of studies comparing the biomechanical properties of surgical PF with IMF of midshaft clavicle fractures. Ideally, these properties would be translated to clinical practice. Several considerations have to be made before attempting to answer these questions. First, it is important to note that this concerns *time-0* testing and without biological influences we can only relate to the short term predictions. Second, as demonstrated in tables and text, the variation in testing set up, tested implants and reporting of data makes comparison among the included studies difficult. This also accounts for comparison with known physiological and failure loads.

There are indications of failure forces in the anterior-posterior direction and axial compressive forces, yet the included studies all conducted load-to-failure testing in the coronal plane. Only studies that included an intact control group can be used for reference with the native clavicle. Although failure torque loads for both plate and IMF were reported these were again the result of testing in the coronal plane. This observation complicates comparison to reported axial *in vitro* measurements.

So, how to summarize these findings? A distinction has to be made between studies testing traditional IM implants (Herbert screw, Rockwood pin)[11-14] and one study testing a relatively new device (Crx).[15] The main difference lies in the 'locking options' of the latter to control for rotational instability, rigidity and possibly secondary fracture shortening.

Inherent in the design of these traditional IM implants (Herbert screw, Rockwood pin), which cannot be statically locked, axial moments are not very-well resisted and both (non-locking) compression plates as well as reconstruction plates outperform the tested IM devices in terms of stiffness and failure loading.[12,14] In the presence of a cortical defect this is further emphasized by a decrease in torsion stiffness.[12] In turn, in the presence of an inferior cortical defect, compression plates are significantly stronger than reconstruction plates.[12]

During postoperative rehabilitation, patients with IM stabilized clavicle fractures should be cautioned during glenohumeral abduction and forward flexion in order to prevent the physiologic axial rotation moment of the clavicle until a certain degree of fracture healing is achieved. At 110° of forward flexion, posterior rotation or the clavicle along the longitudinal axis is reported up to 31°.[19] *In vivo* forces measured across the intact clavicle, in particular axial compressive forces, are greatest during glenohumeral abduction in comparison to internal and external rotation.[7,8] In addition, when fixating a severe oblique fracture, even more care should be taken in the rehabilitation progress since axial compressive clavicle forces occurring during glenohumeral abduction may lead to secondary fracture shortening. Since one of the goals of operative fixation is early return to function, the question arises if these fractures are suitable for IMF altogether. Even more so, in case of comminuted segmental fractures with the absence of residual inferior cortical alignment, the usage of an IM device should probably be advised against. These fractures account for approximately 13% of all clavicle fractures (Robinson IIB2).[18] It seems that early postoperative mobilization is safest following compression plate fixation, considering provided rotational stability.

However, the study by Smith et al. puts this clinical evaluation into a different perspective.[15] Although, unfortunately for this review, the authors did not perform torsional and axial compression testing, the Crx approached or even

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outperformed the current plate and screw constructs in terms of stiffness and failure loading during cantilever testing. Even more interesting, the failure torque for the IM removal group was significantly stronger than the plate removal group. This confirms findings of previous studies of the lower limb, reporting decreased bone strength due to residual screw holes after PF.[5,6] Considering the high rates of patients experiencing plate related irritation and the clinical frequency of implant removals,[20] this IM device seems a promising minimally invasive alternative to PF in carefully selected (transverse) fractures. Especially when considering that these implants can be removed under local anesthesia while general anesthesia is required for plate removal.

Several critical notes should be made, however. Does 'a stronger implant' necessarily mean 'a better implant'? Perhaps the main goal of an implant should be to withstand forces up to a certain known threshold. Yet obviously, we need to know what this threshold is before judging the quality of the implant and being able to provide solid advice concerning postoperative rehabilitation and do's and don'ts. In addition, an implant and the fixation construct should preferably be tested in set up that is most fit. From the current variety in set ups that does not necessarily become clear.

We chose to group the results of included studies based on the fracture types tested. Transverse fractures of the midshaft account for approximately 17% of all clavicle fractures and oblique or comminuted fractures for 50%. Only biomechanical studies reporting on both plate and IMF were included. This allowed for a review of data on various devices under similar testing conditions which we believe is of utmost importance for direct comparison. However, it also meant that several biomechanical studies examining the influence of plate position and plate type were not evaluated here.[21-24] In general, these studies support data presented in this review that compression plates endure higher loads than reconstruction plates. Since they are not the main focus of this review, they are not further reviewed here. Due to the diversity in testing set ups and measured parameters among the different studies included, it was not possible to provide a clear table with results and we chose to report results in a narrative fashion.

CONCLUSIONS

In conclusion, it seems that the question regarding the implications of fracture fixation on direct post-operative rehabilitation in terms of activities in daily living cannot be answered. There seems to be a lack of solid physiologic data and included studies display a large variation in testing set up. However, we may conclude that the presence of a cortical defect does directly influence the fixation stability. Both compression plates as well as reconstruction plates seem to form a more robust construct than the 'traditional' IM devices in terms of stiffness and failure loading, yet a novel IM implant seems a promising alternative. In addition, a benefit of IM devices is that after removal following fracture union, the remaining clavicle is stronger than after plate removal. We believe it would be beneficial for future biomechanical studies to focus on specific activities of daily living. What are the axial rotation moments around the native clavicle during certain loaded and unloaded tasks? Are surgical fixation constructs able to immediately withstand these rotation moments? This kind of information might enable clinicians to specifically inform patients on their *do's* and *don'ts* in the rehabilitation process.

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CHAPTER VI

Treatment of clavicle fractures in The Netherlands; do trauma surgeons and orthopaedic surgeons 'do it' the same way?

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Behandeling van clavicula fracturen; doen Nederlandse chirurgen en orthopaeden "het" hetzelfde?

Martijn H.J. Hulsmans
Olivier A.J. van der Meijden, MD
Frans-Jasper G. Wijdicks, PhD
R. Marijn Houwert, MD, PhD
Egbert J.M.M. Verleisdonk, MD, PhD

Department of Surgery, Diakonessenhuis, Utrecht, The Netherlands

ABSTRACT

Objective

The aim of this study was to determine the treatment of choice of Dutch trauma- and orthopaedic surgeons treating displaced midshaft clavicle fractures (DMCF) in daily practice.

Methods

A survey regarding the treatment of DMCF was conducted on November 1st 2012 during the combined annual meeting of the Dutch Trauma Society and the Dutch Society for Orthopaedic Traumatology, among trauma- and orthopaedic surgeons present. The survey presented a case of a young patient with a DMCF and questioned surgeons regarding their optimal treatment of choice and rationale behind it using a predetermined set of questions.

Results

Of the 326 attendants, 212 (65%) completed the survey. A vast majority (78%) opted for surgical treatment. Trauma surgeons would perform surgery more frequently than orthopaedic surgeons (p = 0.00), there was no significant difference noted between residents of either specialty. Open reduction and internal plate fixation was the surgical technique of choice (88%). A majority of the respondents (71%) believe that there is not sufficient scientific evidence to support their choice of treatment.

Conclusion

In the Netherlands, DMCF are often treated surgically and trauma surgeons are far more likely to proceed to surgical treatment than orthopaedic surgeons. Residents in (orthopaedic) surgery vary less in their choice of treatment. In case of surgery, plate fixation is preferred.

INTRODUCTION

Historically, patients in The Netherlands who suffer traumatic injury to the musculoskeletal system can be treated by either trauma surgeons or orthopaedic surgeons. Only a few countries around the world have similar trauma management implemented and the optimal symbiosis has long since been an ongoing topic of debate.[1] A German commission in charge of managing this process in a correct fashion noted in 1959: "dass sich für die fachgebiete der chirurgie und orthopädie durch die geschichtliche entwicklung und die tägliche praxis eine weitgehende aufgabentrennung sowohl in der ärztlichen betätigung wie in der Lehre und Forschung ergeben hat".[2]

This leads to the interesting question: do trauma surgeons and orthopaedic surgeons treat traumatic injuries the same? Another related question and topic of ongoing discussion is the optimal treatment of dislocated midshaft clavicle fractures (DMCF). To be more specific, should one operate or not? Although recent study results project significantly higher nonunion rates after conservative treatment,[3,4] research regarding the optimal treatment is ongoing.[5] Furthermore, if the choice for operative fracture reduction and fixation has been made, it is unclear which operative technique is most favorable.[6]

In order to obtain an insight in the current status of the treatment of DMCF in The Netherlands, it was decided to conduct a survey. The aim of the survey was to compare treatment strategies between trauma and orthopaedic surgeons.

MATERIAL AND METHODS

On November 1st 2012 a survey was conducted among attendants of the Dutch annual meeting for Traumatology in Amsterdam, The Netherlands. The meeting is a collaboration between the Dutch Trauma Society and the Dutch Society for Orthopaedic Traumatology. The survey considered a case of a young patient who suffered a DMCF and respondents were asked for their treatment preference and rationale behind it (Appendix I). Seven medical students obtained as many completed questionnaires as possible, after being educated on clavicle fractures for an afternoon.

Table I. Baseline characteristics of respondents.

Trauma Surgeon (n)		105
Orthopaedic Surgeon (n)		43
Resident in training: General Surgery (n)		33
Resident in training: Orthopaedic Surgery (n)		31
Mean age (years, range)		41 (25- 66)
Level of trauma center[7]:*		
	I	67
	II	89
	III	55
Training Hospital		
	Yes	157
	No	54

**Missing data for one respondent*

Data analysis

A distinction was made between three groups; data were categorized for the total group of respondents, surgeons per specialty and for residents in training per specialty. The IBM SPSS Statistics version 20.0 was used for data analysis. The responses were analyzed for each profession using the X2-test, except for analysis of the data for residents in training. Due to the small sample size a Fisher's exact test was used. Statistical significance was set at $p < 0.05$.

RESULTS

The survey was completed by 212 of 326 (65%) attendees (Table I). The mean age was 41 years old (range 25 - 66). Non-surgeons and residents-not-in-training

Table II. Treatment of displaced midshaft clavicle fractures for group of respondents as a whole (n = 212)

		Numer of respondents (%)
Treatment	Conservative	47 (22)
	Operative	165 (78)
Motivation Criteria		
Fracture shortening	Yes	126 (59)
	No	86 (41)
Open fracture	Yes	145 (68)
	No	67 (32)
Displacement >1 shaft width	Yes	158 (75)
	No	54 (25)
Age	Yes	79 (37)
	No	133 (63)
Degree of comminution	Yes	55 (26)
	No	157 (74)
Scientific evidence[a]	Yes	64 (30)
	No	148 (70)
Operative treatment of choice	Plate fixation	186 (88)
	IM fixation	22 (10)
	Other	4 (2)
Scientific evidence[b]	Yes	62 (29)
	No	150 (71)

IM = Intramedullary
[a]*Sufficient scientific data proving either treatment option superior to the other.*
[b]*Sufficient scientific data proving either operative technique superior to the other.*

were excluded for analysis. In the presented case, 78% of the total group of respondents opted for operative treatment (Table II).

Trauma surgeons chose surgical intervention more often than orthoapaedic surgeons, 93 (89%) against 26 (60%) respectively (*p*<0.05, Figure I). The main criteria to proceed to operative fixation were clavicle shortening (73 (70%) versus 22 (51%)), open fractures (73 (70%) versus 27 (63%)) and dislocation between fracture parts of more than 1 shaft width (87 (83%) versus 23 (54%, Figure II)).

Treatment choices for residents-in-training for both specialties were more in accordance. Twenty-six (79%) surgeons-in-training and 20 (64%) orthopaedists-in-training would perform operative

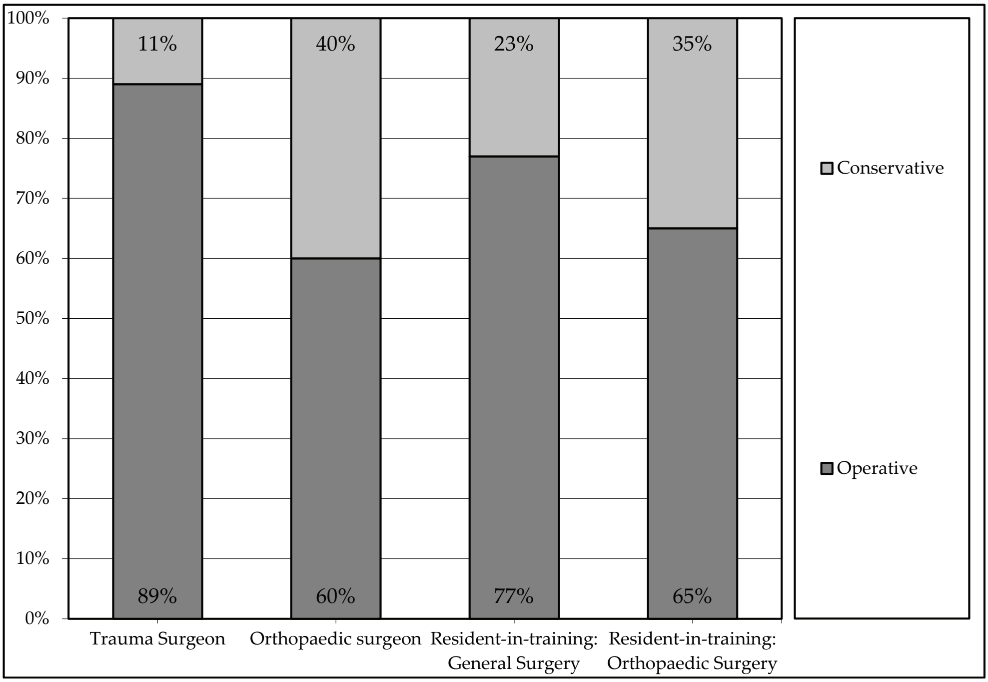

Figure I. Treatment of choice for displaced midshaft clavicle fracture categorized per group of respondents.

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treatment.
In case of operative treatment, the vast majority opted for plate fixation (88%). However, 71% indicates that there are not sufficient scientific data to prove one operative technique superior over the other.

DISCUSSION

This study aimed to report current strategies on treatment of DMCF in The Netherlands. In addition, the treatment preferences of trauma surgeons and orthopaedic surgeons were compared. Trauma surgeons opted significantly more frequently for operative fixation than orthopaedic surgeons. When it comes to the residents-in-training, there seemed to be more agreement.
Operative treatment of DMCF has increased over the past decades. Historically, clavicle fractures, including those showing displacement of >1 shaft width, were predominantly treated conservatively with a sling or a figure-of-eight bandage.[8] However, both meta-analyses of earlier literature as

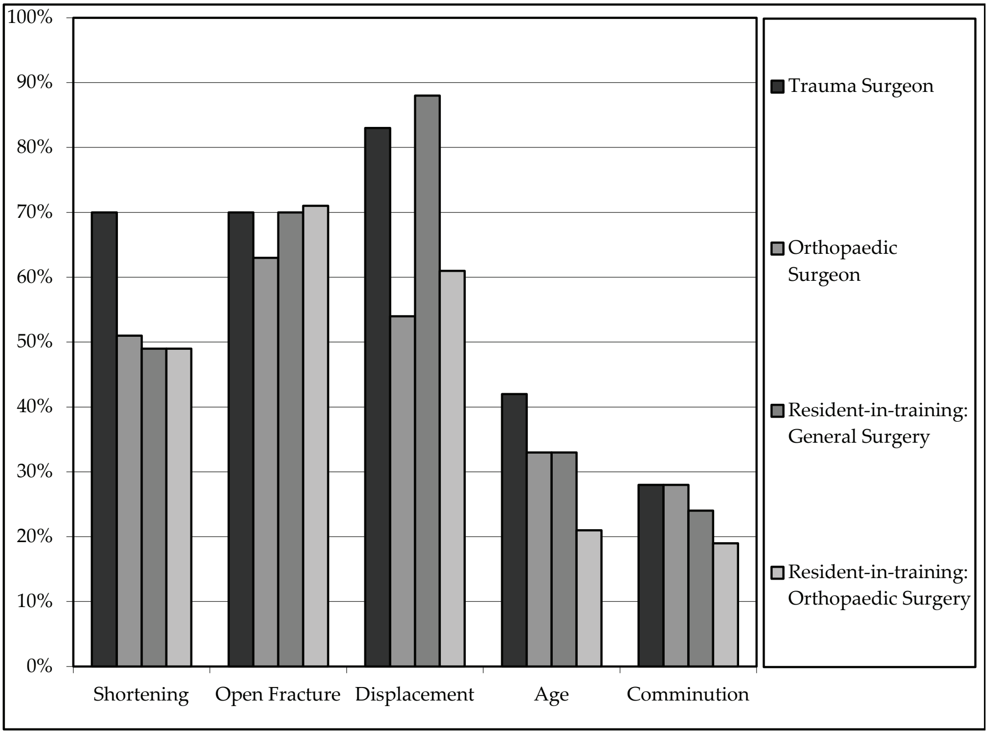

Figure II. Motivation criteria for operative treatment per group of respondents.
Shortening = fracture shortening
Displacement = displacement of fracture parts of > 1 shaft width
Age = patient age
Comminution = degree of fracture comminution

well as more recent prospective clinical trials display possible risk reductions of nonunion of 80% when treating DMCF surgically.[3,9-11] In addition, symptomatic malunions seemed to occur more often than initially appreciated following nonoperative management.[12]

It should be noted, though, that complications of treatment are not necessarily limited to non- and malunion. Prospective studies of surgical fixation of DMCF often report high percentages of patients experiencing implant irritation and, in general, intramedullary implants frequently require routine removal.[3,10,11] In addition, some surgeons prefer surgery of a sterile nonunion over secondary surgery of a failed implant with possible infection. Ideally, all these factors are taken into consideration before deciding on final treatment. Besides, this case focuses on the specific subset of DMCF in young and active patients. Surgical outcome may differ when children and elderly are involved.[13,14] Currently, there are multiple trials ongoing in The Netherlands on the optimal treatment of clavicle fractures.[5,15]

We do not have a valid explanation for the observed difference in treatments strategies between trauma surgeons and orthopaedic surgeons. A possible reason for the similarities among residents-in-training could be that relatively young orthopaedists-in-training still relate to their initial training in general surgery for their choice of treatment.

In the surgical decision making process, fracture shortening and displacement are the main criteria to proceed to operative treatment. This is confirmed by study data. The negative prognostics of both criteria have often been described.[3,16-20]

Yet still, a majority of respondents (70%) indicate there is not sufficient scientific evidence to support either conservative or operative treatment over the other. Interestingly, it appears that an increase in radiographic imaging seems to result in an accelerated decision to operative treatment.[21] One should keep in mind, however, that body posture and therefore the direction of the X-ray beam are of influence on the depicted degree of shortening and displacement. This knowledge could possibly alter the motivation for operation criteria.

In general, it is questionable if the motivation criteria for surgery are applicable to all patients with a DMCF. The decision to operate should be individualized in order to assess the possible benefit of operative treatment. The risk of complications should be taken into account and weighed with activity level, general health and last but not least, the patient's expectations.[20,22]

The response rate to the questionnaire is relatively high with 67%.[23,24] One would assume that the attendants of the Dutch annual Traumatology meeting are those interested in taking care of trauma patients. Even so, it is hard to determine if this group of respondents is representative for all Dutch trauma and orthopaedic surgeons. Another limitation is the way in which the questions regarding scientific evidence are formulated. Although it is our opinion that the goal of the study is reached, it is difficult to rate the 'presence of scientific evidence' as a dichotomous parameter to which an easy yes or no can be answered. Until today, there is relatively little proof to support either surgical technique for the fixation of DMCF.[6,25] To address this issue, the POP-study (Plate or Pin) was designed.[15] The final results of this study, one year after surgery, are expected shortly.

CONCLUSION

In the Netherlands, DMCF are often treated surgically and trauma surgeons are far more likely to proceed to surgical treatment than orthopaedic surgeons. Residents in (orthopaedic) surgery vary less in their treatment preference. In case of surgery, plate fixation is preferred.

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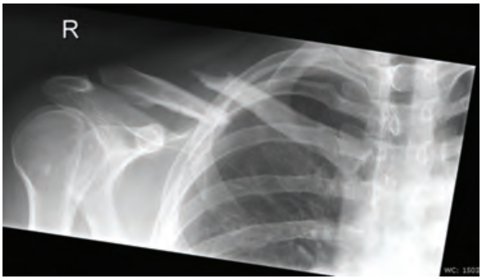
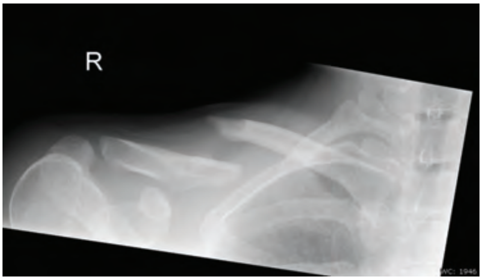
Appendix I. Questionnaire conducted among surgeons present at the annual Traumatology meeting of the Dutch Trauma Society and the Dutch Society for Orthopaedic Traumatology on November 1st 2012.

Case: A 34-year old, active male, fell on his right shoulder during a cycling accident He presents in the Emergency department with the displayed midshaft clavicle fracture (DMCF) shown below.





How would you treat this fracture?

- o Conservative
- o Operative

What do you consider criteria to decide to perform operative fixation? (Multiple answers are possible)

- o Fracture shortening
- o Open fracture
- o Fracture displacement of > 1 shaft width
- o Age
- o Degree of comminution

Do you think that there are sufficient scientific data that prove operative treatment superior to conservative treatment regarding DMCF?

- o Yes
- o No

If you decide to treat a DMCF operatively, what would be your operative technique of choice?

- o Plate fixation
- o Intramedullary fixation
- o Other, being: …

Do you think that there are sufficient scientific data that prove plate fixation superior to intramedullary fixation regarding DMCF?

- o Yes
- o No

VI

CHAPTER VII

Operative treatment of dislocated midshaft clavicle fractures; Plate Or intramedullary Pin fixation? A randomized controlled trial

Submitted

Olivier A.J. van der Meijden, MD[1]
R. Marijn Houwert, MD, PhD[1]
Martijn H.J. Hulsmans[1]
Frans-Jasper G. Wijdicks, PhD[1]
Marcel G.W. Dijkgraaf, PhD[2]
Sven A.G. Meylaerts, MD, PhD[3]
Eric R. Hammacher, MD, PhD[4]
Michiel H.J. Verhofstad, MD, PhD[5,6]
Egbert J.M.M. Verleisdonk, MD, PhD[1]

[1]*Department of Surgery, Diakonessenhuis, Utrecht, The Netherlands*
[2]*Clinical Research Unit, Academic Medical Center, Amsterdam, The Netherlands*
[3]*Department of Surgery, Medical Center Haaglanden, The Hague, The Netherlands*
[4]*Department of Surgery, St. Antonius Hospital, Nieuwegein, The Netherlands*
[5]*Department of Surgery, St. Elisabeth Hospital, Tilburg, The Netherlands*
[6]*Department of Surgery, Erasmus Medical Center, Rotterdam, The Netherlands*

ABSTRACT

Background

Over the past decades there has been a paradigm shift towards more aggressive treatment of dislocated midshaft clavicle fractures (DMCF). Open reduction and internal plate fixation (PF) and intramedullary fixation (IMF) are the most commonly used operative techniques. The aim of this study was to compare short and midterm results of PF and IMF for DMCF.

Methods

A multicenter randomized controlled trial was performed in four different hospitals throughout the Netherlands. A total of 120 patients, age 18 – 65, were included and treated with either PF (n = 58) or IMF (n = 62). Pre- and postoperative shoulder function scores and complications were documented up until 1 year postoperatively. Statistical significance was set at $p < 0.05$.

Results

There were no significant differences noted between the two surgical interventions for both the DASH and Constant-Murley score at 6 months postoperatively (3.0 and 99.2 for the plate group and 5.6 and 95.5 for the IMF group). Until 6 months after surgery, the PF group experienced less disability than the IMF group as indicated by the area under the curve of the DASH score for the time period between 6 weeks and 6 months in favor of the plate group ($p = 0.02$).

There was only one recorded nonunion which occurred in the PF group and there were 2 implant failures in the IMF group. The cumulative number of complications was high and mainly implant related. However, one year after surgery only 3% of patients in the PF group and 6% in the IMF fixation group still experienced implant related irritation.

Conclusion

Patients in the PF group recovered faster than the patients in the IMF group, but groups were similar at final follow-up. The rate of complications requiring revision surgery was low yet implant related complications occurred frequently and could often be treated by implant removal.

INTRODUCTION

Over the past decades, a shift in the treatment of displaced midshaft clavicle fractures (DMCF) towards more aggressive, operative treatment was observed. Rationale for operative fixation of displaced fractures includes reported higher nonunion rates and increased functional deficits following nonoperative treatment of DMCF.[1-5] Two of the most commonly used techniques for operative treatment are open reduction and internal plate fixation (PF) and intramedullary fixation (IMF).[6] Each intervention has its advantages and drawbacks. Therefore the optimal surgical technique for these types of fractures remains a topic of debate.

PF provides immediate rigid fixation, including rotational stability, which is favorable for early rehabilitation protocols and is technically less demanding.[7,8] IMF is in general less invasive, good cosmetic results are reported and in addition, the hardware is less prominent.[4] Despite proposed benefits of surgical treatment, each technique also has its drawbacks. Infection, hypertrophic scarring and hardware irritation and even hardware failure are reported following PF.[9] Intramedullary nails often require routine removal to prevent hardware migration and prior to this, implant related irritation may occur.[10]

So far, prospective randomized data favoring either technique on which surgical decision making can be based are rare.[6,11] The purpose of this multicenter, randomized controlled trial was to report the functional results and complication rates of patients aged 18-65 with a DMCF who were randomized to either open reduction and Plate fixation Or intramedullary Pin fixation (POP-trial).[12] The null hypothesis was that PF would provide faster functional recovery than IMF.

MATERIAL AND METHODS

Study Design

The POP-study, registered in the Dutch Trial Register (NTR 2438), was performed in accordance with the Declaration of Helsinki[13] and approved by the local Medical Ethics Committee (registration number V.10.365/R-10.18D/mg). In this prospective trial, 120 consecutive patients with DCMF were included from January 2011 until August 2012 in four participating hospitals. Displacement was defined as at least one shaft width dislocation on any radiograph between fracture parts, regardless of fracture shortening.

Power Analysis and Randomization

The sample size of 120 patients, 60 per group, was based on an assumed clinically relevant difference in the Disabilities of Arm Shoulder and Hand (DASH) score of six points in relationship to the DASH score of a healthy population and previously reported scores following conservative treatment of DCMF.[1,14] It included an expected loss-to-follow up of 10%. Due to extensiveness, a more detailed rationale can be found in the study protocol.[12]

Patients were recruited in the emergency departments and handed study information if they met the inclusion criteria (Table I). When eligible, they were scheduled for follow up within a week from trauma for study inclusion after obtaining informed consent. Pre-operative data including trauma mechanism and tobacco use were collected. Fractures were classified according to the Orthopaedic Trauma Association classification for clavicle fractures as simple, wedge or complex. Randomization to either PF or IMF fixation was performed by central computerized block randomization in the doctor's office. Further treatment took place according to the intention-to-treat principle. Block sizes varied between 2 to 8 patients and the randomization procedure was stratified by participating center.

Operative Technique; Plate Fixation

One single dosage of prophylactic antibiotics was administered preoperatively. Patients were positioned in beach chair position and prepped and draped in standard fashion. A longitudinal incision was made over the fracture site and the fracture was identified. Following fracture reduction, a plate (DePuy Synthes, Amersfoort, The Netherlands) was positioned on the anterosuperior surface of the clavicle and fixated using (non-) locking screws. Plate types were used according to surgical preference. A minimum of 3 bicortical screws was placed on each side of the fracture to ensure rigid fixation. If interfragmentary compression was possible, lag screws were placed first. Only in fractures with severe comminution, a bridging plate was used. Finally, fascia and skin were closed in layers.

Operative Technique; Intramedullary Fixation

Following antibiotic administration in similar fashion to PF, patients were positioned in the supine position on a radiolucent table. Just lateral to the sternoclavicular joint a small incision was made and the anterior cortex was opened using a pointed reamer. A titanium elastic nail (TEN, DePuy

Table I. Study eligibility criteria

Inclusion criteria	Exclusion criteria
Unilateral, dislocated midshaft clavicle fracture	Polytrauma patients
Age 18 - 65 years old	Open fractures
No pre-existing shoulder pathology on affected side	Pathological fractures
No medical contra-indications to general anaesthesia	Fractures > 1 month old
Ability to provide informed consent	Neurovascular disorders
Ability to comply to follow up	Moderate to severe head injury at time of trauma (GCS < 12)

GCS = Glasgow Coma Scale

Synthes, Amersfoort, The Netherlands or Stryker, Waardenburg, The Netherlands) was inserted from the medial side under fluoroscopic control. Fractures were reduced closed under image intensification with percutaneous clamps or, if closed reduction failed, in an open fashion using an additional small incision over the fracture site. After complete introduction in the lateral fragment and compression of the fracture, the nail was cut at the introduction point. Fascia and skin were again closed in layers.

Postoperative rehabilitation and Follow Up

Regardless of the type of operative fixation, patients were given a sling for comfort yet they were encouraged to start active, non-weight bearing, mobilization as soon as pain permitted. Weight bearing was permitted after (radiographic) fracture consolidation was achieved.

All patients were followed up in the outpatient clinic at 2 weeks, 6 weeks, 3 months, 6 months and 1 year after surgery by the treating surgeon and an independent researcher (F.J.G.W. or M.H.J.H.). Follow up included clinical and radiological assessment. Obtained self-administered outcome scores were always completed prior to the actual follow up appointment.

Study endpoints

The DASH score after 6 months was considered the primary endpoint.[12,14,15] The DASH score consists of a 30-item disability scale ranging from 0 (no disability) to 100 (complete disability). The questionnaire allows patients to subjectively rate their upper extremity disability.[14] Additionally, DASH scores were obtained at 6 weeks, 3 months and 1 year after surgery and the subjective shoulder function over the period between 6 and 24 weeks after the operation was assessed as derived from the measurements at 6 weeks, 3 and 6 months.

Secondary outcome measures included the Constant-Murley and SF-36 questionnaires,[16,17] and a 10-point Likert scale for satisfaction with the cosmetic result (0 = very unsatisfied, 10 = very satisfied). The Constant-Murley score assesses shoulder pain, motion, strength and function. Of the maximum score of 100 points, 35 points are made up by patients' self-assessment and 65 points result from objective assessment.[16] The Constant-Murley score was determined at 6 weeks, 3 months, 6 months and 1 year after surgery. The SF-36 questionnaire measures health related quality of life and consists of 36 items covering 8 health related domains. Responses are summed and then transformed into a scale from 0 (poor health) to 100 (good health) for each domain.[17] Study participants completed the SF-36 questionnaires pre-operatively and 6 months and 1 year after surgery.

Recorded intraoperative data included time of surgery, conversion, performance of open reduction in case of IMF and neurovascular complications.

In contrast to the original study protocol, complications were classified similar to strategies used in recently published systematic reviews.[9,10] Complications were divided into infection (superficial or deep), neurovascular problems (transient brachial plexus syndrome, hematoma, desensitized skin), implant related problems (soft tissue irritation, breakage, failure), bone-healing problems (nonunion, malunion) and, finally, refracture after implant removal. The definition of a superficial infection was redness, swelling and/or purulent discharge of the wound. In case the infection required debridement or implant removal it was considered a deep infection. Brachial plexus lesions were defined as paresthesia of the arm, and/or weakness of the little and index fingers. These lesions were considered transient if spontaneous recovery occurred within a 6 month period. Soft tissue irritation due to the implant was defined as irritation due to a palpable presence of the implant. Lack of radiographic healing with clinical evidence of pain and motion at the fracture site 6 months after surgery was considered nonunion. Lastly, fracture union in a shortened, angulated, or displaced position on X-ray with clinical symptoms was considered malunion.

Statistical analysis

Data were analyzed according to the intention-to-treat principle. Baseline characteristics and postoperative outcome scores were compared using either a Student's T test or Mann-Whitney U test for continuous variables depending data distribution (baseline: BMI, age, SF-36 domain scores; intraoperative: time in days between fracture and surgery, duration of surgery in minutes; endpoints: DASH and Constant-Murley scores at six months (between study arms and between converters and non-converters within study arms), DASH and Constant-Murley scores during the six months of follow-up, SF-36 subscores difference-from-baseline scores) and a Pearson's Chi-square was used for categorical parameters. Compared with first observation carried backward, last observation carried forward and the mean group score approaches for imputation of missing data, interpolation of missing values of the shoulder scores proved to be most in concordance with the complete case approach and was therefore used as imputation method for missing follow up data. A multiple imputation approach of missing shoulder scores including hospital, gender, smoking and sports as co-variates generated scores outside the theoretical scoring range of the shoulder scores and was discarded. To study when differences in shoulder scores between the PF and the IMF group emerged during the first half year, a general linear random effects model was run to assess when the difference emerged.

Bivariate correlations between continuous variables were tested using Pearson or Spearman's rho. The complication rates of both interventions at one year after surgery were compared using a Poisson regression. The IBM SPSS Statistics version 20.0 was used for data analysis. Significance was established at a *p*-value of <0.05.

Source of Funding
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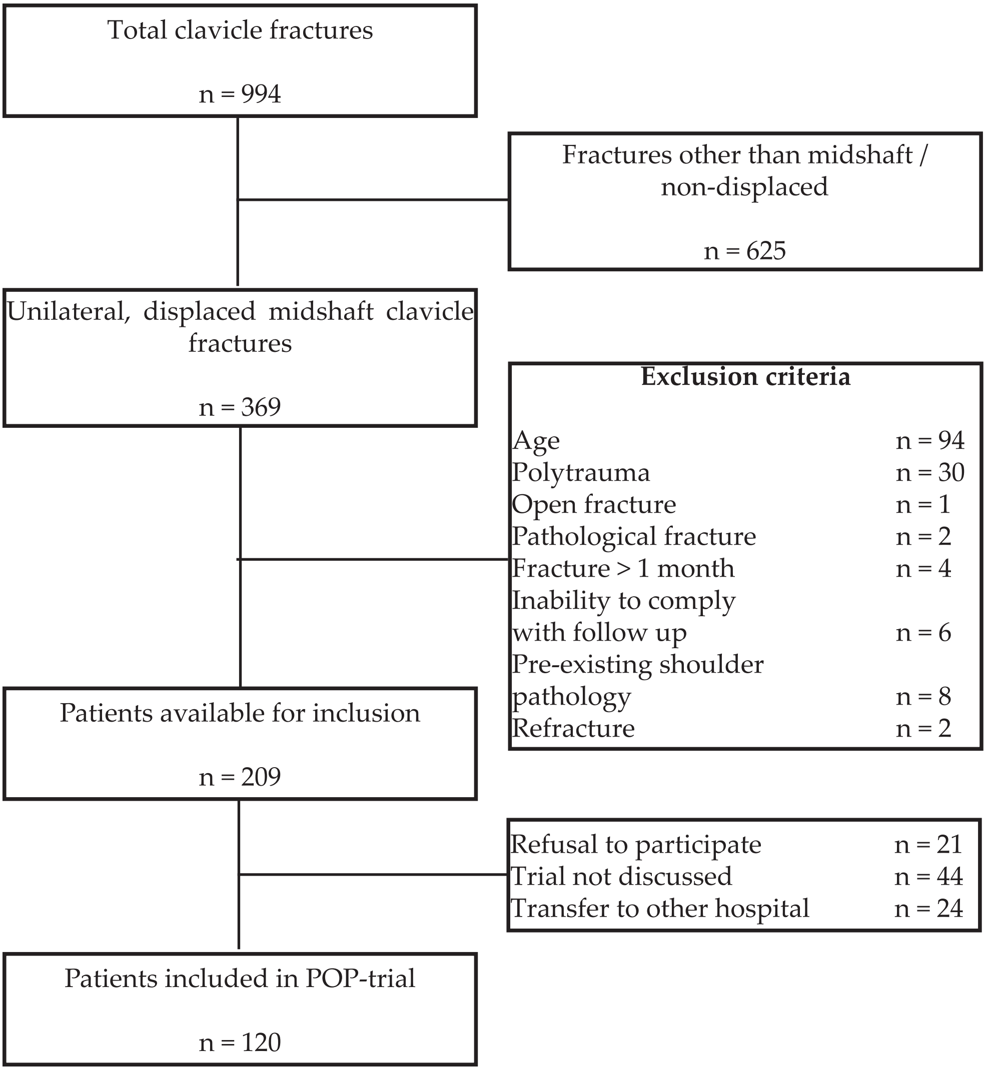


Figure I. Flowchart of inclusion for the POP-trial (Plate Or Pin trial) for fixation of displaced midshaft clavicle fractures.

Table II. Baseline characteristics per group.

Preoperative data		Plate fixation (n = 58)	Intramedullary fixation (n = 62)	*p-values*
Age (years; mean ± SD)		38.4 (14,6)	39.6 (13.2)	*0.64*
Gender	Male	53 (92%)	60 (97%)	*0.21*
Ethnicity	Caucasian	57 (98%)	61 (98%)	*0.37*
BMI (kg/m2; mean ± SD)		24.7 (3,5)	24.2 (3.0)	*0.36*
Smokers	Yes	19 (33%)	20 (32%)	*0.90*
Alcohol/drugs	Yes	7 (12%)	7 (11%)	*0.89*
Dominance	Right	50 (86%)	55 (89%)	*0.68*
Sports activities	No	17 (29%)	20 (32%)	*0.73*
Fracture side	Right	30 (52%)	29 (47%)	*0.59*
Trauma mechanism	Traffic accident	28 (48%)	25 (40%)	*0.17*
	Sports	18 (31%)	29 (47%)	
	Fall from stance/height/other	12 (21%)	8 (13%)	
Fracture Classification*	Simple	27 (47%)	24 (39%)	*0.58*
	Wedge	29 (50%)	34 (55%)	
	Complex/Comminuted	2 (3%)	4 (7%)	
SF-36 score (mean ± SD)	Physical functioning	54.2 (± 22.5)	55.9 (± 22.3)	*0.68*
	Role-physical functioning	20.6 (± 38.1)	21.7 (± 34.3)	*0.87*
	Bodily pain	36.9 (± 19.1	41.9 (± 22.9)	*0.20*
	General health perception	80.7 (± 19.3)	86 (± 16.1)	*0.16*
	Energy/Fatigue (Vitality)	64.5 (± 19.3)	72.6 (± 20.5)	*0.03*
	Social Functioning	67.8 (± 30.2)	75.4 (± 24.7)	*0.24*
	Role-emotional functioning	78.6 (± 38.4)	83.1 (± 35.3)	*0.51*
	Mental Health	80.9 (± 15.7)	79.4 (± 16.1)	*0.61*

SD = Standard Deviation. BMI = Body Mass Index (kg/m2).
**Fracture Classification according to Orthopaedic Trauma Association*

Table III. Intra-operative findings per procedure.

Parameter	Plate fixation (n = 58)	Intramedullary fixation (n = 62)
Time of surgery in minutes (mean, ± SD)	54.0 (16.6)	43.1 (23.9)
Conversion (n, %)	1 (2%)	6 (10%)
Open fracture reduction (n, %)	58 (100%)	46 (74%)
Neurovascular damage (n, %)	0	0
Incomplete reduction (n, %)	0	1 (2%)
Lateral cortical perforation (n, %)	n/a	1 (2%)

SD = Standard Deviation. n/a = not applicable

RESULTS

Baseline and intraoperative findings

Of the 369 patients with a DMCF a total of 120 were enrolled in this study: 58 for PF and 62 for IMF (Figure I). There were no significant differences between groups at baseline apart from the plate group being less vital (64.5 versus 72.6; *p=0.03*) (Table II). At one year after surgery there was a loss to follow up of 3 patients (3%), all in the plate group. These patients did not show up at final follow up, the reason of which was unknown.

In the IMF group, 46 fractures (74%) were reduced in an open fashion. One patient (2%) in the plate group and 6 (10%) patients in the IMF group underwent an intra-operative crossover and were further treated according to the intention to treat analysis (Table III). There was no association between conversion and outcome at 6 months (*p=0.42* in the IMFgroup; plate group not tested, because of just a single converter). In addition, in the IMF group, there was no association between time from fracture to surgery and the rate of open reduction (*p=0.97*); in turn, there was no association between open reduction and outcome (*p=1.0*).

Primary and secondary outcomes

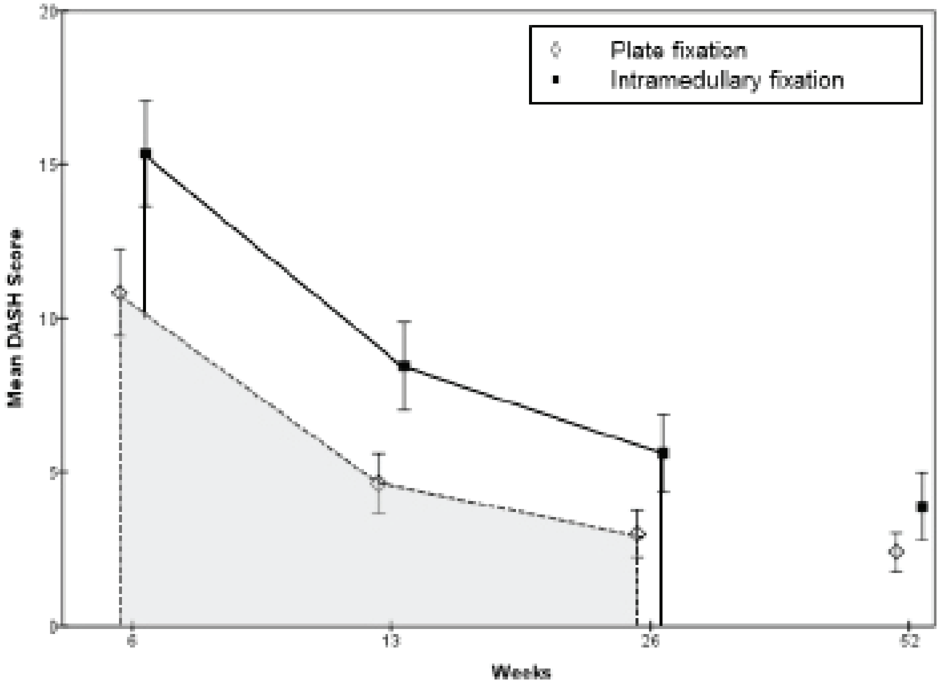
Both the mean DASH score and mean Constant-Murley score at 6 months postoperatively did not significantly differ between both groups (Figure II A-B). Until 6 months after surgery, the PF group experienced less disability than the IMF group as indicated by the area under the curve (AUC) of the DASH score for the time period between 6 weeks and 6 months in favor of the PF group (*p= 0.02*, Figure IIA). At 1 year after surgery there was no difference between groups in terms of cosmetic satisfaction (*p=0.67*).

Table IV shows the mean baseline scores and mean changes from baseline at 6 and at 12 months of follow-up for the SF-36 subscales. At 6 months bodily pain (*p=0.02*) and vitality (*p=0.03*) scores were more improved since baseline in the PF group, while at 12 months the vitality change since baseline scores were still higher (*p=0.02*) in the PF group.

Complications

In the PF group, 29 of 54 patients (54%) had a total of 36 complications (Table V). In the IMF group 39 of 61 patients (64%) endured a total of 43 complications. The mean numbers of complications per patient, irrespective of severity level, was similar in both groups (PF: 0.67, IMF: 0.74; *p=0.65*). The vast majority of complications were implant related. In the IMF group, irritation occurred on the medial side in 31 patients and laterally in 2 patients (1 patient in this group was converted to PF and suffered irritation from the plate).

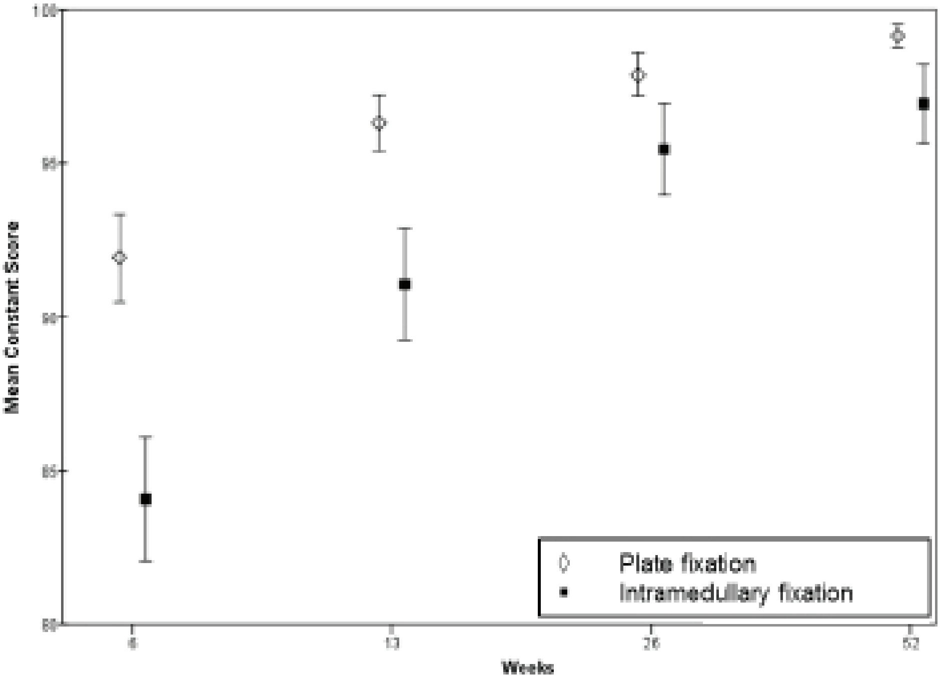
In the IMF group, the rate of complications requiring major revision was low, one of which was a failure of plate fixation according to the intention to treat analysis.



II. A

Figure II. Graph displaying postoperative DASH (A) and Constant-Murley scores (B) at 6, 12, 24 and 52 weeks after surgery respectively.
The DASH scores for PF were 10.8 (SEM 1.4), 4.63 (SEM 1.0), 3.0 (SEM 0.8) and 2.4 (SEM 0.6) and for IMF 15.1 (SEM 1.7), 8.5 (SEM 1.4), 5.6 (SEM 1.3) and 3.9 (SEM 1.1).
2A also displays the Area Under the Curve for the postoperative period of 6 weeks through 6 months.

SEM = Standard Error of the Mean



II. B

VII

The Constant-Murley scores for PF were 91.9 (SEM 1.4), 96.3 (SEM 1.0), 99.2 (SEM 0.4) and 96.0 (SEM 0.8) and for IMF 84.1 (SEM 2.0), 91.1 (SEM 1.8), 95.5 (SEM 1.5) and 91.3 (SEM 1.5).

In the PF group, 5 additional patients had their plates removed at their explicit request following fracture union. Also, 2 patients in the IMF group had the IM device routinely removed under local anesthesia and 10 under general anesthesia to prevent future migration of the implant according to the treating surgeon's practice.

DISCUSSION

There were no significant differences noted between the two surgical interventions for the primary study end parameter, the DASH score at 6 months postoperatively. However, the present study confirms that plate fixation results in a faster improvement in DASH score during the first 6 months after surgery. Complications were mainly implant related and in total similar among groups. The IMF group endured slightly fewer complications requiring major revision.

The DASH and Constant-Murley scores at final follow up were comparable to previously reported values for plate[1,5,18]

Table IV. Mean improvement in SF-36 subscale scores compared to preoperatively.

		Plate fixation	Intramedullary fixation	*p-value*
6 months after surgery compared to preoperative		**n = 47**	**n = 58**	
SF-36 score (mean ± SD)	Physical functioning	44.1 (± 23.4)	35.0 (± 26.2)	*0.07*
	Role-physical functioning	72.3 (± 41.2)	63.8 (± 49.4)	*0.35*
	Bodily pain	55.9 (± 23.8)	42.5 (± 33.6)	*0.02**
	General health perception	2.4 (± 22.0)	2.3 (± 16.9)	*0.22*
	Energy/Fatigue (Vitality)	15.6 (± 25.4)	4.7 (± 26.3)	*0.03**
	Social Functioning	27.7 (± 30.6)	17.7 (± 27.5)	*0.08*
	Role-emotional functioning	15.2 (± 42.6)	5.2 (± 46.6)	*0.26*
	Mental Health	4.3 (± 20.3)	3.4 (± 21.2)	*0.82*
1 year after surgery compared to preoperative		**n = 53**	**n = 59**	
SF-36 score (mean ± SD)	Physical functioning	43.0 (± 22.7)	39.5 (± 22.9)	*0.42*
	Role-physical functioning	76.9 (± 39.8)	68.2 (± 45.7)	*0.29*
	Bodily pain	58.5 (± 19.3)	48.0 (± 28.4)	*0.07*
	General health perception	4.8 (± 19.6)	0.4 (± (26.2)	*0.13*
	Energy/Fatigue (Vitality)	15.7 (± 22.1)	4.6 (± 26.8)	*0.02**
	Social Functioning	27.1 (± 33.9)	19.9 (± 27.2)	*0.36*
	Role-emotional functioning	12.2 (± 40.7)	8.5 (± 48.2)	*0.67*
	Mental Health	4.9 (± 17.5)	5.6 (± 22.1)	*1*

*Missing values were excluded. SD = Standard Deviation. *=p<0.05* and IM fixation.[4,18,19] We further assessed the level of physical functioning between 6 weeks and 6 months and demonstrated better subjective functioning in favor of PF. Assuming that groups were alike at randomization, this is probably even an underestimation of the difference, because the plate group already showed lower DASH scores at 6 weeks.

When looking at the postoperative complications, in general the frequency is similar between interventions. This, however, does not account for the rates of implant related irritation. Medial protrusion of TENs was, similar to previous studies, a considerable problem.[20,21] Since the medial end of the TEN cannot be locked, secondary shortening or rotation of the clavicle could result in protrusion of the TEN. Possible solutions for medial protrusion lie in endcaps which can be placed over the medial end of the TEN.[20] Lateral protrusion only occurred in case of accidental intraoperative penetration of the lateral cortex. In addition, the study protocol did not include routine removal of the IM devices following

Table V. Postoperative complications after Plate fixation (n = 58) and Intramedullary (IM) fixation (n = 62).

Complication		**Resolvement**		**Plate Fixation**	**Intramedullary fixation**
Infection	*Superficial*	Antibiotics		3 (5%)	0
	Deep	Surgical drainage		0	0
Desensitized skin, haematoma		Self-limiting		5 (8%)	6 (10%)
Transient neuralpraxia		Self-limiting		0	1 (2%)
Irritation due to implant protrusion		Wait-and-see		12 (21%)	1 (2%)
		Minor revision*		n/a	10 (14%)
		Hardware removal	*Local Anaesthesia*	n/a	10 (14%)
			General Anaesthesia	17 (31%)	35 (56%)
Implant breakage		Major revision**		1 (2%)	0
Implant failure		Major revision		0	2 (3%)
Nonunion		Major revision		1 (2%)	0
Malunion		Major revision		0	0
Refracture after implant removal		Major revision		2 (3%)	0

**The minor implant revisions, which were performed under local anesthesia, included partial removal of the protruding end of an implant. All 10 patients underwent total implant removal due to persistent irritation after minor revision. Since it involves a similar complication type, it is counted only once when summing the total number of complications per study group.*
***Major revision was defined as revision of surgical fixation.*

fracture union. The interhospital and intersurgeon variation of participating centers in dealing with implant removal also grossly explains the high number of implant irritation in the IMF group. Furthermore, it illustrates that IM implants should be removed in routine fashion after fracture union to avoid irritation, preferably under local anesthesia.

For both interventions, the recording of symptoms of implant irritation were strictly applied, yet this does not form a valid explanation for the high number of plate irritations encountered, especially when comparing to previously reported data.[1,5] Plate placement on the anterior-inferior aspect of the clavicle may be a solution to reduce implant irritation yet this may influence the strength of the repair construct.[22] The previously appreciated and biomechanically confirmed risk of refracture following plate removal was also illustrated in this study.[9,23] It stresses the importance of leaving plate and screw constructs in situ as long as possible and to caution patients in their rehabilitation following removal.

Reported surgical procedure lengths for both techniques were similar to previous values.[19,24] However, the number of open reductions in the IMF group is remarkable when considering that one of the advocated advantages of this antegrade technique is closed reduction. A clear explanation for this high rate of open reduction could not be found. All conversions from IMF to PF considered fractures located in the lateral part of the midshaft. Even when using the smallest diameter nails, the lateral fragment of the clavicle could not be entered. This raises the question of the suitability of these fracture types for antegrade IMF. In turn, the high rate of open reduction may explain the agreement between intervention groups in terms of cosmetic satisfaction. The one crossover in the plate group was the result of a communication error.

Recent study results indicate that patients reach a steady state in shoulder function 1 year after surgery.[25] We included the 1 year outcomes measures as secondary endpoints, showing similar levels of functioning as the primary results at 6 months. The strengths of this study include prospective randomization, power calculation and the report of both objective and subjective outcomes scores with sufficient follow up. In addition, care has been taken throughout the follow up process to note encountered complications and describe these in detail.

However, several encountered limitations need also to be addressed. The first limitation is inherent to the study's multi-center and thus multi-surgeon design. This may lead to variations in and possibly unpredictable results. We believe, however, that this does reflect daily clinical practice in average hospitals and results are therefore representative. Secondly, due to the differences in surgical techniques, both patients and treating surgeons could not be blinded. In addition, all pre- and postoperative data were collected by two investigators (F.J.G.W. and M.H.J.H.) who were not blinded either. The usage of a self-administered outcome score which was always completed prior to the actual follow up appointment, however, limited possible investigator related bias.

The DASH score was chosen as primary end point. It is a frequently used scoring tool that provides reliable results to rate upper extremity function. Yet it should be pointed out that the score does not specifically focus on function and possible pathology of the clavicle. Such a score, however, is lacking and we believe that the addition of the Constant-Murley score as secondary endpoint provides a complete overview of shoulder function. Further, collecting DASH baseline scores was not planned in the original study protocol, disabling correction for remaining differences among study groups after randomization. In contrast, SF-36 scores were collected at baseline and showed that the PF group was less vital than the IMF group. The higher gain in vitality scores in the plate group at 6 and 12 months may have resulted from regression-to-the-mean and should be interpreted with caution. The greater improvement in bodily pain scores between baseline and month 6 after surgery should be assessed with the same caution, for in a secondary analysis of the SF-36 subscales scores at 6 month and 12 months without correction for baseline, no significant differences between study groups were observed. We suggest suspending judgement concerning possible differences in bodily pain and vitality. Further study is needed here.

Finally, study inclusion was not discussed with 44 potential participants because the attending surgeons did not have the required experience with either procedure as stated in the study protocol. Characteristics of these excluded patients, such as age and fracture pattern, proved to be similar to those of the included patients on retrospective comparison.

In conclusion, both procedures show satisfying functional results but patients after PF display a faster recovery the first 6 months after surgery. In turn, the rate of major complications in the PF group tends to be slightly higher than the IMF group. In both groups, the main complication concerns implant related irritation. Future investigation should therefore focus on minimizing implant related irritation after clavicle surgery.

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VII

CHAPTER VIII

Introducing the Surgical Therapeutic Index in trauma surgery; an assessment tool for the benefits and risks of operative fracture treatment

Submitted

Olivier A.J. van der Meijden, MD[1]
R. Marijn Houwert, MD, PhD[1]
Frans-Jasper G. Wijdicks, PhD[1]
Marcel G.W. Dijkgraaf, PhD[2]
Loek P.H. Leenen, MD, PhD[3]
Michiel H.J. Verhofstad, MD, PhD[4,5]
Egbert J.M.M. Verleisdonk, MD, PhD[1]

[1]*Department of Surgery, Diakonessenhuis, Utrecht, The Netherlands*
[2]*Clinical Research Unit, Academic Medical Center, Amsterdam, The Netherlands*
[3]*Department of Surgery, University Medical Center, Utrecht, The Netherlands*
[4]*Department of Surgery, St. Elisabeth Hospital, Tilburg, The Netherlands*
[5]*Department of Surgery, Erasmus Medical Center, Rotterdam, The Netherlands*

ABSTRACT

Background

The surgical therapeutic index has been described as an indicator of benefits and risks of surgical treatment in other fields of surgery. The index is calculated by dividing the cure rate of an operative treatment by the complication rate. This study introduces the STI in trauma surgery by comparing the indices for surgical plate fixation (PF) and intramedullary fixation (IMF) for the treatment of displaced midshaft clavicle fractures (DMCF).

Methods

In a randomized controlled fashion 120 patients were assigned to either PF (n = 58) or IMF (n = 62) with follow up at 6 weeks, 3 months, 6 months and 1 year after surgery. Cure was defined by a Disabilities of Arm Shoulder and Hand (DASH) score of 8 or less. Complications were noted as present or not present for each follow up moment and a panel of experts provided weights to the severity of complications. After bias correction and using nonparametric bootstrapping, STIs were reported along with their 95% confidence intervals. The higher a procedure's STI, the higher the benefit/risk balance of that procedure.

Results

The non-weighed STI after 6 weeks was significantly higher in the PF group. During further follow up the differences level out and turned non-significant. When weighing the STI for severity, the indices decrease but are significantly in favor of the PF group at 6 weeks and 6 months after surgery. At one year postoperatively, differences are not significant.

Conclusion

The STI may be a reliable tool to assess the benefits and risks of operative fracture treatment. Further studies on clavicle and other fractures with consistent results of this new scoring system are needed, before conclusions can be generalized. When determining the indices of PF and IMF, a significant difference in favor of PF was observed during the early phase of recovery, which was prolonged when correcting for the gravity of consequences of complications by using severity weights. One year postoperatively, the STI for PF and IMF were similar.

INTRODUCTION

In recent years, the Surgical Therapeutic Index (STI) has been described as an alternative way to present the pros and cons of surgical treatment. The concept was first described in the field of incontinence surgery in the late 1990's.[1] It is similar to and derived from the therapeutic index in pharmacology which describes the ratio of the desired effect of a certain drug to its possible toxic effect.

The STI is defined as the ratio between the cure rate and complication rate of a surgical intervention. The definition of cure, naturally, depends on the patient's primary source of pathology. Determining the complication rate at a specific moment in time is the sum of all complications associated with the performed surgical procedure. Severity factors can be added to grade the degree of complications and its consequences.[2] The index should be interpreted as expressing a certain level of safety; the higher a procedure's STI, the safer the procedure. This way, it may play an additional informative role in pre-operative counselling of a patient and helping him or her in deciding on the optimal surgical treatment.

The STI is yet to make its entrance in trauma care and fracture management in particular. The optimal treatment of clavicle fractures has been a topic of debate for many years. Although many of these fractures may be treated conservatively successfully, it seems to be the general consensus that displaced midshaft clavicle fractures (DMCF) are best treated surgically. The most frequently applied surgical techniques are open reduction and internal plate fixation (PF) or (closed) reduction and intramedullary fixation (IMF).

The purpose of this study was to introduce the STI in trauma surgery by comparing the indices for surgical PF and IMF for the treatment of DMCF. Our hypothesis was that the index for PF would be higher during the early recovery phase but the indices would be comparable between both groups one year after surgery.

MATERIAL AND METHODS

Study Population

The study population consisted of 120 patients who suffered a DMCF and participated in the Plate Or Pin trial (POP-trial, registration number V.10.365/R-10.18D/mg).[3] Participants in this multi-center, prospective, controlled trial were randomized to either PF or antegrade IMF using a Titanium Elastic Nail (TEN). Postoperative follow up took place at 6 weeks, 3 months, 6 months and one year after surgery. Due to extensiveness we refer to the study protocol and previously reported objective and patient-oriented outcome for full description of in- and exclusion criteria, operative procedures and (functional) outcome parameters.[3,4]

Cure

The primary end parameter in the POP study was the Disabilities of the Arm, Shoulder and Hand score (DASH).[5] Depending on age and patient activity, a normal DASH score ranges from 2 to 8.[5,6] For each follow up moment and per intervention group, the cure rate was therefore defined by dividing the number of patients with a DASH score of 8 or less by the total number of patients included in the operative group.

Complications

Complications were grouped as follows: infection (superficial or deep), neurovascular pathology (transient brachial plexus syndrome, hematoma, and desensitized skin), and implant related problems (soft tissue irritation, breakage, and failure), bone-healing problems (nonunion, malunion) and refracture after implant removal.

Redness and swelling with/without purulent discharge at the wound site was considered a superficial infection while infection requiring debridement or implant removal was defined as a deep infection. Paresthesia of the arm and/or fingers were considered transient after spontaneous recovery within 6 months after surgery and defined as transient brachial plexus lesions. A palpable presence of the implant resulting in soft tissue irritation was considered implant irritation. A nonunion was defined as lack of radiographic healing with clinical evidence of pain and motion at the fracture site at 6 months after surgery. Finally, a symptomatic malunion was defined as a shortened, angulated or displaced position of the clavicle on X-ray with clinical symptoms after 6 months.

Complications were scored as present or not present at 6 weeks, 3 months, 6 months and 1 year postoperatively. In case of two different types of complications registered in one patient at the same time, the complication with the most severe treatment consequences was noted. If relevant, treatment by implant removal was taken into account. In case of occurrence of different types of complications in the same patient but at different follow up moments, both types of complications were registered.

The complication rate was calculated in two ways. First, the sum of all types of complications for each surgical group per follow up moment was determined and divided by the number of patients in the corresponding group. For the second calculation, a severity weight was added. These weights correspond to the impact and consequences of the complications noted in terms of further treatment required.

Complication management

Complication management consisted of a self-limiting/'wait-and-see' policy, treatment with antibiotics, surgical drainage and debridement, minor implant revision, major implant revision and removal of hardware under local or general anesthesia. The minor implant revisions, which were performed under local anesthesia, included partial removal of the protruding end of an implant. Major revision was defined as revision of surgical fixation.

Routine hardware removal

The removal of hardware under local or general anesthesia was also included in the complication rate, even when performed routinely according to the treating physicians practice. Routine removal was not prescribed in the original study protocol.[3]

Surgical Therapeutic Index; Severity Factors

There were no previously published studies on the STI and clavicle fractures for reference. Three expert trauma surgeons (L.P.H.L., M.H.J.V and E.J.M.M.V.) were asked to grade the various complications and in particular the subsequent treatment types to manage the complication on a scale of 1-10. A value of 1 represented an uncomplicated postoperative recovery and 10 the worst possible recovery. This additionally resulted in a ranked order in terms of severity for the listed types of complication management.

From these data two severity weighing models were determined. Model 1 consisted of the mean values assigned by the experts for each complication management type. Model 2 consisted of the ranked order of severity of complication management. Finally, the STI was defined by dividing the cure and complication rates, respectively. The STI was determined at 6 weeks, 3 months, 6 months and 1 year after surgery. In case of a successfully treated complication at for instance 6 months, this complication was not included for STI determination during final follow up after 1 year. This way, if the complication rates decreases, the STI can increase if the cure rate stays the same. This demonstrates a progress of the indices over time.

Statistical Analysis

The unpaired Student's t-test was used to compare continuous variables and the X^2-test for dichotomous variables comparison. Inter-rater reliability reflecting the consistency among the three experts concerning their severity weighing of complications was determined by calculating the two-way mixed intra-class correlation coefficient for average measures.

After bias correction and using nonparametric bootstrapping, surgical therapeutic indices were compared by their confidence intervals. Sample sizes similar to the original sample separately for each group and with replacement were drawn 1000 times. Bootstrapping was used to generate both 83% and 95% confidence intervals. The latter ones were used for reporting, but the significance of observed differences was defined as absence of overlap of the respective 83% confidence intervals.[7] Statistical analysis was performed using version 20.0 of the Statistical Package for the Social Sciences (SPSS) for windows (SPSS, Chicago, IL, USA). A *p*-value of <0.05 was set for statistical significance.

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RESULTS

A total of 58 patients were enrolled for PF and 62 for IMF. At baseline, there were no differences between the two groups (Table I). One year after surgery 50 patients (86%) in the PF group and 55 patients in the IMF group (89%) were considered cured (*p=0.67*, table II).

A summation of complications and consequences for treatment for the entire follow up period is displayed in table III. In the PF group, 3 patients were lost to follow up for reasons unknown. Superficial infection treated with antibiotics occurred in 3 (5%) patients in the PF group and 4 patients (7%) suffered from a complication requiring major surgical revision, one of which was also previously treated for a superficial infection. The IMF failed in 2 patients (3%) but there were no nonunions recorded for this procedure.

Ten patients underwent minor revision in the IMF group but all eventually progressed to total implant removal due to persistent soft tissue irritation. Eleven patients had their TEN removed in routine fashion without experiencing prior soft tissue irritation. In the PF group, five patients had the implants removed at their specific request.

The inter-relater reliability based on consistency of the questioned experts was 0.95 (0.82 – 0.99). This correlates with excellent agreement.[8] The assigned mean values (model 1) and mean ranked order (model 2) for complication management are displayed in table IV.

The unweighed STI after 6 weeks was significantly higher in the PF group. During further follow up the differences leveled out and were not significant (Table V). When weighing the STI following models 1 and 2, the indices were significantly in favor of the PF group at 6 weeks and 6 months after surgery. At 3 months and one year postoperatively, differences were not significant.

Table I. Baseline characteristics per group.

Preoperative data		PF (n = 58)	IMF (n = 62)	*p-values*
Age (years; mean ±SD)		38.4 (14.6)	39.6 (13.2)	*0.64*
Gender (n, %)	Male	53 (92%)	60 (97%)	*0.21*
	Female	5 (8%)	2 (3%)	
BMI (kg/m2; mean ± SD)		24.7 (3.5)	24.2 (3.0)	*0.36*
Smokers (n, %)	Yes	19 (33%)	20 (32%)	*0.9*
	No	38 (67%)	42 (68%)	
Fracture side (n, %)	Right	30 (52%)	29 (47%)	*0.59*
	Left	28 (48%)	33 (53%)	
Trauma mechanism (n, %)	Traffic accident	28 (48%)	25 (40%)	*0.17*
	Sports	18 (31%)	29 (47%)	
	Fall from stance	12 (21%)	8 (13%)	
Fracture Classification (n, %)*	Simple	27 (47%)	24 (39%)	*0.58*
	Wedge	29 (50%)	34 (55%)	
	Complex/Comminuted	2 (3%)	4 (7%)	

PF = Plate Fixation. IMF = IntraMedullary Fixation
SD = Standard Deviation. BMI = Body Mass Index (kg/m2)
**Fracture Classification according to Orthopaedic Trauma Association*

DISCUSSION

This study introduces a tool to assess the benefits and risks of operative fracture treatment. The STI enables medical personnel as well as patients to easily weigh the benefits and adverse sides of different surgical techniques; the higher a procedure's STI, the higher the benefit/risk balance of that procedure. We emphasize that the message of this study is not to be found in the absolute numbers considering the inability to compare with previous studies, but perhaps more to present an alternative philosophy for rationale behind different surgical techniques.

Introduction of a new scoring tool poses certain questions. In this case: what defines cure? And even more so, does every complication have similar impact on patient recovery? Although a slight variation in DASH score in the healthy population is noted, we believe that assuming the lower margins of this 'healthy' function score safely represents a cured patient. The rating of complications and in particular the impact of different types of complications on overall patient recovery, however, was more difficult. The severity weighing was applied to bear meaning to the differences in absolute numbers of complications and the extent of possible consequences. One can imagine that a self-limiting complication is inconvenient yet it does not have the implications of, for instance, a revision surgery. Also, several patients in the PF group explicitly requested the hardware to be removed upon fracture healing which brings the hazards of reoperation under general anesthesia. This also accounted for many patients in the IMF group despite the proclaimed possibility to perform hardware removal under local anesthesia.

We opted to base the severity weighing on the opinion of three skilled surgeons, considering their experience with the complications at hand. Perhaps, however, in times in which patient based outcome measures are increasingly important, it would have also been interesting to survey the patient population for their opinion.

Our hypothesis was that STI's would be higher for PF during the early postoperative phase but similar between groups one year after surgery which was confirmed. The number of patients cured was comparable among the two

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Table II. Number of patients cured per operative group for each follow up moment.

Follow up	PF	IMF	*p-value*
6 weeks	32 (55%)	25 (40%)	*0.54*
3 months	47 (81%)	44 (71%)	*0.60*
6 months	50 (86%)	50 (81%)	*0.12*
1 year	50 (86%)	55 (89%)	*0.67*

Cure is defined as the number of patients with a DASH score of 8 or less.
PF = Plate Fixation. IMF = IntraMedullary Fixation

groups although there was a trend in favor of the PF group during the early recovery phase. In combination with lower early postoperative complications, in particular implant related soft tissue irritation, this resulted in a higher STI than the IMF group. The application of severity weights naturally lowers the indices for both groups but also created significant differences in favor of the PF group at two moments of follow up: 6 weeks and 6 months after surgery.

Table III. Total registered complications and treatment per operative group after final follow up.

Complication		**Management**		**Overall**	
				PF (n = 55)	IMF (n = 62)
Infection	*Superficial*	Antibiotics		3	0
	Deep	Surgical drainage		0	0
Hypesthesia, haematoma		Self-limiting		5	6
Transient neuralpraxia		Self-limiting		0	1
Soft tissue irritation due to implant		Wait-and-see		12	2
		Minor revision		0	10
		Hardware removal	*Local Anaesthesia*	0	10
			General Anaesthesia	17	35
Implant breakage		Major revision		1	0
Implant failure		Major revision		0	2
Non-union		Major revision		1	0
Mal-union		Major revision		0	0
Refracture after implant removal		Major revision		2	0

PF = Plate Fixation. IMF = IntraMedullary Fixation

This can be explained by the severity weights assigned to implant removal and major surgical revision. At 3 months postoperatively, the rate of implant removals and surgical revisions is equally low. At 6 months, however, the implant removal rate in the IMF group is much higher corresponding with a lower STI. It should be mentioned that at one point in the analysis the STI is in favor of IMF, although not significant. This is without severity weighing at one year after surgery. The advantage of the IMF at this stage can be explained by the occurrence of late major complications such as clavicle refracture after plate and screw removal in the PF group.

Overall, the gradual decrease in STI for PF and relatively stable STI for IMF are remarkable. They can be explained by the high rates of implant related soft tissue irritation. Surgeons tend to leave plate and screw constructs in situ unless removal is absolutely warranted or explicitly requested by the patient. If performed, removal generally takes place after full recovery and always requires general anesthesia. TENs were often removed sooner and removals were distributed more evenly during the entire follow up period. Despite the proclaimed advantage that IM devices can preferably be removed under local anesthesia, this was only performed in 22% of TEN removals, regardless of the presence of implant related irritation. We believe that the high rates of implant related soft tissue irritation, also in comparison to previous studies,[9-14] stresses the importance of meticulous operative technique and in case of IMF, routine implant removal upon achieving fracture union.

Several study limitations need to

Table IV. Assigned severity weights for each type of complication and subsequent management.

Complication management		Model	
		Mean Value (1)	*Mean Rank (2)*
Self-limiting / Wait-and-see		3.3	1.5
Antibiotics		4	2
Surgical drainage		8	6.5
Minor revision		4.7	2.7
Hardware removal	*Local Anaesthesia*	5.3	3.8
	General Anaesthesia	6.3	5
Major revision		8	6.5

Three expert trauma surgeons (L.P.H.L., M.H.J.V and E.J.M.M.V.) were asked to grade the various complications and in particular the subsequent treatment types to manage the complication on a scale of 1-10. A value of 1 represented an uncomplicated postoperative recovery and 10 the worst possible recovery. This additionally resulted in a ranked order in terms of severity for the listed types of complication management. From these data two severity weighing models were determined.

Weigh Model 1 consists of the mean values assigned by experts.

Weigh Model 2 consists of the mean ranked order of severity of complications.

be addressed. First, the number of patients included is relatively low. This introduces the risk of type II errors and the possibility that very rare, but disabling complications have accidentally not been observed in our cohort. For example, brachial plexus lesions after IMF are rare, but have been described. One iatrogenic palsy of the arm will change the STI immediately. Ideally, a STI is continuously updated with new patient data and its reliability therefore improves. Secondly, we opted to base the severity factors on the opinion of three skilled surgeons, considering their experience with the complications at hand. A larger group of experts will reduce the dispersion in the assessment of severity. Moreover, in times in which patient reported outcome measures are increasingly important, it would also be interesting to survey the patient population for their opinion. A third limitation of our current study is that multiple, but contemporary complications in one patient, only the most severe treatment consequence was noted. This could have led to relatively optimistic STI's. However, this was only noted in one patient who experienced hypoesthesia around the operation scar and soft tissue irritation due to the

Table V. Surgical Therapeutic Indices (STI) per operative group at each follow up moment with and without correction for severity factors.

STI - Unweighed (95% CI)	**PF**	**IMF**
6 weeks*	3.6 (1.6 - 7.8)	1.2 (0.7 - 1.9)
3 months	3.3 (1.9 - 5.8)	3.5 (1.9 - 7.0)
6 months	4.5 (2.4 - 8.6)	3.3 (2.1 - 5.5)
1 year	4,5 (2.3 - 9.3)	10.8 (2.1 - 49.9)

STI - Model 1 weighing (95% CI)	**PF**	**IMF**
6 weeks*	0.9 (0.5 - 1.9)	0.3 (0.2 - 0.4)
3 months	0.8 (0.5 - 1.5)	0.4 (0.3 - 0.8)
6 months*	0.7 (0.4 - 1.4)	0.3 (0.2 - 0.5)
1 year	0.4 (0.2 - 0.5)	0.3 (0.2 - 0.4)

STI - Model 2 weighing (95% CI)	**PF**	**IMF**
6 weeks*	1.9 (1.0 - 4.2)	0.5 (0.3 - 0.9)
3 months	1.6 (0.8 - 3.3)	0.7 (0.4 - 1.3)
6 months*	1.2 (0.5 - 2.7)	0.5 (0.3 - 0.8)
1 year	0.5 (0.3 - 0.8)	0.4 (0.3 - 0.5)

Weigh factor 1 consists of the mean values assigned by experts.
Weigh factor 2 consists of the ranked order of severity of complications.
* = significant difference. CI = Confidence Interval.
PF = Plate Fixation. IMF = IntraMedullary Fixation

implant at the same follow up moment.

With regards to inter-rater correlation of the severity weights, deep infections requiring surgical debridement did not occur in this study but were nevertheless assigned a severity factor for possible future applications in other patient populations. This did, however, did not influence the inter-rater reliability based on consistency.

In conclusion, the STI may be a reliable tool to assess the benefits and risks of operative fracture treatment. Further studies on clavicle and other fractures with consistent results of this new scoring system are needed, before conclusions can be generalized. When determining the indices of PF and IMF, a significant difference in favor of PF was observed during the early phase of recovery, which was prolonged when correcting for the gravity of consequences of complications by using severity weights. One year postoperatively, the STI for PF and IMF were similar.

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CHAPTER IX

Scapulothoracic kinematics after surgical fixation of clavicle fractures; report of an experiment

Submitted

Olivier A. J. van der Meijden, MD[1,2,3]
Martijn H.J. Hulsmans[1]
Egbert J.M.M. Verleisdonk, MD, PhD[1]
Bart J. Burger, MD, PhD[2,3]
Marco Hoozemans, PhD[3,4]
R. Marijn Houwert, MD, PhD[1]
Norman D'hondt, MSc[4]
Dirk Jan Veeger, PhD[4]

[1]*Department of Surgery, Diakonessenhuis, Utrecht, The Netherlands*
[2]*Department of Orthopaedic Surgery, Medical Center Alkmaar, Alkmaar, The Netherlands*
[3]*Centre for Orthopaedic Research Alkmaar, Medical Centre Alkmaar, Alkmaar, The Netherlands*
[4]*MOVE Research Institute, Faculty of Human Movement Sciences, VU University, Amsterdam, The Netherlands*

ABSTRACT

Background

The goal of this experiment was to explore if scapulothoracic dyskinesia would be visually detectable one year after uncomplicated operative fixation of displaced midshaft clavicle fractures (DMCF) by means of expert analysis. Our hypothesis was that in patients with uncomplicated fracture union after plate fixation (PF) or intramedullary fixation (IMF), no differences could be visualized.

Material and Methods

Ten patients, one year after either PF or IMF of DMCF, performed a series of ten maximum abduction motions of both arms followed by ten maximum forward flexion motions. Motions were recorded by video and analyzed by two experts individually. Ten healthy volunteers with no history of shoulder pathology acted as control group. Inter-observer reliability and percentage of agreement was determined by calculating Cohen's Kappa values.

Results

The question if a participant was a patient or a control was answered correctly by the two experts 8 and 13 times out of 20, respectively. If applicable, the affected side was judged correctly 1 and 2 times out of 10 patients, respectively. The Cohen's kappa value for inter-observer reliability was -0.100 (95% CI: -0.54 – 0.34) and the percentage of agreement was 45%.

Conclusion

We did not find convincing evidence based on expert clinical evaluation that justifies any negative statements regarding the visual presence of altered scapulothoracic kinematics after uncomplicated operative fixation of clavicle fractures one year after surgery. The low inter-observer reliability and limited agreement between expert evaluation and actual patient or control status clearly indicates the difficulty in visually detecting gross scapulothoracic dyskinesia.

INTRODUCTION

The overhead shoulder motion is a result of complex synchronous motions of multiple joints often referred to as the scapulohumeral rhythm (SHR).[1] This rhythm is determined by a balanced contribution of the glenohumeral and scapulothoracic articulations, the latter in return being considered a summation of sternoclavicular and acromioclavicular joint motion over the scapulothoracic gliding plane.[2]

Several pathological conditions of the shoulder girdle have been identified to contribute to alterations in both the resting position and dynamic behavior of the scapula. This influences normal scapulothoracic kinematics and as a result also the motion of the shoulder girdle.[3] Such shoulder disorders include rotator cuff tears, glenohumeral instability, subacromial impingement syndrome and adhesive capsulitis.[4-8] Since scapular position and motion is dependent on the strut function of the clavicle and its contact with the thorax, shortening of the clavicle will by definition alter scapular kinematics. Recently Hillen et al[9] showed the effect of shortening of the clavicle on scapulothoracic kinematics following fracture malunion and suggested these kinematic changes to be a possible contributor to pain and discomfort of the shoulder girdle.

Fractures of the clavicle are either treated conservatively or by (open) reduction and surgical fixation.[10] As described throughout this thesis, plate fixation (PF) and intramedullary fixation (IMF) are the most commonly used surgical techniques. Operative results in terms of objective and subjective outcomes scores and rate of complications are described in **Chapter VII** and **VIII**. Little is known about the longterm effects of these fixation methods on motion patterns of the shoulder girdle. Small changes in orientation and length of the clavicle will affect kinematics. In addition, the effect of fixation itself might also lead to changes due to proprioceptive changes or to mechanical effects of the structure of the fixation.

Before engaging into analysis by means of advanced motion technology such as tracking sensors and ElectroMyoGraphy monitoring, this experiment was conducted to see if clinical expert evaluation could detect alterations in scapulothoracic kinematics in both post-clavicle fractured and normal shoulders. The goal of this experiment, therefore, was to explore if scapulothoracic dyskinesia would be visually detectable one year after operative fixation of displaced midshaft clavicle fractures by means of expert analysis. Our hypothesis was that in patients with uncomplicated fracture union after plate or IMF, no differences could be visualized.

MATERIALS AND METHODS

Study population

Following approval of the local Medical Ethics Committee (Addendum to registration number V.10.365/R-10.18D/mg), patients enrolled in the Plate or Pin (POP) study were asked to participate in this additional pilot study (please see **Chapter VII** of this thesis). The POP study is a randomized controlled multicentre trial in which plate fixation and intramedullary pin fixation of displaced midshaft clavicle fractures are compared in 120 patients with a one-year follow up.

Ten patients due for final study follow up were selected in chronological order; five from each surgical group. For all selected patients an uncomplicated follow up and radiographic union had been documented 6 months after surgery. Prior to the appointment in the

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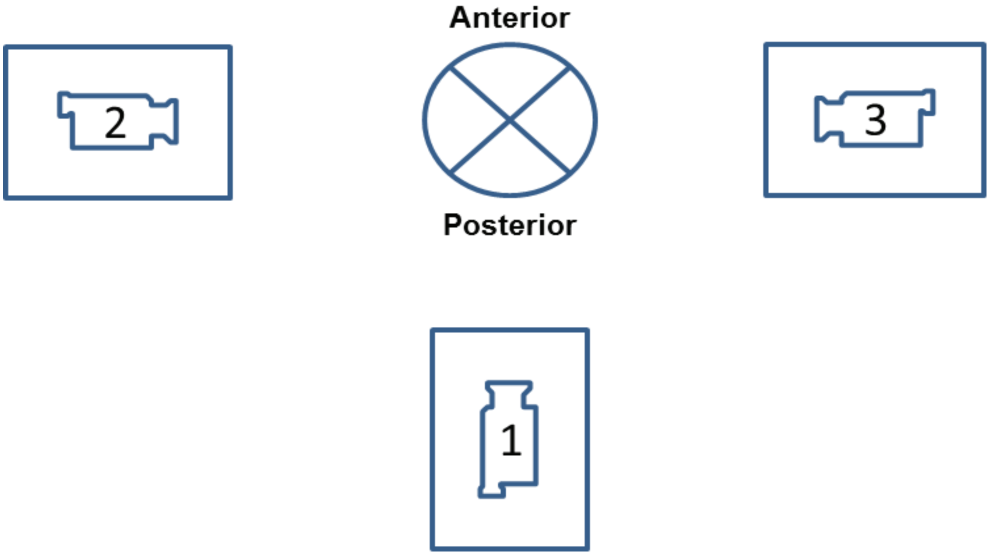

Figure I. Testing set up. Participants were asked to take place in the 'x-marked' spot and their motion exercises were filmed from posterior (1), left lateral (2) and right lateral (3).

outpatient clinic, patients were informed on the study addendum by telephone and received additional information by mail. Upon arrival for follow up further oral explanation was provided if necessary and informed consent was obtained. Ten healthy volunteers, matched for age, formed a control group and were tested in a similar manner. The volunteers had no history of shoulder pathology and had no symptoms of either shoulder at time of testing.

Data collection

Each participant performed a series of motion exercises while sitting on a chair with their backs straight, elbows and fingers extended and thumbs pointing forward. Ten maximum abduction motions of both glenohumeral joints simultaneously in the sagittal plane followed a series of ten maximum forward flexion motions of both arms simultaneously in the frontal plane with a brief pause in between. Motions were recorded from the left lateral side, right lateral side and from posterior (Figure I, video I). For both patients and volunteers, both clavicles were covered with tape for blinding of the experts.

Analysis

An experienced shoulder physical therapist (N.D'h.) and professor in human movement sciences (D.J.V.) independently reviewed the participants' motion exercises. They were asked to complete a questionnaire for analysis (Appendix I). The videos were blinded for review. Following individual review, they had a consensus meeting. Inter-observer reliability and percentage of agreement was determined by calculating Cohen's Kappa values using the IBM SPSS Statistics version 20.0. A Kappa value of 0 means that the inter-observer reliability is equal to chance. Values between 0.4 and 0.75 indicate a moderate inter-observer reliability and a value >0.75 indicates a strong reliability.[11]

RESULTS

There were no differences between the study group and control group with regards to sex and age (table I). The question if a participant was a patient or a volunteer was answered correctly by the two experts 8 and 13 times out of 20, respectively. If applicable, the affected side was judged correctly 1 and 2 times out of 10 patients, respectively. The Cohen's kappa value for inter-observer reliability was -0.100 (95% CI: -0.54 – 0.34) and the percentage of agreement was 45% (Table II).

The provided answers to questions three through eight of the questionnaire were heterogeneous and in many cases incomplete. Therefore they could not be reported.

Table I. Baseline characteristics study group and control group.

	Study group (n = 10)		**Control group (n = 10)**
	PF	IMF	n/a
Mean age (range)	43 (22 - 53)	32 (20 - 43)	35 (20 - 61)
Male ; Female	1 ; 4	1 ; 4	2 ; 8

n/a = not applicable. PF = plate fixation. IMF = IntraMedullary Fixation

Table II. Cross tabs displaying inter-observer agreement on judgment of participants' status as patient or volunteer. A. Represents the agreement between both observers and the actual status. B. Represents the agreement among the observers.

A.		Patient?	
		Yes	No
Observer 1	Yes	4	6
	No	6	4
Observer 2	Yes	6	3
	No	4	7

B.		Observer 1	
		Yes	No
Observer 2	Yes	4	5
	No	6	5

DISCUSSION

Scapulothoracic dyskinesia was not visually detectable one year after uncomplicated operative fixation of displaced midshaft clavicle fractures by means of expert analysis. The low inter-observer reliability and limited agreement between expert evaluation and actual patient or control status clearly indicates the difficulty in visually detecting gross scapulothoracic dyskinesia. Even more so when considering that, prior to the assessment, the observers were aware that 10 of 20 participants were in fact patients.

A negative Kappa value means that the observed agreement (45%) is lower than the hypothetical probability of chance agreement (50%). This major lack of agreement between observers suggests that there is a substantial variation in scapulothoracic motion between left and right within and between individuals. This variation is likely to be higher than the variation caused by the possible effect of a healed fracture on shoulder kinematics. The assessment of the scapulothoracic motion in relation to pathologic shoulder conditions should therefore be performed with great caution. Clearly, differences in kinematics do not necessarily correlate to symptoms and vice versa.

Ideally, one of the goals of operative treatment is to restore the normal length of the clavicle and therefore a kinematic difference is not expected. However, traditional intramedullary implants, including those used in the POP-study, do not control for rotational moments and do not have locking options. This means that in the early postoperative phase prior to fracture consolidation, secondary rotation of fractured clavicle parts and even shortening of severe oblique fractures may occur. In this experiment, patients with uncomplicated union following fracture fixation did not display visual differences in scapulothoracic motion patterns for the operated and non-operated shoulder.

Several other studies previously concluded that even in the presence of shoulder pathology, the magnitude of alterations in kinematics is very small and they also confirm that they are hard to detect in the first place.[6,7,12-14] McClure et al. however, have described that it is possible to clinically rate scapular dyskinesia.[15] Differences between their methodology and this study include a larger sample size, a superior camera position and the fact that 'their' volunteers performed loaded tasks. The sample size used in this experiment was small which introduces the risk of type II errors. In addition, perhaps something as simple of quality of used video cameras may have played a role. Finally, as the observers were aware that 10 of 20 study participants were in fact patients included in the POP-study, they were 'forced' to point out 10 participants as patients. This might be considered a limitation, yet the exact effect on observer reliability is unknown.

Nonetheless, in our experiment we did

not find convincing evidence based on expert clinical evaluation that justifies any negative statements regarding the visual presence of altered scapulothoracic kinematics after operative fixation of clavicle fractures one year after surgery. This is in line with the mechanical explanation of the three-point support of the scapula, in which the strut (clavicle) is anatomically reconstructed, which should therefore lead to only marginally, if any, scapulothoracic motion changes.

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IX

APPENDIX I. Evaluation form used for scapulothoracic motion analysis.

1. Is this a patient or a volunteer?
   Patient / Volunteer

2. If this is a patient, which side has been previously fractured?
   Right / Left

3. Is there a side-to-side difference in scapular positioning in a resting position?
   Yes (Left / Right) / No / cannot be determined

4. Is there a side-to-side difference scapulothoracic motion during arm elevation?
   Yes (Left / Right) / No / cannot be determined

5. During which motion phase does the side-to-side difference develop?
   0 - 60° abduction / forward flexion   > 60° abduction / forward flexion

6. What is the scapulohumeral motion rhythm?
   Right; 3:1 / 2:1 / 1:1 / primarily scapulothoracic
   Left; 3:1 / 2:1 / 1:1 / primarily scapulothoracic

7. Is there a side-to-side difference in maximum range of motion?
   Yes / no

8. Give an estimate of the maximum angle of humeral elevation.
   Right; ....
   Left; ....

CHAPTER X

General discussion and future perspectives

GENERAL DISCUSSION

Surgical decision making should never be taken lightly and is hardly ever straightforward. Despite years of debate, progressing insights and the benefits of modern technology, this also applies to the fixation of clavicle fractures. Two popular fixation techniques are plate fixation (PF) and intramedullary fixation (IMF). This thesis reports on biomechanical and clinical aspects of these two popular surgical techniques for the operative treatment of displaced midshaft clavicle fractures (DMCF).

Biomechanical Comparison

The implications of different types of fracture fixation on direct post-operative activities in daily living are hard to interpret. There seems to be a lack of solid physiologic data and studies analyzed in this thesis, comparing the fixation strength of PF and IMF, display a large variation in testing set up. However, the conclusion may be drawn that the presence of a cortical defect does directly influence the fixation stability. Both compression plates as well as reconstruction plates seem to form a more robust construct than the 'traditional' IM devices in terms of stiffness and failure loading. However, a novel IM implant, with the possibility to provide a more rigid and statically locked fixation, may be a promising alternative. A benefit of IM devices is that after removal following fracture union, the remaining clavicle is stronger than after plate removal.

In terms of shoulder motion, no evidence was found that justifies any negative statements regarding the visual presence of altered scapulothoracic kinematics after operative fixation of clavicle fractures one year after surgery. This experiment was based on the clinical evaluation of two experts in the field and their findings and accounted for both PF and IMF. Although it concerned an experimental setup with a small number of patients and controls, the low inter-observer reliability and limited agreement between expert evaluation and actual patient or control status were sufficiently convincing and clearly indicated the difficulty in visually detecting gross scapulothoracic dyskinesia.

Clinical outcome

Postoperative rehabilitation was similar for both operative techniques in the Plate or Pin study, stimulating early functional recovery, which allowed for easy and direct comparison. It might be advisable, however, to instruct patients after IMF, not to abduct the arm over 90 degrees for the first few weeks in order to prevent secondary shortening and thus possible implant related soft tissue irritation.

Overall, both PF and IMF demonstrated good recovery rates. Recovery was faster in the PF group, with a 55% recovery rate at 6 weeks after surgery according to the DASH score. However, at one year after surgery results were similar.

The rate of complications was rather high for both surgical techniques, in particular implant related soft tissue irritation. Implants were removed in high numbers, which in the PF group always required general anesthesia but in the IMF group was performed under local anesthesia in several occasions.
An objective scoring tool comparing different aspects of different techniques for surgical fixations of fractures is lacking. Therefore the Surgical Therapeutic Index (STI) was introduced into trauma care. When comparing the indices of PF and IMF, a significant difference in favor of PF was observed during the early phase of recovery. One year postoperatively, the STI for PF and IMF were similar.

Treatment recommendations
Different surgeons of different areas of practice have varying approaches in fracture management, as illustrated in **Chapter VI**. This does not necessarily imply a negative effect on the standard of care since often there is more than one solution available and justified.
Based on the results presented in this thesis, however, solid treatment recommendations can be made. In general PF has clearly the advantage over unlocked IMF. The fixation construct is more rigid allowing for early functional rehabilitation and both objective and subjective recovery is faster. In addition, lower cumulative complication rates were observed. Therefore, weighing the benefits and risks of surgery, for most fracture types PF is recommended.
But does that completely discard IMF for treatment of DMCF? Perhaps not and a closer look is needed here. IM fixation seems technically more challenging but it carries low risks of infection and complications requiring major revision surgery. The high rate of implant related soft tissue irritation confirms the general consensus that the implant is better to be removed as a matter of routine following fracture healing. Causes for implant related irritation, besides surgical technique, may be found in secondary fracture shortening after establishing realignment due to fracture comminution and obliquity. It could possibly be argued that IMF may still be an appropriate surgical technique but for a specific subset of fractures.

FUTURE PERSPECTIVES

From a biomechanical perspective, future studies might wish to focus on the influences of surgical repair on specific activities of daily living directly after surgery. What are the axial rotation moments around the native clavicle during certain loaded and unloaded tasks? Are surgical fixation constructs able to immediately withstand these rotation moments? This kind of information might enable clinicians to more specifically advise patients on their *do's* and *don'ts* in the rehabilitation process.
Considering the good recovery rates, other challenges ahead mainly lie in

diminishing the complications of surgical fixation. For both surgical techniques, there is clearly room for improvement. Obviously, the meticulous application of surgical techniques is a precondition, yet this does not always prevent complications.

The most frequently encountered complication was implant related soft tissue irritation. This is probably due to plate placement on the superior aspect of the clavicle with little soft tissue coverage. Alteration of plate positioning to the anteroinferior surface of the clavicle has been proposed as an alternative. However, laboratory results seem conflicting in terms of biomechanical stability which may influence the progress of recovery and so far large comparative clinical series are lacking.[1-3] Finally, recent biomechanical research confirmed the decreased strength of the healed clavicle following temporary plate and screw fixation and hardware removal.[4] It is not exactly clear from literature how long complete recovery of the bone takes to regain its original strength but clearly, patients should be cautioned following hardware removal by clear instructions. The effects of minimally invasive plating, plate positioning and clavicle strength after hardware removal on the possible reduction of related complications require further research.

With regards to IMF, the challenge mainly lies in identifying pre-operative risk factors for implant related soft tissue irritation. This may result in the identification of specific fractures suitable for IMF. Additionally, future research should address the possibilities to prevent secondary clavicle shortening following realignment and IM fixation. Locking options providing rotatory stability and so called End Caps, a smooth cap placed on the medial end of the IM fixation device, may aid in this process.[5]

Finally, the STI may be a reliable tool for the assessment of potential benefits and risks of operative fracture management. It should facilitate medical personnel as well as patients to easily assess the benefits and adverse sides of different surgical techniques. Further studies on operative fracture management are needed, however before conclusions can be generalized.

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CHAPTER XI

Summary

SUMMARY

This thesis focused on comparing two surgical techniques for the fixation of displaced midshaft clavicle fractures (DMCF). **Chapter I** provided a general introduction to the clavicle and clavicle fractures and contained the aims and an outline of content. The aims were;

1. To provide a general overview of clavicle fractures followed by a systematic report of current data on surgical complications of the most commonly used fracture fixation techniques and a comprehensive summary of the biomechanical characteristics of these techniques.

2. To evaluate the daily practice of management of displaced midshaft clavicle fractures among surgeons in The Netherlands.

3. To report objective and subjective results of a clinical trial comparing plate fixation (PF) and intramedullary fixation (IMF) of DMCF and introduce a new tool (Surgical Therapeutic Index) to assess surgical outcome.

4. To study the scapulothoracic kinematics of patients after surgical fixation of DMCF in an experimental setting.

Chapter II comprised a literature review of clavicle fractures in general and current concepts on fracture treatment. A distinction has been made between fractures of the medial, middle and lateral thirds of the clavicle and between children and adults. Regardless of fracture location and age of the patient, non-dislocated fractures are usually treated nonoperatively and a patient is provided with a sling of figure-of-eight bandage. In addition, children are also nearly always treated conservatively. A subset of patients in which an increase in surgical fixation is noted are those patients with displaced fractures of the middle third, or midshaft, of the clavicle. This is mainly due to reported higher nonunion rates for these patients following nonoperative management.

Chapter III documented a systematic literature search and critical appraisal of studies reporting on the complications of PF of DMCF. Studies were scored based on the Level of Evidence provided and on the Quality Assessment Tool of the Cochrane handbook. Complications were reported as minor or major, in which case additional surgery was required. Eleven studies were found eligible, three of which were considered to provide the highest level of evidence. In all but one study, nonunion and malunion rates less than 10% were reported. Implant related complications such as irritation or failure occurred in a wide range of 9% up to 64%.

In a methodologically identical manner described in the previous section, **Chapter IV** focused on the complications after IMF of DMCF and again displayed

a systematic analysis of encountered minor and major complications. Three out of six eligible studies were graded the highest level of evidence. Minor complications, including wound infection and implant irritation, were noted up to 31%. Nonunions and malunions, which were considered major complications, were as low as 3% in the studies with the highest levels of evidence. However, it was noted that IMF often requires an additional procedure to remove the used implant in routine fashion.

The literature review part of this thesis is concluded in **Chapter V**. This chapter demonstrated that despite extensive laboratory testing, the exact implications of fracture fixation on direct post-operative rehabilitation in terms of activities in daily living remains unclear. There seems to be a lack of solid physiologic data and included studies displayed a large variation in testing set up. Both compression plates as well as reconstruction plates seem to form a more robust construct than the 'traditional' IM devices in terms of stiffness and failure loading, yet a novel IM implant might provide a promising alternative. A benefit of IM devices is that after removal following fracture union, the remaining clavicle is stronger than after plate removal.

Chapter VI reported the results of a questionnaire, completed by both trauma and orthopaedic surgeons at the annual meeting of the Dutch annual meeting for Traumatology in 2012, regarding the (operative) treatment of DCMF in The Netherlands. The survey presented a case of a young patient with a DMCF and was completed by 212 (65%) of 326 attending physicians. It was found that 78% would decide for surgical treatment and that trauma surgeons more frequently opted for surgical fixation than orthopaedic surgeons ($p=0.00$). Open reduction and internal PF would be the surgical technique of choice for 88% of respondents. A majority of the respondents (71%) indicated that they consider that there is not sufficient scientific evidence to support either choice of treatment or surgical technique.

The objective and subjective results of a randomized controlled, multicenter trial which compared PF (n = 58) of DMCF with IMF (n = 62) were reported in **Chapter VII**. Patients were followed up until one year after surgery. Patients in the PF group recovered faster than the patients in the IMF group, but groups were similar at final follow-up. The rate of complications requiring revision surgery was low, yet implant related complications occurred frequently and were often treated by implant removal.

Chapter VIII introduced the Surgical Therapeutic Index (STI) into fracture management. The STI facilitates medical personnel as well as patients to easily assess the benefits and adverse sides of different surgical techniques; the higher a procedure's STI, the safer the procedure. When determining the indices of PF and IMF, a significant difference in favor of PF was observed during the early phase of recovery, which was prolonged when correcting for the gravity of consequences of complications by using severity factors. One year postoperatively, the STI for PF and IMF were similar. Of course this new scoring system for the assessment of potential benefits of operative fracture management needs further studies on operatively treated fractures before conclusions can be generalized. The STI might, however, be a reliable tool to assess the safety of operative fracture treatment.

Finally, **Chapter IX** reported on an experiment in which the scapulothoracic motion pattern of ten patients after surgical fixation of DMCF and ten healthy volunteers were visually analyzed by experts. No convincing evidence was found that justifies any negative statements regarding the visual presence of altered scapulothoracic kinematics after uncomplicated operative fixation of clavicle fractures one year after surgery. The low inter-observer reliability and limited agreement between expert evaluation and actual patient or control status clearly indicated the difficulty in visually detecting gross scapulothoracic dyskinesia.

CHAPTER XII - HOOFDSTUK XII

Samenvatting, doelstellingen en conclusies (Nederlands)

SAMENVATTING

De mens is zich vaak pas bewust van (onderdelen van) het lichaam als het niet meer naar behoren functioneert. De *clavicula*, de Latijnse en medisch gangbare naam voor het sleutelbeen, is nou typisch zo'n onderdeel. Het bot ontleent zijn naam aan het feit dat het rondom de lengte as kan draaien en hoe klein ook, voor een normale bewegelijkheid van de schouder is deze 'sleutel', die het borstbeen met het schouderblad verbindt, essentieel.

Ongeveer 5% van alle fracturen die volwassenen oplopen betreft de clavicula. De 'typische' patiënt met een clavicula fractuur is een actieve man jonger dan 30 jaar of een kwetsbare oudere man van boven de 70 jaar. Over het algemeen treedt een fractuur op na een directe val op de schouder, bijvoorbeeld bij sporten als wielrennen.

Voor het gemak worden fracturen van de clavicula opgedeeld in 3 types, afhankelijk van de locatie van de fractuur. In dit proefschrift ligt de focus op fracturen van het middelste 1/3 deel van het bot. De reden hiervoor is dat dit het meest controversiële deel is. Dat heeft met name betrekking op de optimale behandeling. Al sinds 3550 v.Chr. zijn medici met elkaar inconclaaf of je een patiënt nu beter kan behandelen middels een operatie of middels een mitella en rust. Voor beide behandelingen zijn argumenten te bedenken.

Zoals vaker binnen de geneeskunde is er een golfbeweging te ontdekken in de filosofie achter een bepaalde behandeling. Eind jaren '60 van de vorige eeuw was men van mening dat conservatieve behandeling, dat wil zeggen niet-operatief, hele lage kansen gaf op het niet helen van de fractuur (een zogeheten *nonunion*). Echter, in de jaren '90 en '00 toonden studie resultaten aan dat het operatief fixeren van de fractuur bij een bepaalde patiënten categorie juist toch tot betere resultaten leidde. Deze subgroep betreft patiënten waarbij er sprake is van volledige dislocatie, of verplaatsing, van de gebroken fragmenten en die gelokaliseerd zijn in het middelste 1/3 van de clavicula. Als we deze groep zonder operatie behandelen bestaat er een grotere kans op nonunion, het niet helen van de fractuur, en kan de functie van de schouder ook achter blijven. Een ander voordeel van operatieve fixatie is dat de weg naar herstel vaak korter is. Een extreme illustratie hiervan vormde afgelopen jaar de Spanjaard Jorge Lorenzo. Deze wereld kampioen in de MotoGP van 2012 viel tijdens de training van onze eigen Dutch TT van Assen (2013) dusdanig van zijn motor dat hij zijn clavicula brak. Nadat hij een operatie onderging finishte hij, binnen 24 uur na het ongeval coureur, toch nog keurig als vijfde. Hoewel dit natuurlijk een mooi voorbeeld is van een snel herstel en chirurgen in de afgelopen jaren sneller tot operatie van gedisloceerde midschacht claviclua fracturen (GMCF) zijn overgegaan, leeft de discussie hier omtrent nog steeds.

Indien men het besluit tot opereren heeft genomen rest echter ook nog de vraag: wat is de optimale chirurgische techniek? De twee meest toegepaste chirurgische technieken zijn fixatie van de fractuur delen middels een plaat die met schroeven aan weerszijden van de fractuur op het bot is bevestigd (plaat fixatie of PF), of door het plaatsen van een pin met een zekere mate van flexibiliteit binnen in de mergholte van het bot (intramedullaire fixatie of IMF). Ondanks jaren van voortschrijdend inzicht is nog niet duidelijk welke techniek de voorkeur zou moeten krijgen. Dit vraagstuk vormt de hoofdmoot van dit proefschrift.

DOELSTELLINGEN

In dit proefschrift worden twee technieken voor de fixatie van gedisloceerde midschacht clavicula fracturen met elkaar vergeleken. **Hoofdstuk I** beschrijft een algemene introductie van de clavicula en de doelstellingen van dit proefschrift. Deze doelstellingen zijn als volgt:

1. Het geven van een algeheel overzicht van clavicula fracturen, een systematische weergave van de complicaties die kunnen optreden na operatieve fractuur fixatie en daarnaast een overzicht van de biomechanische aspecten van deze fixatie technieken.

2. Weergeven hoe de huidige behandeling van gedisloceerde midschacht clavicula fracturen onder Nederlandse trauma chirurgen en orthopaeden is.

3. Presentatie van de uitkomsten van een prospectief gerandomiseerd onderzoek naar plaat en schroef fixatie versus intramedullaire pin fixatie van gedisloceerde midschacht fracturen van de clavicula en het introduceren van een nieuwe parameter waaraan operatief succes kan worden afgemeten.

4. Onderzoeken of middels klinische beoordeling door experts het bewegingspatroon van het schouder blad verandert na operatieve fixatie van een clavicula fractuur.

Hoofdstuk II bestaat uit een algemeen overzicht van clavicula fracturen en behandeling. Er wordt onderscheid gemaakt tussen fracturen van het mediale, middelste en laterale 1/3 deel van de clavicula en tussen fracturen bij kinderen en bij volwassenen. Ongeacht de anatomische locatie van de fractuur en de leeftijd van de patiënt, worden fracturen die niet gedisloceerd zijn vrijwel altijd conservatief behandeld middels een sling of een zogeheten 'figure-of-eight' bandage. Zodra de pijn het toelaat kan snel begonnen worden met oefenen van de schouder. Daarnaast geldt voor de behandeling van kinderen dat deze over het algemeen zonder operatie behandeld worden gezien de groeipotentie van het jonge bot. Binnen de patiënten populatie met een clavicula fractuur is er echter een subgroep waar te nemen onder wie een toename van het het aantal operatieve fixaties heeft plaats gevonden in het afgelopen decennium. Dit betreft patiënten met een volledig gedisloceerde midschacht clavicula fractuur en komt hoofdzakelijk door onderzoek dat aantoont dat er zonder operatie een significant grotere kans op nonunion is bij dit type fractuur.

Een systematische analyse van de beschikbare literatuur aangaande de complicaties die na PF van GMCF voorkomen wordt beschreven in **Hoofdstuk III.** De studies werden aan de hand van een tweetal meetinstrumenten beoordeeld en de complicaties werden gescoord als '*minor*' en '*major*'. Er was sprake van een *minor* complicatie indien de gevolgen hiervan beperkt waren en vanzelf overgingen danwel met bijvoorbeeld antibiotica konden worden behandeld. In geval van een *major* complicatie bleek een nieuwe operatieve ingreep noodzakelijk om deze te verhelpen. Er werden 11 studies geïncludeerd waarvan er 3 de hoogste Level of Evidence (wetenschappelijk bewijs) hadden. In deze studies was sprake van *minor* complicaties uiteenlopend van 9 tot 64% en van major complicaties tot 10%.

Middels een identieke methodologie wordt de systematische analyse van de literatuur van complicaties na IMF van GMCF beschreven in **Hoofdstuk IV**. Drie van de zes geselecteerde studies bevatten de hoogste Level of Evidence. *Minor* complicaties zoals wondinfecties en irritatie van de huid als gevolg van het geplaatste implantaat werden gerapporteerd tot 31%. *Major* complicaties zoals nonunion werden bij 3% van de patiënten vermeld. Wel dient vermeld te worden dat IMF vaak een secundaire ingreep nodig maakt om het implantaat te verwijderen.

De studie van de literatuur wordt afgesloten met **Hoofdstuk V** waarin de biomechanische aspecten van PF en IMF van clavicula fracturen met elkaar worden vergeleken. Ondanks veelvuldig testen van beide operatieve technieken in het laboratorium blijken de exacte gevolgen van de verschillende vormen van fractuur fixatie op de revalidatie direct na operatie onduidelijk te zijn. Met andere woorden; wat een patiënt precies wel en niet mag doen zonder daarbij de fixatie van de fractuur te schaden wordt niet duidelijk. Naast een op het oog gebrek aan fysiologische data is er tevens sprake van een grote variatie in onderzoeks methodologie tussen verschillende beschreven studies. Wel lijkt vast te staan dat zowel compressie platen als reconstructie platen een stevigere en robustere constructie vormen dan 'traditionele' IM implantaten als het gaat om construcie stijfheid en maximaal te verduren krachten voordat de constructie faalt. Er bestaat echter een nieuwer IM implantaat dat een veelbelovend alternatief kan zijn en voor meer stabiliteit zou kunnen zorgen. De reden hiervoor is dat dit implantaat na inbrengen kan verstijven en daardoor voor een meer rigide constructie kan zorgen. Tot slot komt wel uit onderzoeken een groot voordeel van IMF naar voren. Indien het implantaat na heling van de fractuur wordt verwijderd dan is het 'resterende' sleutelbeen na IMF sterker dan na PF. Dit kan voordelen hebben voor patiënten die snel hun activiteiten niveau weer dienen te bereiken.

Historisch gezien is er in Nederland sprake van een grote overlap in de behandeling van traumatisch letsel tussen trauma chirurgen en orthopaedisch chirurgen. **Hoofdstuk VI** geeft de resultaten weer van een enquête die afgenomen is onder aanwezigen op het gezamenlijke jaarlijkse congres van de Nederlandse Vereniging voor Traumachirurgie en de Nederlandse Vereniging voor Orthopaedische Traumatologie in november 2012. In de enquête werd een casus gepresenteerd van een jonge actieve patiënt met een GMCF. Naar aanleiding van de casus werden een aantal vragen gesteld. De enquete werd ingevuld door 212 (65%) van de 326 aanwezigen. Hieruit bleek dat van alle aanwezigen die de enquete hebben ingevuld 78% dit type fractuur operatief zou behandelen. Als er onderscheid gemaakt wordt tussen de verschillende type chirurgen blijkt dat trauma chirurgen significant vaker zouden opereren dan orthopaedisch chirurgen. PF bleek bij 88% van de respondenten de operatieve techniek van keuze. Tot slot gaf 71% aan dat er onvoldoende wetenschappelijk bewijs is die de ene dan wel de andere vorm van behandeling (operatief of niet operatief) of operatieve techniek (PF of IMF) ondersteunt.

Hoofdstuk VII beschrijft de objectieve en subjectieve resultaten van een prospectief gerandomiseerd onderzoek waarin PF met IMF werd vergeleken voor de behandeling van GMCF. Deze Plaat of Pin (POP) studie vond plaats in vier ziekenhuizen in Nederland en betrof in totaal 120 patiënten die lootten voor een van beide operatieve methoden en tot een jaar na operatie werden gevolgd. Hierin bleek dat patienten na PF sneller herstelden in het eerste half jaar na operatie, zowel op basis van objectieve als subjectieve uitkomst maten, maar dat de resultaten na een jaar vergelijkbaar zijn. Het complicatie percentage welke revisie operatie noodzakelijk maakte was laag (3-4%), maar irritatie van de huid als gevolg van het gebruikte implantaat bleek in beide groepen veel voor te komen (>50% in beide groepen) en maakte verwijdering van het implantaat na genezing vaak noodzakelijk.

De chirurgische therapeutische index wordt in **Hoofdstuk VIII** geïntroduceerd in de trauma chirurgie. De zogeheten 'Surgical Therapeutic Index' (STI) werd eerder beschreven in de incontinentie chirurgie en wordt bepaald door het percentage genezing van een ingreep te delen door het percentage complicaties. Deze index kan zowel medisch personeel als patiënten helpen om een afweging te maken van de voordelen en risico's van verschillende operatieve technieken en, in dit geval, fixatie van clavicula fracturen. De STI dient als volgt te worden geïnterpreteerd: 'hoe hoger de STI, hoe veiliger de ingreep.' Bij het vergelijken van de indices van PF en IMF is er in de direct postoperatieve fase een significant hogere STI na PF. Indien er zogeheten weegfactoren worden toegekend aan de complicaties, deze factoren geven een weging aan de zwaarte van de gevolgen van opgetreden complicaties, dan wordt de duur van de hogere STI in de PF groep verlengd. Een jaar na operatieve fixatie is er geen verschil tussen beide groepen meer te bestaan. Het spreekt voor zich dat dit scorings systeem nog nader bestudeerd en toegepast moet worden voordat gegeneraliseerde conclusies kunnen worden getrokken. In de toekomst zou de STI echter mogelijk een betrouwbaar scorings systeem kunnen zijn om de veiligheid van operatieve procedures te kunnen vergelijken.

Tot slot wordt in **Hoofdstuk IX** een experiment beschreven waarin het bewegings patroon van het schouderblad na twee verschillende manieren van chirurgische fixatie werd geanalyseerd. Recent onderzoek heeft namelijk aangetoond dat, indien een sleutelbeen breuk niet goed vastgroeid, dit negatieve gevolgen kan hebben voor het gehele bewegingspatroon van de schouder gordel met mogelijk klachten op de lange termijn tot gevolg. In dit experiment beoordeelden twee experts op het gebied van de schouder middels video analyse het bewegingspatroon van de geopereerde schouders van tien patienten uit de POP studie. Uit iedere chirurgische groep werden de beide schouders van 5 patiënten die een probleemloos herstel hebben gehad vergeleken met de schouders van 10 gezonde vrijwilligers zonder schouder klachten. Daarbij bleek dat er voor beide operative fixaties geen overtuigend visueel bewijs kon worden gevonden dat er sprake was van een veranderd beweginspatroon een jaar na operatie in vergelijking met de 'gezonde' schouder. Verder bleek dat de overeenkomsten in beoordeling tussen beide experts erg laag was, in het bijzonder als het ging om het beoordelen van de status van de onderzoeks deelnemers als patiënt of vrijwilliger. Dit geeft aan dat het zeer lastig blijkt te zijn om afwijkingen in het bewegings patroon van de schouder gordeel visueel te ontdekken.

CONCLUSIES

Voor de oplossing van een probleem zijn vaak meerdere mogelijkheden en verschillende chirurgen hebben verschillende opvattingen. Op basis van onderzoek gepresenteerd in dit proefschrift lijkt PF over het algemeen de voorkeur te hebben boven IMF als het gaat om de operatieve fixatie van GMCF. De constructie is steviger waardoor eerder functioneel herstel mogelijk is en zowel het objectieve als subjectieve herstel is sneller dan na IMF. De belangrijkste uitdaging voor de toekomst ligt in het verminderen van het hoge percentage irritatie dat patienten ervaren als gevolg van de gebruikte implantaten. Het is duidelijk dat daar nog veel ruimte voor verbetering is.

CHAPTER XIII - ADDENDUM

Review committee

Acknowledgements

About the author

REVIEW COMMITTEE

Prof. dr. F.J.G. Backx

Prof. dr. R.M. Castelein

Prof. dr. F.C. Oner

Prof. dr. K.C.B. Roes

Prof. dr. M.H.J. Verhofstad

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Op Google levert 'HSD' 17.000.000 hits op in 0.45 seconden. Toch zit de belangrijkste link daar niet tussen. Heren van de Hugo de Grootstraat 1, dat zij leve! Dank voor een pracht tijd in Utrecht.

Voormalige bewoners van de Maliebaan, Haverstraat, Rooseveltlaan en Overtoom, aan hen die maar al te vaak 'ik moet even iets doen', 'nee ik kan vanavond niet' en 'ik moet nu echt naar huis' hebben gehoord. Dank voor jullie geduld, begrip, ironie en relativeringsvermogen.

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Gezelligheids wielervereniging d'n Chasse Patate, alle aspecten van het leven zijn verenigd in de wielrennerij en ik kan me geen mooiere groep voorstellen om dat mee te delen. Een band die lek is moet geplakt worden, en geen flauwekulletjes!

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Lieve Do, ik heb intens genoten van onze symbiose aan de Amstelveenseweg. Dat kan ik op velerlei manieren uitdrukken maar onze gemiddelde woordkeuze is of onbegrijpelijk voor anderen of politiek niet geheel correct. Fantastisch de je m'n paranymf wil zijn.

Lieve pap en mam, opgroeien in een veilige omgeving met onvoorwaardelijke steun en stimulans is denk ik hetgeen ieder kind wil. Dank voor dit alles en daarnaast de mogelijkheden die jullie me gegeven hebben. Eind 20 zijn, in een jaar 3 maanden met je ouders in een appartement doorbrengen en er nog met plezier op terug kijken ook is denk ik niet iedereen gegeven. Dit proefschrift is natuurlijk ook een beetje voor de opa's en oma's die dit helaas niet meer kunnen mee maken en voor dokter Winnifred.

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CURRICULUM VITAE AUCTORIS

Olivier Antoine Joseph van der Meijden was born on January 18th 1984 in Assen, The Netherlands. After graduating from the Rijnlands Lyceum in Wassenaar in 2002 he started Medical School of the University of Utrecht. As a teenager his dream of becoming a professional football player was chattered when he suffered from Anterior Cruciate Ligament tears in both his knees. However, it did lead him to his interest in Orthopaedic Surgery.

Following graduation from Medical School he started working as a resident in General Surgery at the end of 2009, Diakonessen Hospital Utrecht, and later in Orthopaedic Surgery at the Medical Centre Alkmaar in Alkmaar. In 2010, doctor Peter J. Millett granted him a visiting research fellowship position at the Steadman Philippon Research Institute in Vail, CO, USA. On his return home, he started the residency training program for Orthopaedic Surgery at the Spaarne Hospital in Hoofddorp (dr. G.J.M. Akkersdijk) and currently works at the Medical Centre Alkmaar (dr. B.J. Burger) again.

During his residency, he continued his research work. Close collaboration with dr. E.J.J.M. Verleisdonk and dr. R.M. Houwert at the Diakonessenhuis Utrecht has led to this thesis under supervision of prof. dr. L.P.H. Leenen (Head Department of Trauma Surgery, University Medical Centre, Utrecht).

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Bijtende brievenbus

Mijn vrouw wist het al, want zij is een tijdje postbode geweest: sommige brievenbussen kunnen bijten. Te strakke veer, er nooit iets met je vinger helemaal doorheen duwen, want ze hebben vaak ook nog scherpe randen. Ik wist dat niet toen ik bij de buren een dunne kartonnen doos door de bus duwde. Klein stukje nog – hap!

Terwijl de chirurg op de eerste hulp mijn vingertop voorziet van vijf hechtingen, zeg ik: „Dat zal vast niet vaak voorkomen: dat mensen worden aangevallen door een brievenbus.” Zijn antwoord: „Laat ik het zo zeggen: u bent vanavond de eerste.”

Ewoud Sanders