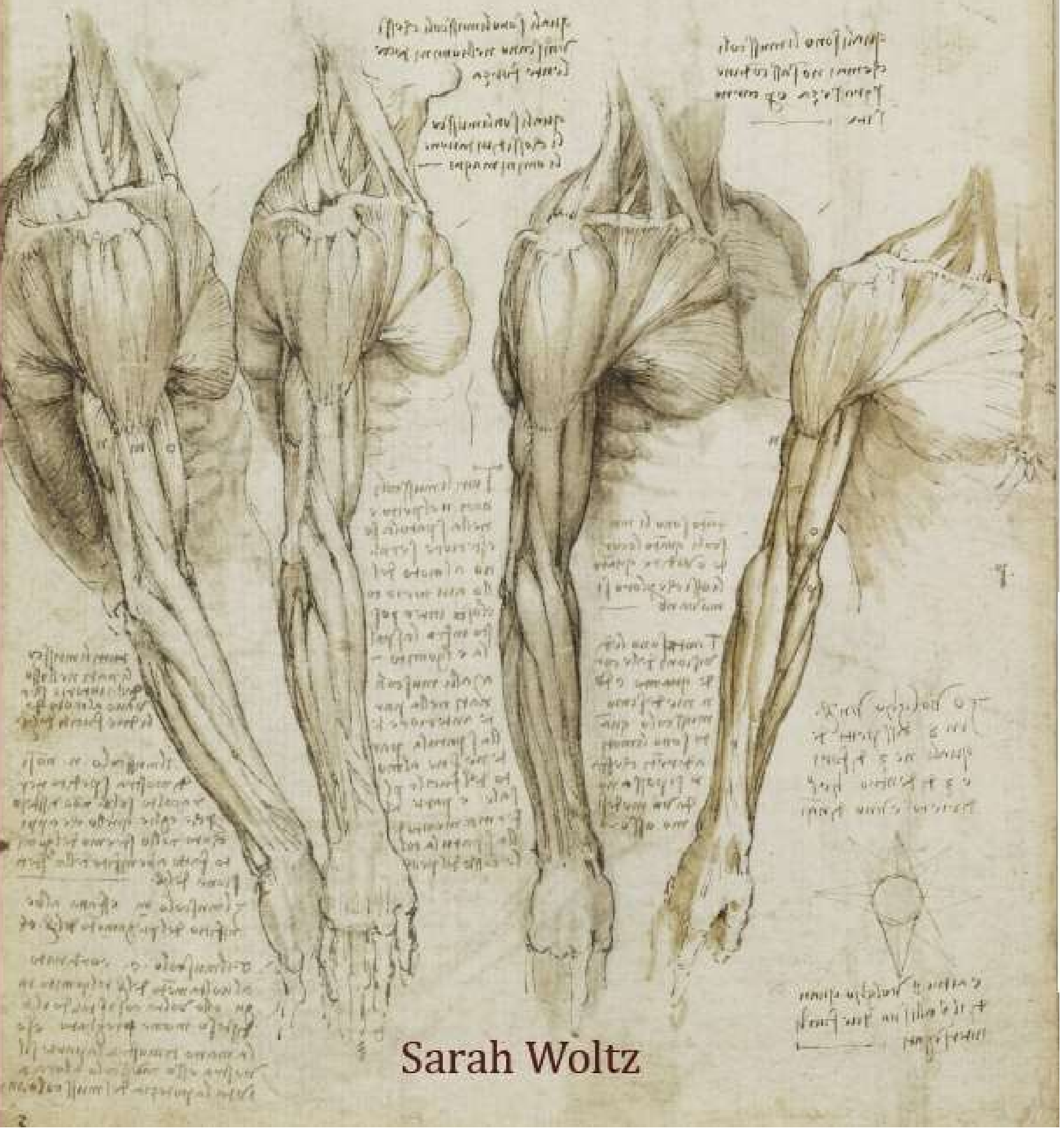
CLAVICULAR FRACTURE TREATMENT

CHOICES AND CHALLENGES



Sarah Woltz

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CONTENTS

CHAPTER 1

Introduction and outline

BACKGROUND AND EPIDEMIOLOGY

Fractures of the clavicle comprise about 2.6-4% of all fractures in adults, of which the majority involves the middle part of the bone[1]. As in many fractures, males are more frequently affected in all age categories up to 75 years, with a peak incidence under 25 years. The mechanism of injury is mostly bicycle and motorcycle accidents in males, and same-level falls in females and older patients[1]. Although clavicular fractures are seldom permanently invalidating, the young and active patient population warrants optimal treatment aiming for a quick and complete functional recovery.

Anatomy

The clavicle is the only true connection between the torso and the arm. It is the first bone to ossify after 5-6 weeks of gestation, and the last to reach complete ossification at about 27 years[2]. The particular shape of the bone is prismatic at the sternoclavicular joint medially, and gets rounder and thinner as it curves in an s-shape to end flat at the acromioclavicular joint laterally[3] (Figure 1[4]). About 75% of clavicular fractures occur in the

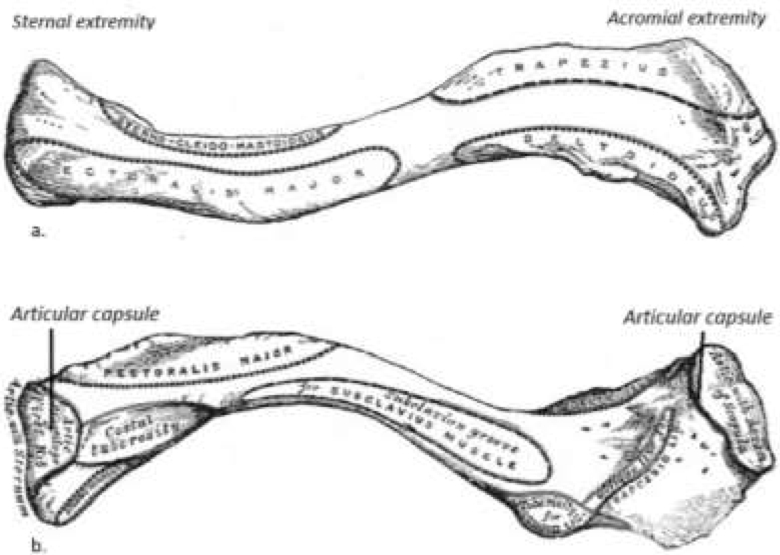

Figure 1. *Anatomy of left clavicle with muscle attachments. (a) superior surface, (b) inferior surface*[4].

middle segment, where the bone is thinnest and curvy, and lacks the muscular and ligamentous protection that both ends have[2]. These muscles cause the typical displacement that is seen in the majority of midshaft fractures: the medial fragment is pulled upwards and dorsally, while the lateral fragment moves ventro-caudally and to medial (Figure 2)[3].

In close relation to the clavicle are the brachial plexus and subclavian artery and vein, with the top of the lung directly underneath. Damage to these structures is rare but can occur both during injury and operative treatment, and should be actively ruled out by thorough clinical examination[5]. Running vertically over the clavicle are small sensory nerve branches, often leaving the skin around the scar numb if cut during surgery.

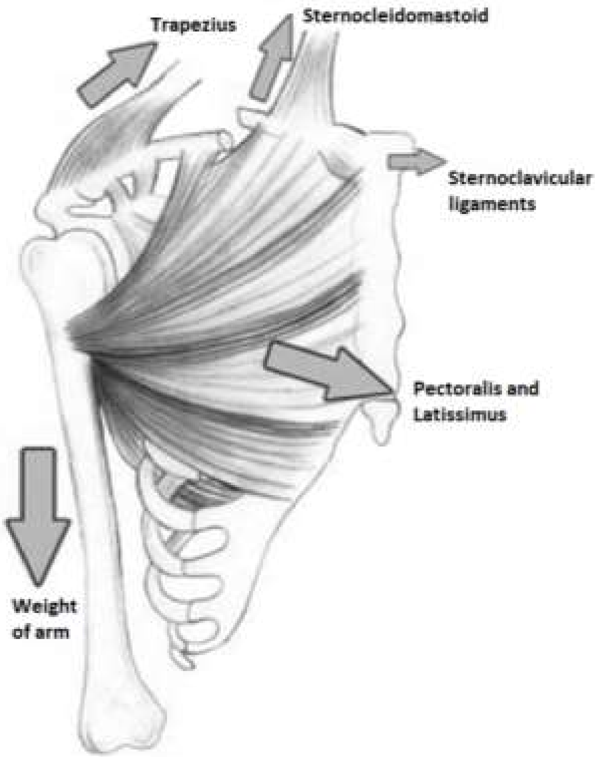

Figure 2. *Typical displacement of midshaft clavicular fractures.*

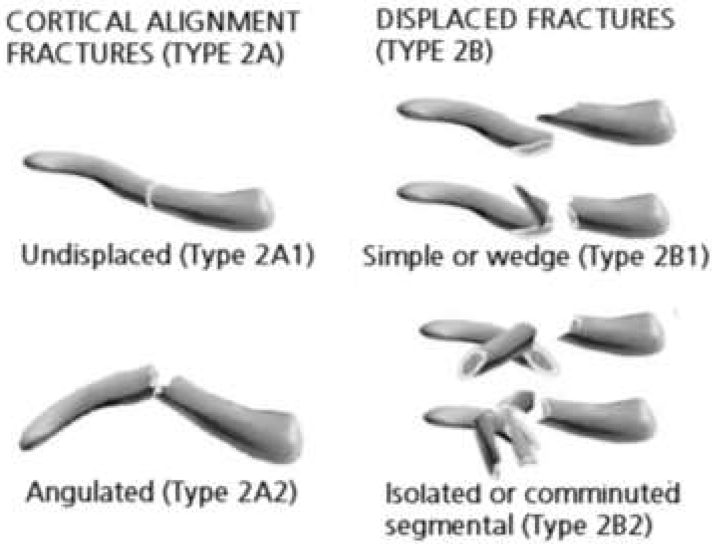

Figure 3. *Robinson (Edinburgh) classification of (in this case midshaft) clavicular fractures.*

Classification

Different systems have been proposed to classify clavicular fractures, mostly based on the anatomical location of the fracture rather than on prognostic characteristics, such as the Allman and Neer classifications[2]. The most recent and more detailed classification system was introduced by Robinson in 1998[6]. This 'Edinburgh' or 'Robinson' classification is based on anatomical location of the fracture (1 for medial, 2 for midshaft and 3 for lateral), but then subdivides according to displacement, and further according to fracture pattern along the same line as the general AO classification (Figure 3). It is the fully displaced midshaft clavicular fractures, Robinson type 2B1 and 2B2, that are the subject of this thesis. Example X-rays of a displaced, midshaft clavicular fracture are shown in Figure 4, p13.

Treatment history

As early as 400 B.C., Hippocrates proposed in his *The Articulations* that clavicular fractures need but benign neglect from the physician:

"A fractured clavicle, like all other spongy bones, gets speedily united; for all such bones form callus in a short time. When, then, a fracture has recently taken place, the patients attach much importance to it, as supposing the mischief greater than it really is, and the physicians bestow great pains in order that it may be properly bandaged; but in a little time the patients, having no pain, nor finding any impediment to their walking or eating, become negligent; and the physicians finding they cannot make the parts look well, take themselves off, and are not sorry at the neglect of the patients, and in the meantime the callus is quickly formed."[7]

This statement marked a long history of nonoperative treatment for clavicular fractures, supported by two large studies in the 1960s that reported excellent results and virtually nonexistent nonunion rates[3,8]. It was not until the turn of the century that more evidence became available showing that the true prevalence of nonunion was as high as 10% to 15%, and that long-term sequelae such as pain were common after nonoperative treatment[9,10]. More fracture displacement, comminution and shortening were identified as risk factors for healing problems and sequelae, suggesting that a more severe fracture pattern needs a different and more active approach than the more forgiving, undisplaced clavicular fractures[9,10]. In 2007, the Canadian Orthopaedic Trauma Society published the first randomized controlled trial (RCT) comparing nonoperative treatment with plate fixation, showing lower nonunion rates and a better arm function after plate fixation[11].

These studies led to a dramatic increase in operations[12,13], since many surgeons considered routine operative treatment superior to nonoperative treatment for all patients with a fully displaced clavicular fracture. Since then, many RCTs and meta-analyses have been published on the subject. While the body of evidence on the subject grew, it appeared that operative treatment for clavicular fractures was perhaps not the Holy Grail after all: complications were common, shoulder function often similar, and due to the superficial subcutaneous position of the clavicle, many plates caused irritation and had to be removed[14-16]. Therefore, a more individualized treatment should be pursued, in which patient and fracture characteristics are taken into account.

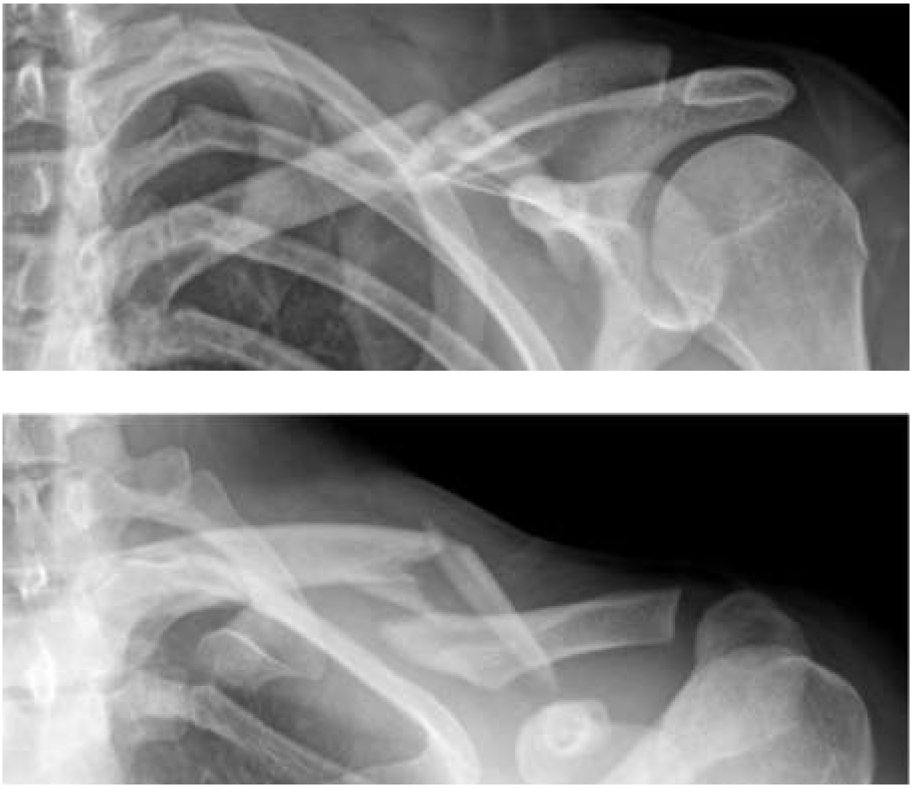

Figure 4. *Midshaft fracture of the left clavicle in a 26-year old male, Robinson type 2B1. Two standard X-ray views are shown: anteroposterior (above) and 30 degree cephalad tilt (below). The latter clearly shows the value of an additional, 15-40 degree tilted X-ray to assess displacement.*

TREATMENT OPTIONS

Nonoperative treatment

Nonoperative treatment is aimed to allow fracture healing while confining pain and discomfort, ideally with a minimum amount of malunion. Usually, relative rest is advised for 2 weeks, followed by careful motion exercises for 4-6 weeks until callus is formed. Numerous supportive devices have been proposed that can be roughly divided into those that merely support the arm, such as a sling or collar-and-cuff, and those that aim to reduce the fracture, such as a figure-of-eight bandage[17]. The effectiveness of fracture reduction by a figure-of-eight bandage is doubtful at best, and it might even cause more discomfort than a simple sling[17]. In the Netherlands, the standard nonoperative treatment therefore is a sling or collar-and-cuff without any attempt to reduce the fracture. In addition, thorough explanation and advice regarding motion exercises and daily life restrictions is essential for treatment compliance and to prevent patients from feeling they receive no treatment at all.

Operative treatment

The most common operative treatment for clavicular fractures is open reduction and internal plate fixation (Figure 5). This straightforward procedure provides excellent exposure of the fracture fragments, aiding in an anatomical reduction and fixation. Many different plates are on the market, ranging from inexpensive reconstruction plates that can be easily bent to fit the s-shape of the clavicle, to stronger straight locking and non-locking plates (DCP and LC-DCP). More recently, anatomically pre-shaped plates became available, aiming to reduce implant failure and irritation because they supposedly have a better fit, and to reduce operating time because intra-operative shaping is no longer necessary. However, they are expensive and the fit is not always ideal[18].

Complications after plate fixation are numerous, including infection, numbness around the scar, implant failure (e.g., plate loosening and/or breakage), plate irritation and nonunion[19,20]. Alternatives for plate fixation include minimally invasive plate fixation and pin fixation, but neither has shown to be superior[21].

Figure 5. *Midshaft clavicular fracture 3 months after fixation with a precontoured superior-anterior locking clavicle plate and a lag screw (30 degree cephalad tilt view, same patient as Figure 4).*

SHARED DECISION MAKING

As discussed above, both operative and nonoperative treatment for midshaft clavicular fractures can be sensible options. The treatment choice is therefore preference-sensitive. For decisions of this kind, shared decision making (SDM) has become more widely known and accepted in the last decades. SDM is an approach to decision making in which the patient expresses his or her priorities and goals and the surgeon and patient together select the treatment that best matches these preferences[22]. The growing wish for more patient involvement in treatment decisions in the Netherlands is illustrated by the explicit support of the Minister of Health, who has made promoting SDM one of the top priorities in 2013[23].

AIM AND OUTLINE OF THIS THESIS

Choices and challenges

As discussed above, one ideal treatment for all patients with a displaced, midshaft clavicular fracture does not exist. The first chapters of this thesis evaluate different aspects of clavicular fracture treatment, aiming to aid in making the choice between operative and nonoperative treatment.

Chapter 2 evaluates the influence of shortening in a healed clavicle on shoulder function, in order to determine if shortening should be an indication to operate. **Chapter 3** discusses whether reconstruction plates are a suitable choice for clavicular fracture fixation.

Knowledge about treatment results, such as the incidence of nonunion and secondary operations, is essential to make a treatment decision. **Chapter 4** describes a randomized controlled trial comparing plate fixation with nonoperative treatment on various outcomes. **Chapter 5** summarizes six previously published RCTs – including the one described in chapter 4 - comparing plate fixation with nonoperative treatment by evaluating a total of 614 patients, highlighting the different pros and cons of both treatment options.

Individualized treatment should involve not only taking the influence of patient and fracture characteristics into account, but also incorporating patient preferences and goals into the treatment choice using SDM. This, however, can be quite challenging[22]. The second part of this thesis focuses on the patient and the decisional process, to provide more knowledge about the perspective of the patient on the treatment choice and outcomes.

In **chapter 6**, longer-term patient satisfaction and residual symptoms after plate fixation and nonoperative treatment are studied. **Chapter 7** evaluates the occurrence of SDM in clavicular fracture care. Finally, surgeons' attitude and experiences with respect to SDM are studied in **chapter 8**, in which SDM indeed proves to be a challenge for most trauma surgeons.

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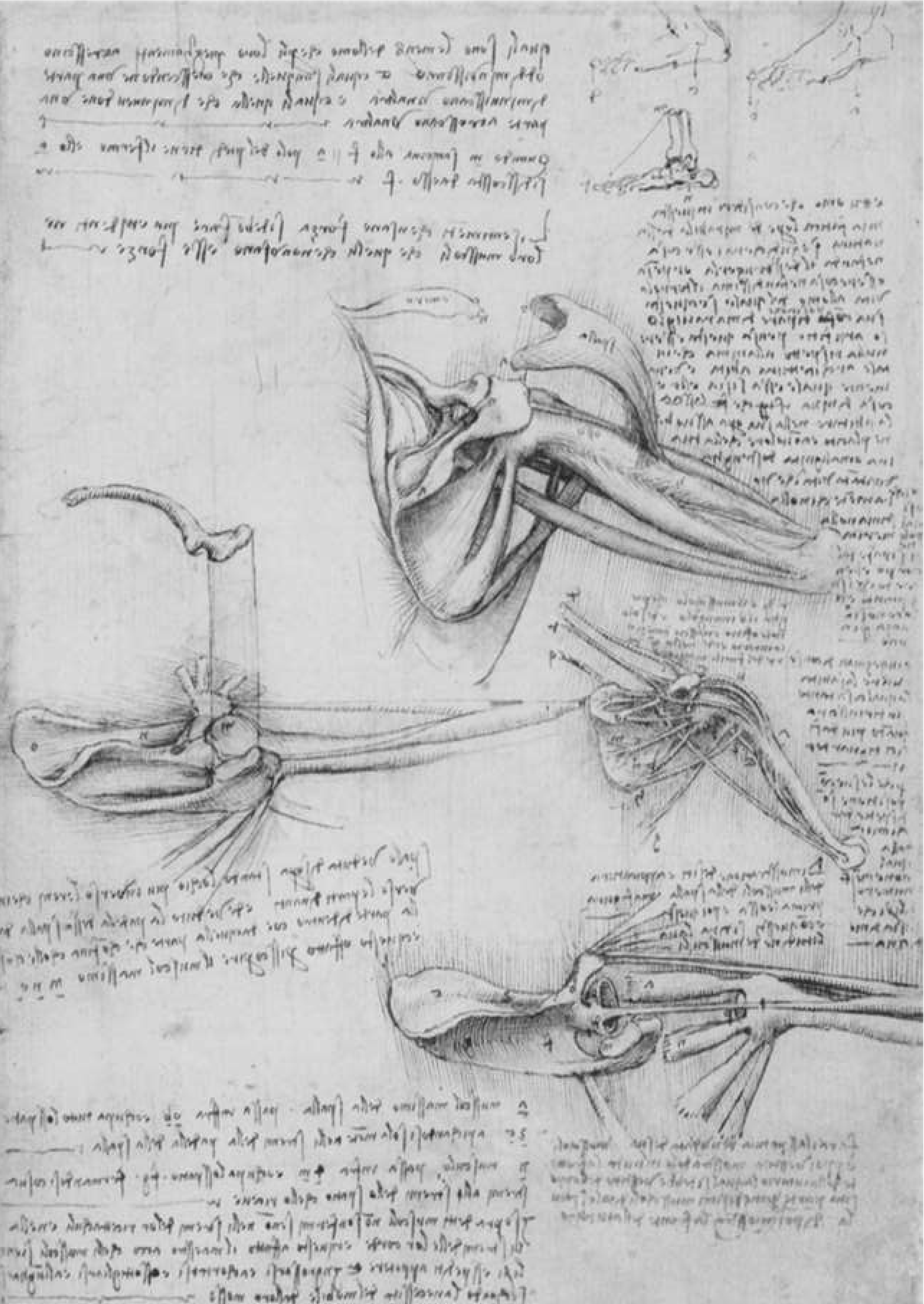

CHAPTER 2

Does clavicular shortening after nonoperative treatment of midshaft fractures affect shoulder function? A systematic review

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Arch Orthop Trauma Surg 2017;137(8):1047-1053

ABSTRACT

Introduction

Clavicular shortening due to non-anatomical healing of displaced clavicular fractures is believed to have a negative effect on shoulder function after recovery. The evidence for this, however, is equivocal. This review aimed to systematically evaluate the available literature to determine whether the current beliefs about clavicular shortening can be substantiated.

Patients and methods

This systematic review was performed following the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement. PubMed, EMBASE, Web of Science and the Clinical Trial Registry were searched to identify all studies published in English that evaluated the association between clavicular shortening and shoulder function in patients aged ≥16 years with a nonoperatively treated, displaced midshaft clavicular fracture. Relevant data from the selected studies was extracted and summarized. Risk of bias of the included studies was assessed using the MINORS instrument.

Results

Six studies, of which five were retrospective, were included in this review analysing a total of 379 patients. Due to heterogeneity in methods and reporting across studies, a pooled analysis of the results was not feasible. No clear associations were found between shortening and shoulder function scores (DASH and Constant score) or arm strength in each of the included studies.

Conclusion

The existing evidence to date does not allow for a valid conclusion regarding the influence of shortening on shoulder function after union of nonoperatively treated midshaft clavicular fractures. Shortening alone is currently not an evidence-based indication to operate for the goal of functional improvement. Well-powered prospective comparative studies are needed to draw firm conclusions.

INTRODUCTION

Midshaft fractures of the clavicle are common and often displaced[1,2]. Treatment of these fractures is aimed at a complete recovery of the shoulder function, especially in younger patients. In nonoperatively treated patients, closed reduction of the fracture is difficult to achieve and to maintain, and is therefore no longer attempted[3,4]. A certain degree of clavicular shortening often remains after union due to overlap of the fracture fragments, caused by traction of the pectoral and deltoid muscles and the weight of the arm that pull the lateral fragment ventro-caudally and medially, while the sternocleidomastoid muscle pulls the medial fragment upwards and dorsally[5].

In addition to the historic indications for operative fixation of displaced clavicular fractures (i.e., open fracture, neurovascular compromise and compromised skin), evidence-based reasons for operative fixation include reduction of the risk of nonunion and a quicker recovery[2,6-8]. Substantial shortening of the clavicle is also considered to be an indication for operative treatment, partly because it may increase the risk of nonunion[9,10], but also because shortening is thought to lead to a poorer functional outcome after fracture union. It is believed that the significant changes in the position of the glenoid fossa and shoulder girdle, and winging of the scapula after shortening of the clavicle are responsible[4,11-13]. Also, muscle balance and tension can be reduced if the clavicle is shortened[12]. This altered anatomy may result in the sequelae that have been reported after nonoperative treatment[4,9]. Recent comparative studies, however, have not demonstrated a functional benefit for healed fractures after restoration of the anatomy with operative fixation compared with nonoperative treatment[7,8].

It is important to clarify whether there is sufficient evidence to support the assumption that shortening is an indication for surgery to improve the functional outcome. Studies that have evaluated this relationship, however, show inconsistent results. While some reported that a larger shortening causes more complaints, pain and dissatisfaction[9,14,15], others found no association between shortening and sequelae[16-18]. These studies, however, did not clearly evaluate an association with the function of the shoulder. The aim of this review, therefore, was to summarize the available literature to evaluate whether clavicular shortening is negatively associated with shoulder function (i.e., patient-reported function, range of motion or arm strength) at latest follow-up after nonoperative treatment.

MATERIALS AND METHODS

This systematic review was performed according to the 'Preferred Reporting Items for Systematic reviews and Meta-Analyses: the PRISMA statement'[19].

Search strategy and eligibility criteria

The literature search was performed in Pubmed, Embase, Web of Science and the Clinical Trial Registry in December 2016. The search strategy was composed by an experienced medical librarian and combined various synonyms of the keywords 'clavicle', 'fracture', 'midshaft', 'nonoperative' and 'shortening' (see also Appendix 1, p165).

Studies were eligible if they (1) included patients older than 15 years of age with a nonoperatively treated, displaced midshaft clavicular fracture, (2) evaluated the association between the extent of clavicular shortening and function of the shoulder (i.e., patient-reported functional outcome, range of motion and/or arm strength), and (3) were written in English.

Articles were excluded if they (1) included less than 20 patients, or (2) also analysed medial and/or lateral clavicular fractures and the results for midshaft fractures were not reported separately. No date range was specified.

After removal of duplicates, the title and abstract of the identified articles were independently screened for eligibility by the first two authors. The full-text articles of the potentially relevant studies were read and judged for eligibility. The reference lists of these articles were searched for additional relevant studies, which were included if the above mentioned inclusion criteria applied. Disagreements were resolved by discussion.

Data extraction

From each included article, data were extracted by the first two authors, including study characteristics (study design, number of included patients and duration of follow-up) and patient characteristics (age, gender and type of nonoperative treatment). Outcomes of interest were clavicular shortening and shoulder function (measured by means of the DASH-score[20], Constant score[21], arm strength and/or range of motion), and the reported association between shortening and function. A meta-analysis could not be performed because there was considerable variation in the definitions of shortening and the statistical methods across studies.

Quality assessment

Methodological quality of the included studies was independently assessed by the first two authors using the ''Methodological Index for Non-Randomized Studies'' (MINORS) instrument, which consists of eight items regarding the design of non-comparative studies[22]. Each item is appointed a score (''0'' = not reported; ''1'' = reported but inadequate; ''2'' = reported and adequate) with an optimal total score of 16.

RESULTS

Literature search

The search in Pubmed, Web of Science, Embase and the Clinical Trial Registry identified 151 potentially eligible articles (Figure 1). After removal of duplicates, 78 articles were

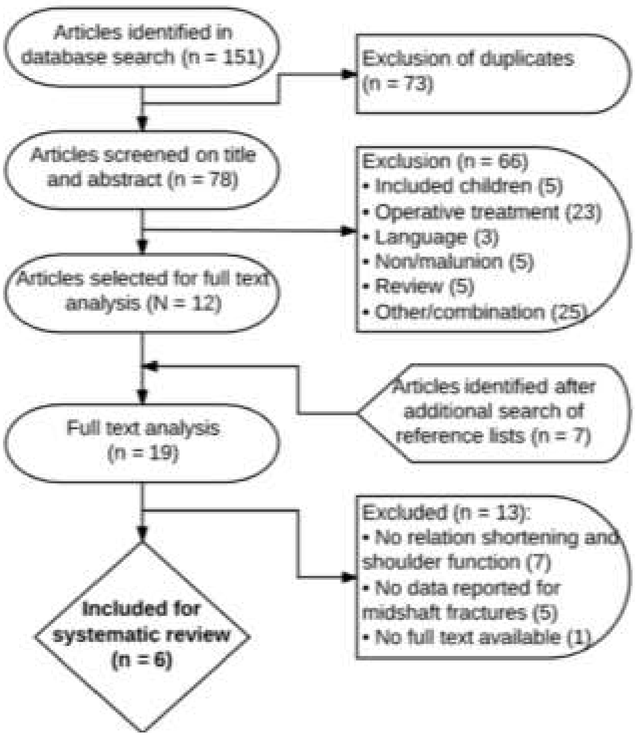

Figure 1. *Flowchart of the included articles.*

screened based on title and abstract, of which 12 were selected. Screening the reference lists yielded another 7 potentially relevant articles. After reading the full text of these 19 articles, 6 articles were included in this systematic review based on the selection criteria.

Study characteristics

The included studies were published between 2006 and 2015, and evaluated a total of 379 patients (Table 1). Five studies were retrospective[5,23-26] and one was prospective[27]. In four studies, determining the relationship between shortening and shoulder function was the primary study aim[23,24,26,27]. Follow-up was at least 12 months in all studies, with a frequency-weighed mean of 4.5 years. Most patients were immobilized with a sling or figure-of-eight bandage for various time periods. The prospective study reported a loss to follow-up of 8.5%[27].

Table 1. Characteristics of the included studies and patients analysed

Reference	Study design (retro/ prospect)	No. of evaluated patients[a]	Mean months since trauma	Mean age, years (SD)	Male (%)	Type of nonoperative treatment (n)
Fuglesang[26] 2016	R	59 / 92	32 (12-59)	39.1 (12.3)	83	Sling
Figueiredo[27] 2015	P	54 / 59	12	34 (13)	81	FEB + PT
Stegeman[23] 2015	R	32 / 74	12-72	Median 31 (21-62)	84	Not reported
Rasmussen[24] 2011	R	136 / 237	55 (24-83)	35 (15)	79	FEB (50); sling (70); C&C (13); no support (3)
Postacchini[25] 2010	R	68 / 119[b]	104	36.9	65	Sling or FEB
McKee[5] 2006	R	30 / 63	55 (12-72)	37	73	Sling

SD=standard deviation; R=Retrospective; P=Prospective; FEB=figure of eight bandage; C&C=collar and cuff; PT=physiotherapy.
[a] No of evaluated patients / no of eligible patients (or included patients for prospective study).
[b] 119 patients were eligible for inclusion in total. Number of eligible patients with Allman type 1b/c fracture not stated.

Clavicular shortening

The studies expressed clavicular shortening in different ways; either by measuring the difference in length between the injured and the contralateral clavicle[5,24,27], or by measuring the overlap of fracture fragments[26]. Stegeman and Postacchini additionally calculated the proportional shortening by dividing the overlap of fracture fragments by the sum of the length of the injured clavicle and the measured overlap[23,25]. Shortening was also measured at different time points: on the index trauma radiographs[24-27], or on radiographs taken after the fracture had united[5,23].

The reported mean shortening (Table 2, p28) ranged from 9.2 mm (SD 6.4) to 25 mm (SD 16). Three studies compared patients with a shortening less than 20 mm with those having 20 mm or more shortening. In these studies, 15, 37 and 19% of the study population had a shortening of ≥20 mm[5,24,27]. Fuglesang used the median shortening of 15 mm as cut-off value to determine small or large shortening, thus creating two equally sized groups[26].

Shoulder function

Various outcome measures were used to evaluate shoulder function at final follow-up (Table 2). Mean DASH scores ranged from 3.38 to 24.6 in four studies[5,23,26,27]. The mean Constant score was reported in five studies (range 71–96)[5,23-26]. McKee found much poorer mean Constant and DASH scores than the other studies, and both functional scores were significantly worse than the normative value for the general population (71 vs 92 and 24.6 vs 10.1, respectively)[5,28,29]. One study that compared the injured with the healthy shoulder, reported a significant difference in Constant score (86.3 vs 93.7, $p<0.001$)[24], whereas Constant and DASH scores of the patients in another study were similar to those of matched controls[23].

Strength was measured by Stegeman and McKee with a hand-held dynamometer and with the Baltimore Therapeutic Equipment (BTE) Work Simulator, respectively[5,23]. Whereas Stegeman found no significant mean differences in strength compared with the contralateral shoulder for six different motions, McKee reported that the injured shoulder had 81–85% of the strength and 67–82% of the endurance of the patients' uninjured shoulder ($p<0.05$ for all motions) (Table 3, p29).

Table 2. Relation between clavicular shortening and Constant score and/or DASH score

Reference	Mean shortening in mm (SD)	Constant score	DASH score	Correlation (r) or p-value
Fuglesang[26] 2016	17.1 (7.1)	81 (69-90) (median)	6.7 (0.8-19) (median)	
	<15mm: n ≈ 30	80 (64-88)	7 (3-27)	p=0.5 (Constant)
	>15mm: n ≈ 30	84 (74-90)	7 (0-11)	P=0.1 (DASH)
Figueiredo[27] 2015	9.2 (6.4)	N/A	3.38 (9.21)	r = -0.017; p=0.90
	<20mm: n=47 (81%)		3.38 (CI 9.56)	
	>20mm: n=11 (19%)		3.33 (CI 7.02)	p=0.53
Rasmussen[24] 2011	11.6 (8.2)	86.3 (29-100)	N/A	r = 0.14; p>0.05
	<20: n=116 (85%)	7.2 (10.3)[a]		
	>20: n=20 (15%)	7.9 (10.3)		p=0.79
Postacchini[25] 2010	Males: 14.1 (8.9); 8.9% (5.6%)[b]	Allman 1B[c]: 87.1	N/A	
	Females: 10.9 (7.8); 8.3% (6.0%)[1]	Allman 1C: 85.6		p<0.05
		CS≥90 (n=55): 7.7%		
		CS≤80 (n=9): 13.2%		
McKee[5] 2006	14.5 (8.6)	71 (SD not given)		r = -0.20; p=0.44
			24.6 (SD not given)	r = 0.32; p=0.11
			DASH>30	
	<20mm: n=19 (63%)		3/19 (16%)	p=0.06
	≥20mm: n=11 (37%)		7/11 (64%)	

The values are given as the mean and the standard deviation with the standard deviation in parentheses.
[a] Mean difference in Constant score between injured and uninjured shoulder. [b] Proportional shortening: overlap of fracture fragments divided by sum of overlap and length of injured clavicle.
[c] Allman type 1B: displaced fractures, Allman type 1C: displaced with third bone fragment.

Three studies reported the range of motion of the injured and contralateral shoulder but did not analyse its association with clavicular shortening[5,23,25]. For this reason, results on range of motion are not included in this review.

Association between shortening and shoulder function

The association between clavicular shortening and the DASH score was analysed in three studies. Results are presented in Table 2. No statistically significant linear correlations were found[5,27]. Also, no difference in DASH scores existed between patient groups when shortening was dichotomized using cut-off values of 15 mm[26] or 20 mm[27].

McKee reported that among patients with ≥20 mm shortening, a poor DASH score of >30 seemed more prevalent than among patients with <20 mm shortening (64 vs 16%, p = 0.06)[5].

Four articles reported on the association between shortening and Constant score (Table 2)[5,24-26]. No linear relationship was found[5,24]. Also, a larger shortening (more than 20 or

Table 3. Relation between clavicular shortening and shoulder strength

References	Mean shortening in mm (SD)	Mean strength in Newton (95% CI)	Correlation (p-value)
Stegeman[23] 2015	25 (16) 13% (8%)[a]	Adduction: 7.2 (-3.5 - 18)[b]	β = –1.29 (p=0.07)
		Abduction: -0.1 (-8.8 - 8.6)	β = –0.47 (p=0.4)
		Anteflexion: 9.6 (-3.1 - 22)	β = 0.59 (p=0.5)
		Retroflexion: 14.6 (-6.7 - 9.8)	β = –0.08 (p=0.9)
		Exorotation: 2.0 (-3.2 - 7.3)	β = 0.08 (p=0.8)
		Endorotation: 5.1 (-0.8 - 11.1)	β = 0.37 (p=0.3)
McKee[5] 2006	14.5 (8.6)	Flexion: 81%, 75%[c]	ns
		Abduction: 82%, 67%	r = –0.32 (p=0.06)
	<20: n=19 (63%)	Exorotation: 81%, 82%	ns
	≥20: n=11 (37%)	Endorotation: 85%, 78%	ns

[a] Proportional shortening: overlap of fracture fragments divided by sum of overlap and length of injured clavicle. [b] Difference in strength between uninjured and injured shoulder. P>0.05 for all comparisons. [c] Strength and endurance of injured shoulder as a percentage of the uninjured shoulder.

15 mm) did not result in a significantly lower Constant score[24,26]. Only Postacchini found that shortening was significantly larger in patients with a Constant score below 80, than in patients with a Constant score of 90 or higher[25]. Stegeman reported that all DASH and Constant scores were in the normal range of values, and therefore, did not analyse a relation with shortening[23].

Two studies evaluated arm strength (Table 3, p29)[5,23]. Only the association between shortening and abduction endurance approached statistical significance in one study[5]. There was no relation between shortening and endurance for all other motions, nor with strength[5,23].

Table 4. Methodological quality of included studies assessed according to the Methodological Index for Non-Randomized Studies (MINORS) instrument[20]

	Fuglesang[26]	Figueiredo[27]	Stegeman[23]	Rasmussen[24]	Postacchini[25]	McKee[5]
1. A clearly stated aim	2	2	2	2	2	2
2. Inclusion of consecutive patients	1	2	1	1	1	1
3. Prospective collection of data[a]	2	2	2	2	2	2
4. Endpoints appropriate to the aim of the study	2	2	2	2	2	2
5. Unbiased assessment of the study endpoint	0	0	0	0	1	1
6. Follow-up period appropriate to the aim of the study	2	2	2	2	2	2
7. Loss to follow up less than 5%	2	1	2	2	2	2
8. Prospective calculation of the study size	0	0	1	0	0	0
Total	11	11	12	11	12	12

The items are scored 0 (not reported), 1 (reported but inadequate) or 2 (reported and adequate). Maximum score is 16.

[a] Data were collected according to a protocol established before the beginning of the study.

Risk of bias and quality assessment

Table 4 shows the results for the assessment of the methodological quality for each study. All studies had a clear aim and collected appropriate data according to a beforehand established protocol. In most studies, however, there was risk of observer bias because function scores and shortening were measured by the same researcher, and of selection bias because only a portion of the eligible patients participated. Only one study mentioned the intended sample size, but no calculation or rationale was stated[23].

DISCUSSION

In daily practice, shortening of a midshaft clavicular fracture is often regarded as a risk factor for functional impairment after fracture union. This review of the available literature included six studies and showed that there is not enough evidence to substantiate this assumption. Therefore, shortening of a fractured clavicle should currently not be regarded as an evidence-based indication to operate for the goal of functional improvement. In a clear evidence-supported approach, other indications should be considered such as the reduced risk of nonunion and earlier functional recovery. Also, following the principles of shared decision making, patients' preferences could be reason to opt for surgical treatment.

A difficulty in studying possible influences on shoulder function is that Constant and DASH scores are generally in the upper range of the scale after clavicular fractures. Due to this ceiling-effect subtle differences in scores remain undetected, although such small differences in scores are unlikely to be clinically relevant for most patients. Also, the number of patients with a large amount of shortening in the included studies was low. For instance, the association that was found between a larger shortening and a Constant score below 80 in one study, was based on only nine patients[25].

The most important limitation of this review is the heterogeneity in methods and definitions across studies. The research groups obviously differed in their ideas about the best way to measure clavicular shortening. Most conspicuous are the different time points at which shortening was measured; either directly after the injury, or after fracture union. Fuglesang reported that the median difference in clavicular length between initial and final radiographs was 7.5 mm (25th–75th percentiles 4–10), and that there were large individual adjustments suggesting that the final amount of shortening cannot be reliably

predicted on initial radiographs[26]. Two previous studies by Smekal et al., however, showed no significant difference between initial and final proportional shortening [5.4 (SD 4.0) vs 4.7 (SD 3.9), p = 0.16; and 5.0 (SD 3.3) vs 5.1 (SD 3.5), p = 0.86][30,31].
Also, different techniques were applied to measure shortening. Three studies used the length of the contralateral clavicle, assuming that the clavicles had been equally long before the fracture[5,24,27]. It is, however, well known that a considerable asymmetry of both clavicles may exist within individuals: a mean difference in clavicular length of 4.25 mm (SD 3.8) and an asymmetry of C5 mm in 28.5% of uninjured, skeletally mature adults has been reported[32].
In addition, four of the studies expressed shortening as the absolute difference in clavicular length[5,24,26,27]. A large absolute shortening, however, potentially has more influence on shoulder kinematics in a patient with a short clavicle than in a tall patient with a long clavicle[33]. Stegeman and Postacchini accounted for these issues by expressing shortening as a proportion of the clavicular length, and using the estimated length of the original bone instead of the contralateral clavicle for comparison[23,25].

In summary, the existing evidence to date does not allow for a valid conclusion regarding the influence of shortening on shoulder function after union of nonoperatively treated midshaft clavicular fractures. Shortening alone is currently not an evidence-based indication to operate for the goal of functional improvement. Well-designed prospective studies including sufficient numbers of patients with a substantial amount of shortening are needed to formulate a conclusion.

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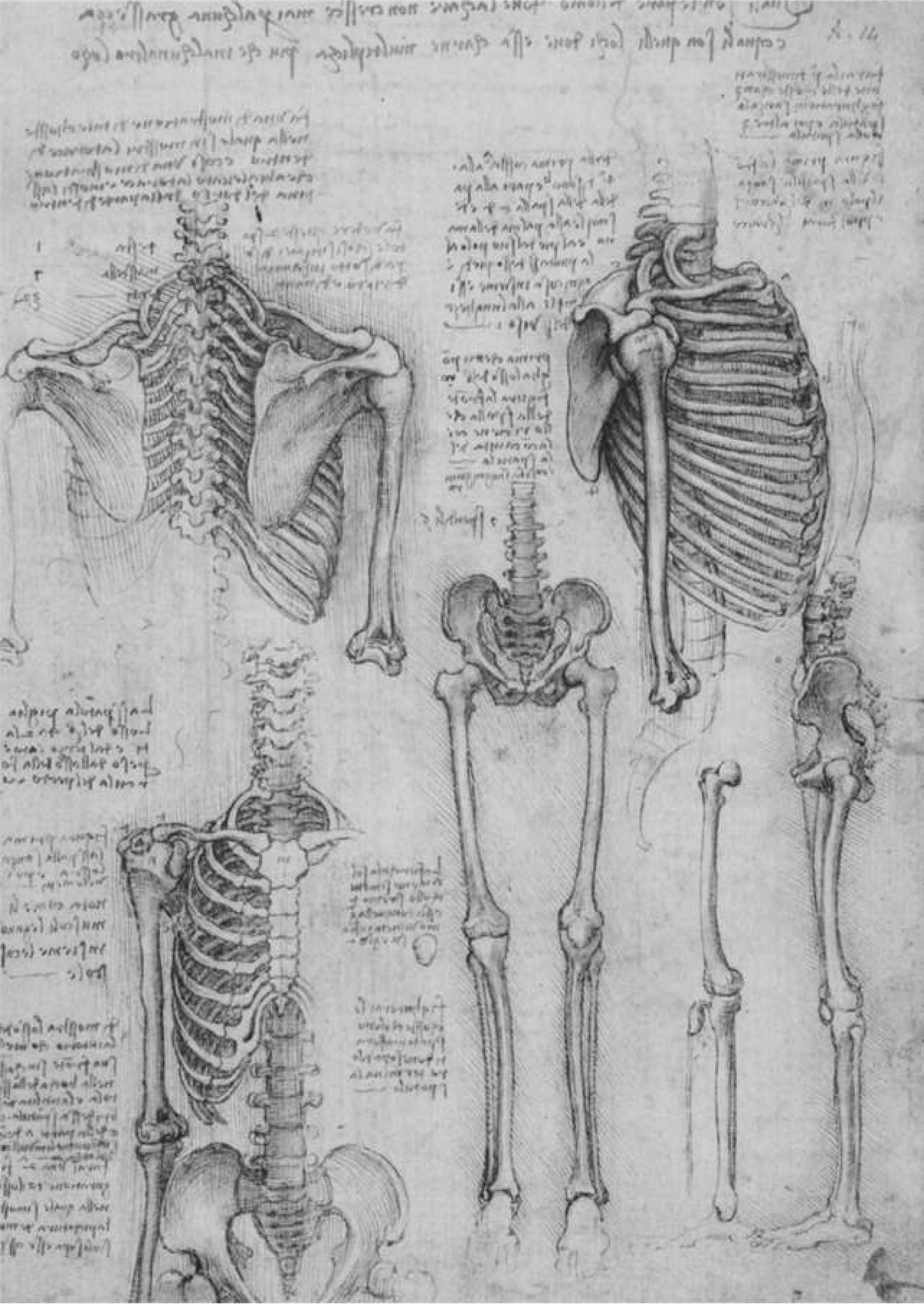

CHAPTER 3

Reconstruction plates for midshaft clavicular fractures: A retrospective cohort study

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ABSTRACT

Background

For the fixation of displaced midshaft clavicular fractures different plates are available, each with its specific pros and cons. The ideal plating choice for this lesion remains subject to ongoing discussion. Reconstruction plates are cheap and easily bendable, but their strength and stability have been questioned. The aim of this study was to evaluate the failure rate of reconstruction plates in the fixation of clavicular fractures.

Patients and methods

A multicenter, retrospective cohort study of all consecutive patients with a displaced, midshaft clavicular fracture (Robinson type 2a/2b) treated with a 3.5-mm reconstruction plate between 2006 and 2013 were evaluated. The primary outcome measure was reoperation rate due to implant failure. Secondary outcome measures were nonunion, symptomatic malunion and elective plate removal.

Results

One hundred and eleven patients were analysed. During a median follow-up of 8 months, 14 patients (12.6%) had implant failure, of which 7 (6.3%) required a reoperation. Three nonunions (2.7%) and no symptomatic malunions occurred. Plate removal was indicated in 37.8% of patients because of implant irritation.

Conclusion

The incidence of reoperation due to implant failure following clavicular plate fixation with a reconstruction plate is 6.3%. Although comparison with other plate types is difficult since rates in literature vary greatly, reoperation rates in other plates are reported around 2–3%, suggesting that reconstruction plates have a higher incidence of implant failure warranting reoperation. Therefore, especially in patients with known risk factors for complications (e.g. smoking, osteoporosis, comminuted fractures), a stronger plate than a reconstruction plate should be considered.

INTRODUCTION

In the past decade, operative treatment of dislocated midshaft clavicular fractures has become more common. The evidence in favour of operative treatment still grows, as recent studies show lower nonunion and symptomatic malunion rates and earlier return to work compared with conservative treatment[1-4]. With the development of the more advanced anatomically preshaped plates, the discussion is shifting from indications for operation towards the choice of implant for the midshaft clavicle[5-7].
Reconstruction plates, available in a locking and non-locking design, are frequently used for the fixation of clavicular fractures. Originally designed for pelvic fixation, reconstruction plates have a lower profile than standard compression plates with a concentrated mass around the screw holes. These characteristics reduce plate stiffness, facilitating easy contouring in all planes to fit the anatomic shape of the clavicle[6]. However, implant failure such as bending or breaking of the plate has been reported and subsequently the strength of reconstruction plates for the fixation of clavicular fractures was questioned[2,8].
Alternatives for reconstruction plates include limited contact–dynamic compression plates (LC-DCP) and small fragment locking compression plates (LCP), which are both straight and strong but are difficult to fit well on to the clavicle. More recently, anatomically preshaped locking plates were introduced to fit the s-shaped clavicle without having to bend the plate. These plates supposedly provide more biomechanical stability and reduce the incidence of implant failure and plate irritation, but conclusive results are lacking. Also, they are more expensive compared with other plates such as the reconstruction plate[5].

These disadvantages of other plate types cause the cheap and easily applied reconstruction plate to remain popular for fixating clavicular fractures, but clinical evidence on implant failure rates is limited. This lack of data warrants clinical evaluation of the use of reconstruction plates for displaced midshaft clavicular fractures. Therefore, the primary aim of this study was to investigate the incidence of implant failure (i.e. plate breaking, bending and screw loosening) that necessitates reoperation. Secondary outcome measures were nonunion, symptomatic malunion and elective plate removal.

PATIENTS AND METHODS

This study describes a retrospective cohort of all consecutive patients with a displaced midshaft clavicular fracture treated with a 3.5-mm reconstruction plate between 2006 and 2013 in two non-university teaching hospitals in The Netherlands, including one level 1 trauma center. Data were presented according to the guidelines for reporting observational studies as formulated in the "Strengthening the reporting of observational studies in epidemiology" (STROBE) Statement[9].

In- and exclusion criteria

Patients were identified using the procedure-code for open reduction and internal plate fixation of clavicular fractures. Patients were included for analysis if they met the following inclusion criteria: (1) Fully displaced, midshaft clavicular fracture (fracture type Robinson 2a/2b)[10] and; (2) 3.5 mm reconstruction plate fixation.

In both hospitals, indications for operative fixation of an acute fracture were: more than one shaft width of dislocation, ≥ 2 cm shortening, compromised skin, open fractures, neurovascular injury, or a combination of these reasons. Patients were excluded if: (1) Follow-up was shorter than two months or; (2) Indication for surgery was nonunion or malunion of a previous fracture.

Surgical technique, rehabilitation and follow-up

All operations were performed or supervised by a certified orthopaedic trauma surgeon, according to the AO-principles and under fluoroscopic guidance. Patients were operated under general anaesthesia. Standard prophylactic antibiotics were administered. After reduction, fixation was done with lag screws and a neutralization plate or with a bridging technique. The plates were contoured by the surgeon to fit the shape of the clavicle and were positioned on either the superior or anterior-inferior surface of the bone. Plate fixation was locking or non-locking, with a minimum of three bi-cortical screws in both the proximal and distal end. All locking plates were made of titanium, whereas the non-locking plates were made of steel.

Postoperative treatment consisted of active non-weight bearing motion exercises of the shoulder throughout the first six weeks. After satisfactory radiographic control at six weeks postoperatively, patients were allowed to start weight bearing motion exercises. Further clinical and radiological evaluation was done on indication.

Data

Medical records and diagnostic imaging were reviewed to obtain patient characteristics, fracture type according to the Robinson classification[10], mode of fixation (locking or non-locking) and postoperative complications. The quality of fracture reduction was judged on the intra- and postoperative X-rays as "anatomical" or "non-anatomical". In the latter, a gap or step-off of 2 mm or more was present after reduction of the fracture. Bridge plating of severely comminuted fractures was also defined as non-anatomical.
The primary outcome parameter was defined as reoperation due to, or in the presence of plate breaking, plate bending or screw loosening. Overall implant failure also included asymptomatic patients. In all patients, at time of inclusion at least a year had passed since surgery. Secondary outcome parameters including nonunion, malunion, and plate removal were obtained from digital records. Nonunion was defined as no bony bridging after nine months in the presence of pain and/or impaired function.

Statistical analysis

Data were analysed using SPSS version 20.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics were calculated for all variables, including frequency counts for categorical variables and median with range for continuous variables. Differences between groups were evaluated with the Fisher's exact test for categorical variables and with the Mann Whitney U test for continuous variables. Statistical significance was assumed if two-sided P-values were below 0.05.

RESULTS

One hundred and thirty-five consecutive patients received plate fixation of a clavicular fracture during the study period, of whom 123 patients met the inclusion criteria. Twelve patients were excluded because indication for surgery was nonunion or malunion (n = 9) or follow-up was shorter than two months (n = 3).The remaining 111 patients with 111 midshaft clavicular fractures were included for analysis.

Table 1. Baseline characteristics of the included patients

	n = 111
Gender	
Male	89 (80.2)
Female	22 (19.8)
Age in years, median (range)	41 (14-65)
Smoking, current	
Yes	25 (22.5)
No	68 (61.3)
Unknown	16 (16.2)
Cause of injury	
Sports	51 (47.8)
High energy	41 (36,9)
Low energy	10 (9)
Other	7 (6.3)
Fracture Type[a]	
2a2	2 (1.8)
2b1	80 (72.1)
2b2	28 (25.1)
Unknown[b]	1 (0.9)

The values are given as the number of patients, with the percentage in parentheses.
[a] According to the Robinson classification[10]. [b] No preoperative X-ray available for fracture classification.

Patient demographics and baseline characteristics

The median age was 41 years and most patients were male (Table 1). Surgery was performed after a median of 9.0 days (range 0–47 days). Seven patients had surgery more than three weeks after injury because the initially preferred conservative treatment was too painful or fracture dislocation increased.

Forty-six fractures (41.4%) were fixated with a non-locking reconstruction plate and 65 with a locking reconstruction plate. Most plates were positioned superiorly (83.8%). Anatomical reduction was accomplished in 90.1% of cases. Median time of follow-up was 8.0 months (range 2–54 months). All patients with a short time of follow-up had been discharged from further check-up because they were doing well at that point.

Primary outcome: reoperation due to implant failure

Reoperation due to implant failure was indicated in 7 patients (6.3%). Reasons for reoperation were plate breakage in five cases, screw loosening with nonunion in one case, and breakout of the plate in one case. In three patients with a broken plate, there was previous plate bending (n = 2), or nonunion (n = 1) (Table 2). There were no significant differences between locking (titanium) and non-locking (steel) plates.

Smokers required a reoperation more often (20.5% of smokers versus 1.5% of non-smokers, P = 0.005, Fisher's exact). Of the patients with a non-anatomical fracture reduction, 18.2% needed a reoperation versus 5% of patients who had an anatomical reduction (P = 0.14).

Seven patients had implant failure but were asymptomatic and were treated conservatively. In some of these patients more than one implant problem occurred, including screw migration in five patients, plate bending in three and plate breakage in one patient (Figure 1, p44).

Secondary outcomes: nonunion and malunion

Nonunion occurred in three patients (2.7%), two of whom had concomitant implant failure, i.e. one plate breakage and one screw migration. One patient had a spontaneous refracture one week after elective plate removal, ten months after initial surgery and was recorded as nonunion. In all three, reduction had been anatomical. In all cases a reoperation was performed with uneventful recovery. Malunion occurred in five cases and was treated conservatively in all.

Table 2. Complications after reconstruction plate fixation

	n = 111
Reoperation[a]	7 (6.3)
Breaking of plate	5 (4.5)
Bending of plate	2 (1.8)
Screw loosening	2 (1.8)
Implant complications (total)	14 (12.6)
Nonunion	3 (2.7)
Malunion (all asymptomatic)	5 (4.5)
Plate removal	42 (37.8)

The values are given as the number of patients, with the percentage in parentheses.

[a] Reoperation due to implant failure. Some patients had more than one complication.

Figure 1a *A 39-year-old male sustained a Robinson 2B1 clavicular fracture;*

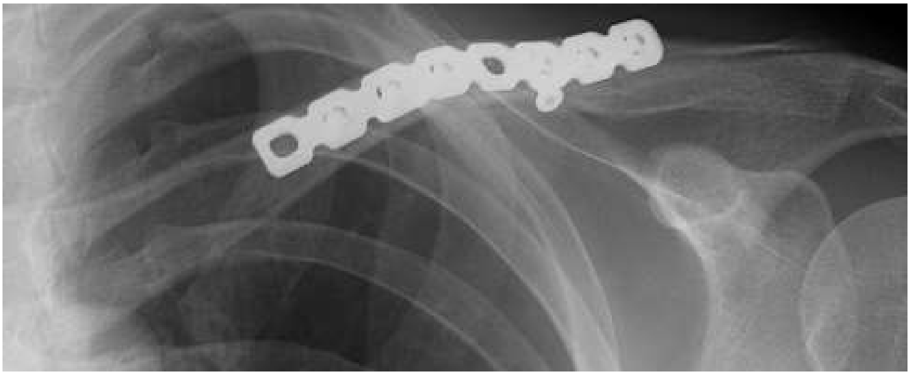

Figure 1b *The fracture was fixated with a non-locking reconstruction plate and a lag screw;*

Figure 1c *After three months, screw loosening and plate bending were seen on X-rays. Since the patient had excellent function and no pain, this was treated nonoperatively.*

Other complications

One superficial wound infection occurred that warranted antibiotic treatment. There were no deep infections nor neurological injuries. One patient treated with a locking reconstruction plate developed a pneumothorax during operation and needed a chest tube for three days. One patient developed a subclavian venous thrombosis three days after surgery and was treated with anticoagulants but otherwise recovered uneventfully.

Plate removal

Forty-two plates (37.8%) were removed because of implant irritation after a median of 10.5 months (3–54 months). Nine patients complained of implant irritation but chose not to have the plate removed.

DISCUSSION

This study evaluates over one hundred patients with a displaced clavicular fracture treated exclusively with reconstruction plates. In these 111 patients, implant failure occurred in 12.6% with a reoperation rate of 6.3%.

A substantial part of the available evidence on reconstruction plates is derived from biomechanical and cadaveric studies, with varying results. Overall, the advantages of reconstruction plates –reduced stiffness and easy to bend – seem to account for their weaknesses as well, causing reconstruction plates to offer less biomechanical stability than other plates[11,12].

In clinical studies, the incidence of reconstruction plate failure varies widely. An overview of the literature is provided in Table 3, p46. Several authors report 0% reoperations due to implant related complications, but all cohorts consisted of less than 40 patients[2,7,13-15]. Other small studies report reoperation rates of 4–7%[16-19]. The only large group treated with reconstruction plates, other than the present study, was a cohort of 125 patients described by Shin in 2012, showing results very similar to ours: 12% implant failure with a reoperation rate of 8%[20]. Therefore, the results of our study seem consistent with those previously published.

The incidence of nonunion (2.3%) found in the present study is comparable with nonunion rates stated in literature (0–3%)[1-4,21,22]. Apparently reconstruction plates offer sufficient stability needed for bone healing. Elective plate removal was performed in

37.8%. This suggests that the easily bendable reconstruction plate does not guarantee a better fit resulting in less plate removal, since the incidence of elective plate removal of clavicle plates in general is around 30%[21].
Comparing reconstruction plates with other plate types, is difficult for a number of reasons. The majority of studies on clavicular plate fixation use more than one plate type and do not state whether any differences between plate types regarding implant failure were found. Also, many studies do not differentiate between reoperations due to implant failure, complications such as deep infection and elective removal because of plate irritation[3,5,16,21,23-25].

Considering failure of all plates following fixation of clavicular fractures, reoperation rates range from 0–9.4%[3,4,21,24,27]. A few studies use a single non-reconstruction plate, and explicitly address implant failure. Jones for instance, used 2.7 mm antero-inferiorly placed

Table 3. Implant failure of reconstruction plates, summary of literature

Study	No of patients	Plate type / location[a]	Implant failure	Reoperation due to implant failure
Gilde et al, 2014[17]	71	2.7-mm reconstruction, anterior	8.5%	5.6%
Galdi et al, 2013[13]	37	2.7-mm and 3.5-mm reconstruction, anterior	0	0
Virtanen et al, 2012[2]	28	2.8-mm reconstruction, anterior	7	0
Chen et al, 2012[8]	84	reconstruction	7%	Not stated
Shin et al, 2012[20]	125	reconstruction, superior	12%	8%
Tarng et al, 2012[14]	32	3.5-mm reconstruction, superior	6%	Not stated
Kulshrestha et al, 2011[19]	45	reconstruction, superior	4.4%	4.4%
Mirzatolooei et al, 2011[18]	26	3.5-mm reconstruction, superior	7.7%	3.8%
Cho et al, 2010[7]	41	reconstruction and locking reconstruction	7%	0
Liu et al, 2010[28]	59	locking reconstruction	8.5%	Not stated

[a] Some authors did not state the thickness or location of the plate.

dynamic compression plates in 129 patients and described 0% implant failure[26]. Recently, Robinson et al. reported a reoperation rate of 2.3% due to implant failure, using precontoured Acumed plates in 86 patients[4].
The only comparative data available stems from a recent retrospective study evaluating the incidence of failure of 2.7 mm reconstruction plates and dynamic compression plates (DCP) in a total of 156 patients. They reported significantly more implant related complications in reconstruction plates (8.5% vs 1.2%,P = 0.03)[17]. Reoperation rate due to implant failure in the reconstruction group was 5.6%, but significance was not stated. Overall, reconstruction plates appear to have a somewhat higher incidence of implant related complications warranting reoperation than other plate types. Therefore, it is important to carefully choose the implant that best suits the patient, fracture and surgeon: not only should one consider a stronger plate, but different surgical techniques such as intramedullary pin fixation can also be an option.

There are obvious limitations to the retrospective design of this study. The major limitation is the short follow-up time for some patients. This was due to patients' quick recovery and subsequent discharge from further check-up with instructions to come back in case of any complaints. For each patient, at least a year had passed after surgery in which the patient could have returned with late complications. However, it is possible that an unknown number of patients went to another hospital with complaints, resulting in an underestimation of reoperation rate. To estimate this error, we assume that most clavicular fractures that heal uncomplicated are consolidated after four months, and thus the patients who were discharged after less than four months are the subjects most likely to develop implant failure after follow-up. If all of these patients would develop implant failure, the failure rate would be 8.1% instead of 6.3%. This would strengthen the conclusion that reconstruction plates should only be used in patients with no risk factors for complications.
A second limitation is the heterogeneity of the group. Locking as well as non-locking reconstruction plates were used, in both anterior and superior position. Although no significant differences in failure rates were found between plate types or plate position, a randomized design is warranted to compare these variables more reliably.

Also, follow-up was not standardized and in some patients late postoperative X-rays were made on indication only. Therefore, and due to early discharge of many patients, the rate of asymptomatic implant failures was probably underestimated.

CONCLUSION

In conclusion, our study comprises one of the largest analysed cohorts of patients with displaced midshaft clavicular fractures treated with 3.5 mm reconstruction plates. Reconstruction plates are cheap and easy to use, but the incidence of reoperations due to implant failure seems to be higher than for other plate types. This should be taken into account when choosing a plate for clavicular fixation. Especially if any risk factors for implant failure are present (e.g. tobacco use, very comminuted fracture, osteoporosis), a stronger plate should be considered. However, a prospective, randomized trial comparing different plates is necessary to draw firm conclusions.

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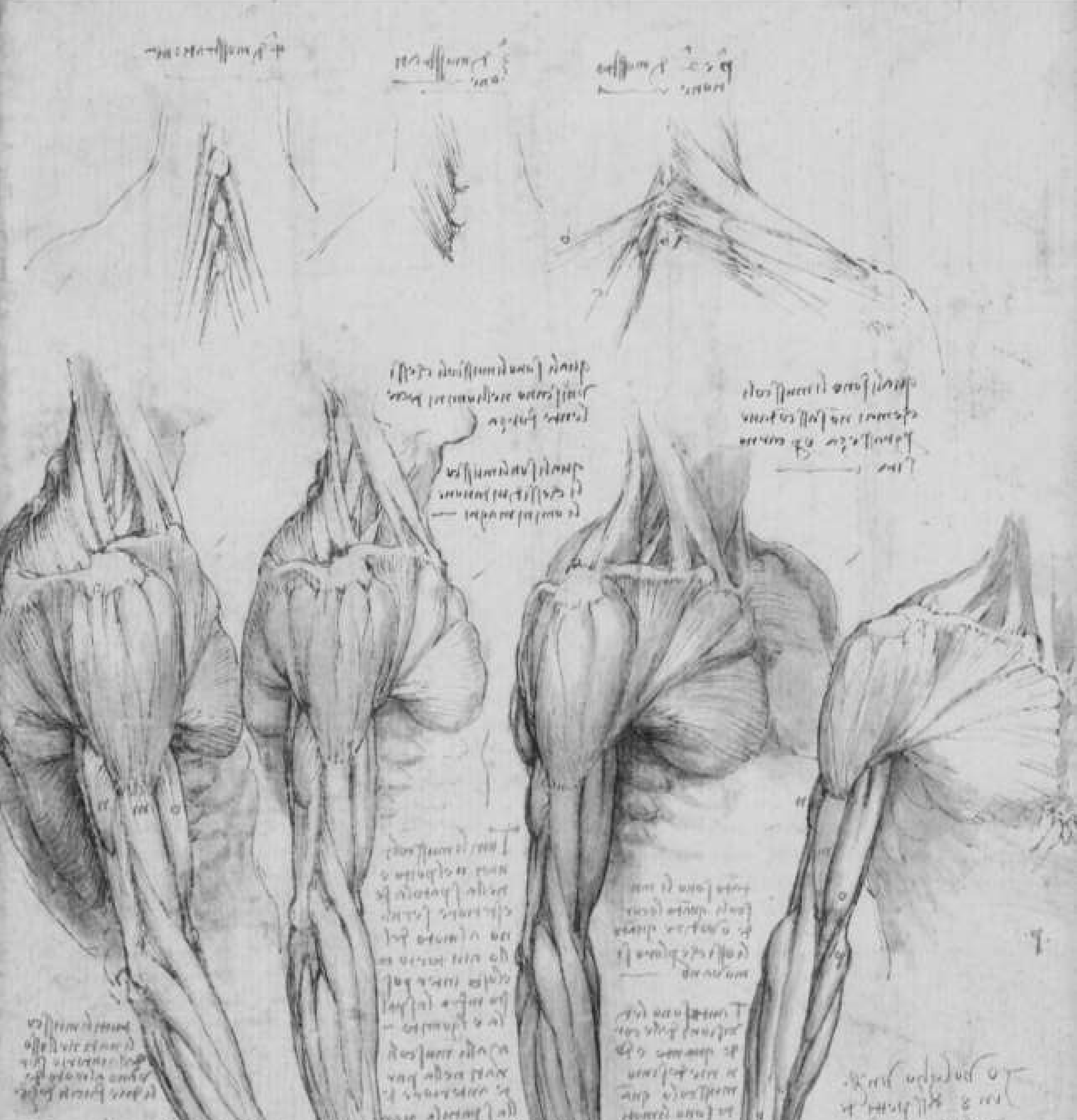

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CHAPTER 4

Plate fixation compared with nonoperative treatment for displaced, midshaft clavicular fractures: A multicenter randomized controlled trial

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ABSTRACT

Background

The use of operative treatment for clavicular fractures is increasing, despite varying results in previous studies. The aim of this study was to compare plate fixation and nonoperative treatment for displaced midshaft clavicular fractures with respect to nonunion, adverse events, and shoulder function.

Patients and methods

In this multicenter, prospective, randomized controlled trial, patients between 18 and 60 years old with a displaced midshaft clavicular fracture were randomized between nonoperative treatment and open reduction with internal plate fixation. The primary outcome was evidence of nonunion at 1 year. Other outcomes were secondary operations, arm function as measured with the Constant shoulder score and Disabilities of the Arm, Shoulder and Hand (DASH) score, pain, cosmetic results, and general health status. Outcomes were recorded at 6 weeks, 3 months, and 1 year following trauma.

Results

One hundred and sixty patients were randomized. The rate of nonunion was significantly higher in the nonoperatively treated group than in the operatively treated group (23.1% compared with 2.4%; $p < 0.0001$), as was the rate of nonunion for which secondary plate fixation was performed (12.9% compared with 1.2%; $p = 0.006$). The rate of secondary operations was 27.4% in the operatively treated group (16.7% for elective plate removal) and 17.1% in the nonoperatively treated group ($p = 0.18$). Nineteen percent of the patients in the operatively treated group had persistent loss of sensation around the scar. No difference was found between the groups with respect to the Constant and DASH scores at all time points.

Conclusion

For patients with a diaphyseal fracture of the clavicle displaced at least 1 shaft width, plate fixation improves the chances that the bone will heal; however, the rate of patients who need a second operation is considerable. In addition, the procedure does not improve

shoulder function or general symptoms, and it does not decrease limitations compared with nonoperative treatment in a sling.

INTRODUCTION

Midshaft clavicular fractures have a long history of being treated nonoperatively. This strategy originates from the time of Hippocrates, who was the first to describe that these fractures merely need benign neglect from the physician[1]. Many centuries later, in the 1960s, this vision was supported by the results of 2 large studies that showed extremely low nonunion rates following nonoperative treatment (0.71% and 0.13%, respectively)[2,3]. By the turn of the century, however, more evidence became available showing that the true prevalence of nonunion after nonoperative treatment was much higher than previously thought, i.e., approximately 10% to 15%[4,5]. Also, sequelae such as pain and cosmetic defects were shown to remain in a quarter of the patients up to 10 years after nonoperative treatment[5]. In 2007, the Canadian Orthopaedic Trauma Society published the first randomized controlled trial (RCT) comparing nonoperative treatment with plate fixation, showing lower nonunion rates and a better arm function after plate fixation[6]. That study appears to have led many surgeons to consider routine operative treatment for displaced fractures of the midshaft of the clavicle to be superior to nonoperative treatment. Although several other RCTs have been published since then, the issue remains very relevant because the question of whether operative treatment is most suitable for all patients with a displaced midshaft clavicular fracture remains unsettled, and published meta-analyses are equivocal[7-11].

The aim of the present multicenter randomized trial was to compare the results of open reduction and plate fixation with nonoperative treatment in patients with a displaced midshaft clavicular fracture with respect to nonunion, adverse events and secondary operations, shoulder function, and general health status.

MATERIALS AND METHODS

Design and Setting

Approval for this multicenter RCT was obtained from the institutional ethics review committee of each participating hospital. The trial was registered in the Netherlands National Trial Register (NTR2399). Patients were recruited between June 2010 and December 2013 in 16 teaching and nonteaching hospitals in the Netherlands, including

4 university hospitals. The results were reported following the Consolidated Standards of Reporting Trials (CONSORT) guidelines[12].

Inclusion Criteria

Patients were eligible for inclusion if they had (1) a fracture of the middle third of the clavicle with displacement of at least 1 shaft width (Robinson type 2B1 or 2B213), (2) an age between 18 and 60 years old, (3) no contraindications for surgery or general anaesthesia, and (4) provided signed informed consent.

Exclusion Criteria

Patients were excluded if they had ≥1 of the following criteria: (1) a pathologic fracture, (2) an open fracture, (3) a neurovascular injury of the shoulder region with objective neurologic findings on primary physical examination, (4) an associated head injury (Glasgow Coma Scale score of <12), (5) an ipsilateral upper extremity fracture, (6) first presentation >14 days after injury, (7) pre-existing impaired shoulder function or previous surgery of the shoulder, and (8) an inability to comply with follow-up.

Sample Size

The sample size calculation was based on a difference of 15 percentage points in nonunion rates between the treatment groups. The initial calculation suggested that 350 patients were needed[14], but after the trial had started, this was discovered to be incorrect. No interim analysis was performed. The sample size was recalculated with the same power (80%), significance level (0.05), and drop-out rate (10%), using evidence available at that time that showed a difference in nonunion rates of 13 percentage points (15% compared with 2%)[15], which indicated that 160 patients were needed to find a significant difference in nonunion rates between groups. The recalculation was approved by the scientific and ethics review committee. Accordingly, the trial inclusion was stopped after the 160th patient.

Randomization

All eligible patients received verbal and written study information at the emergency room or outpatient clinic. All participants provided written consent. Minimization randomization was accomplished with the online registration and randomization program TENALEA

(Trans European Network for Clinical Trials Services). Patients were randomly assigned to nonoperative treatment or to open reduction and plate fixation in a 1:1 ratio stratified by hospital. For each subsequent participant, the allocation depended on the included participants to minimize imbalance[16].

Nonoperative Treatment

For patients assigned to nonoperative treatment, follow-up started at the day of inclusion. During the first 2 weeks, patients used a sling and were advised to perform non-weight-bearing pendulum exercises after instruction by a physiotherapist, followed by more active movement up to the horizontal plane. After 6 weeks, full range of motion was permitted and strengthening exercises were started. If an indication for surgical treatment arose, secondary plate fixation (with bone-grafting if judged appropriate by the treating surgeon) was offered to the patients.

Operative Treatment

Patients assigned to operative treatment had the operation within 3 weeks after injury. Follow-up started on the day of the operation. All operations were performed by, or under direct supervision of, a fracture surgeon. In the Netherlands, fractures are generally treated by trauma surgeons rather than orthopaedic surgeons. Surgery was performed according to the AO standards for osteosynthesis (i.e., 6 cortices on each side of the fracture and use of a lag screw if possible). There were no restrictions regarding incision, plate location, or type of plate. All patients received single-dose preoperative antibiotic prophylaxis. The postoperative mobilization protocol was the same as for nonoperatively treated patients.

Outcome Measures

Study evaluation points were at 6 weeks, 3 months, and 1 year. Radiography consisted of an anteroposterior and a 30°-caudocephalad radiograph made after injury and at each follow-up examination. Radiographs were evaluated by the surgeon.

The primary outcome was evidence of nonunion at 1 year, defined as the absence of complete osseous bridging of the fracture on the radiograph after ≥6 months. Also, nonunion was scored if it was evident during a secondary operation at least 4 months after trauma.

Secondary outcomes were arm function, adverse events, pain, general health status, and satisfaction with the cosmetic appearance. These were assessed at 6 weeks, 3 months, and 1 year. Function was measured with the Constant score[17] and with the Disabilities of the Arm, Shoulder and Hand (DASH) outcome measure[18]. As part of the Constant score, strength was measured using a dynamometer (microFET2; Hoggan Scientific), which is a handheld dynamometer measuring the force a patient can produce against a stationary counterforce.

Adverse events and secondary operations were assessed by the investigator. Secondary operations were all procedures apart from the initial operation for fracture treatment (e.g., surgery for nonunion or plate failure, debridement for deep infection, and implant removal). Symptomatic malunion was diagnosed if secondary surgery was performed in an attempt to address symptoms thought to be related to deformity of the clavicle.

Adverse events were all unexpected and unwanted outcomes related to the treatment or admission (e.g., perioperative pneumothorax, infection, and nonunion).

Pain was scored by the patient on a numeric rating scale from 0 (no pain) to 10 (extreme pain). General health status based on general symptoms and limitations was measured using the Short Form (SF)-36 questionnaire, expressed as the physical and the mental component summary score[19]. A score of 50 represents the expected value for the general population. Satisfaction with the cosmetic appearance of the shoulder was scored on a 3-point Likert scale (as unsatisfied, partly satisfied, and [very] satisfied).

All patients who did not return for follow-up or had missing radiographs after 1 year were contacted by telephone to ask whether they had complaints and whether they had received (operative) treatment for their clavicular fracture elsewhere.

Statistical Analysis

Statistical analysis was performed using SPSS statistical software (version 20; IBM). Differences in percentages for the primary outcome were analysed using the chi-square test. Constant, DASH, and SF-36 scores were compared using the Student t test. Pain scores were analysed using the Mann-Whitney test. Differences among >2 groups were analysed using analysis of variance and post hoc Bonferroni tests.

In the review process, it was noted that we did not plan how to address missing data prior to the trial and we did not use the preferred strict intention-to-treat approach for randomized trials. With the help of a statistician, we compared our original analysis with an analysis using multiple imputations to address missing data, found no differences in the analysis, and decided to present our original complete case analysis.

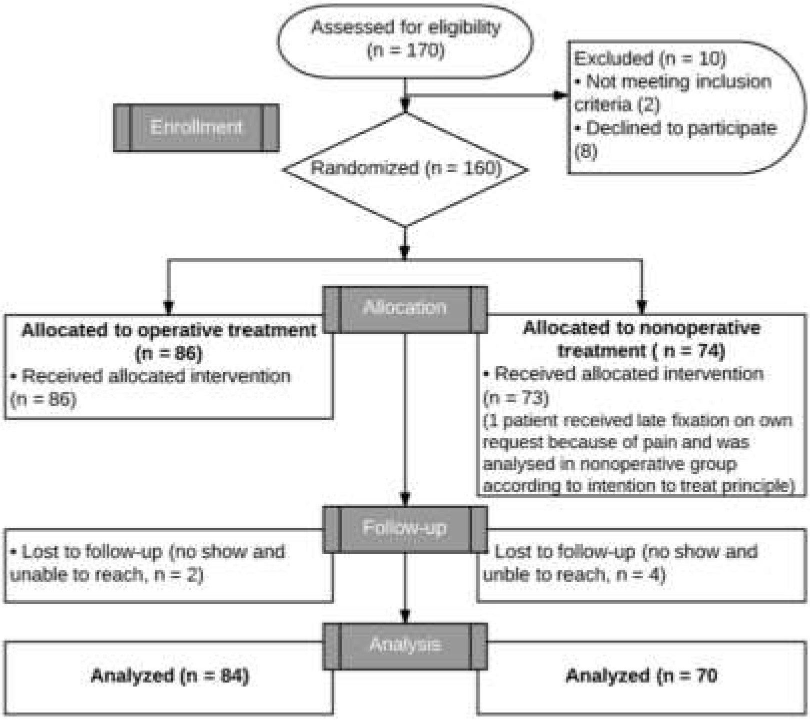

Figure 1. *Flowchart of the included patients. The imbalance of the treatment groups was probably a result of stratification by hospital, with some hospitals including only a few patients.*

RESULTS

Between June 2010 and December 2013, 160 patients were included, and of those, 86 were randomized to operative treatment and 74 to nonoperative treatment (Figure 1). Baseline features of the included patients are shown in Table 1. One patient who was randomized to nonoperative treatment received plate fixation within a week because of pain and was analysed in the nonoperative group according to the intention-to-treat principle.

Most operatively treated patients (80%) were treated with a precontoured clavicular plate (various manufacturing companies). The plates were placed superiorly (52%), anteriorly (12%), or anterosuperiorly (21%); placement was not documented for 15%.
At 1 year, no radiograph was made for 18 patients. Six of them had already reached radiographic consolidation earlier and were regarded as having achieved union. Six others (1 in the operatively treated group and 5 in the nonoperatively treated group) could be reached by telephone and reported that they had excellent function, no pain, and no complaints. They were regarded as lost to follow-up for the primary outcome (radiographic nonunion), but were counted as not having a symptomatic nonunion. Six patients (3.8%; 2 in the operatively treated group and 4 in the nonoperatively treated group) were lost to follow-up before the union status was determined and could not be reached by telephone after 1 year.

Table 1. Baseline characteristics of the included patients

	Plate fixation (n=86)	**Nonoperative treatment (n=74)**
Male patients	80 (93)	66 (89)
Age[a] (mean yrs, [SD])	38.3 (12.7)	37.2 (12.5)
Current smoker[a]	18 (22)	19 (27)
Trauma mechanism[b]		
Traffic	42 (49)	31 (43)
Sports	33 (38)	33 (46)
Fall from a height	3 (4)	2 (3)
Other	8 (9)	6 (8)
Dominant arm[c]	36 (44)	30 (42)
Robinson classification[d]		
2B1	50 (59)	37 (53)
2B2	34 (41)	33 (47)

The values are given as the number of patients, with the percentage in parentheses unless stated otherwise.
[a] Data not available for 6 patients (3 in each group). [b] Data not available for 2 patients in the nonoperative treatment group. [c] Data not available for 4 patients in the plate fixation group and 2 in the nonoperative treatment group. [d] Data not available for 2 patients in the plate fixation group and 4 in the nonoperative treatment group.

Fracture healing

At 1 year, 2 patients (2.4%) in the operatively treated group and 15 (23.1%) of 65 patients with radiographs available in the nonoperatively treated group had developed nonunion ($p < 0.0001$). The number needed to treat to prevent 1 nonunion was 4.8 patients.

One patient in the operatively treated group was diagnosed with nonunion when the plate loosened after 9 months. The plate was removed, and the nonunion was treated nonoperatively. The other patient sustained an early spontaneous refracture after elective plate removal 1 year after primary surgery and was treated with secondary plate fixation with bone-grafting, during which nonunion was confirmed. The fracture healed.

In the nonoperatively treated group, a nonunion developed in 15 patients and 9 of them had symptoms requiring secondary plate fixation. Five of them received secondary plate fixation within 1 year after fracture (at 4 months [3 patients], 8 months [1 patient], and 9 months [1 patient]), whereas the other 4 received the plate after the study follow-up period. Secondary plate fixation for nonunion was performed in 1.2% in the operatively treated group and in 12.9% (9 of 70 patients with data available) in the nonoperatively treated group ($p = 0.006$).

Functional Outcomes

After 1 year, the functional scores of 75 (87%) of 86 patients in the operatively treated group and 58 (78%) of 74 patients in the nonoperatively treated group were available for analysis. Constant scores were similar for both treatment groups at all time points, as were DASH scores (Table 2).

At the 1-year follow-up evaluation, the mean functional scores of the patients who received secondary plate fixation because of nonunion within 1 year were similar to those of the patients with a primarily united fracture in both treatment groups (the mean Constant scores [and standard deviations] were 98.5 ± 2.8 and 96.3 ± 6.7, respectively, and the mean DASH scores were 2.9 ± 4.2 and 3.3 ± 6.1). The 5 patients with a nonunion who had not received surgery at that time had significantly poorer function scores at 1 year than the patients with a united fracture: the mean Constant scores were 86.2 ± 11.7 and 96.3 ± 6.7, respectively ($p = 0.01$) and the mean DASH scores were 14.7 ± 14.6 and 3.3 ± 6.1 ($p = 0.005$).

Table 2. Functional results for the treatment groups

Scoring System	Plate fixation		Nonoperative treatment		P Value
	No.	Score	No.	Score	
Constant score					
6 wk	76	87.3 ±11.9	68	83.6 ±12.7	0.07
3 mo	80	93.8 ±8.2	62	93.8 ±7.4	1.00
12 mo	75	95.4 ±7.8	58	96.6 ±6.3	0.35
DASH-questionnaire					
6 wk	77	15.2 ±12.6	70	19.0 ±14.4	0.08
3 mo	75	7.3 ±9.8	64	6.9 ±8.0	0.79
12 mo	80	4.5 ±7.6	64	3.2 ±7.4	0.30

The values are given as the mean and the standard deviation.

Secondary Operations

In the operatively treated group, a reoperation for adverse events was performed in 9 patients (10.7%) because of deep wound infection (2 patients), early implant failure (5 patients), late implant failure (1 patient), and nonunion that became manifest with a refracture after implant removal (1 patient) (Table 3, p64). After 1 year, implant removal was performed in or scheduled for 16.7% (14) of the 84 patients. There were no differences between different plate positions with regard to implant failure (p = 0.69) or plate removal (p = 0.53).

In the nonoperatively treated group, 11 patients (15.7%) had a secondary operation for adverse events including nonunion (9 patients), malunion (1 patient), and late neurologic complications (1 patient). One patient who underwent secondary plate fixation because of nonunion later had the plate removed. The secondary operation rate did not differ significantly between the treatment groups (p = 0.47 for adverse events and p = 0.18 for adverse events including elective implant removal operations) (Table 3, p64).

Other Adverse Events

Perioperative complications were thrombosis of the cephalic vein, superficial wound infection, and a cardiovascular event in 1 patient each. More than half of the operatively

Table 3. Secondary operations

Indication	Plate fixation (n=84)	Nonoperative treatment (n=70)	P value
Adverse events	9 (10.7)	11 (15.7)	0.47
Nonunion	1 (1.2)[a]	9 (12.9)	
Malunion	0	1 (1.4)	
Deep infection	2 (2.4)	0	
Early implant failure[b]	5 (6.0)	0	
Late implant failure[c]	1 (1.2)	0	
Neurologic complications	0	1 (1.4)	
Elective implant removal	14 (16.7)	1 (1.4)[d]	
Total (all)	23 (27.4)	12 (17.1)	0.18

The values are given as the number of patients, with the percentage in parentheses.
[a] Nonunion was diagnosed when spontaneous refracture occurred after plate removal. [b] All early implant failures occurred within 2 months. In 2 patients (1 with a broken plate and 1 with a loose plate), plate fixation was repeated. In 2 other patients, the plate had broken or become loose (in 1 each) and was removed after union had been achieved. In 1 patient, a loosened screw was removed. [c] Late implant failure occurred after 9 months. The loose plate was removed, and the concomitant nonunion was treated nonoperatively. [d] One patient who had nonoperative treatment received secondary plate fixation for nonunion and later had the plate removed.

Table 4. General health status (SF-36)

	Plate fixation		Nonoperative treatment		
SF-36	No.	Score	No.	Score	P Value
Physical component score					
6 wk	78	49.3 ±7.3	70	46.7 ±7.8	0.03
3 mo	76	53.5 ±7.1	63	53.4 ±6.9	0.92
12 mo	79	55.2 ±6.1	64	56.1 ±5.7	0.36
Mental component score					
6 wk	78	51.6 ±8.6	70	53.1 ±7.1	0.25
3 mo	76	53.6 ±7.1	63	54.9 ±6.1	0.25
12 mo	79	52.6 ±9.1	64	52.2 ±9.3	0.80

The values are given as the mean and the standard deviation. A score of 50 represents the expected score for the general population.

treated patients experienced numbness of the skin around the scar during follow-up, and it persisted in 15 (19.2%) of 78 patients 1 year after surgery.

General Health Status

The SF-36 physical component score was somewhat lower in the nonoperatively treated group (p = 0.03), but only at 6 weeks (Table 4). The mental component scores were comparable with the score for the general population in both groups.

Pain and Cosmetic Results

Pain scores were somewhat higher in the nonoperatively treated group, but only at 6 weeks (median score 2 compared with 1; p = 0.04). Five percent of the patients in the operatively treated group and 18% in the nonoperatively treated group indicated that they were unsatisfied with the cosmetic result after 1 year (p = 0.06).

DISCUSSION

The present RCT demonstrated a significantly lower rate of nonunion after plate fixation than after nonoperative treatment for patients with a displaced midshaft clavicular fracture.

There was no difference in functional outcomes. The rate of secondary operations was considerable and was not significantly different between both groups. Pain scores and general physical health status were marginally better after operative treatment, but only at 6 weeks, and the clinical relevance can be disputed.

Since the start of the present study, a number of RCTs that have shown a similar reduction in the rate of nonunion after operative treatment have been published, leading to an explosive increase in routine surgical fixation of clavicular fractures. However, the clinical interpretation of some of the previous results can be debated[6,11,20-22].

For instance, in the first RCT that was published in 2007, all patients with a nonunion underwent secondary surgery; however, it was not mentioned whether they had complaints and chose to have surgery, or if nonunion was regarded as the indication for the operation[6]. In another RCT by Virtanen et al.[20], all 6 patients with a nonunion in the nonoperatively treated group declined the offered surgical treatment, suggesting that they did not have sufficient symptoms or limitations to choose surgery. Also, this assumption is supported by the fact that functional scores did not differ between the treatment groups. Mirzatolooei described a difference in function in favour of plate fixation[22]. That study noted an exceptionally high number of malunions in the nonoperatively treated group (73%) and was the only one that found no difference in nonunion rates. Recently, Robinson et al.[21] demonstrated a moderately better function after plate fixation (a mean difference in the Constant score of 4.2 points; $p = 0.01$); however, when only fractures that had united were analysed, the functional difference between the operatively treated and nonoperatively treated groups ceased to exist.

These results endorse our findings that plate fixation itself does not improve functional outcomes, especially not in the long term. Also, since many hospitals cannot provide immediate surgery, operative treatment does not remove possible disadvantages of nonoperative treatment for the patient in the first week.

Even though plate fixation considerably reduces the rate of nonunion compared with nonoperative treatment, it fails to reduce the risk of a secondary operation. Secondary operations were performed in 27.4% of the operatively treated patients, and this number is likely to increase in the second year after surgery since more patients are expected to have their plate removed after longer follow-up.

Potter et al. showed that delayed fixation of a nonunited, nonoperatively treated clavicular fracture led to functional outcomes similar to those after immediate operative treatment[23]. Our results showed the same, despite the small numbers, which suggests that failed nonoperative treatment does not preclude the opportunity of effective treatment, although it does result in a longer recovery time.

The present study had several limitations. First, there was an imbalance between the groups regarding treatment allocation (86 had plate fixation compared with 74 who had nonoperative treatment). This was probably caused by having very few patients enrolled from some hospitals and using stratification per hospital and not central or block randomization.

Second, there was substantial loss to follow-up, especially regarding the functional scores (the Constant score was not available for 12.8% in the operatively treated group and 21.6% in the nonoperatively treated group). Although loss to follow-up is frequently higher after nonoperative treatment because patients have less commitment to return to

the hospital than patients after an operation, this could have led to a bias and reduces the power for these outcomes.
Third, the surgical treatment protocols varied among the participating hospitals, resulting in differences in plate type, plate position, and incision. However, this heterogeneity within the study group reflects daily clinical practice and enhances the external validity of the outcomes of this study.
Also, radiographs were judged by the treating surgeon only, which could have biased the results because of a possible underestimation of the complication rate of the surgeon's own work and less than perfect interobserver reliability. Finally, because of the duration of inclusion, new publications on the topic became available, resulting in a stronger tendency of treating physicians toward operative treatment and a subsequent reduction in the patient inclusion rate.

Since neither treatment option is clearly superior for all patients, the clavicular fracture is pre-eminently suitable for shared treatment decision-making, in which the personal values and beliefs of the patient are addressed along with medical information about both treatment modalities in a way that individualizes treatment. In this process, it is important to explain to patients that they have a choice: patients with pain, deformity, and striking radiographic findings might imagine that they have no other option than fixation. If surgeons help patients to fully understand the data that are currently available to guide them, they might realize that their first impressions are not consistent with their values and their true preference is to avoid surgery.

In conclusion, the present study shows a significantly lower nonunion rate after plate fixation of the fully displaced midshaft fracture of the clavicle compared with nonoperative treatment in a sling. However, the rate of secondary operations was comparably high in both groups, and there were no differences in functional outcomes or general symptoms and limitations. We therefore do not advocate routine operative treatment for displaced midshaft clavicular fractures. Initial nonoperative treatment is a good option for the majority of patients with normal requirements regarding their arm function. If patients have high physiological demands shortly after surgery, high pain scores, or a strong preference for surgery, early plate fixation can offer advantages.

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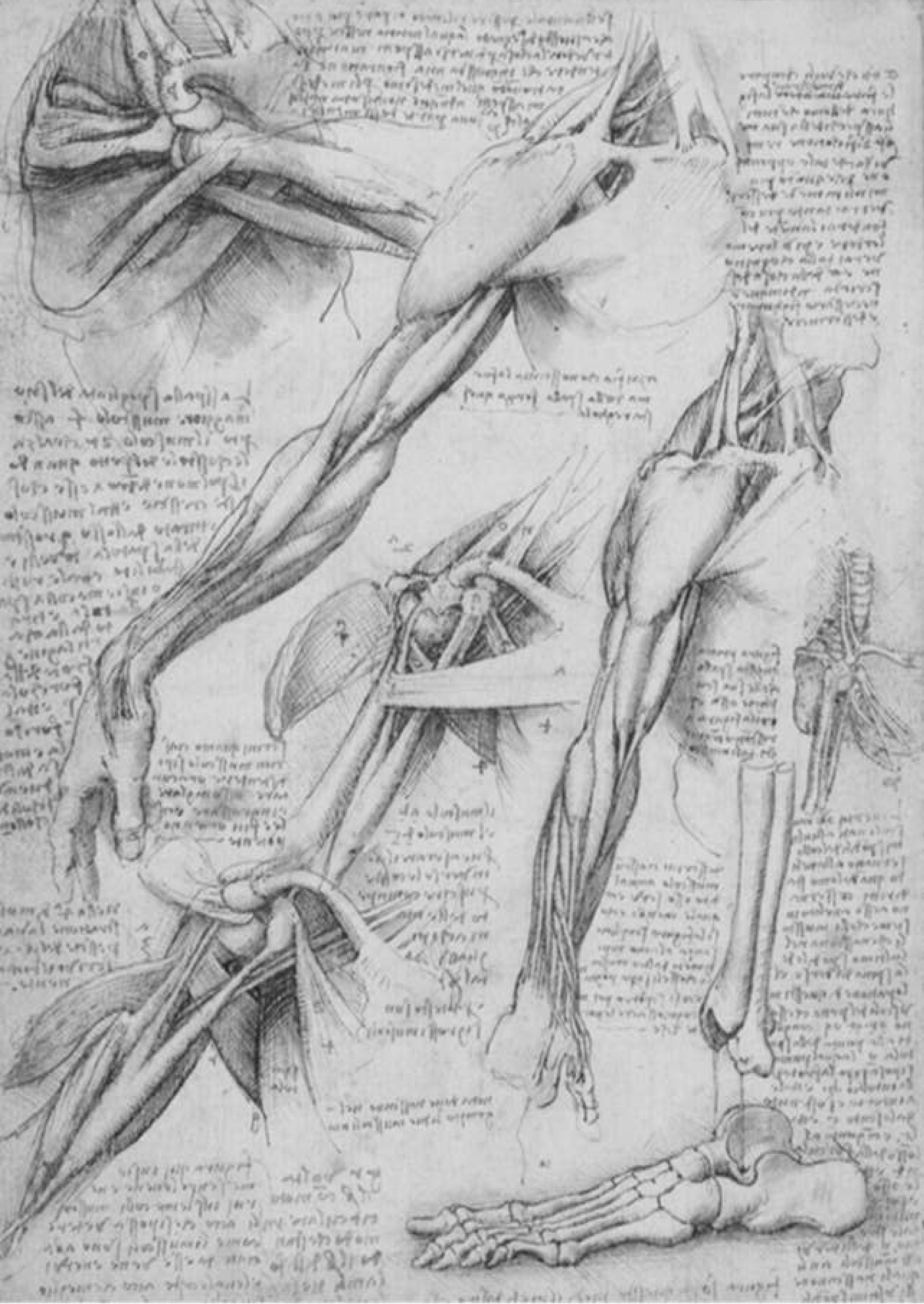

CHAPTER 5

Plate fixation versus nonoperative treatment for displaced midshaft clavicular fractures: A meta-analysis of randomized controlled trials

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ABSTRACT

Background

The aim was to analyse whether patients with a displaced midshaft clavicular fracture are best managed with plate fixation or nonoperative treatment with respect to nonunion, secondary operations, and functional outcome, by evaluating all available randomized controlled trials (RCTs) on this subject.

Patients and methods

A systematic search of electronic databases (PubMed, MEDLINE, Embase, and Web of Science) was performed to identify RCTs comparing nonoperative treatment with plate fixation for displaced midshaft clavicular fractures. Risk of bias of the studies was assessed. Outcomes evaluated were nonunion, shoulder function (Constant score and Disabilities of the Arm, Shoulder and Hand [DASH] score), and secondary operations.

Results

Six RCTs (614 patients) were included. The risk of nonunion was lower in the operatively treated patients (relative risk [RR] = 0.14, 95% confidence interval [CI] = 0.06 to 0.32). One-third of the patients with a nonunion did not receive further treatment. Secondary operations for adverse events were performed less often in the operatively treated patients (RR = 0.42, 95% CI = 0.25 to 0.71). When plate removal operations were also included, a secondary operation was performed in 17.6% in the operative group and 16.6% in the nonoperative group (RR = 1.01, 95% CI = 0.64 to 1.59). Constant and DASH scores after 1 year were somewhat better after plate fixation, with mean differences of 4.4 points (95% CI, 0.9 to 7.9 points) and 5.1 points (95% CI, 0.1 to 10.1 points), respectively.

Conclusion

Plate fixation significantly reduces the risk of nonunion, but does not have a clinically relevant advantage regarding final functional outcome. Secondary operations are common after both treatments. Overall, there is not enough evidence to support routine operative treatment for all patients with a displaced midshaft clavicular fracture.

INTRODUCTION

Clavicular fractures are common and occur typically in younger patients, posing a burden for this active population. Nonunion of nonoperatively treated, fully displaced midshaft clavicular fractures occurs much more frequently than was thought for centuries[1-3]. As a result, operative treatment has substantially gained in popularity in the past decade, even though complications following surgery are substantial and not all studies have shown that operative treatment results in better shoulder function[4-7].
Remarkably, more meta-analyses than randomized controlled trials (RCTs) have been published on this subject[8-13]. Unfortunately, all have limitations that reduce their value for daily practice and evidence-based treatment guidelines. Most of the available meta-analyses compare nonoperative with operative treatment, but include 2 essentially different operative techniques (plate and pin fixation), each of which is known to have specific characteristics and complications, and thus cannot be regarded as a single treatment modality[9,10,12,13]. Also, some meta-analyses include nonrandomized trials, which may introduce bias[11,14], or include only a few studies[8].

In the current meta-analysis, we chose to compare nonoperative treatment with open reduction and plate fixation, as the latter is the most widely used operative technique for clavicular fixation.
Compared with previous meta-analyses, we include 2 recent RCTs that substantially add to the number of patients analysed. Furthermore, not only nonunion and function but also secondary operations were studied. To our knowledge, the only previous meta-analysis that explicitly evaluated secondary operation rates incorrectly performed the calculation using the number of patients randomized, instead of the number of patients who completed follow-up[14].
The aim of this meta-analysis was to analyse all RCTs that compared nonoperative treatment with plate fixation in patients with a displaced midshaft clavicular fracture and to provide high-quality evidence for treatment of displaced midshaft clavicular fractures in daily clinical practice.

MATERIALS AND METHODS

This meta-analysis was conducted following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Statement[15,16].

We selected RCTs comparing plate fixation with nonoperative treatment in patients with a displaced midshaft clavicular fracture and reporting data for ≥1 of the following outcome measures: nonunion, shoulder function, complications, and secondary operations. Studies were excluded if they concerned children (<16 years), if they had a follow-up of <12 months, or if the full-text article was not available in English, Dutch, French, or German.

With the help of a trained medical librarian, we searched PubMed, MEDLINE, Embase, and the Web of Science in April 2016, using a combination of different terms and synonyms for "clavicle," "fracture," and "randomized controlled trial" (see Appendix 2, p166, for the full search strategy). In addition, the reference lists of previously published randomized trials, review articles, and meta-analyses were manually searched for additional eligible studies. Duplicates were removed. The titles and abstracts of the search results were independently screened by 2 reviewers (S.W. and P.K.). In case of presumed eligibility, the full-text article was reviewed using the same inclusion and exclusion criteria. In case of disagreement, consensus was reached by discussion and by consulting a third reviewer (I.B.S.) if necessary.

The 2 reviewers independently extracted data on study characteristics (year of publication, randomization method, patient and treatment characteristics). Data on the following outcome measures were documented: nonunion, secondary operations due to adverse events (e.g., nonunion, wound infection, plate failure), implant removal operations at the request of the patient due to plate irritation or cosmetic considerations, and function measured with the Constant score or the Disabilities of the Arm, Shoulder and Hand (DASH) score. If mean outcomes were reported with a 95% confidence interval (CI), the corresponding standard deviation (SD) was calculated.

Seven aspects of the studies related to the risk of bias were assessed, following the instructions in the Cochrane Handbook for Systematic Reviews of Interventions[17].

RevMan software (version 5.3; The Cochrane Collaboration)[18] was used for the analysis. Treatment effects were estimated by calculating the relative risk (RR) with 95% CI for dichotomous variables, and the mean difference with 95% CI for continuous variables.

Studies were weighted by the inverse of the variance (IV) of the outcome. A random-effects model was used for all analyses, as clinical heterogeneity was assumed to exist because of differences in study methods (e.g., plate type) and outcome definitions (e.g., nonunion) across studies.

RESULTS

The search terms described above identified 301 references (Figure 1). A manual search of reference lists yielded 4 additional references. After removal of duplicates, 131 articles were screened for relevance on the basis of the title and abstract. Of the 11 articles that were possibly eligible for inclusion, 5 were excluded because no full text was available (n = 1), the article was in Portuguese (n = 1), the study was not an RCT (n = 2), and medial and lateral fractures were included (n = 1). The remaining 6 studies were included in this meta-analysis.

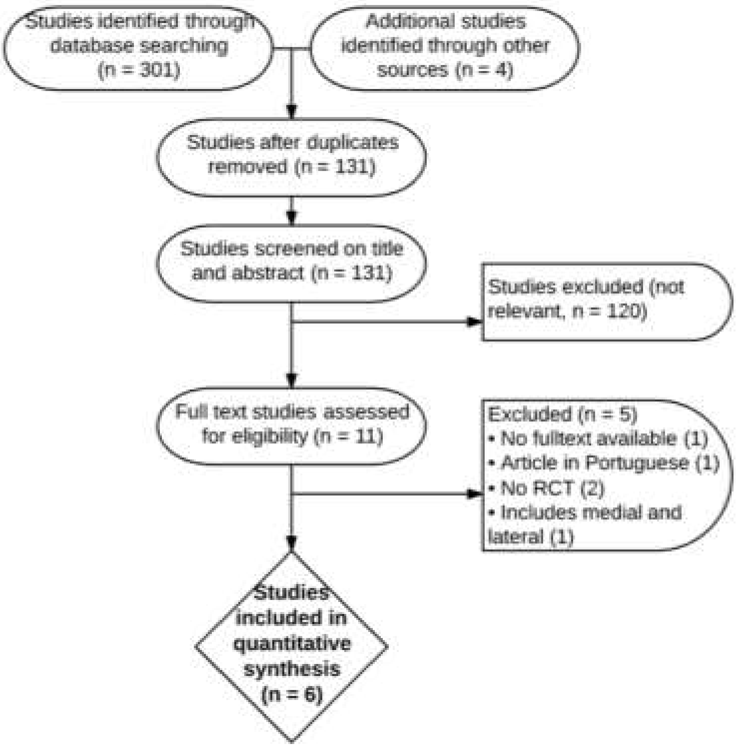

Figure 1. *Flowchart of study selection.*

Study Characteristics and Quality

Five of the included studies were published between 2007 and 2015[6,7,19-21]; the remaining RCT on 160 patients had been accepted for publication[22] at the time, and data were available to the authors prior to its publication (Table 1). The 6 studies included a total of 614 patients (317 treated with plate fixation and 297 treated nonoperatively). One study only included comminuted fractures and did not exclude open fractures[20], and 1 studied a working population who had had labor-related accidents[21]. The primary outcome was nonunion in 2 studies[19,22] and the Constant and/or DASH scores in 2 other studies[6,7]. In the remaining 2 studies, the primary outcome was not explicitly defined.

Table 1. Characteristics of the included studies

Study	No of patients randomized (O/N)	No of patients analysed[a] (O/N)	Age criteria (yr)	% Male (O/N)	Operative intervention: plate type[b] (n)	Nonop. Intervention
COTS, 2007[7]	132 (67/65)	111 (62/49)	16-60	78 (85/69)	LCDCP (44), REC (15), precontoured (4), other (4)	Sling
Melean, 2015[21]	76 (34/42)	76 (34/42)	>18	Not stated	3.5mm LCP / locking REC	Sling 6 wks
Mirzatolooei, 2011[20]	60 (29/31)	50 (26/24)	18-65	82 (77/88)	3.5mm REC	Sling and elastic cotton band
Robinson, 2013[19]	200 (95/105)	178 (86/92)	16-60	88 (87/88)	Locking Clavicle Plate (Acumed)	Collar and cuff
Virtanen, 2012[6]	60 (28/32)	51 (26/25)	18-70	87 (86/88)	2.8mm REC	Sling
Woltz, 2017[22]	160 (86/74)	148 (83/65)	18-60	91 (93/89)	Precontoured (68), REC (2), LCDCP (2), unknown (11)	Sling 2 wks

[a] Number of patients analysed for the primary outcome measure (operative/nonoperative).
[b] LCDCP=limited contact dynamic compression plate, REC=reconstruction, and LCP=locking compression plate.

An overview of the estimated risk of bias for each study is presented in Figure 2. The researchers were blinded when assessing functional outcomes in only 1 study (by letting the patient wear a t-shirt)[19], and the primary outcome measurements could not be blinded in any of the studies. In 2 studies, the numbers on which sample size calculations were based were unclear[20,21]. Risk of "other" types of bias was judged to be present in 1 study because the exact rate of follow-up was not reported[21], and in 1 study because all patients who were not included or declined participation in the study were treated nonoperatively, which could have led to a selection bias[19].

Nonunion

Nonunion was defined as absence of cortical bridging of the bone on computed tomography imaging in 2 studies[19,21] and on radiographs in the other 4, after a period ranging from 4 to 12 months. Six (1.9%) of 317 operatively treated patients developed a

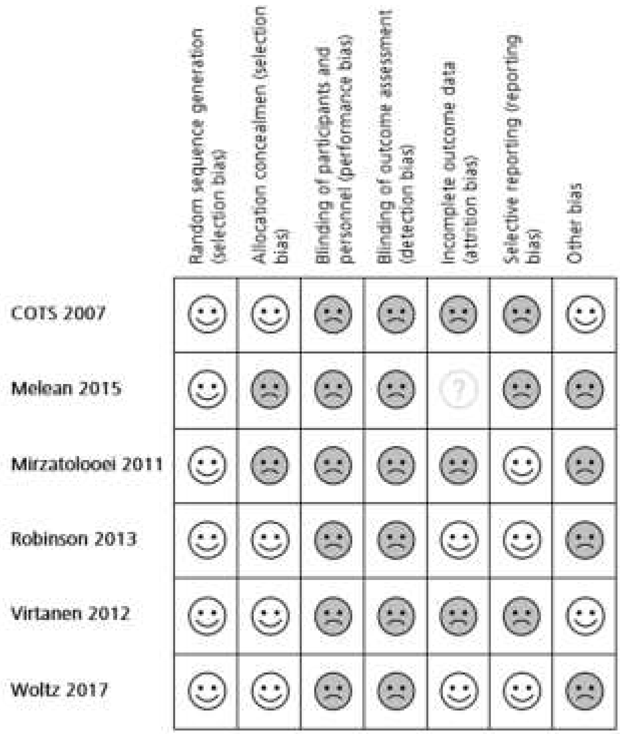

Figure 2*. Risk of bias summary for included studies. "Happy face"= risk of bias not present, "unhappy face" = risk of bias present, and "?" = insufficient information to judge risk of bias.*

nonunion, compared with 49 (16.5%) of 297 nonoperatively treated patients (RR = 0.14, 95% CI = 0.06 to 0.32, p < 0.0001) (Figure 3).

The method for dealing with patients with a nonunion differed among the studies. Overall, nonunion was treated with secondary plate fixation in 67% of the patients (n = 37), whereas the remaining one-third of patients with a nonunion did not receive further treatment. Robinson et al. offered secondary plate fixation to all patients with fracture nonunion after 6 months, and 13 of 16 consented[19]. In the Canadian Orthopaedic Trauma Society (COTS) study, all patients who had a nonunion after 1 year of follow-up underwent a secondary operation[23]. In the study by Melean et al., all 4 patients with a nonunion received secondary plate fixation, but the timing was not reported[21]. In the study by Woltz et al., 5 patients with a nonunion were operated on within the study follow-up period of 1 year, 5 others received surgery after >1 year, and 7 were asymptomatic and chose to receive no further treatment[22]. In 2 studies, none of the patients with a nonunion elected to receive the offered secondary surgical treatment, and therefore could not be included in the analysis of this outcome[6,20]. Overall, secondary operations for nonunion occurred more often after nonoperative treatment than after plate fixation (10.9% versus 1.3%, RR = 0.14, 95% CI = 0.05 to 0.36, p < 0.0001).

Secondary Operations

Reports on whether secondary operations were performed, and on their details, varied among studies. Mirzatolooei[20] described 19 patients with a malunion, but did not state if these patients underwent secondary operative treatment; it was noted that at least 1 patient did not. Indications for all secondary operations are presented per study in Table 2, p81. Secondary operations for adverse events occurred less frequently in the plate fixation group than in the nonoperative treatment group (6.9% versus 16.2%, RR = 0.42, 95% CI = 0.25 to 0.71, p = 0.001) (Figure 4). This would have been true even if all patients with a malunion in the study by Mirzatolooei had received a secondary operation. The overall rate of secondary operations (i.e., operations due to adverse events and implant removal operations) did not differ significantly between the treatment groups (17.6% for plate fixation versus 16.6% for nonoperative treatment, RR = 1.01, 95% CI = 0.64 to 1.59, p = 0.97). Implant removal was performed frequently in four studies[7,19,21,22]. Mirzatolooei[20] reported that some plates were removed, but did not state how many. Virtanen et al.[6] did not mention elective plate removal operations.

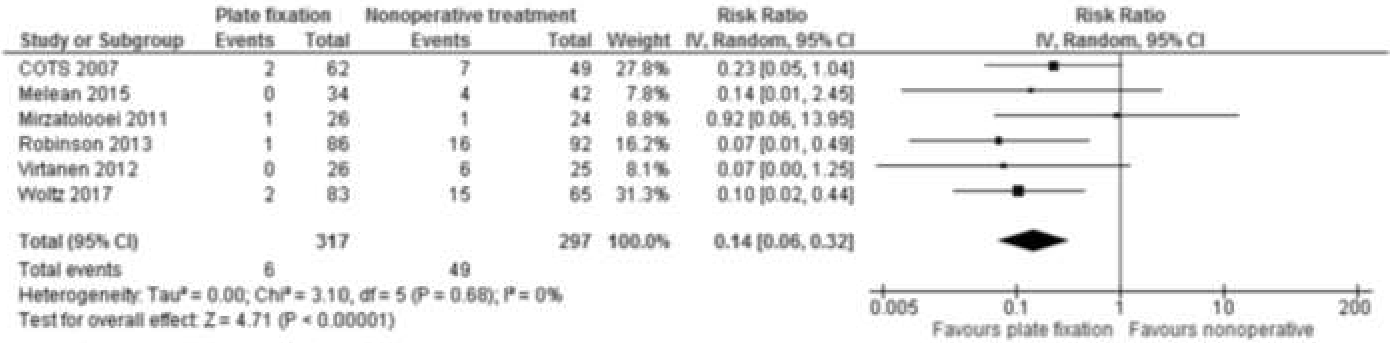

Figure 3. *Nonunion after plate fixation versus nonoperative treatment. IV = inverse variance, and df = degrees of freedom.*

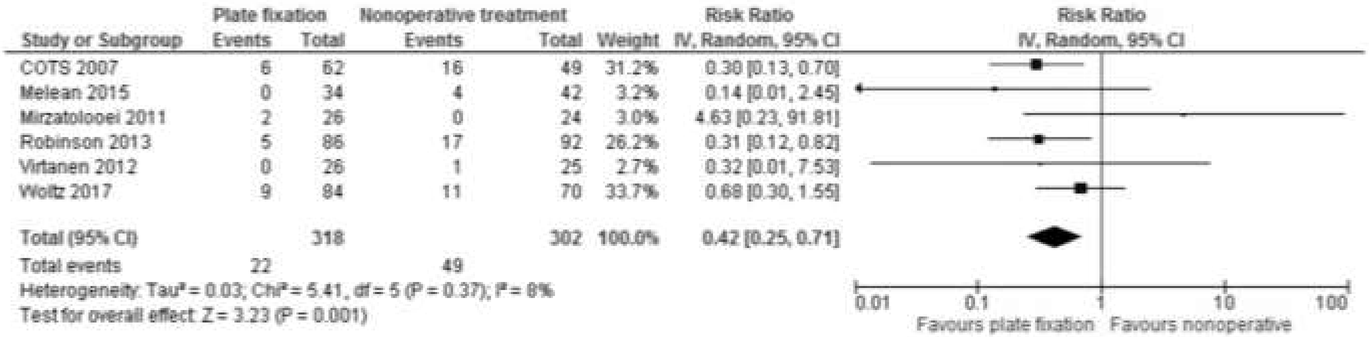

Figure 4. *Secondary operations for adverse events after plate fixation versus nonoperative treatment. IV = inverse variance, and df = degrees of freedom.*

Study or Subgroup	Plate fixation Mean	SD	Total	Nonoperative treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
COTS 2007	96	5	62	90	20	49	13.3%	6.00 [0.26, 11.74]
Melean 2015	93	1	34	87	4	42	20.3%	6.00 [4.74, 7.26]
Mirzatolooei 2011	89.8	6	26	78.8	8	24	16.4%	11.00 [7.06, 14.94]
Robinson 2013	92	9.5	86	87.8	12.5	92	17.6%	4.20 [0.95, 7.45]
Virtanen 2012	86.5	11.5	26	86.1	8.9	25	13.5%	0.40 [-5.23, 6.03]
Woltz 2017	95.4	7.8	75	96.6	6.3	58	18.9%	-1.20 [-3.60, 1.20]
Total (95% CI)			**309**			**290**	**100.0%**	**4.39 [0.90, 7.87]**

Heterogeneity: Tau² = 15.20; Chi² = 39.71, df = 5 (P < 0.00001); I² = 87%
Test for overall effect: Z = 2.47 (P = 0.01)

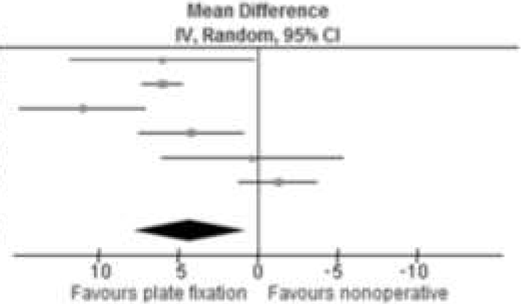

Figure 5. *Constant score 1 year after plate fixation versus nonoperative treatment. IV = inverse variance, and df = degrees of freedom.*

Study or Subgroup	Plate fixation Mean	SD	Total	Nonoperative treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
COTS 2007	5	2.5	62	13	6.25	49	21.1%	-8.00 [-9.86, -6.14]
Mirzatolooei 2011	8.6	2	26	21.3	6	24	20.6%	-12.70 [-15.22, -10.18]
Robinson 2013	3.4	7.1	86	6.1	9.8	92	20.7%	-2.70 [-5.20, -0.20]
Virtanen 2012	4.3	6.1	26	7.1	13.5	25	16.9%	-2.80 [-8.59, 2.99]
Woltz 2017	4.5	7.6	80	3.2	7.4	64	20.7%	1.30 [-1.16, 3.76]
Total (95% CI)			**280**			**254**	**100.0%**	**-5.07 [-10.08, -0.06]**

Heterogeneity: Tau² = 30.00; Chi² = 73.05, df = 4 (P < 0.00001); I² = 95%
Test for overall effect: Z = 1.99 (P = 0.05)

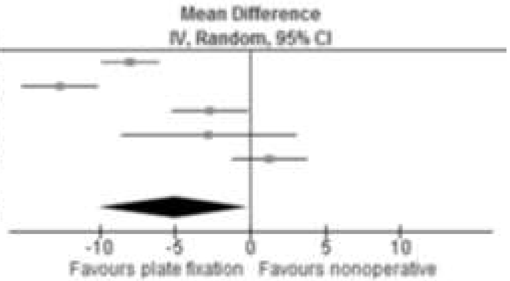

Figure 6. *DASH score 1 year after plate fixation versus nonoperative treatment. IV = inverse variance, and df = degrees of freedom.*

Table 2. Numbers and reasons for secondary operations

Study	Plate fixation	Nonoperative treatment
COTS, 2007[7]	2 nonunion	7 nonunion
	1 implant failure	9 malunion
	3 infection	
	5 plate removal	
Melean, 2015[21]	4 plate removal	4 nonunion
Mirzatolooei, 2011[20]	1 implant failure	-
	1 infection	
Robinson, 2013[19]	1 nonunion	13 nonunion
	1 implant failure	4 malunion
	1 refracture	
	1 neurologic complication	
	2 fracture lateral to plate	
	10 plate removal	
Virtanen, 2012[6]	-	1 neurologic complication
Woltz, 2017[22]	1 nonunion	9 nonunion
	6 implant failure	1 neurologic complication
	2 infection	1 malunion
	14 plate removal	1 plate removal[a]
Total	56	50

[a] One nonoperatively treated patient developed a nonunion and was treated with secondary plate fixation after four months. At one year, plate removal was scheduled. This patient was analysed in the nonoperative group following the intention to treat principle.

Functional Outcomes

Constant scores were measured after 1 year in all 6 studies, and DASH scores were reported in 5 studies. One study only graphically presented Constant and DASH scores and SDs, and we measured values by hand on the graphs[7]. The mean scores reported in the 6 studies, however, may not reflect the final shoulder function for all patients, as some studies also included the patients with a nonunion who were yet to receive surgery[7,22] or those who had received secondary plate fixation only a few months prior to analysis[19,22]. Melean et al.[21] did not state whether secondary plate fixation was performed before or after the 1-year follow-up time point. When ignoring this information and including all patients in the meta-analysis, the mean Constant score of the operatively treated patients was 4.4 points (95% CI = 0.9 to 7.9 points, p = 0.01) higher than that of the nonoperatively treated patients (Figure 5). The mean difference in DASH scores at 1 year after trauma was 5.1 points (95% CI = 0.1 to 10.1 points, p = 0.05) in favour of plate fixation (Figure 6, p80). Robinson et al.[19] reported that the difference in functional scores between groups ceased to be significant when considering the united fractures only: mean Constant scores for plate fixation and nonoperative treatment were 89.4 and 82.5, and mean DASH scores were 4.8 and 3.2, respectively (SDs not reported). Woltz et al.[22] reported that the patients with a nonunion who were yet to receive surgery had a lower functional score than the patients with a united fracture: mean Constant scores were 86.2 (SD = 11.7) and 96.3 (SD = 6.7) (p = 0.01), and mean DASH scores were 14.7 (SD = 14.6) and 3.3 (SD = 6.1) (p = 0.005), respectively.

DISCUSSION

This meta-analysis of 6 RCTs that evaluated a total of 614 patients shows that plate fixation significantly reduced the rate of nonunion of displaced midshaft clavicular fractures to 2% compared with 16% for nonoperative treatment. Plate fixation resulted in somewhat better DASH and Constant scores, but the clinical relevance of this difference is unclear. Also, approximately 17% of the patients in each group had a secondary operation after the initial treatment.

Overall, approximately two-thirds of the patients with nonunion elected to undergo secondary fixation, whereas one-third did not receive any further treatment. In the 2 studies in which all patients with a nonunion received secondary fixation, it was not stated whether all of these patients had symptoms and deliberately opted for surgery, or whether this was the physicians' standard treatment choice[7,21]. In light of the current trend toward shared decision-making, it is important to thoroughly explain the treatment options and inquire about the patient's preferences in case of nonunion, as it is clear that not all nonunions require operative treatment. Also, secondary surgery for nonunion should be considered earlier than after 9 to 12 months, to minimize delay in recovery for those patients.

Secondary operations were performed in approximately 17% of patients in each group. However, in the majority of patients in the operative group (33 of 56), this was a plate removal operation, which generally is technically simpler, imposes less risk of complications, and has a shorter rehabilitation time than other operations such as secondary plate fixation with bone-grafting. Excluding these plate removal operations, secondary operations occurred more often in the nonoperative group (16.2%) than in the operative group (6.9%, p = 0.001). It is conspicuous, however, that the 3 largest studies[7,19,22] reported much higher percentages of patients with secondary operations than the 3 smaller studies[6,20,21], in which, for instance, only 1 infection and 1 implant failure requiring a secondary operation appeared to have occurred. This discrepancy may be the result of either underreporting or coincidence due to the small study samples.

After 1 year, Constant and DASH scores were significantly better after plate fixation than after nonoperative treatment. However, the mean differences were only 4.4 (95% CI = 0.9 to 7.9) and 5.1 (95% CI = 0.1 to 10.1) points, respectively, which are less than the 10 to 15 points generally regarded as the minimal difference to be clinically relevant[24-26]. The implications of the difference in scores for daily practice are therefore limited. Also, patients with a symptomatic nonunion who were yet to receive a secondary operation were included in these mean scores, which probably influenced the results to the detriment of the nonoperative group. When analyzing united fractures only, as Robinson et al.[19] did, there was no longer a functional difference between the groups after 1 year. This implies that nonoperative treatment itself is not associated with functional impairment, but symptomatic nonunion is.

An early functional benefit is generally regarded as a well-established advantage of operative treatment. Three of the 5 studies that evaluated early functional outcomes reported such a difference[7,19,21], but it was measured in various ways (e.g., time to return to work, functional scores) and at different time points (6 weeks and 3 months), so no pooled analysis could be performed. However, short-term differences should be discussed with the patient when choosing the best treatment.

Limitations of this meta-analysis are partly inherent to the design: the quality of our conclusions can only be as good as that of the included studies, and although only Level-I RCTs were included to optimize the quality of the data, there was a considerable risk of bias in all studies.

In addition, the included studies used different plate types and plate positions, which could have influenced implant failure and removal rates and may have been a source of clinical heterogeneity. Unfortunately, plate location and plate type could not be related to complications on the basis of the information provided in the articles. The way in which patients with a nonunion were identified and treated also differed among the studies, as did the timing of secondary operations.

We did not evaluate other operative techniques such as pin fixation in this meta-analysis. This was a deliberate choice for reasons previously discussed. A Bayesian network meta-analysis showed lower nonunion rates after pin fixation than after nonoperative treatment, and lower infection rates after pin fixation than after plate fixation, but that study did not address arm function or secondary operations[11]. A recent meta-analysis comparing plate and pin fixation, found no differences regarding nonunions, infections, and reoperations[27]. Another surgical alternative is minimally invasive plate fixation, which is thought to reduce both the interference with the blood supply to the bone that promotes healing and the infection risk by minimizing skin incision. Both pin fixation and minimally invasive plate fixation are good treatment alternatives, provided that the surgeon is experienced in these techniques[5].
Overall, plate fixation offers clear advantages but also has considerable drawbacks. It is a good option for patients who demand quick recovery and optimal arm function, and for patients with risk factors for nonunion such as large displacement, comminution, and smoking[28,29]. For less active patients and in case of relatively favourable fracture characteristics, however, the risks and benefits must be weighed differently and nonoperative treatment appears to be the better option.

In conclusion, this meta-analysis shows that plate fixation dramatically reduces nonunion rates but does not appear to offer a clinically relevant advantage in terms of final functional outcome. Secondary operations are common, regardless of the initial treatment. One-third of the patients with a nonunion did not opt for further treatment. For daily clinical practice, we do not advocate routine plate fixation for all patients, but rather an individualized treatment based on shared decision-making, guided by the presence of risk factors for nonunion and patients' values and preferences.

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CHAPTER 6

Mid-term patient satisfaction and residual symptoms after plate fixation or nonoperative treatment for displaced midshaft clavicular fractures

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Submitted

ABSTRACT

Background

To evaluate mid-term patient-reported satisfaction and residual symptoms after plate fixation (PF) and nonoperative treatment (NOT) for displaced midshaft clavicular fractures.

Patients and methods

One hundred and sixty adult patients with a fully displaced, midshaft clavicular fracture who had been included in a multicenter randomized controlled trial comparing PF and NOT, were interviewed for a mid-term follow-up survey. Outcomes were satisfaction with the received treatment, with the cosmetic result and with the shoulder function (on a scale of 1 to 10), and presence of residual symptoms.

Results

Seventy-nine patients (40 after PF, 39 after NOT) could be contacted and agreed to participate. The median follow-up was 53 months (range 34 -79). Overall satisfaction was similar for PF and NOT (mean±SD: 7.7±2.1 vs 6.9±2.4, $p=0.12$), as was satisfaction with the shoulder function (8.9±1.6 vs 8.4±2.0, $p=0.27$). Satisfaction with the cosmetic result was higher after PF (8.2±1.6 vs 6.8±2.0, $p=0.002$). Less than half of the patients felt that their shoulder had fully recovered (48% for PF vs 46% for NOT, $p=1$) and residual symptoms were frequently present in both groups (55% for PF vs 41% for NOT, $p=0.26$). After PF, 88% of patients would prefer the same treatment again, compared with 41% after NOT ($p<0.001$).

Conclusion

Aspects of satisfaction seem higher after plate fixation. Residual symptoms, however, were common after both treatments for displaced midshaft clavicular fractures. The present results can be used to manage patients' expectations and provide objective information regarding both treatment options before a shared treatment decision is made.

INTRODUCTION

Most research comparing plate fixation and nonoperative treatment for displaced midshaft clavicular fractures focuses primarily on objective short-term outcomes such as nonunion, complications and arm function scores. Results show that both treatment strategies have specific risks and benefits: plate fixation significantly reduces nonunion and results in earlier functional recovery, while final shoulder function scores are equally good. Also, complications and reoperations after plate fixation are common[1-4].

In the absence of a hard operation indication (i.e., open fracture, compromised skin, neurovascular injury), treatment therefore should be individualized, based on patient- and fracture-related characteristics such as risk factors for nonunion and other complications, but also on patient's goals and preferences. Subjective outcomes such as satisfaction and patient-reported sequelae, could also be relevant when weighing the treatment options together with the patient. Subjective outcomes of clavicular fracture treatment, however, have been evaluated to a much lesser extent than objectively determined clinical results. Although some studies reported higher satisfaction after plate fixation than after nonoperative treatment[5-7], others have found no difference[1,4,8]. The presence of residual symptoms has been reported primarily after nonoperative treatment[9,10], but is rarely mentioned in comparative studies[7].

Recently, our study group published a randomized controlled trial comparing plate fixation with nonoperative treatment in 160 patients with a fully displaced midshaft clavicular fracture[11]. Nonunion rates were significantly higher in the nonoperatively treated group at one year follow-up, but functional outcome scores, pain, general health status and secondary operation rate were similar. Satisfaction with the cosmetic result seemed in favor of plate fixation. These results, however, were measured after just one year, and other subjective outcomes were not studied.

The present study evaluated the original study group, aiming to compare plate fixation and nonoperative treatment with respect to different aspects of mid-term satisfaction and patient-reported residual symptoms and limitations.

PATIENTS AND METHODS

Setting and design

The patients in the current study had participated in a multicenter, prospective study that randomized 160 patients between 18 and 60 years old with a midshaft clavicular fracture that was at least 1 shaft width displaced (Robinson 2B1 and 2B2), between open reduction and plate fixation (n=86) and nonoperative treatment with a sling (n=74) between 2010 and 2013[11]. A total of 154 patients had completed one-year follow-up (148 for the primary outcome radiologic nonunion). The original randomized controlled trial (RCT) had been approved by the institutional ethics review committee of each participating hospital and all patients had provided written informed consent to participate in the trial including a follow-up by telephone. Between October 2016 and February 2017, all patients of the original study group were contacted by telephone for a mid-term follow-up survey (see Appendix 3, p167, for full survey). Several attempts were undertaken to reach as many patients as possible.

Outcome measures

Different aspects of satisfaction were evaluated: overall satisfaction with the received treatment, satisfaction with the cosmetic result and satisfaction with the function of the shoulder. All three aspects were measured on a 10-point scale ranging from 1 (completely dissatisfied) to 10 (completely satisfied).

Residual symptoms were recorded (yes or no) including the character (pain, weakness, stiffness, tingling sensation or other) and frequency (daily, weekly, monthly or less than once a month). The perceived impact of the symptoms ('How bad are these complaints for you?') was measured on a scale of 1 (no impact) to 10 (large impact). It was also asked if the patients presently experienced any limitations in daily life activities compared to the situation before the fracture, and whether they felt the shoulder had completely recovered.

Then, the patients were asked if they would opt for the same treatment if they would fracture their other clavicle in the future, and why (not). Finally, the patients were asked if they had any additional comments. The presence and type of complications and reoperations that had occurred after one year of trial follow-up were also documented.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows, version 20.0 (IBM Corp., Armonk, N.Y., USA). Differences in percentages between the groups were analysed using the Pearson Chi-Square test. Differences in satisfaction scores were analysed using the independent samples t-test. Differences between groups were regarded significant if the p-value was ≤ 0.05. All patients were analysed in the treatment group they were originally randomized for following the intention-to-treat principle.

RESULTS

Patients and baseline characteristics

Seventy-nine patients of the original study group (49%; 40 in the PF group and 39 in the NOT group) were reached and answered the questions after a median follow-up of 53 months (range 34 -79) since the start of the initial treatment (Table 1). The remaining 51% of the original study group could not be reached by telephone despite several attempts.

Regarding age and gender, the included patients were representative of the original study group. A total of 17/79 patients received 22 secondary operations since the initial treatment (Table 1). Two of these occurred after the 1 year follow-up moment (one

Table 1. Baseline characteristics of the included patients

	Plate fixation (n=40)	Nonoperative treatment (n=39)
Median age (range)	46 (22 - 65)	45 (23 – 64)
Male, n (%)	36 (90)	(90)
Median follow up, months (range)	52 (34 – 79)	55 (35 – 76)
Secondary operations, n (%)[a]	13 (32.5)	9 (23.1)
Nonunion	1 (2.5)	7 (17.9)
Plate failure	1 (2.5)	1 (2.6)
Refracture	1 (2.5)	0
Plate removal	9 (22.5)	1 (2.6)
Other	1 (2.5)	0

[a] A total of 22 secondary operations in 17 (21.5%) patients were performed since initial treatment. Two secondary operations were performed after the one-year follow-up moment: one elective plate removal and one re-plate fixation after failure of a plate fixation that was performed in a nonoperatively treated patient with nonunion.

elective plate removal and one re-plate fixation after failure of a plate fixation that was performed in a nonoperatively treated patient with nonunion).
In the present study, patients who had received a secondary operation for nonunion - all of which occurred during the first year after the initial treatment - seemed somewhat overrepresented compared with the original study group (2.5% in the PF and 17.9% in the NOT group vs 1.2% in the PF and 12.9% in the NOT group, respectively).

Satisfaction

Results for different aspects of patient satisfaction are shown in Figure 1. Scores for overall satisfaction with the received treatment were similar after PF and NOT (mean score ±standard deviation: 7.7 ±2.1 vs 6.9 ±2.4, respectively; p=0.12), as were scores for satisfaction with the function of the shoulder (8.9 ±1.6 vs 8.4 ±2.0, respectively; p=0.27).

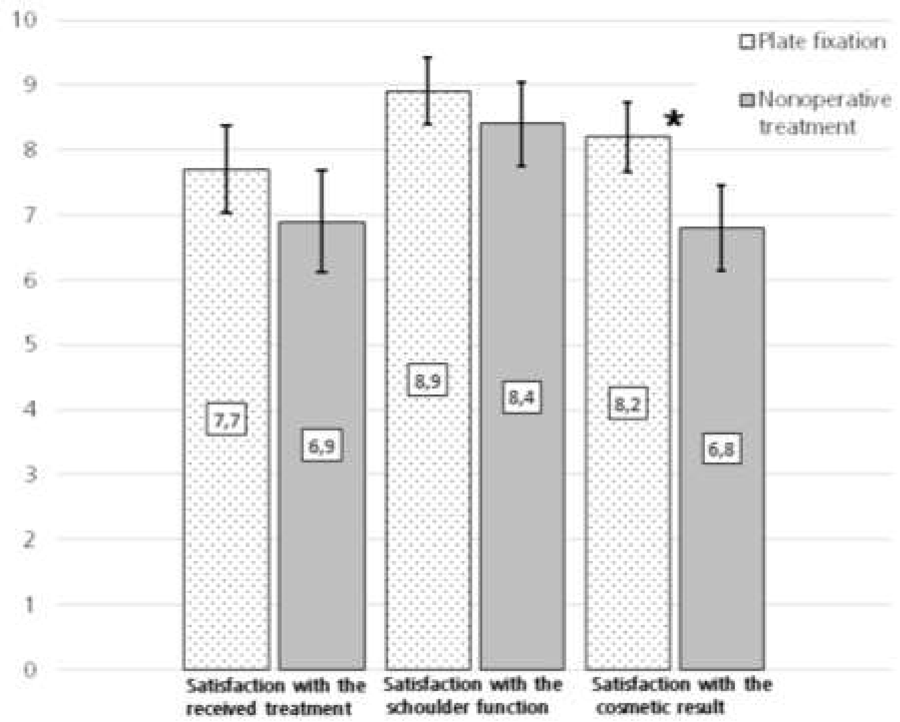

Figure 1. *Patient satisfaction after plate fixation and nonoperative treatment (mean and 95% confidence interval). * p = 0.002*

Patients were more satisfied with the cosmetic result after plate fixation (8.2 ±1.6 vs 6.8 ±2.0; p=0.002).
The 17 patients who had received a secondary operation since the initial treatment were less satisfied with the overall treatment than the patients who had not (7.8 ±1.8 vs 5.8 ±3.1, respectively; p=0.02). Having had a secondary operation was not related with satisfaction with the shoulder function or with the cosmetic result (data not shown).

Table 2. Mid-term residual symptoms after treatment of midshaft displaced clavicular fractures

	Plate fixation (n=40)	Nonoperative treatment (n=39)	P value
Residual symptoms[a], n (%)	22 (55)	17 (41)	0.26
Pain	9 (22.5)	9 (23.1)	
Weakness	2 (5)	6 (15.4)	
Tingling sensation	1 (2.5)	1 (2.6)	
Stiffness	9 (22.5)	2 (5.1)	
Other	4 (10)	3 (7.7)	
Limitations in daily life, n (%)	3 (7.5)	10 (25.6)	0.04
Impact of symptoms[b]	4.4	4.6	0.80
Perception of incomplete recovery, n (%)	21 (53)	21 (54)	1

[a] Some patients reported more than one residual symptom. [b] Measured on a scale from 1 (no impact) to 10 (large impact)

Residual symptoms and limitations

In both groups, less than half of the patients felt that their shoulder had fully recovered (Table 2). Residual symptoms were common (55% after PF and 41% after NOT) and were experienced mostly every day (35%) or week (32%) in both groups, if present. The perceived impact of the symptoms did not differ between the groups, although more patients after NOT reported limitations in daily life activities (7.5% vs 25.6%; Table 2). Reported limitations varied, including not being able to reach far, to deliver a lot of strength (e.g., doing push-ups) or to lie on the affected side.
Of the patients who had received PF as primary treatment, 88% reported to prefer the same treatment if they would fracture their contralateral clavicle in the future, compared

to 41% in the group that had received NOT as primary treatment ($p<0.001$). The most frequently reported reason for patients after NOT to prefer an operation for their other clavicle, was that they expect a quicker and better recovery after plate fixation. The cosmetic result was not mentioned as a reason. All 7 patients who had received a secondary operation because of complications following nonoperative treatment would not opt for that treatment again. Eight out of ten patients with secondary surgery due to complications (including elective plate removal) would prefer operative treatment again.

Additional comments

The majority of the additional comments (13/15) concerned doctor-patient communication. Some patients felt that the provided information about the treatment and outcomes, and especially the instructions about restrictions had not been sufficient or objective. For example, one patient was dissatisfied because "A 6.5cm scar is not the 'small incision' I was told to get".

DISCUSSION

This study shows that overall satisfaction with the received treatment was reasonably high after a median follow-up of 4.5 years for both plate fixation and nonoperative treatment of a displaced midshaft clavicular fracture. Although satisfaction with the shoulder function was excellent in both groups (mean 8.9 and 8.4 points out of 10), not even half of the patients felt that they had fully recovered and residual symptoms were common regardless of type of treatment. The impact of these symptoms was rated similarly in both groups, although patients reported more limitations in daily activities after nonoperative treatment.

The widespread shift from nonoperative to operative treatment for displaced clavicular fractures[12,13] started when outcomes after nonoperative treatment were reported to be poorer than traditionally assumed: nonunion rates were considerable and sequelae were observed in up to 46% of patients[9,10], which has been confirmed by more recent studies[3,14]. Despite the higher nonunion rate after NOT, the present study finds that mid-term complaints after plate fixation and nonoperative treatment are equally common: half of the patients still have symptoms such as pain and stiffness, and feel that they have not fully recovered. Another study comparing both treatments found an even higher

prevalence of long-term sequelae: 76% after plate fixation and 58% after nonoperative treatment[7]. The fact that surgery fails to prevent residual symptoms is a drawback that many surgeons seem to overlook when weighing the treatment options[15].
Although the presence of residual symptoms and their perceived impact were similar in both groups, patients after NOT described more limitations in daily life than after PF. This might be explained by the different nature of the residual symptoms: besides pain, most patients reported stiffness after PF whereas patients after NOT primarily reported weakness. Despite experiencing more limitations in daily life, there was no difference between groups with respect to satisfaction with the functional result and the feeling of (in)complete recovery. Therefore, it is unclear how relevant the difference in reported limitations is for the patient. This was unfortunately not evaluated more specifically. More research on the way in which specific residual symptoms and limitations relate with (satisfaction with) the functional outcome might help to further guide the choice for the best treatment.

Satisfaction with the cosmetic result was significantly better after operative treatment, which is consistent with previous findings[5,16,17]. A contributing factor might be that patients anticipate a scar when choosing an operation, but do not realize that a bump may be permanently visible after nonoperative treatment. The cosmetic outcome should be addressed when discussing the options and treatment plan with the patient. In this conversation, it is important to realize that patients may have a different frame of reference, and that the provided information should be objective. Exemplary is the patient who was dissatisfied because he felt that the 6.5cm scar was not the 'small incision' he was told to get. Most surgeons, however, would probably agree that 6.5cm is perfectly acceptable for a clavicular fixation.

Despite comparable results for overall satisfaction and the presence of residual symptoms, the operatively treated patients were far more likely to choose the same treatment again than the nonoperatively treated patients, even if they had experienced operation-related complications. Many nonoperatively treated patients believed that residual symptoms would have been avoided with surgery, whereas the opposite did not occur. Despite the fact that satisfaction with the cosmetic result was significantly lower after NOT, none of the patients mentioned this as a reason to prefer PF in the future. In a recent non-randomized study, the same effect was even more pronounced: satisfaction with the treatment choice (in which the patients had been involved) was higher after an operation, despite significantly more complications, reoperations and residual symptoms compared with nonoperative treatment[7]. These findings show that patient satisfaction can be unpredictable, and does not always follow surgeons' standards for a successful treatment. These expectations about the final result should be managed early to prevent that patients prefer operative treatment for the wrong reasons. On the other hand, the feeling described by some nonoperatively treated patients that recovery would have been quicker after surgical treatment is clearly supported by previous publications[3,16,18].

This study has several limitations. The most important limitation is that only half of the original study group could be included. The residual study group may have been too small to demonstrate clinically meaningful differences between the intervention groups. For overall satisfaction in particular, one could imagine that a larger sample size would show a significant difference in favor of plate fixation (PF 7.7 ±2.1 vs NOT 6.9 ±2.4, p=0.12). Also, the loss to follow-up may have introduced selection bias: Patients with unfavorable results may be more willing to participate in the survey. However, all patients who were successfully contacted also agreed to participate, so we believe that participation in the study was not related to the outcomes. Nevertheless, patients who received a secondary operation for nonunion were somewhat over-represented. This may have caused an underestimation of satisfaction with the received treatment in the nonoperative group, since most nonunions occurred in that group and a secondary operation was associated with less overall satisfaction.
Secondly, shoulder function was not measured at the time of this evaluation and thus satisfaction with the shoulder function and residual symptoms could not be correlated with a standardized measurement of shoulder function at the same moment in time. However, in the original cohort, Constant and DASH-scores were similar for both treatment groups at one year follow-up. It was assumed that shoulder function scores had not changed dramatically since then, following Schemitsch's findings that Constant and DASH-scores plateau after one year[19]. Also, one of the major drawbacks of the Constant and DASH-score is that scores are generally in the upper regions of the scale and are not sufficiently sensitive to pick up on the effects of minor symptoms or limitations. These minor changes in function however might be relevant to the patient.

CONCLUSION

This study compared plate fixation and nonoperative treatment in patients with a midshaft clavicular fracture with respect to mid-term patient-reported outcomes. In conclusion, primary plate fixation results in a higher patient satisfaction with the cosmetic result, and causes less subjective limitations in daily life than nonoperative treatment. Nevertheless, residual symptoms after a median of 4.5 years are common and the majority of patients do not experience full recovery after either treatment. Despite this, expectations regarding full recovery after plate fixation seem higher. When discussing treatment options for clavicular fractures, the patient should be informed objectively about options and potential sequelae in order to select the treatment that suits the individual patient best and to adequately manage the patient's expectations.

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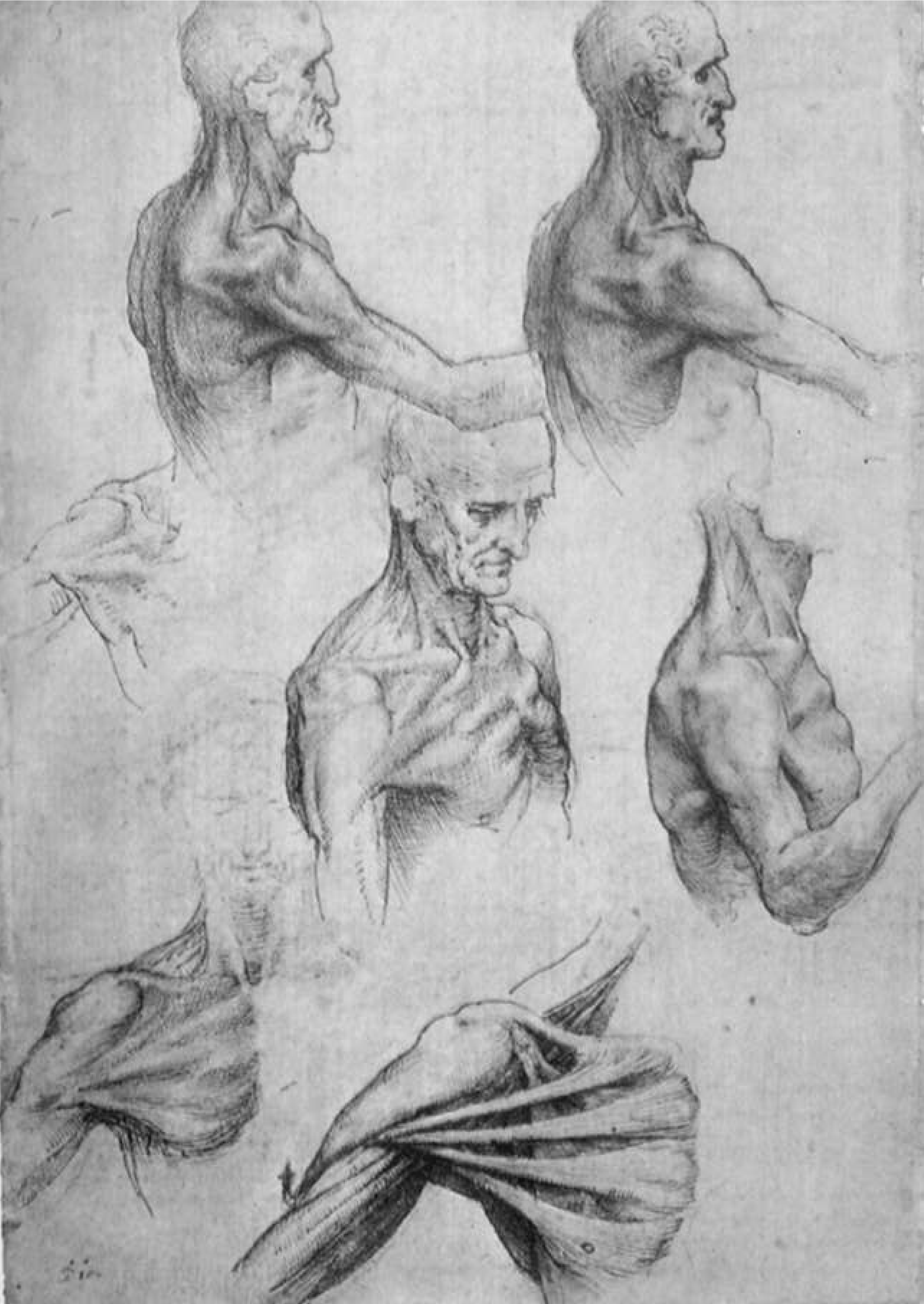

CHAPTER 7

Shared decision making in the management of midshaft clavicular fractures: Nonoperative treatment or plate fixation

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ABSTRACT

Background

Most patients with a displaced midshaft clavicular fracture can be treated either operatively or nonoperatively, with similar long-term outcomes. The treatment choice depends on individual preferences, and is therefore suited for a shared decision making (SDM) approach. However, little is known about SDM in fracture treatment. The purpose of this study was to evaluate the current daily practice of shared decisional behaviour in clavicular fracture treatment, in order to assess the need for improvement and set a baseline level for future research.

Patients and methods

All consecutive adult patients treated in two hospitals for a displaced, midshaft clavicular fracture in 2015 filled out a questionnaire shortly after the decision making moment, that consisted of questions concerning their knowledge and preferences regarding the treatment options; the SDM-Q-9-NL to measure the perceived degree of SDM, and the Control Preferences Scale to measure patients' preferred and actual roles in decision making.

Results

Fifty patients were included. Eighteen percent of the patients were unaware of the treatment options before the consultation, 48% had no preference for either treatment option. The mean score for perceived degree of SDM was 74 out of 100 (SD 23, range 12.5–100). In 68% of patients, the preferred role matched the actual role in making the decision. Sixteen patients (32%) would have preferred either a less (n = 8) or a more (n = 8) active role.

Conclusion

The patient-reported level of SDM in treatment decisions for clavicular fractures was high, but not all patients had the role in this process that they preferred. To improve patients' involvement in the treatment decision making process for clavicular fractures, it is important to create general awareness about SDM, and increase knowledge regarding SDM behaviour among orthopaedic trauma surgeons.

INTRODUCTION

Shared decision making (SDM) is a patient-centred approach to treatment decision making, in which the patient is actively involved to weigh different treatment options in order to decide which treatment matches his or her preferences and priorities best. SDM is more than providing the patient with the available information about the treatment options: the essential characteristic of SDM is that communication is directed equally in both ways, instead of primarily from doctor to patient[1,2].

SDM is thought to improve patients' knowledge about their condition, their commitment to and satisfaction with their treatment, and to reduce decisional conflict and patients' anxiety[3–5]. SDM is pre-eminently preferred in case of 'preference-sensitive' decisions, i.e., decisions for which two or more evidence-based and medically reasonable options are available (of which one could be not to intervene). This is typically the case for displaced, midshaft clavicular fractures: operative treatment dramatically reduces the risk of nonunion and leads to a faster recovery compared with nonoperative treatment, but it also imposes a considerable risk of adverse events and reoperations, and does not result in a better shoulder function[6–9].

Originating from non-surgical disciplines, SDM has also been described in non-traumatic orthopaedic surgery and in the emergency department setting[10–14]. Very little is known about SDM behaviour in fracture treatment[15].

The purpose of this study was to evaluate levels of patient involvement in current daily practice of decisional behaviour in clavicular fracture treatment, in order to assess the possible need for improvement and set a baseline level for future research. This study therefore aimed to investigate patients' knowledge and preferences regarding their treatment options, to describe the extent to which patients feel to have been involved in the decision about their treatment, and to assess patients' preferred and actual roles in deciding on the treatment for their clavicular fracture.

PATIENTS AND METHODS

Design and setting

This exploratory cross-sectional study included all consecutive adult patients with a displaced midshaft clavicular fracture treated at a university hospital and a large teaching hospital in The Netherlands, between December 2014 and January 2016. After the doctor-patient consultation during which the choice of treatment for their fracture was made, the patients received a written questionnaire on the decision making process. The study was approved by the institutional ethics review committee (P14.287) and registered in The Netherlands National Trial Registry (NTR4957). Study results are presented according to the STROBE Guidelines[16].

Study procedure

Patients were eligible for inclusion if they had a displaced midshaft clavicular fracture (Robinson type 2A2, 2B1 or 2B2)[17], were between 18 and 70 years old and were able to read and understand Dutch. Patients were excluded if an absolute operation indication existed (e.g., open fracture, compromised skin, neuro-vascular damage), or if SDM was not feasible for another reason (e.g., mental status, inoperability due to comorbidities, or referral to another hospital where the final treatment decision would be made).

In both participating hospitals, standard care protocols for displaced clavicular fractures were followed. In all but one case, the choice for either nonoperative (i.e., sling for two weeks) or operative treatment (i.e., open reduction and plate fixation) was made during the first consultation at the outpatient clinic within a week after trauma. Patients were identified through a weekly search of the diagnosis-code listings and confirmation of the diagnosis by reviewing the X-radiographs. Eligible patients were informed about the study and were asked to participate after the treatment decision had been made. Patients who gave written informed consent filled out the questionnaire at the outpatient clinic or at home. In the latter case, patients were encouraged to fill out the questionnaire as soon as possible after the consultation, to ensure an optimal ability to adequately recollect the decision making process.

The physicians in the participating hospitals did not receive extra education nor training in SDM skills prior to this study, to ensure that measurements would reflect the current daily practice in decisional behaviour and would not be affected by any intervention.

Outcome measures

The questionnaire comprised two surveys (see Appendix 4, p169, for full questionnaire). The degree of perceived SDM was measured using the validated Dutch version of the SDM-Q-9[18,19]. This survey consists of nine items that each represent one step in a shared decision making process. Item scores are summarized in an overall score for participation in the decision making process from the patient's perspective. The raw scores (range 0–45) were transformed to range from 0 to 100, as advised by the designers of the questionnaire, since this is more intuitively interpretable (0 = no SDM, 100 = optimal SDM). Also, the scores on the nine individual items were dichotomized into 'disagreement' (scores from 0 to 2) and 'agreement' (scores from 3 to 5) in order to calculate for each step the proportion of patients who believed that the step had been realized.

An adapted version of the Control Preferences Scale (CPS)[20,21] was used to measure the patients' preferred and actual decisional role in making the treatment decision, and was rephrased to match the specific situation for this patient group. The CPS consists of one question concerning the preferred and one question concerning the actual role of the patient in the treatment decision on a five-point scale, ranging from autonomous (patient decides alone) to passive (doctor decides alone). In the present study, answers to the CPS questions were collapsed into three categories (score 1 and 2 = 'autonomous'; score 3 = 'shared'; score 4 and 5 = 'passive').

In addition, patients were asked about their awareness of the available treatment options and their preference for one particular treatment option, prior to the decision consultation. Finally, the questionnaire included questions about educational level, daily activities and sports. Patient demographics, the gender of the treating physician and whether it was a surgeon or resident, and the received treatment were derived from the electronic patient records.

Statistical analysis

IBM SPSS Statistics for Windows (version 20.0, Armonk, NY: IBM Corp.) was used for statistical analysis. Descriptive statistics were used to report mean SDM-Q-9 and CPS scores. Differences between patient subgroups (e.g., age, sex, actual and preferred roles) in mean SDM scores were compared using a t-test or ANOVA. The perceived and preferred roles in decision making within patient subgroups were compared using the Chi-squared test. P-values below 0.05 were considered statistically significant.

Sample size calculation

Since this was an exploratory cross-sectional study, no formal sample size calculation was performed. The aim was to include a minimum of 50 patients, with the assumption that this sample size would be large enough to reliably reflect the occurrence of SDM in daily practice, and the study could be achieved in a reasonable amount of time.

RESULTS

Patient and physician characteristics

Seventy patients met the inclusion criteria (Figure 1). Twelve patients were excluded because they could not be contacted in time (n = 6), received further treatment elsewhere (n = 4), or because SDM was not feasible due to compromised skin (n = 1) or severe concomitant head trauma (n = 1). Fifty-eight patients were asked and initially willing to participate. Five patients did not return the questionnaire and written consent form. Three patients filled out the questionnaire more than three weeks after the consultation, and were excluded because three weeks was assumed to be too long to reliably recall the decision making process. A total of 50 patients were included for analysis, of whom 34 were treated in one hospital, and 16 in the other.

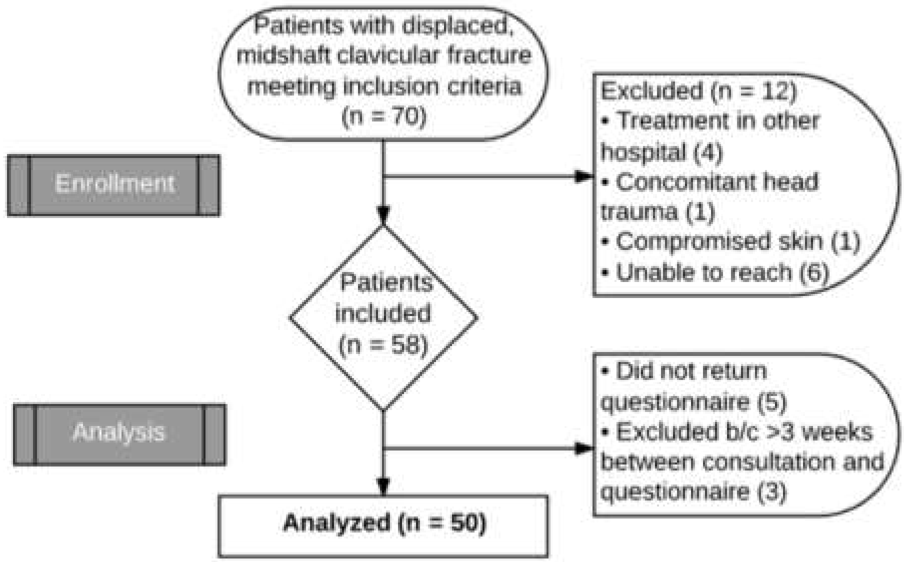

Figure 1. *Flow chart of the included patients.*

Table 1. Baseline characteristics and their association with patients' perceived level of shared decision making (univariate analysis)

	N (%)	SDM-Q-9, mean (SD)	P value
Patient age	43 (14)[a]	-0.208[b]	0.15
Patient gender			
Male	37 (74)	76 (20)	0.32
Female	13 (26)	67 (30)	
Highest educational level			0.26
Primary/high school	14 (28)	75 (18)	
Intermediate vocational education	12 (24)	82 (24)	
Higher vocational ed. / University	24 (48)	69 (25)	
Primary daily activity			0.44
Paid job	36 (72)	76 (22)	
Domestic work	7 (14)	63 (33)	
Study/other	7 (14)	74 (17)	
Sports			
Yes	38 (76)	73 (24)	0.67
No	12 (14)	76 (23)	
Treating Hospital			
Hospital I	34 (68)	77 (20)	0.20
Hospital II	16 (32)	67 (29)	
Consultation with			
Surgeon	35 (70)	77 (19)	0.21
Resident	15 (30)	66 (30)	

[a] Mean (Standard Deviation). [b] Pearson correlation coefficient.

The included patients had a mean age of 43 years and 74% was male (Table 1). The majority of the patients had no comorbidities (American Society of Anaesthesiologists score ASA-I 88%, ASA-II 10%, ASA-III 2%). About half of the patients (48%) received operative treatment for their clavicular fracture. Patients filled out the questionnaires a median of 6 days after the consultation (range 0 – 19).

Thirteen different certified trauma surgeons conducted 35 of the consultations during which the decision was made (in the Netherlands fractures are mostly treated by trauma surgeons). The other 15 consultations were conducted by 12 different surgical residents who were indirectly supervised by one of the surgeons. Eighty percent of the physicians were male.

Patient awareness and preferences prior to consultation

Forty-one patients (82%) reported that they had been aware of both treatment options before the consultation. Almost half of the patients (48%) had no preference for either treatment option, whereas 18 patients (36%) preferred surgery and 8 (16%) preferred nonoperative treatment. Patients with an a priori treatment preference for either treatment did not differ regarding sex, age, or educational level (data not shown). Patients who reported to play sports, preferred operative treatment more often than patients who did not play sports (81% vs 20%, p = 0.02).

Perceived degree of shared decision making

The mean score on the SDM-Q-9 was 74 (SD 23), ranging from 12.5 to the maximum score of 100. Age, sex, educational level and primary daily activities had no significant influence on the perceived degree of SDM (Table 1, p109). Whether the patient consulted with a surgeon or a resident, was also of no significant influence, nor was the hospital in which the patient was treated (Table 1). The step in the decision making process that most patients (92%) indicated to have occurred, was: "My doctor and I reached an agreement on how to proceed". The step that least patients (66%) reported to have happened, was "My doctor and I selected a treatment option together" (Table 2).

Table 2. Occurrence of behaviours indicative of a shared decision making process measured with the SDM-Q-9

		Agree, n (%)
1.	My doctor made clear that a decision needs to be made	40 (80)
2.	My doctor wanted to know exactly how I want to be involved in making the decision	34 (68)
3.	My doctor told me that there are different options for treating my medical condition	45 (90)
4.	My doctor precisely explained the advantages and disadvantages of the treatment options	45 (90)
5.	My doctor helped me understand all the information	43 (86)
6.	My doctor asked me which treatment option I prefer	37 (74)
7.	My doctor and I thoroughly weighed the different treatment options	37 (74)
8.	My doctor and I selected a treatment option together	33 (66)
9.	My doctor and I reached an agreement on how to proceed	46 (92)

All items are scored on a 6-point scale (0-5). Item scores were dichotomized into score 0-2=disagree, score 3-5=agree.

Preferred and actual decisional roles

Patients preferred similarly often an autonomous, shared or passive role (34%, 36% and 30%, respectively), whereas the actual decisional role was less frequently shared (24%) (Table 3).

For most patients (68%), the preferred role corresponded with the actual role in the decision making process. Eight patients (16%) would have liked more involvement, and eight patients (16%) would have preferred to be less involved in the decision making. The preferred role in the decision making process was not significantly associated with patient sex ($p = 0.30$) or age ($p = 0.60$), nor was the actual role ($p = 0.33$ for sex, $p = 0.20$ for age).

Patients with different preferred roles had similar scores of perceived SDM (mean score 77 for autonomous, 74 for shared and 71 for passive, $p = 1.0$). Patients who reported that their actual role in the decision had been passive, had a significantly lower mean score on the SDM-Q-9 than patients who considered their role as autonomous or shared (55, 83 and 88 respectively, $p < 0.001$).

Three patients (all healthy according to the American Society of Anaesthesiologists score; ASA-I) did not receive the treatment they preferred (i.e., operative treatment). There was no reason for this stated in the patient records. These patients had low SDM-Q-9 scores (18, 31 and 33) and all indicated that they would have wanted more influence on the treatment decision.

Table 3. Patients' preferred and actual decisional roles

	Preferred role, n (%)			
Actual role, n (%)	Autonomous	Shared	Passive	Total
Autonomous	12 (24)	5 (10)	2 (4)	19 (38)
Shared	1 (2)	10 (20)	1 (2)	12 (24)
Passive	4 (8)	3 (6)	12 (24)	19 (38)
Total	17 (34)	18 (36)	15 (30)	50

Highlighted in grey: congruence between preferred and actual role.

DISCUSSION

This study describes the current occurrence of SDM and patients' roles in treatment decisions for displaced, midshaft clavicular fractures. The choice of treatment for most midshaft clavicular fractures is preference-sensitive. From the doctor's perspective, this is clearly illustrated by the poor agreement among surgeons regarding the preferred treatment for these fractures[22,23]. From the patient's perspective, individual preferences are relevant especially because the treatment options are fundamentally different, with one being far more invasive than the other. Interestingly, the majority of the existing literature regarding preference-sensitive decisions in fracture treatment – although rarely explicitly described as such – focuses solely on physicians' preferences, and completely passes over that patients' individual values and preferences should also play a role[24,25]. Displaced midshaft clavicular fractures are specifically suitable for a SDM approach, but it can be challenging to apply in practice[2,26,27].

Eighteen percent of the patients reported that they were unaware of the treatment options before the consultation, and half of all patients did not have a treatment preference, despite the fact that most of these patients visited the emergency department for their fracture in the previous week. A way to prepare patients for decision making, could be to offer them a decision tool at the emergency department[11]. A decision tool could be a simple leaflet with information about the diagnosis and the treatment options including their most important pros and cons. This would enable patients to consider the options at home, prepare for the decision consultation and support them in developing a well-considered treatment preference. Decision tools are known to have a positive influence on the process of SDM[28], but evidence about their effect in elective orthopaedic surgery is limited[10], let alone in fracture treatment decisions.

In the present study, the mean score for the perceived degree of SDM in the choice of treatment was quite high, which is comparable with the results of a study that validated the Dutch version of the SDM-Q-9 among patients with various non-traumatic medical conditions[18]. A recent study on the occurrence of SDM in vascular surgery however, presented much higher scores with a mean of 93 on the SDM-Q-9[29].

When interpreting these scores, it is important to realize that SDM is a challenging concept to measure, and that many different instruments are available that measure SDM in various ways (patient-, observer- or physician-reported)[3,4,30]. Moreover, patient-reported levels of SDM usually are systematically higher than physician- and observer-based levels, even when they assess the same consultation[29,30]. The mean score of 74 therefore probably overestimates the degree in which SDM occurred from an observer's perspective. Also, the scores in the present study showed a wide range: 18% of the patients scored below 50, which leaves obvious room for improvement.

The majority of patients in the present study preferred an active role in making the decision, which matches the increasing tendency in many medical fields for SDM[31]. In one-third of the patients, their preferred decisional role did not match their actual role. Previous studies reported similar incongruences[32]. Notably, Hack et al. found that more involvement in treatment decision making was positively related to quality of life, irrespective of patients' preferred role[33], which emphasizes the relevance of actively engaging patients in health care decisions. It is therefore paramount for the physician to try to uncover patients' preferences, even if patients do not explicitly want to be involved in making the decision[34]. Physicians should also realize that patients' preferences are not always similar to their own; patients frequently choose different and less invasive options than doctors[35]. Moreover, a previous study found that surgeons were more likely to choose surgical treatment for a patient's clavicular fracture than for their own fracture[36].

There are several limitations to this study. First, there are shortcomings inherent to questionnaire-based studies in general. Although the SDM-Q-9 is a validated questionnaire and the best available option to date to assess patient perceptions using a self-report measure, some patients had difficulties understanding the questions, or indicated that some questions did not match their situation. Also, a ceiling effect may be present with many patients scoring the maximum level of SDM.

A second limitation is that preferred and actual decisional roles were both measured after the consultation, instead of measuring the preferred role before the start of the consultation and the actual role afterwards. Retrospective assessment of the preferred decisional role was previously found to be associated with higher levels of reported congruence between the preferred and actual roles than prospective assessment, and with more patients reporting to prefer a passive role[32].

Finally, only the patient-reported degree of SDM was measured. Although this was a deliberate choice because the patients' perspective was the primary study interest, additional information regarding physician- or observer-reported SDM could have been of value for the interpretation of the results.

Although previous studies have reported that SDM is generally supported by orthopaedic surgeons[14], SDM skills are currently not routinely trained and it is unclear how surgeons actually interpret the concept and its implications. To learn if there is a knowledge gap that needs to be closed by education or training, we are presently performing a survey among trauma surgeons about what they understand by SDM and what difficulties they encounter in using SDM in daily practice, if any.

A second focus of future research should aim to understand SDM from the patients' perspective. Patient-reported levels of SDM correlate poorly with observer ratings of SDM, and it is often unclear what leads a patient to experience a decision as having been shared[3]. Structured patient interviews could give insight in how patient conceive SDM, and help understand what is needed to improve the process from their perspective. Also, like surgeons, patients have to get used to becoming more active and involved in making decisions, and it would be helpful to investigate how patients feel they could be best prepared for the decisional conversation.

Finally, this exploratory study should be followed by larger scale investigations of the extent to which SDM occurs. In addition to the patients' perspective, SDM levels should also be assessed from physicians' and observers' perspectives. This would provide more complete evidence on the degree of SDM in clavicular fracture treatment.

In conclusion, this exploratory study showed that the majority of patients with a displaced clavicular fracture felt they had been involved in the treatment decision. Still, there is room for improvement. Not all patients had the role in this process that they would have preferred, and many patients had no clear idea of the treatment options prior to the decision consultation, leaving them less time to consider their options. To improve patient involvement in decision making, it is important to increase awareness and knowledge among orthopaedic trauma surgeons about SDM, to understand the patient's perspective of SDM, and to consider offering decision support to the patient in the form of a decision tool.

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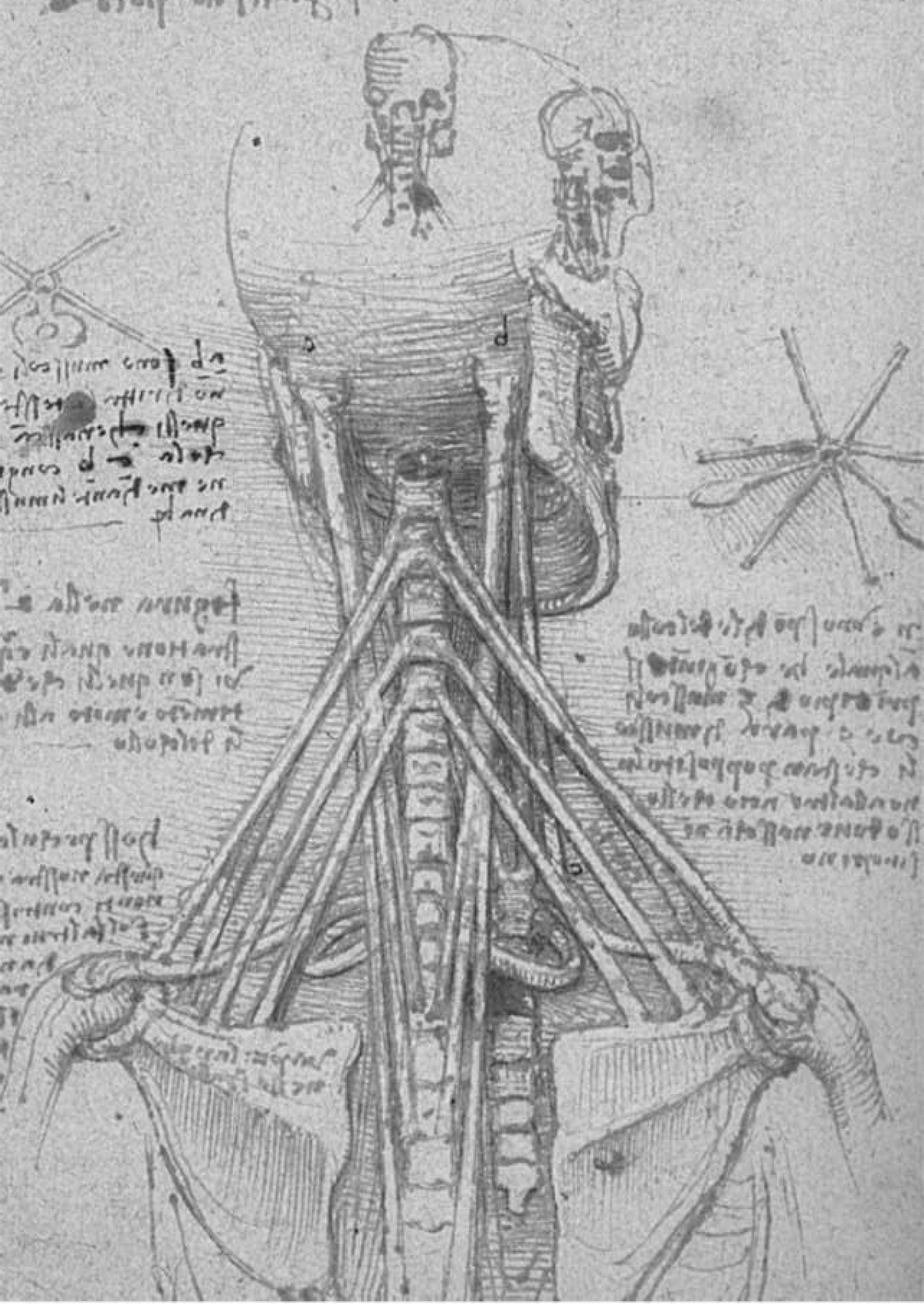

CHAPTER 8

Surgeons' perspective on shared decision making in trauma surgery: A national survey

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Submitted

ABSTRACT

Objective

This study aimed to answer the following research question: What is the knowledge, attitude and experience of trauma surgeons with respect to shared decision making (SDM)?

Methods

An online survey was sent out in September 2016 to all 257 surgeons registered as a trauma surgeon with the Dutch Association of Trauma Surgery, to gather demographic, knowledge and practice based information regarding their use of SDM.

Results

The questionnaire was filled out by 112 (44%) trauma surgeons. Opinions about what SDM entails differed, but 27% described a process that was clearly discordant with current consensus. Eighty-six percent of trauma surgeons regarded SDM (very) relevant for providing good care. Sixty-two percent reported to encounter problems in achieving SDM.

Conclusion and implications

The general attitude of Dutch trauma surgeons towards SDM is very positive, but many lack the understanding of what SDM really implies and surgeons report SDM to be difficult to accomplish. To improve the occurrence of SDM in trauma surgery, there is an obvious need for education and training in SDM skills for surgeons.

INTRODUCTION

Originated in non-surgical disciplines, shared decision making (SDM) has become an accepted way of decision making in many medical fields and is particularly appropriate for decisions with more than one reasonable treatment option (i.e., preference-sensitive decisions). SDM is thought to improve patients' commitment to and satisfaction with their treatment, and to reduce decisional conflict and patients' anxiety[1-3]. In the light of the increasing importance of patient autonomy in contemporary health care and the role that physicians have in supporting that autonomy, it is ethically imperative to make decisions that incorporate the patient's values and priorities. Apart from some decisional challenges with a highly acute nature, many decisions in trauma surgery are preference-sensitive, and thus suitable for SDM. However, the concept has proven to be complex to apply and measure in practice[4,5].

In SDM, a medical decision is based not only on scientific evidence, objective patient characteristics, and on the knowledge and experience of the treating physician, but also on the individual preferences and values of the patient[6]. Opposed to other models of medical decision making, the communication in SDM is aimed in *two directions*, so that the patient expresses his or her personal priorities and goals[7]. If these are taken into account when designing a treatment plan together with the patient, it is irrelevant whether the patient or the physician makes the actual decision[8].

The little research that has been done on SDM in orthopaedic trauma surgery focuses mainly on measuring the occurrence and implementation of SDM, and its influence on patient-related outcomes[9,10]. It is however also important to study the concept from the surgeon's perspective, and evaluate what surgeons believe true SDM comprises and what their attitude and experiences are regarding SDM. SDM is not a routine part of surgical training in most countries, and the approach is relatively new in orthopaedic trauma surgery compared with for instance primary care[4]. Also, although literature suggests that most surgeons support SDM and decision aids[11,12], attitudes towards this new concept are likely to vary, which could influence the effect of interventions aimed to improve SDM or attempts to implement decision aids.

This study aimed to answer the following research question: What is the knowledge, attitude and experience of trauma surgeons with respect to SDM?

METHODS

Design and setting

This exploratory study of Dutch trauma surgeons used a population based online survey to gather demographic, knowledge and practice based information regarding their use of SDM. An online survey was sent out in September 2016 to all 257 surgeons who are registered as a trauma surgeon with the Dutch Association of Trauma Surgery. In the Netherlands, trauma surgeons are specialists who treat both visceral and orthopaedic trauma, with a clear emphasis on orthopaedic trauma for most. Invitations were sent out by email with up to three reminders, as appropriate.

The full survey is shown in Appendix 5, p174. The terminology for shared decision making used to introduce the survey was: 'Shared decision making (SDM, gedeelde besluitvorming or samen beslissen)', in which SDM is the acronym that is often used in the Netherlands. 'Gedeelde besluitvorming' is the literal Dutch translation of SDM, and 'samen beslissen' is a less formal but commonly used Dutch expression for SDM. These terms were used interchangeably throughout the rest of the questionnaire.

The survey consisted of questions assessing the surgeon's gender and years of experience, and the type of trauma center that he or she worked in (academic / non-academic). The first open question was: "What is your understanding of SDM?" The literal Dutch translation 'gedeelde besluitvorming' was used in this phrase. The extent to which the answers were in line with prevailing views in the literature on what SDM processes entail[7,8] was rated as "concordant", "inconclusive" or "discordant". To be rated as concordant, answers had to contain some aspects indicative of an understanding of key elements of SDM, as shown in Table 1, p124 (physician-related behaviours that are regarded as essential for SDM). An answer was rated as inconclusive if it was too general (e.g., talk with the patient about the decision) or too short to reliably determine whether the surgeon understands the concept. Finally, answers were rated as discordant if they disagreed with key elements of SDM (e.g., the patient has to make the decision alone), or did not contain any aspect unique to SDM (e.g., describing SDM only as informing the patient about the pros and cons of the treatment and alternatives).

Then, the surgeons were asked if they qualified thirteen different physician-related behaviours to be essential for SDM or not. The thirteen behaviours were selected with the help of an expert on decision making (AP), and seven of them are regarded as essential according to current consensus in the literature as indicated with an asterisk in Table 1, p124[7,8]. The other six were a selection of common behaviours in a decisional conversation, but not essential or even not adequate in an SDM process (e.g., letting the patient decide after giving thorough information).

Next, the survey enquired if surgeons regarded SDM as relevant to provide good care on a five-point scale (1 = 'not relevant at all' to 5 = 'very relevant'), after which they were asked to explain their answer in free-text. The surgeons were asked in what percentage of SDM-suitable decisions they engage in SDM in daily practice ('0%' to '100%' on a 5-point scale), and to tick up to three out of six provided reasons for not attempting SDM. Finally, the surgeons were asked to indicate in free-text what decisions they find particularly suitable for SDM and what difficulties they encounter when engaging in SDM, if any. The online questionnaire did not allow going back to previous answers.

Statistical analysis

Quantitative data were analysed using summary statistics; qualitative (free-text) data were analysed by hand and frequencies of given answers were reported. IBM SPSS Statistics for Windows, version 20.0 (IBM Corp., Armonk, N.Y., USA) was used for descriptive statistics to report the outcomes.

RESULTS

Participants

A total of 112 trauma surgeons responded to the survey (44%). They had a median of 12.5 years of experience as a surgeon (range 2-34). Ninety-three percent was male and the median age was 48 years (range 35 – 68). Twenty-two percent worked in an academic hospital.

Interpretation of the concept

The respondents gave various descriptions of SDM, most including some variation of 'making the decision together'. About half of the answers (51%) was rated concordant, of which fifteen respondents (13%) explicitly mentioned letting the patient express his or her priorities or treatment goals. More than a fifth of the answers (22%) were rated as inconclusive because it was impossible to determine whether they were concordant or not: they were so short that it was difficult to interpret their exact meaning, or because only a synonym of the term SDM was provided (e.g., "deciding together"). Descriptions given by thirty surgeons (27%) indisputably did not match with the current consensus about what SDM is: they described a process of obtaining informed consent (n=14), or indicated that the patient has to make the final decision alone (n=14). Two other respondents described SDM as a consultation process between physicians to reach mutual agreement about a treatment plan.

Eleven of the thirteen physician-related behaviours were considered essential for SDM by most surgeons (Table 1). Of the seven behaviours that experts usually regard as essential for SDM, the one most frequently (27%) considered not essential was: "Informing the patient that a decision has to be made".

Table 1. Physician-related behaviours considered essential for SDM according to 112 trauma surgeons

Physician-related behaviours during a consultation	Participants considering the behaviour as essential (%)
Informing the patient about the possible pros and cons of the treatment*	111 (99)
Explaining to the patient that there is more than one treatment option*	111 (99)
Informing the patient how big the chance of these pros and cons is*	104 (93)
Explaining to the patient why a certain treatment is chosen	99 (88)
Making the decision together with the patient*	98 (88)
Explaining to the patient that his/her opinion is important in making the decision*	96 (86)
Asking the patient about his/her personal values and preferences*	89 (80)
Informing the patient that a decision has to be made*	82 (73)
Giving information in more ways than only verbally (e.g., leaflet, website)	68 (61)
Letting the patient decide after giving thorough information	65 (58)
Letting the patient repeat the given information	60 (54)
Asking the patient to bring someone to the consultation	47 (42)
Allowing the patient time by making the decision in a second consultation	42 (38)

*Physician-related behaviours usually described as being essential in SDM models[7,8].

General attitude towards SDM

The vast majority (94/109 respondents for this item; 86%) regarded SDM as (very) relevant for providing good care by trauma surgeons (Figure 1). Motivation for a high score included that having a say in a decision is part of patients' autonomy, that SDM is a good way to manage expectations, and that a shared decision means shared responsibility, resulting in less patient dissatisfaction, less complaints, and higher patient compliance.

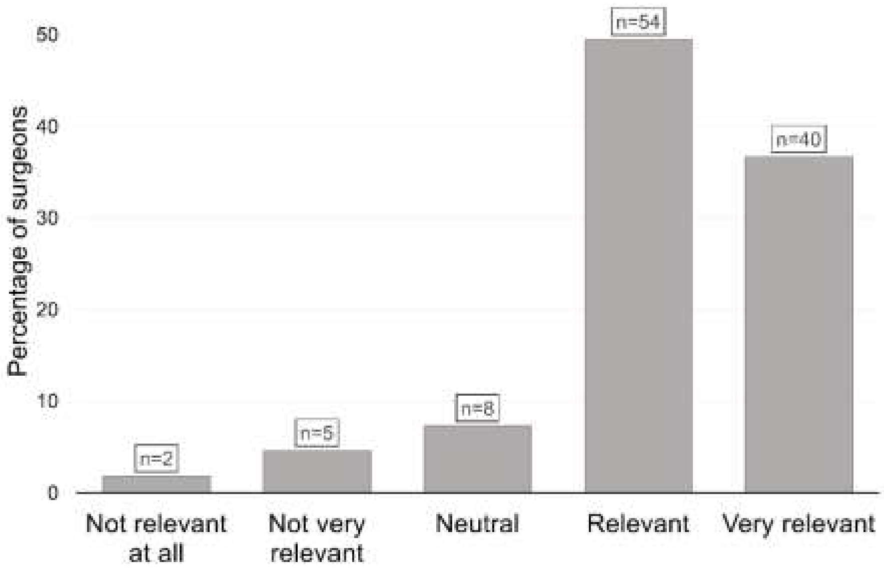

Figure 1. *Surgeons' response to the question: "How relevant do you regard SDM for providing good care by the trauma surgeon?" (n=109).*

The use of SDM in clinical practice

The four decisions that were most frequently mentioned as being suitable for an SDM approach, were the choice between operative and nonoperative management for clavicular fractures (n=39), Achilles tendon ruptures (n=17), distal radius fractures (n=11) and proximal humerus fractures (n=11). Many surgeons (n=22) however indicated a wide range of decisions as suitable, or stated that "all (decisions) that are not life-threatening" are suitable for SDM.

Forty respondents (36%) indicated that they always engage in SDM when dealing with a decision they consider suitable for SDM (Figure 2). For the others, the two most frequently indicated barriers to engage in SDM were that "the patient wants the surgeon to make the decision" (71%), and that "SDM is too complex for many patients" (57%) (Table 2). Sixty-two percent of the surgeons reported to encounter problems when engaging in SDM. The most frequently described difficulty in the free-text answers was that the patient is not able to make a decision because the information is often too extensive and complex for a lay person to fully understand (n=24). Also, patients can feel unsettled by the invitation to participate in decision making and want the surgeon to decide (n=15). Finally, some described that SDM is very time-consuming (n=10), or that they find it difficult if a patient prefers a treatment for what the surgeon thinks are the wrong reasons (n=5).

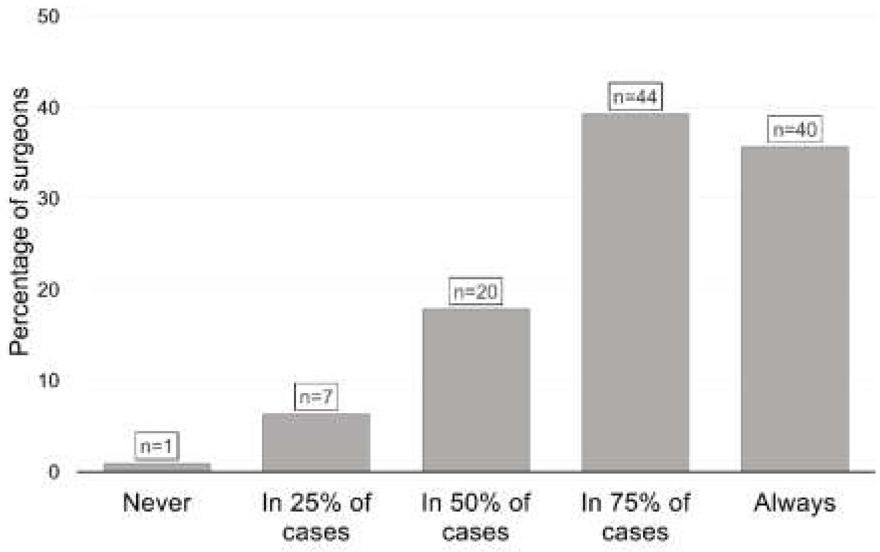

Figure 2. *Surgeons' response to the question: "How frequently do you engage in SDM if a decision is suitable for this?" (n=112).*

Table 2. Surgeon-reported reasons for not engaging in SDM in case of a preference-sensitive decision (n=72)[a]

Reason for not engaging in SDM	No. of surgeons (%)
The patient wants the surgeon to make the decision	51 (71)
SDM is not feasible in many patients because it is too complex for them	41 (57)
Other	23 (32)
The surgeon often knows better than the patient what the best treatment is	16 (22)
It takes extra time	12 (11)
I do not exactly know how to engage in shared decision making	0

[a] Surgeons who reported that they do not always engage in SDM in decisions that are suitable for SDM (n=72) were asked to indicate up to three reasons.

DISCUSSION AND CONCLUSION

Discussion

Much research in the field of SDM focuses on its implementation and the impact on patient-related outcomes, and the use of decision aids[1,13]. Additionally, the perspective of the physician is important because SDM requires an active role and possibly a change in physicians' behaviour. Especially in orthopaedic trauma surgery, where SDM is a relatively new approach and routine training in SDM skills is lacking, it is valuable to know how SDM is understood and if there is general support for SDM. This survey showed that most trauma surgeons have a positive attitude towards SDM, which is in line with previous findings[12]. However, this is the first study that evaluates what surgeons believe SDM actually is, showing that one in four does not fully comprehend what SDM entails and two-third encounters difficulties in achieving SDM in clinical practice.

More than a quarter of the surgeons in this survey had an interpretation of SDM that is discordant with current beliefs[8]. SDM was often confused with the process of informed consent or with the informative model of decision making. Informed consent means that a patient agrees with a (treatment) choice after understanding the risks, benefits and alternatives. Providing this information to obtain informed consent is a requisite before initiating any (non-life saving) treatment, but it does not refer to the way in which the

best option was selected. Informed consent is sufficient only in a treatment choice with just one medically reasonable option.
In the informative model of decision making (or informed decision making), the physician provides all the necessary information about the options for the patient to make the decision[14]. However, SDM is more than providing information and risk calculations: it is guiding patients in the deliberation and helping them imagine how they might experience complications, to ensure that the decision matches individual preferences[15]. It is thus essential that surgeons know the difference between *informed* and *shared* decision making if the aim is to improve the use of SDM in trauma surgery.

Most surgeons correctly named examples of decisions that were suitable for SDM. Also, the majority adequately identified the seven physician-related behaviours that experts consider essential for SDM. Nevertheless, more than one out of four felt that "informing the patient that a decision has to be made" is not essential. This step however is identified as the very first step and an essential element in prevailing SDM models[7,8]. Illustrative of the suggestion that many surgeons lack a clearly defined idea of what SDM is, was a respondent's reflection: "If SDM involves these behavios, I do not think I engage in SDM after all".

The most frequently reported reason for not attempting SDM was the belief that patients want the physician to make the decision. Although understandable, this need not be a barrier for a number of reasons. First, who makes the actual decision is irrelevant for the extent to which SDM has occurred if patient preferences are adequately incorporated in the final choice[16]. More important than making the actual decision is that a patient is well-informed about the options and shares his or her personal priorities and treatment goals. If the patient expresses an informed treatment preference, the physician can base the final decision on that preference. Otherwise, the physician can make a 'preference diagnosis' as best as possible based on the patient´s priorities and goals[17].
Secondly, physicians often incorrectly assume that patients do not want to be actively involved in the decision process. Contrary to common beliefs, patient characteristics such as age and educational level are not reliable predictors of patients´ preferred role in treatment decision making[16]. Also, more involvement in treatment decision making is

thought to be positively related to quality of life, even in patients who say to prefer less involvement[18].

Finally, as discussed previously, many surgeons do not explicitly tell the patient that a decision has to be made. This step in the process however is an excellent opportunity to encourage the patient to be part of the decision process. If patients understand that their opinion is important, they might think differently about being involved.

There are limitations to this study, which are in part inherent to the design. As with every survey including open questions, the quality of the answers highly depended on the effort that the surgeons invested in responding to the items. More than a fifth of the surgeons gave a very short description of SDM or only a synonym of the term, rendering it impossible to judge whether they grasped the concept of SDM. The 27% percent that reported a discordant interpretation of SDM therefore could be an underestimation.

Secondly, SDM is high on the national health agenda in the Netherlands, and the Dutch federation of medical specialists, patient organizations and policy makers increasingly urge clinicians and patients to make decisions together. This could have resulted in socially desirable answers. To minimize this risk, participation the questionnaire was anonymous, which was explicitly stated in the introduction of the questionnaire.

A third limitation is the response rate of 44%. It is possible that this is an underestimation if not all emails reached the surgeons, in case they had changed hospitals for instance. Nevertheless, there could be selection bias if the surgeons who feel strongly about SDM – either in a positive or negative way – were more or less likely to fill out the questionnaire. There is no reason to assume that the surgeons who did not respond know perfectly well what SDM is and never encounter problems. On the contrary: it is more realistic that the non-responders do not know what SDM entails or are not particularly for it, which would imply that the present conclusion is even too optimistic.

Conclusion and practice implications

In conclusion, this national survey shows that Dutch trauma surgeons generally regard SDM to be valuable for good patient care. Nevertheless, SDM is complex: there is a clear lack in understanding among surgeons what SDM really implies, and surgeons indicate it to be difficult to accomplish. To improve the occurrence of SDM in (orthopaedic) trauma surgery, there is an obvious need for education and training in SDM skills for health care professionals, as well as surgical and non-surgical residents. There are currently some physician- and government initiated activities to promote and discuss SDM such as symposia, but education and training should be incorporated in the curriculum of medical school and specialist training, in order to reach all health care professionals rather than only those who already have an interest for SDM.

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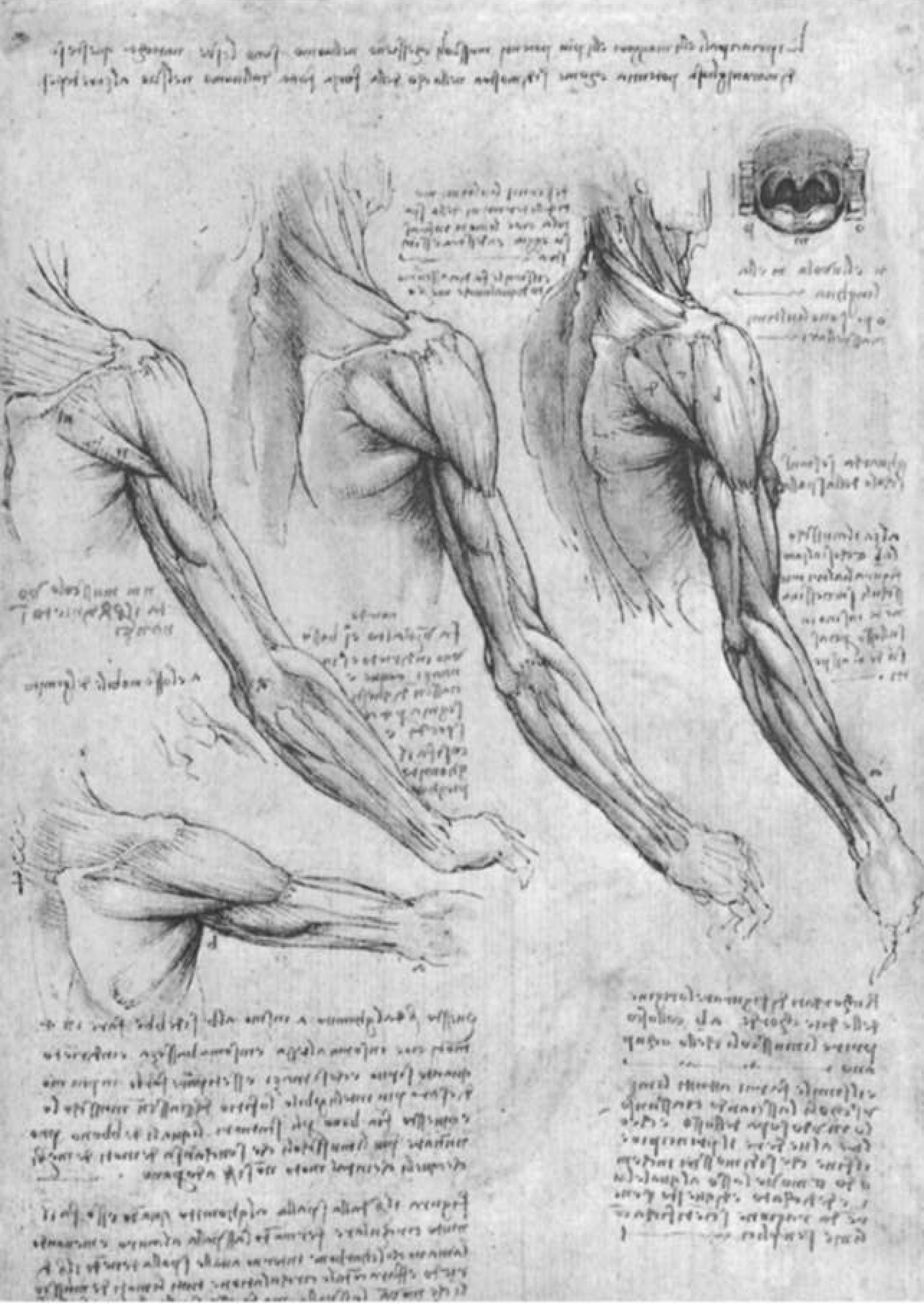

CHAPTER 9

General discussion

GENERAL DISCUSSION

A fractured clavicle may not kill a patient, but the way surgeons provide information and the treatment choices that are made, are of vital importance for the recovery and satisfaction of the patient. After the turn of the century, the amount of research papers on this small bone has doubled since the first publication in 1945. New RCTs comparing operative and nonoperative treatment pop up like daisies on PubMed, rendering meta-analyses outdated before they are even published. And with every new study, novel questions arise as quickly as the previous ones are answered.

The aim of this thesis was to gain more knowledge about all aspects of treatment for displaced, midshaft clavicular fractures, including the decisional process, treatment choice and short- and long-term results.

WHERE DO WE COME FROM?

At present, it is well-known that operative treatment substantially decreases the incidence of nonunion of displaced fractures compared with nonoperative treatment. This thought however was not indisputably proven when the “Sleutel” trial (chapter 5) was designed a decade ago. This explains why the primary outcome of this trial was nonunion and not, for instance, arm function or even satisfaction. In a rapidly evolving research area, some second thoughts about the optimal design of a large, time-consuming study are difficult to avoid.

The insight regarding nonunion rates - possibly in combination with the introduction of fancy anatomically pre-shaped plates - caused a steady increase in the amount of operations that were performed to treat clavicular fractures[1], and common practice in Europe started to lean towards routine operative treatment for all adults with a displaced midshaft fracture. Only in the later literature, including the publication of the “Sleutel” trial, one notices more critical notes regarding operative treatment, with more attention to complications and reoperations rather than only the excellent nonunion rates[2,3]. In short: it seems that the pendulum starts to swing in the opposite direction again.

WHERE ARE WE GOING?

Abandoning first routine nonoperative treatment, and later routine operative treatment for all displaced fractures, leaves us with an obvious problem: if not every patient, then *who* should be operated? Fundamentally improving clavicular fracture treatment could be established in several ways. One way would require the identification of risk factors for failure of both treatments, in order to improve patient selection and reduce the number needed to treat. A second way is to lower the burden of surgery by means of improved technique, type of fixation, plate position, size and location of the incision, etcetera.

Optimizing nonoperative treatment

Failure of nonoperative treatment can result in nonunion or symptomatic malunion. Identifying risk factors for nonunion could help reduce the number needed to treat to prevent one nonunion, which is currently about 5 (chapter 4). Some general risk factors for nonunion are agreed upon, such as major displacement and possibly also a high degree of comminution and shortening[4, 5]. In addition, recent studies identified several patient-related risk factors for nonunion: female sex, older age and smoking[5]. These factors should be regarded when weighing the treatment options, but are not undisputed: different studies have found different risk factors and corresponding risk ratios[6]. Also, it is important to realize that one-third of the patients with a nonunion have little or no symptoms and choose conservative treatment for their nonunion (chapter 5).

Malunion after nonoperative treatment can also cause functional deficits or complaints, sometimes to such a degree that a correction osteotomy is performed. However, because fracture reduction is not accomplished, a nonoperatively treated displaced fracture never heals without a certain degree of malunion. It is therefore difficult to determine what symptomatic malunion exactly is. This lack of clear definition is illustrated by the wide range of reported malunion rates between 0[2] and 61%[7] after nonoperative treatment of displaced clavicle fractures. It is comprehensible that sequelae after nonoperative treatment are sometimes attributed to malunion, although we have discovered in chapter 7 that long-term complaints are frequently present after *both* operative and nonoperative treatment, and thus are not necessarily the result of malunion but have a different aetiology. In addition, in chapter 2 we have shown that a united but shortened clavicle (i.e., shortened malunion) is not proven to affect shoulder function, a finding that is supported by another recent study on clavicle fracture malunion[8]. Overall, it seems that the clinical impact of malunion is sometimes overrated.

Optimizing operative treatment

Operative treatment can fail as well. Some patient-related risk factors for complications are impossible, or difficult, to control such as female sex, older age, smoking, and diabetes[9,10], and thus the room for improving operative treatment mainly lies in optimizing operation-related risk factors. For instance, the type of plate selected to fix the fracture could be important to reduce the risk of failure. In chapter 4, we found that failure rates of reconstruction plates (6.3% reoperation) seemed higher than of other plates, leading to the conclusion that reconstruction plates should preferably not be routinely used for displaced clavicle fractures. Most interestingly, the implant failure rate in the "Sleutel" trial (chapter 4) was even higher (7.2% reoperation), while predominantly anatomically pre-contoured plates were used. Compared with other studies, implant failure rates in the "Sleutel" trial were high. The reason for this remains unclear.

Implant failure in general has two substrates: failure of the surgeon and/or failure of the patient (or bone). Surgeon-related factors such as inadequate surgical technique (e.g., suboptimal reposition, insufficient stability) can cause implant failure[11], but unfortunately we did not have sufficient resources to critically review all X-rays after follow-up of the "Sleutel" trial again with an emphasis on the adequacy of the surgical technique. Other factors can be patient-related: a previous study reported that all patients with a broken plate had engaged in early heavy exercise (within a month)[11]. This aspect was not documented in the "Sleutel" trial. It is however clear that one of the most stated advantages of plate fixation – a quicker return to work and normal life – might be the very cause of complications. Exercise *as pain allows* is not a good advice after plate fixation, as most patients must be explicitly restrained from heavy weight-bearing and sports for the first six weeks.

Elective plate removal

A downside of plate fixation that needs attention is irritation and complaints caused by the implant for which an elective plate removal is performed. Plate removals are relatively quick and easy operations, but nevertheless expose the patient to a second admission, general anaesthesia, and risk of infection, bleeding and refracture. Moreover, a recent study showed that after a median follow-up of over 4 years, patients after plate removal scored worse on DASH, EQ-5D (quality of life), satisfaction, scar satisfaction and subjective shoulder function than patients with a retained plate[12]. This finding suggests that the discomfort these patients experience is not always caused by the plate, emphasizing that reserve is appropriate when dealing with plate removal requests.

Nevertheless, measures should be taken to diminish plate prominence. Pre-contoured plates are supposed to have a better fit on the s-shaped clavicle, although in practice this is not always true[13]. Also, a large meta-analysis showed that anteroinferior placement of the plate results in less plate prominence and irritation, and lower plate removal rates (5% vs 11%, p=0.008) than superior plating[14].

Our own studies illustrate the variation in elective plate removal rates, ranging from 10% in 318 patients (chapter 6), 17% of patients in the "Sleutel" trial (chapter 5), up to 38% removal of the reconstruction plates in chapter 4. Removal rates are not only dependent on plate type and location and on the patient (e.g., females are more like to have the plate removed[12]), but also on the surgeon and cultural differences across countries. It would be interesting to measure various outcomes such as complaints, irritation and satisfaction before and after plate removal to evaluate if there really is any symptom relief for the individual patient.

Subjective outcomes

When it became clear that objective outcomes such as nonunion and arm function scores do not help to clearly identify one ideal treatment for all patients with a displaced midshaft clavicular fracture, we realized that more subjective outcomes might be needed to tip the scale. In chapter 7, long-term satisfaction and sequelae after plate fixation and nonoperative treatment were studied. It turned out that residual symptoms are common after both treatments – an important finding that should be communicated to the patient in advance. However, patients after operative treatment were much more likely to opt for that treatment again in the future compared with nonoperatively treated patients. This finding suggests that patients will generally consider an operation the next step, and that, unless the recovery after nonoperative treatment is quick and absolutely flawless, patients will be inclined to assume that an operation would have given a better result. Expectation management at an early stage is paramount to adjust unrealistic hopes. Also, in case of a patient with many risk factors for complications, this knowledge should be used to paint a realistic picture to the patient regarding the treatment options and possible – or even probable – complications.

Individualized treatment

In the final part of this thesis, the focus shifts towards the decisional process and the role of the patient in the treatment choice – the one thing that all RCTs neglect by definition. Shared decision making (SDM) is advised for preference-sensitive decisions, and in certain situations one could even argue that SDM is ethically imperative. SDM can however be difficult for surgeons to fully understand, let alone achieve[15], as shown in chapter 9. A common misconception is that the patient has to make the final decision in order to achieve SDM, rendering SDM to the surgeons' opinion impossible because patients are often not equipped to make that decision. As explained in chapter 8 and 9, it is essential that surgeons understand what SDM is in order to successfully attempt SDM. An interesting finding in chapter 9, is that the vast majority of surgeons feels that SDM is relevant for providing good care, although 27% has a wrong interpretation of the concept.

A frequently heard objection to SDM is that the surgeon will always implicitly direct the patient towards the surgeons own preferred treatment, which is supposedly done by the way in which the surgeon presents the decision and the words that are chosen to describe the risks and benefits of the treatment options. In this line of reasoning, the patient has no real free choice, but is steered towards choosing one particular option. We believe that this is often the case, but as long as the surgeon guides the patient towards the direction of the *patient's* preferred treatment, it can still be SDM. The surgeon however must make an effort to uncover what the patient's preferences are[16].

Of course, several issues can make SDM difficult in case of clavicular fractures. First, clavicular fractures need a semi-acute decision: ideally, an operation is performed within the first 7 to 10 days, limiting the time to deliberate about the treatment choice. Secondly, multiple specialties are involved. No matter how well surgeons internalize the process of SDM, the patient usually sees an emergency care physician immediately after the injury. It is important therefore that trauma surgeons and emergency care doctors are on the same page with respect to the information patients receive. Thirdly, there is hardly ever an existing surgeon-patient relationship prior to the decisional conversation, whereas the presence of one is known to improve the process and outcomes of SDM[17]. Fourth, as discussed before, about one in four trauma surgeons do not know what SDM is. To date, to our knowledge, SDM is not routinely discussed in surgical training, and no training in SDM skills is provided for residents or surgeons. This needs to change in the future in order to improve SDM in fracture surgery.

AIMS FOR THE FUTURE

To further optimize treatment for displaced, midshaft clavicular fractures, several things are needed, some of which have been discussed above. Specific fracture- and patient-related risk factors for adverse outcomes have to be uncovered to more specifically identify the patients who benefit most from an operation. Then, these risk factors should be incorporated in guidelines. The current Dutch guidelines[18,19] mention only severe displacement or comminution as relative indications for surgery (besides the hard indications such as compromised skin), without providing any nuance.
Secondly, in the pursuit of shared treatment decisions, education and training for physicians about SDM should be incorporated in surgical training. SDM simply is not something 'a good surgeon does automatically', as some believe. To realize that is to accept that training is necessary. In addition - although not discussed in this thesis – the use of decision aids such as a website or leaflet can facilitate the use of SDM[20,21].

Final consideration

What are we aiming for? It seems that the majority of patients have higher expectations of operative than of nonoperative treatment. Indeed, plate fixation has many objective and subjective advantages (less nonunion, better cosmetics, early functional recovery), but in the long term, results are more or less the same (arm function, reoperation rates, residual symptoms). Therefore, should we protect patients from wanting to expose themselves to the risks of surgery without clear long-term benefits? Or should we just operate - because we can?
Overall, it is essential that physicians realize that clavicular fracture treatment is not black-and-white, just like many things in fracture surgery. A fractured clavicle is not a tumour that needs surgery in every operable patient, and deciding to take up the scalpel after only looking at the X-ray is too simplistic. In the end, avoiding nonunion is the only real

reason to operate. Taking risk factors for nonunion into account is therefore essential when making a balanced treatment choice, in order to help as many patients as best as possible. This also implies refraining from operating patients who will heal by themselves. After all, a good surgeon knows how to operate, a better surgeon knows when to operate and the best surgeon knows when not to operate[22].

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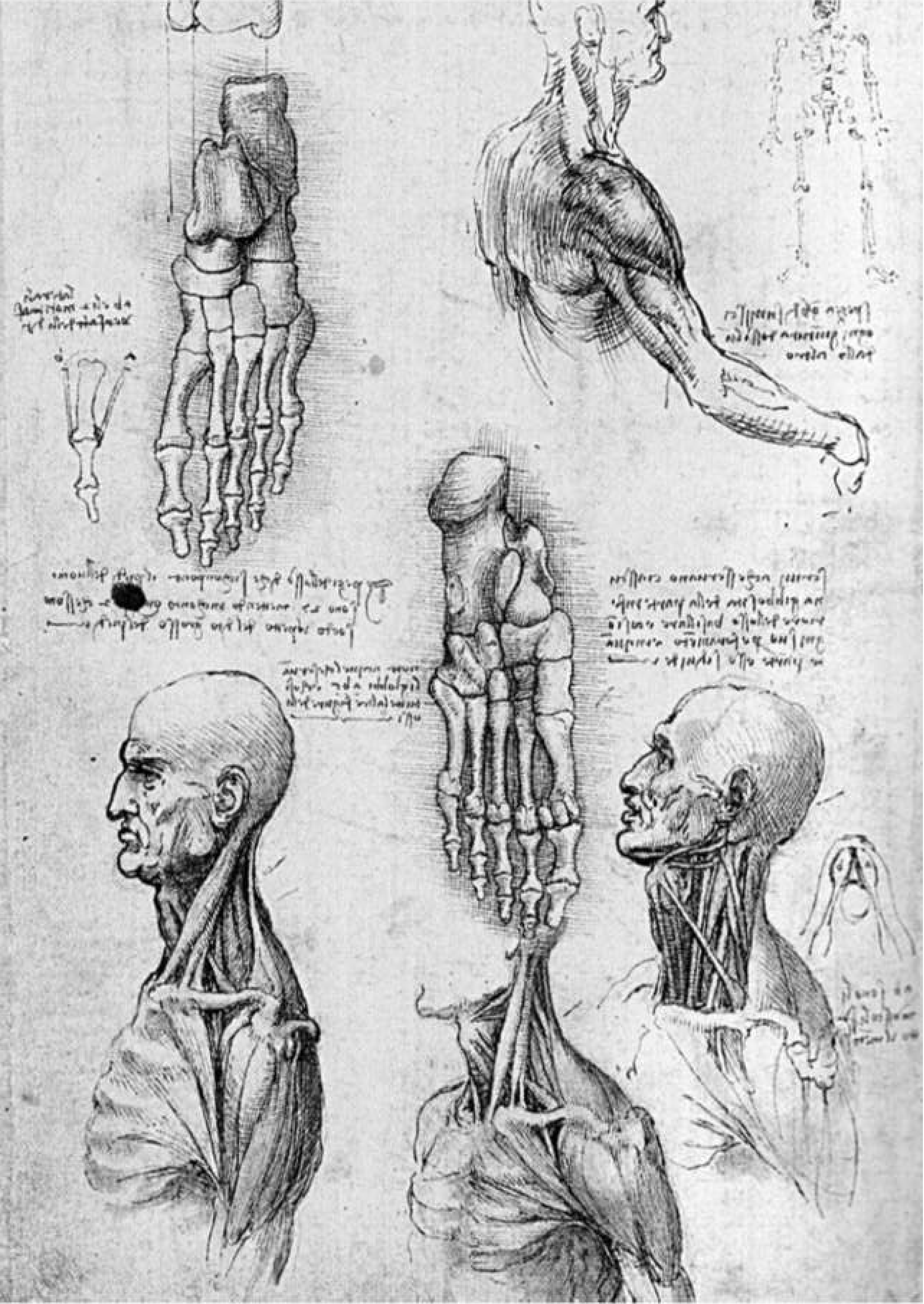


CHAPTER 10

Summary and conclusion

SUMMARY

Fractures of the midshaft clavicle are common and most of them are displaced. Although they seldom result in permanent invalidation, the patient population that is mostly affected is young and often active, warranting an optimal treatment aiming for a complete functional recovery. What the optimal treatment is, however, remains subject for debate. **Chapter 1** provides background information with respect to history, anatomy, classification and treatment options of displaced, midshaft clavicular fractures, and gives a general outline of the problems that this thesis aims to answer. The subsequent chapters evaluate different aspects of the two most frequently used treatment options for clavicular fractures: open reduction and internal plate fixation, and nonoperative treatment. Indications, objective and subjective treatment results, as well as the decisional process are discussed, to help select the optimal treatment for patients with a displaced, midshaft clavicular fracture.

Chapter 2 evaluates the influence of shortening on shoulder function in a healed clavicle. Clavicular shortening is by some authors identified as a risk factor for nonunion, but it is also frequently considered to have a negative influence on shoulder function after union. This review discusses six relevant studies on the subject, with a twofold conclusion. First, the definition and methods of measuring shortening greatly vary across studies. Secondly, the current literature provides no clear evidence that shoulder function is worse in a shortened, united clavicle compared with a fracture that healed without shortening. Therefore, shortening is not an evidence-based reason to operate when aiming to optimize shoulder function. Consensus about the preferred way and moment to measure the amount of shortening is important for both future research and clinical practice.
Chapter 3 discusses whether reconstruction plates are a suitable choice for clavicular fracture fixation. Pelvic reconstruction plates are popular for clavicular fixation – especially before anatomically pre-contoured plates became available - because they are easily bendable to fit the s-shape of the clavicle. This characteristic, however, is thought to make the plate less strong and more susceptive to plate failure such as bending and breaking. This retrospective study of 111 patients treated with a reconstruction plate describes a rate of plate failure needing a reoperation of 6.3%. This seems higher than in various other plate types reported in the literature. Additionally, the study provides an overview

of failure rates of reconstruction plates described in the literature, concluding that the results of the study are comparable with those of other studies. Therefore, reconstruction plates should be used with caution and not in patients with risk factors for plate failure.

Chapter 4 of this thesis describes a randomized controlled trial comparing plate fixation with nonoperative treatment. One-hundred and sixty adult patients with a displaced midshaft clavicular fracture were randomized. After one year, nonunion rates were significantly higher after nonoperative treatment (23.1% compared with 2.4%; $p < 0.0001$). The rate of secondary operations was 27.4% in the operatively treated group (16.7% for elective plate removal) and 17.1% in the nonoperatively treated group ($p = 0.18$). There was no difference between the groups with respect to shoulder function measured with Constant and DASH scores. This study concludes that although plate fixation offers advantages, complications and reoperations are considerable whereas no clear functional benefit could be demonstrated.

In **chapter 5,** six previously published RCTs on treatment of midshaft clavicular fractures are summarized – including the one described in chapter 4. Plate fixation and nonoperative treatment are compared by evaluating a total of 614 patients. The meta-analyses of various outcome measures highlight the different pros and cons of the treatment options. Although plate fixation reduces the risk of nonunion, according to this meta-analysis reoperations occur in about 17% of patients (comparable with nonoperative treatment). Function scores after plate fixation were better, but only 4.4 points on Constant (CI 0.9 – 7.9) and 5.1 points on DASH (CI 0.1 – 10.1) scores, which is less than the 10-15 points that are regarded as the minimal clinically relevant difference. Overall, it seems that there is no evidence to support routine operative fixation for all patients with a displaced clavicular fracture, and that treatment should therefore be individualized by selecting patients who are most likely to benefit from surgery.

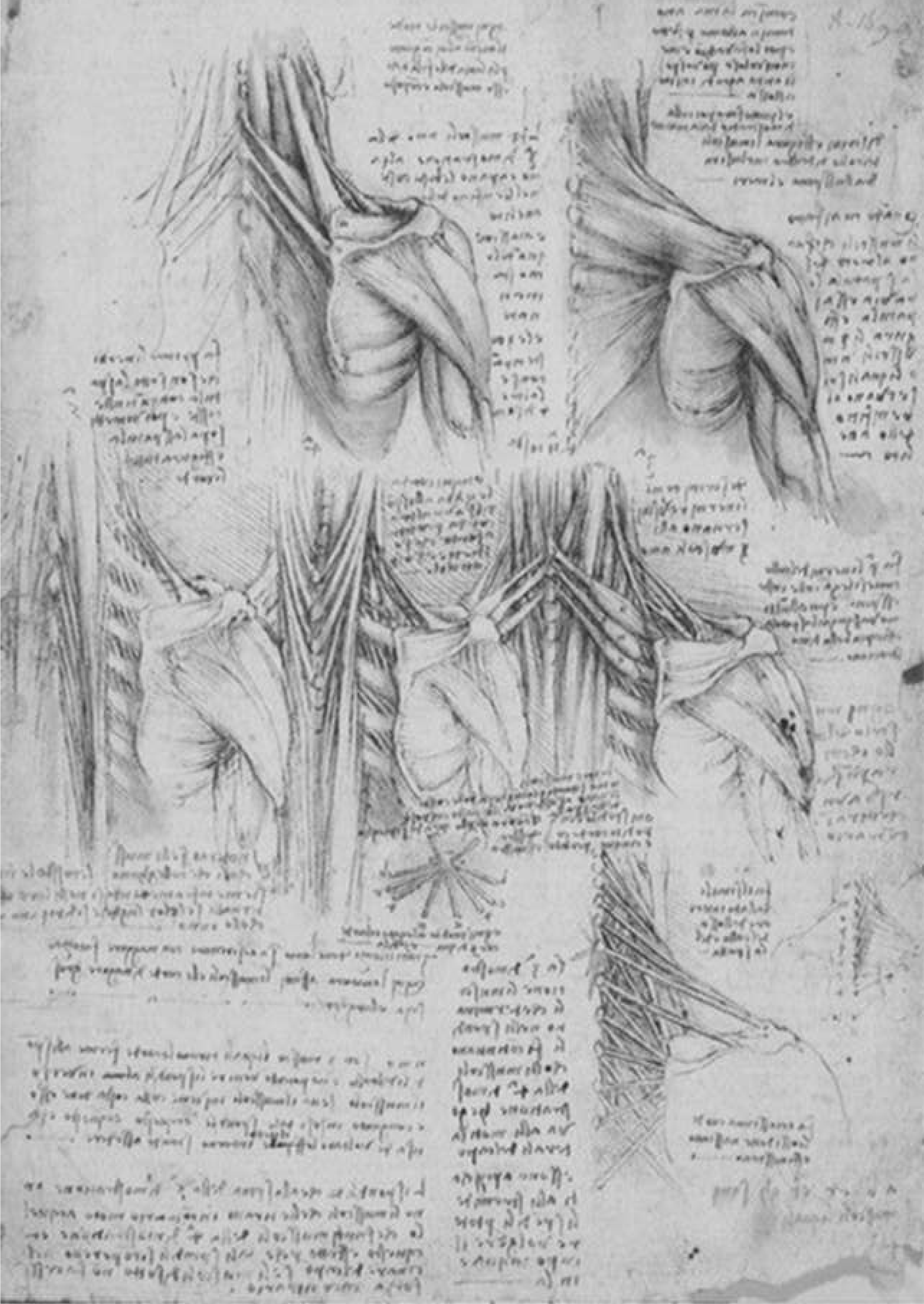
Chapter 6 evaluates long-term patient satisfaction and residual symptoms after plate fixation and nonoperative treatment. All patients included in the RCT (Chapter 4) were contacted by telephone after a median of 4.5 years. Seventy-nine of the 160 patients of the original trial were reached, of whom 40 were treated with plate fixation and 39 nonoperatively. Overall satisfaction and satisfaction with the shoulder function were similar, but patients were more satisfied with the cosmetic result after plate fixation (Mean score out of 10: 8.2±1.6 vs 6.8±2.0, p=0.002). Patients experienced more limitations in daily life after initial nonoperative treatment. About half of the patients in each treatment group still had complaints such as pain, and less than half felt fully recovered. Despite this, more patients after plate fixation would choose the same treatment if they would now fracture their other clavicle (88% vs 41%; p<0.001). Nonoperatively treated patients reported to expect a faster and better recovery after plate fixation. The results of this study can be used to help weigh the treatment options, and to inform patients in an early stage to prevent them from having unrealistic expectations or preferring one treatment or the other for the wrong reasons.

The last two chapters discuss shared decision making (SDM) in (clavicular) fracture care. In SDM, a joint (treatment) decision is reached, based not only on scientific evidence, the experience of the physician and objective patient characteristics (e.g., age, fracture pattern), but also on the individual preferences and values of the patient. This approach is relatively new in trauma surgery, partly because many decisions in trauma surgery are not preference-sensitive and/or have a semi-acute nature. **Chapter 7** evaluates the current use of SDM in the treatment of clavicular fractures. Fifty consecutive adult patients with a displaced clavicular fracture were included, of which about half were treated operatively and the other half nonoperatively. All patients filled out a questionnaire about the consultation in which the treatment decision for their clavicular fracture was made. Patients gave the occurrence of SDM a mean score of 74 out of 100 using the SDM-Q-9-NL, a validated questionnaire to measure patient-reported SDM. One third of the patients reported to have preferred a different role in the decision than they actually had. Overall, it seems that there is room for improvement of SDM in clavicular fracture care.

In **chapter 8,** the attitude and experiences of trauma surgeons with respect to SDM in fracture care are studied. Although the majority of the included trauma surgeons (n = 112) feel that SDM is (very) relevant to provide good care, 27% of the surgeons have an incorrect interpretation of SDM when asked to define the concept in their own words. In addition, almost two-third indicate to encounter problems when engaging in SDM. Overall, knowledge about SDM can be improved and training in SDM-skills for trauma surgeons is necessary in order to improve SDM in fracture care.

CONCLUSION

There is not one clearly superior treatment for all adult patients with a displaced, midshaft clavicular fracture. Plate fixation has multiple objective and subjective advantages (less nonunion, better cosmetics, early functional recovery), but in the longer term, results are more or less the same as with nonoperative treatment (arm function, reoperation rates, residual symptoms). Therefore, it is essential to incorporate fracture- and patient-related risk factors for complications, as well as the patients' values and preferences in a balanced treatment choice in order to individualize treatment and help as many patients as best as possible.



CHAPTER 11

Samenvatting en conclusie

SAMENVATTING

Midschacht claviculafracturen komen veel voor, en zijn meestal gedisloceerd. Hoewel ze zelden permanent invaliderend zijn, komen claviculafracturen met name voor bij jonge en actieve patiënten, en dus is een optimale behandeling en een volledig functioneel herstel essentieel. Welke behandeling het beste is, blijft echter onderwerp van discussie. **Hoofdstuk 1** van dit proefschrift beschrijft de anatomie, classificatie, (behandel)-geschiedenis en huidige behandelopties van gedisloceerde, midschacht claviculafracturen en bespreekt de onderzoeksdoelen van dit proefschrift. In de daarop volgende hoofdstukken worden onderzoeken beschreven naar alle facetten van de twee meest toegepaste behandelopties voor claviculafracturen: open reductie en interne plaatfixatie, en conservatieve behandeling met een sling of mitella. Zowel operatie-indicaties en objectieve en subjectieve behandelresultaten, als het proces van besluitvorming komen aan bod, met als doel de keus voor de beste behandeling te vergemakkelijken.

In **hoofdstuk 2** wordt de invloed van verkorting op de schouderfunctie in een genezen clavicula onderzocht. Verkorting wordt door sommige auteurs genoemd als risicofactor voor nonunion, maar wordt daarnaast vaak gezien als negatieve invloed op de schouderfunctie na genezing van de fractuur. In deze review worden zes relevante studies besproken, met een tweeledige conclusie. Ten eerste blijkt dat de definitie en manier van het meten van verkorting aanzienlijk wisselt tussen de verschillende studies. Ten tweede toont de huidige literatuur geen bewijs dat de schouderfunctie slechter is in een genezen, maar verkorte clavicula dan in een claviculafractuur die genezen is zonder verkorting. Verkorting is daarom geen evidence-based indicatie om een claviculafractuur te opereren met als doel de schouderfunctie te verbeteren. Consensus over de beste manier en het beste tijdstip waarop verkorting wordt gemeten is bovendien essentieel voor zowel toekomstig onderzoek als de klinische praktijk.

Hoofdstuk 3 bespreekt of reconstructieplaten geschikt zijn voor de fixatie van midschacht claviculafracturen. Bekken-reconstructieplaten waren populair voor de fixatie van claviculafracturen, vooral vóórdat anatomisch voorgevormde platen op de markt kwamen, omdat ze makkelijk te buigen zijn in de s-vorm van de clavicula. Deze buigzaamheid lijkt echter ook te resulteren in een minder sterke plaat, waardoor ze kwetsbaarder zijn voor falen (buigen of breken). Deze retrospectieve studie analyseerde

111 patiënten die behandeld zijn met een reconstructieplaat, waarvan 6.3% een re-operatie heeft ondergaan vanwege plaatfalen. Dit lijkt hoger dan bij verschillende andere typen platen beschreven in de literatuur. Daarnaast geeft deze studie een overzicht van de huidige literatuur over falen van reconstructieplaten, waaruit blijkt dat de gevonden resultaten vergelijkbaar zijn met de uitkomsten van andere studies. De conclusie luidt dat reconstructieplaten met enige terughoudendheid gebruikt moeten worden, en niet bij patiënten met risicofactoren voor plaatfalen.

Hoofdstuk 4 beschrijft een gerandomiseerd multicenter onderzoek (RCT) dat plaatfixatie en conservatieve behandeling met elkaar vergelijkt. Honderdzestig patiënten met een volledig gedisloceerde, midschacht claviculafractuur werden geïncludeerd. Na één jaar kwam nonunion significant minder vaak voor na plaatfixatie dan na conservatieve behandeling (2.4% versus 23.1%; $p < 0.0001$). Secundaire operaties werden uitgevoerd in 27.4% van de patiënten na plaatfixatie (waarvan 16.7% het electief verwijderen van de plaat betrof), en 17.1% na conservatieve behandeling ($p = 0.18$). Er was geen verschil tussen de groepen in schouderfunctie gemeten met Constant en DASH-scores. Concluderend biedt plaatfixatie voordelen, maar zijn het aantal complicaties en re-operaties aanzienlijk, zonder duidelijk beter functioneel herstel.

Hoofdstuk 5 betreft een meta-analyse van zes RCT's – waaronder die beschreven in hoofdstuk 4 – waarbij in totaal 614 patiënten met een claviculafractuur geanalyseerd zijn. De meta-analyse van verschillende uitkomstmaten benadrukt dat zowel plaatfixatie als conservatieve behandeling voor- en nadelen heeft: plaatfixatie verkleint het risico op nonunion, maar re-operaties komen voor in ongeveer 17% van de patiënten, net als na conservatieve behandeling. Scores voor schouderfunctie waren beter na plaatfixatie, maar slechts 4.4 punten op de Constant score (CI 0.9 – 7.9) en 5.1 punten op de DASH-score (CI 0.1 – 10.1), wat minder is dan de 10 tot 15 punten die meestal beschouwd worden als het minimale verschil dat klinisch relevant is. Al met al lijkt er geen bewijs voor het *routinematig* opereren van alle patiënten met een volledig gedisloceerde, midschacht claviculafractuur. Een geïndividualiseerde behandeling heeft de voorkeur, waarbij patiënten geselecteerd worden die het meeste voordeel hebben van een operatie.

Vervolgens evalueert **hoofdstuk 6** de patiënttevredenheid en restklachten na plaatfixatie en conservatieve behandeling op de langere termijn. Alle patiënten die meededen aan de RCT (hoofdstuk 4) werden telefonisch benaderd na een mediane follow-up van 4.5 jaar.

Negenenzeventig van de 160 patiënten uit de oorspronkelijke studiegroep werden bereikt, van wie 40 gerandomiseerd waren voor plaatfixatie en 39 voor conservatieve behandeling. Algemene tevredenheid en tevredenheid met de schouderfunctie verschilde niet tussen de groepen, maar patiënten na plaatfixatie waren meer tevreden met het uiterlijk van hun schouder (gemiddelde score op een schaal van 1-10: 8.2±1.6 vs 6.8±2.0, p=0.002). Na conservatieve behandeling gaven patiënten aan meer beperkingen te ervaren in het dagelijks leven. Ongeveer de helft van de patiënten in beide groepen rapporteerde restklachten zoals pijn, en minder dan de helft voelde zich helemaal de oude. Toch zouden patiënten na plaatfixatie significant vaker voor dezelfde behandeling kiezen als ze nu hun andere clavicula zouden breken (88% vs 41%; p<0.001). Patiënten in de conservatieve groep gaven aan een sneller en beter herstel te verwachten na een operatie. Resultaten van deze studie kunnen worden gebruikt om de behandelopties af te wegen, en patiënten in een vroeg stadium te informeren om te voorkómen dat er onrealistische verwachtingen zijn of dat patiënten een bepaalde behandeling prefereren om een onjuiste reden.

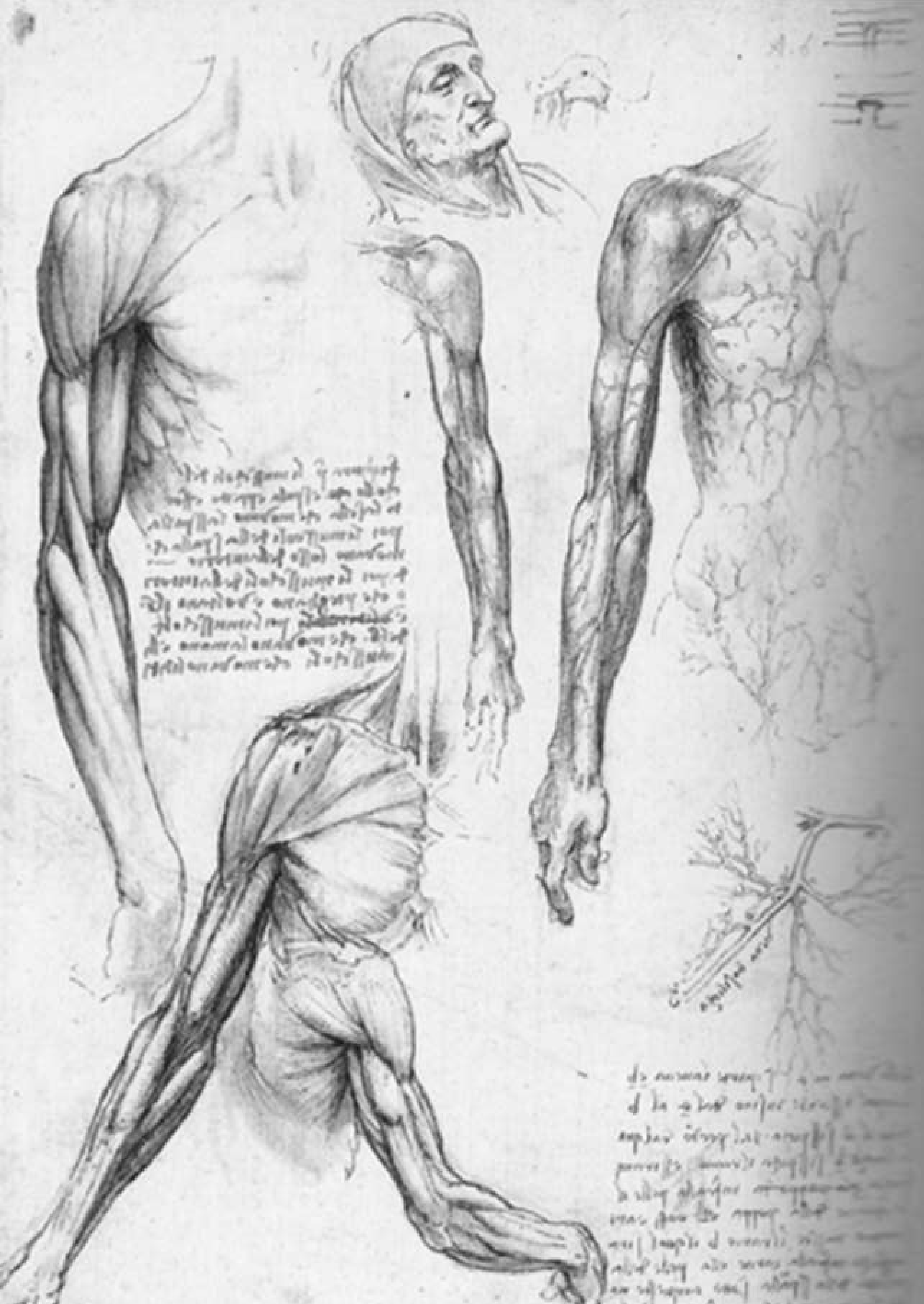
De laatste twee hoofdstukken van dit proefschrift gaan over gedeelde besluitvorming of samen beslissen, ofwel shared decision making (SDM) bij de behandeling van clavicula en andere fracturen. In SDM wordt door de arts en patiënt samen een beslissing genomen, gebaseerd niet alleen op wetenschappelijk bewijs, de ervaring van de arts, en specifieke karakteristieken van de patiënt (b.v. leeftijd) of fractuur (b.v. verplaatsing), maar ook op individuele voorkeuren en waarden van de patiënt. Deze benadering is relatief nieuw in de traumachirurgie, deels omdat veel beslissingen acuut genomen moeten worden en/of niet ‘voorkeursgevoelig’ zijn. In dat laatste geval is er duidelijk één beste optie, en is de voorkeur van de patiënt dus minder een meewegende factor.

Hoofdstuk 7 evalueert het huidige vóórkomen van SDM bij de behandeling van claviculafracturen. Vijftig volwassen patiënten met een gedisloceerde, midschacht claviculafractuur werden geïncludeerd, waarvan ongeveer de helft operatief en de helft conservatief behandeld werd. Alle patiënten vulden éénmalig een vragenlijst in over het polikliniek bezoek waarin de behandelbeslissing voor hun claviculafractuur was genomen. Patiënten gaven de mate van SDM een gemiddelde score van 74 uit 100 op de SDM-Q-9-NL, een gevalideerde vragenlijst die patiënt-gerapporteerde SDM meet. Eén derde van

de patiënten gaf aan dat ze liever een andere rol in de behandelbeslissing hadden gehad dan dat daadwerkelijk het geval was (meer of minder actief). Kortom, er lijkt ruimte voor verbetering in het toepassen van SDM bij beslissen over claviculafracturen.
In **hoofdstuk 8** worden de mening en ervaringen van traumachirurgen onderzocht wat betreft SDM in de traumachirurgie. Hoewel de meerderheid van de ondervraagde traumachirurgen (n = 112) meent dat SDM (zeer) relevant is voor het leveren van goede zorg, geeft 27% een definitie van het begrip SDM die volgens de huidige consensus onjuist is. Daarnaast geeft bijna twee derde van de traumachirurgen aan problemen te ondervinden bij het toepassen van SDM. Al met al lijkt verbetering van kennis over SDM en training in het toepassen van SDM nodig om het gebruik van SDM in traumachirurgie te verbeteren.

CONCLUSIE

Er is niet duidelijk één superieure behandeling voor alle patiënten met een volledig gedisloceerde, midschacht claviculafractuur. Plaatfixatie heeft veel objectieve en subjectieve voordelen (minder nonunion, beter cosmetisch resultaat, sneller functioneel herstel), maar op de lange termijn zijn de resultaten vergelijkbaar met conservatieve behandeling (armfunctie, aantal re-operaties, kans op restklachten). Daarom is het essentieel om zowel fractuur- en patiënt-gerelateerde risicofactoren voor complicaties, als de waarden en voorkeuren van de patiënt te incorporeren in een afgewogen beslissing, en de behandeling te individualiseren om zo veel mogelijk patiënten zo goed mogelijk te behandelen.



CHAPTER 12

Appendices

APPENDIX 1. SEARCH STRATEGY CLAVICULAR SHORTENING (CHAPTER 2)

Pubmed: ("Clavicle"[Mesh] OR "Clavicle"[tw] OR "clavicular"[tw] OR "clavicula"[tw]) AND ("fractures, bone"[MeSH] OR "fractures"[tw] OR "fracture"[tw]) AND ("midshaft"[tw] OR "mid-shaft"[tw] OR "mid shaft"[tw] OR "middle third"[tw] OR "middle-third"[tw]) AND ("Shortening"[tw] OR "Shortenings"[tw] OR "shortened"[tw]) AND ("conservative"[tw] OR "conservatively"[tw] OR "nonoperative"[tw] OR "nonoperatively"[tw] OR "non-operative"[tw] OR "non-operatively"[tw] OR "nonsurgical"[tw] OR "nonsurgically"[tw] OR "non-surgical"[tw] OR "non-surgically"[tw] OR "sling"[tw] OR "immobilisation"[tw] OR "immobilization"[MeSH Terms] OR "immobilization"[tw] OR "bandages"[MeSH] OR "bandages"[tw] OR "bandage"[tw])

Embase: (((exp "Clavicle"/ OR "Clavicle".mp. OR "clavicular".mp. OR "clavicula".mp.) AND (exp "fracture"/ OR "fractures".mp. OR "fracture".mp.)) OR exp clavicle fracture/) AND ("midshaft".mp. OR "mid-shaft".mp. OR "mid shaft".mp. OR "middle third".mp. OR "middle-third".mp.) AND ("Shortening".mp. OR "Shortenings".mp. OR "shortened".mp.) AND (exp conservative treatment/ OR "conservative".mp. OR "conservatively".mp. OR "nonoperative".mp. OR "nonoperatively".mp. OR "non-operative".mp. OR "non-operatively".mp. OR "nonsurgical".mp. OR "nonsurgically".mp. OR "non-surgical".mp. OR "non-surgically".mp. OR "sling".mp. OR "immobilisation".mp. OR exp fracture immobilization/ OR "immobilization".mp. OR exp bandage/ OR "bandages".mp. OR "bandage".mp.)

Web of Science: TS=(("Clavicle" OR "clavicular" OR "clavicula") AND ("fractures" OR "fracture") AND ("midshaft" OR "mid-shaft" OR "mid shaft" OR "middle third" OR "middle-third")) AND TS=("Shortening" OR "Shortenings" OR "shortened") AND TS=("conservative" OR "conservatively" OR "nonoperative" OR "nonoperatively" OR "non-operative" OR "non-operatively" OR "nonsurgical" OR "nonsurgically" OR "non-surgical" OR "non-surgically" OR "sling" OR "immobilisation" OR "immobilization" OR "bandages" OR "bandage")

Clinical Trial Register: "Clavicle" AND "fractures" AND ("mid-shaft" OR "middle third") AND "Shortening"

APPENDIX 2. SEARCH STRATEGY META-ANALYSIS (CHAPTER 5)

PubMed: ("Clavicle"[MeSH] OR "clavicle"[tw] OR "clavicles"[tw] OR "clavicular"[tw] OR clavic*[tw] OR "clavicula"[tw] OR "claviculae"[tw]) AND ("Fractures, Bone"[MeSH] OR fractur*[tw] OR "fracture"[tw] OR "fractures"[tw] OR "fractured"[tw]) AND ("Randomized Controlled Trial" [Publication Type] OR "randomized controlled"[tw] OR "random allocation"[tw] OR "randomised controlled"[tw] OR "RCT"[tw])

MEDLINE: (exp Clavicle/ OR "clavic*".mp.) AND (exp Fractures, Bone/ OR "fractur*".mp.) AND (exp Randomized Controlled Trial/ OR "randomized control*".mp. OR "randomised control*".mp. OR "random allocation".mp.)

Embase: (exp Clavicle/ OR "clavic*".mp.) AND (exp Fractures, Bone/ OR "fractur*".mp.) AND (exp Randomized Controlled Trial/ OR "randomized control*".mp. OR "randomised control*".mp. OR "random allocation".mp.)

Web of Science: TS=("clavic*") AND TS=("fractur*") AND TS=("randomized control*" OR "randomised control*" OR "random allocation")

APPENDIX 3. LONG-TERM FOLLOW-UP QUESTIONNAIRE (CHAPTER 6)

Date of telephone contact:……………………………………………………………………….

Study number patient: ………………………………………………………………………

Hospital: ……………………………………………………………………………..................

Date of inclusion:……………………………………………………………………………

Randomization for: plate fixation / nonoperative treatment

Received treatment: plate fixation / nonoperative treatment

In case of nonoperative treatment:

Did you receive a secondary operation? Yes / No

If yes, when? ……………………………………………………………………….(month+year)

What kind of operation/for what?

…………………………………………………………………………………………………

In case of plate fixation:

(initial or secondary)

Was the plate later removed? Yes / No

If yes, when? ……………………………………………………………………….(month+year)

If yes, why? complaints / cosmetic / tingling / other, namely:

…………………………………………………………………………………………………

Did you have a second operation for another reason? Yes / No

If yes, when? ……………………………………………………………………….(month+year)

If yes, why? ………………………………………………………………………………………

Satisfaction (all patients)

Your broken collar bone has been treated with an operation / with a sling.

1. How satisfied are you with the overall treatment?

Very Dissatisfied 1 2 3 4 5 6 7 8 9 10 Very Satisfied

2. How satisfied are you with the appearance of your shoulder?

Very Dissatisfied 1 2 3 4 5 6 7 8 9 10 Very Satisfied

3. How satisfied are your with the function of your shoulder?

Very Dissatisfied 1 2 3 4 5 6 7 8 9 10 Very Satisfied

Do you feel you have fully recovered with respect to your shoulder, compared with before the fracture? Yes/ No

If no, why not? ……………………………..……………………………………………………….

Do you ever have symptoms of your shoulder such as pain, a tingling sensation, weakness or stiffness? Yes / No

If yes, what? Pain Tingling Weakness Stiffness Other:………..

If yes, how often? Daily / Weakly / Monthly / Less than monthly

How bad are these complaints for you?

Not bad at all 1 2 3 4 5 6 7 8 9 10 Very Bad

Are there things you are not able to do because of your shoulder, that you could do before the fracture? Yes / No

If yes, what? ………………………………………………………………………………………

Would your now choose the same treatment as the one you received, if you would fracture your other clavicle? Yes / No

If no, why not? ………………………………………………………….……………………………

Additional comments:

……………………………………………………………………………………………………

……………………………………………………………………………………………………

APPENDIX 4. QUESTIONNAIRE ON SHARED DECISION MAKING (CHAPTER 7)

Onderdeel 1: vóór de beslissing

Hieronder volgen een paar vragen over hoe u dacht over de behandeling van uw sleutelbeenbreuk voordat u met de chirurg op de polikliniek had gesproken.

1. Voordat ik op de polikliniek kwam, wist ik dat mijn breuk op twee verschillende manieren behandeld kon worden (operatie of mitella).
   - o Nee
   - o Ja
   - o Weet ik niet (meer)

2. Voordat ik op de polikliniek kwam, had ik een voorkeur voor één van de twee behandelingen.
   - o Nee
   - o Ja, namelijk operatie / mitella (omcirkel het antwoord dat bij u past)

Ik had een voorkeur omdat………………………………………………………………………

   - o Weet ik niet (meer)

Onderdeel 2: de beslissing

Mensen verschillen in de mate waarin zij betrokken willen worden bij het nemen van beslissingen over hun medische behandeling. Sommige mensen willen wél graag betrokken worden bij deze beslissingen, anderen laten dit liever aan hun dokter over.

De volgende vragen gaan over de beslissing die genomen is om uw sleutelbeenbreuk te opereren of met een mitella te behandelen.

1. Er is een beslissing genomen over de behandeling van uw sleutelbeenbreuk (namelijk wél of geen operatie). Welke van de volgende omschrijvingen past het beste bij u?
   - o Ik heb de beslissing over mijn behandeling zelf genomen

- o Ik heb de beslissing over mijn behandeling zelf genomen, waarbij ik sterk rekening heb gehouden met de mening van mijn arts
- o Ik heb de beslissing over mijn behandeling samen met mijn arts genomen
- o Ik heb de beslissing over mijn behandeling over gelaten aan mijn arts, waarbij deze wel sterk rekening heeft gehouden met mijn mening
- o Ik heb de beslissing over mijn behandeling over gelaten aan mijn arts

2. Hieronder worden 9 stellingen gegeven die betrekking hebben op het zojuist gevoerde gesprek met uw arts. Kunt u per stelling aangeven in hoeverre u het met deze uitspraak eens bent?

a. Mijn arts heeft me duidelijk gemaakt dat er een beslissing genomen moet worden.

Geheel mee oneens	Sterk mee oneens	Enigszins mee oneens	Enigszins mee eens	Sterk mee eens	Geheel mee eens
❑	❑	❑	❑	❑	❑

b. Mijn arts wilde precies van me weten hoe ik betrokken zou willen worden bij het nemen van de beslissing.

Geheel mee oneens	Sterk mee oneens	Enigszins mee oneens	Enigszins mee eens	Sterk mee eens	Geheel mee eens
❑	❑	❑	❑	❑	❑

c. Mijn arts heeft me verteld dat er voor mijn klachten verschillende behandelings-mogelijkheden zijn

Geheel mee oneens	Sterk mee oneens	Enigszins mee oneens	Enigszins mee eens	Sterk mee eens	Geheel mee eens
❑	❑	❑	❑	❑	❑

d. Mijn arts heeft me de voor- en nadelen van de behandelingsmogelijkheden precies uitgelegd.

Geheel mee oneens	Sterk mee oneens	Enigszins mee oneens	Enigszins mee eens	Sterk mee eens	Geheel mee eens
❑	❑	❑	❑	❑	❑

e. Mijn arts heeft me geholpen alle informatie te begrijpen

Geheel mee oneens	Sterk mee oneens	Enigszins mee oneens	Enigszins mee eens	Sterk mee eens	Geheel mee eens
❑	❑	❑	❑	❑	❑

f. Mijn arts heeft me gevraagd welke behandelingsmogelijkheid mijn voorkeur heeft.

Geheel mee oneens	Sterk mee oneens	Enigszins mee oneens	Enigszins mee eens	Sterk mee eens	Geheel mee eens
❑	❑	❑	❑	❑	❑

g. Mijn arts en ik hebben de verschillende behandelingsmogelijkheden grondig afgewogen.

Geheel mee oneens	Sterk mee oneens	Enigszins mee oneens	Enigszins mee eens	Sterk mee eens	Geheel mee eens
❑	❑	❑	❑	❑	❑

h. Mijn arts en ik hebben samen een behandelingsmogelijkheid uitgekozen.

Geheel mee oneens	Sterk mee oneens	Enigszins mee oneens	Enigszins mee eens	Sterk mee eens	Geheel mee eens
❑	❑	❑	❑	❑	❑

i. Mijn arts en ik hebben een afspraak gemaakt over het verdere vervolg.

Geheel mee oneens	Sterk mee oneens	Enigszins mee oneens	Enigszins mee eens	Sterk mee eens	Geheel mee eens
❑	❑	❑	❑	❑	❑

3. Er is een beslissing genomen over de behandeling van uw sleutelbeenbreuk (namelijk wél of geen operatie). Hoe had u het liefst gewild dat de beslissing genomen was? Let op: het gaat er dus niet om hoe de beslissing uiteindelijk genomen is, maar over wat u het liefste had gewild.
   - o Ik had de beslissing over mijn behandeling het liefst zelf genomen
   - o Ik had de beslissing over mijn behandeling het liefst zelf genomen, waarbij ik sterk rekening houd met de mening van mijn arts

- o Ik had de beslissing over mijn behandeling het liefst samen met mijn arts genomen
- o Ik had de beslissing over mijn behandeling het liefst over willen laten aan mijn arts, waarbij deze wel sterk rekening houdt met mijn mening
- o Ik had de beslissing over mijn behandeling het liefst over willen laten aan mijn arts

4. Krijgt u nu de behandeling waar u van te voren een voorkeur voor had?
   - o Ja
   - o Nee

Waarom niet?……………………………………………………………………………………

Onderdeel 3: algemene vragen

1. Waaruit bestaan momenteel uw voornaamste dagelijkse bezigheden?
   (één antwoord aankruisen)
   - o betaalde baan, voor ………. uur per week
   - o vrijwilligerswerk / onbetaalde baan
   - o huishoudelijke taken
   - o volgen van studie / opleiding
   - o anders, nl.: ……………………………………………………………………………..

2. Wat is uw hoogst voltooide opleiding?
   - o lagere school
   - o lager beroepsonderwijs (bijv. huishoudschool, LTS, LHNO, LEAO)
   - o MULO, MAVO, 3 jaar HAVO
   - o hoger algemeen onderwijs (bijv. HAVO)
   - o voorbereidend wetenschappelijk onderwijs (HBS, VWO)
   - o middelbaar beroepsonderwijs (bijv. MTS, MEAO, INAS, VHBO)
   - o hoger beroepsonderwijs (HBO)
   - o wetenschappelijk onderwijs (universiteit)
   - o anders, nl.: …………………………………………………………………………

3. Sportte u voordat u uw sleutelbeen brak?
    - o Nee
    - o Ja

Zo ja, wat voor sport(en)?

………

Hoeveel uur sportte u per week? .... uur

APPENDIX 5. SURVEY AMONG TRAUMA SURGEONS ABOUT SDM (CHAPTER 8)

1. Wat is uw geslacht?
    - o Man
    - o Vrouw

2. Wat is uw leeftijd?

3. Sinds welk jaar bent u chirurg?

4. In wat voor soort ziekenhuis werkt u?
    - o Academisch Centrum
    - o Perifeer level 1 traumacentrum
    - o Perifeer level 2 traumacentrum
    - o Perifeer level 3 traumacentrum

Shared decision making (SDM, ofwel gedeelde besluitvorming; samen beslissen) is een proces waarbij de arts en patiënt beiden betrokken zijn, en waarin een beslissing wordt genomen over bijvoorbeeld diagnostiek of behandeling.

5. Wat verstaat u onder samen beslissen?……………………………………………………
……

De volgende vragen gaan over het nemen van een beslissing over een behandeling

6. Is het volgende gedrag volgens u wel of niet essentieel voor SDM? (aankruisen indien wel essentieel, meerdere antwoorden mogelijk)
    - o Patiënt informeren over de mogelijke voor- en nadelen van een behandeling
    - o Patiënt informeren hoe groot de kans op deze voor- en nadelen is
    - o Patiënt informeren dat er een beslissing genomen moet worden
    - o Patiënt de tijd geven en pas bij een tweede consult samen de beslissing nemen
    - o Patiënt vragen naar zijn/haar persoonlijke voorkeuren en waarden

- Patiënt na zorgvuldig informeren de behandeling zelf laten kiezen
- Patiënt vragen iemand mee te nemen naar het gesprek
- Patiënt uitleggen dat er meerdere behandelopties zijn
- Patiënt uitleggen waarom voor een bepaalde behandeling gekozen wordt
- Samen met de patiënt een behandeling uitkiezen
- De patiënt uitleggen dat zijn mening belangrijk is in het nemen van de beslissing
- De patiënt de informatie laten herhalen
- Informatie mondeling en op andere manieren overdragen (bv door een folder mee te geven)

7. Past u SDM/gedeelde besluitvorming toe in uw praktijk, als u de beslissing ervoor geschikt acht?
    - Ja, altijd
    - In ongeveer 75% van de gevallen
    - In ongeveer 50% van de gevallen
    - In ongeveer 25% van de gevallen
    - Nee, nooit

8. Wat is de reden dat u niet altijd SDM toepast als een situatie daarvoor geschikt is? (max 3 antwoorden)
    - Het is bij veel patiënten niet haalbaar omdat het te ingewikkeld voor ze is
    - De patiënt wil dat de chirurg beslist
    - Ik weet niet precies hoe ik SDM moet toepassen
    - De chirurg weet vaak beter dan de patiënt wat de beste keuze is
    - Het kost extra tijd
    - Anders, namelijk………………………………………………………………………….

9. Loopt u wel eens tegen problemen aan bij het toepassen van SDM?
    - Ja
    - Nee
    - Ik pas nooit SDM toe

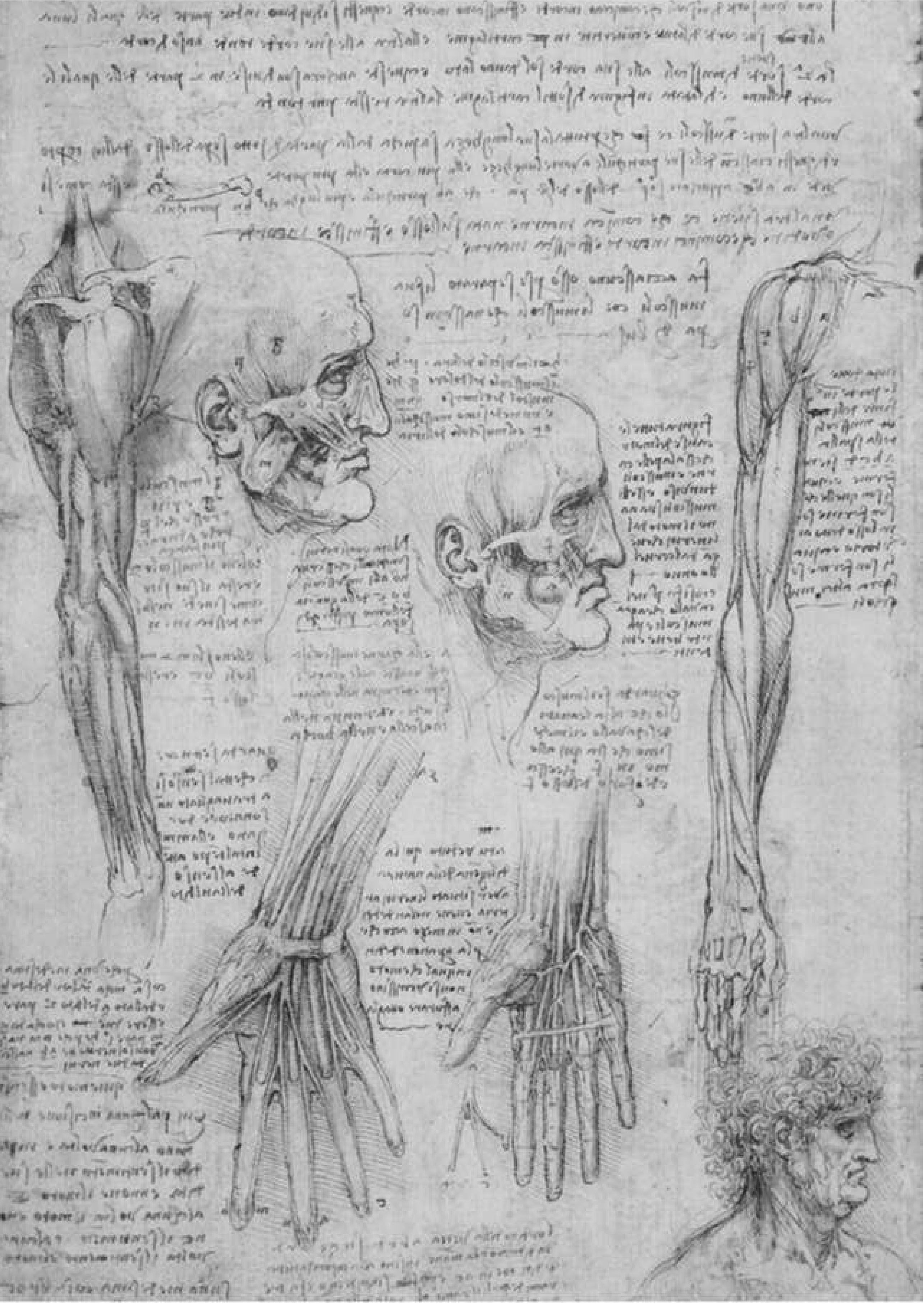
10. Tegen welke problemen loopt u aan bij het toepassen van SDM?……………………………

11. Kunt u een voorbeeld geven van een situatie/diagnose binnen de traumachirurgie die u geschikt vindt voor SDM/gedeelde besluitvorming?...
....

12. Vindt u SDM relevant voor het leveren van goede zorg door de traumachirurg?

Helemaal niet relevant 1 2 3 4 5 Zeer relevant

13. Kunt u uw antwoord op de vorige vraag toelichten?..
....



CHAPTER 13

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Dankwoord

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CURRICULUM VITAE

Sarah Woltz was born on 3 February 1984 in The Hague, the Netherlands. After graduating from the Gymnasium Haganum in The Hague in 2002, she studied Psychology at Leiden University. In 2004 she switched to Medicine at the LUMC. In 2005, she participated in a student exchange program and studied a semester at the Karolinska Institutet in Stockholm, Sweden. There, she wrote several columns for the Swedish University magazine *Bukpressen*. During the following four years of medical school, Sarah wrote monthly columns for the Dutch magazine *Medisch Contact* under the pseudonym Julia Franken, which were published as the book 'In Opleiding' in 2011. For her scientific internship in 2008, Sarah did research at the Edinburgh Centre for Neuro-Oncology in Edinburgh, Scotland, investigating the correlation between tumour laterality and distress in brain tumour patients. She finished medical school with a surgical internship at the St. Elizabeth Hospitaal in Willemstad, Curaçao, and graduated in December 2010.
Sarah worked at the Medisch Centrum Haaglanden, Westeinde, as a surgical resident not in training in 2011, where she started her surgical training a year later (supervisor Dr. S.A.G. Meylaerts). Since 2013, Sarah is one of the editors for the Nederlands Tijdschrift voor Heelkunde, for which she regularly writes columns and interviews.
While continuing her surgical training at the LUMC (supervisor Prof dr J.F.P. Hamming), Sarah started her scientific research on clavicular fractures under the supervision of Prof dr I.B. Schipper and Dr. P. Krijnen in 2014. Quickly, Sarah was captured by the never-ceasing challenge of doing research, and it was decided to expand the research into a PhD trajectory, of which the result lies before you. Sarah had the opportunity to present the scientific work described in this thesis at multiple national and international conferences, including the results of the "Sleutel" trial at the Traumadagen 2015, for which she received the prize for the best oral presentation, and in the "Highlight Paper Session" at the Annual Meeting 2016 of the Orthopaedic Trauma Association (OTA) in Washington, USA.
Currently, Sarah works at the Haga Hospital in The Hague (supervisor Dr J. Wever), where she subspecializes in trauma surgery. In 2017, she worked six months as a Senior Clinical Fellow Trauma and Emergency Surgery at King's College Hospital in London (supervisor Dr D. Bew and A. Greeven) to expand her experience in dealing with severe polytrauma patients. She will finish her surgical training in the summer of 2018.

Aan iedereen die op welke manier dan ook – door aanmoediging, kritische noot of juist afleiding - heeft bijgedragen aan dit proefschrift: heel veel dank. We did it!