Traumatic Dislocation of the Elbow Joint

Jeroen de Haan

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Promotor: Prof.dr. P. Patka

Overige leden: Prof.dr. H.J. ten Duis
Prof.dr. C.H.J. van Eijck
Prof.dr. G-J. Kleinrensink

Copromotoren: Dr. D. den Hartog
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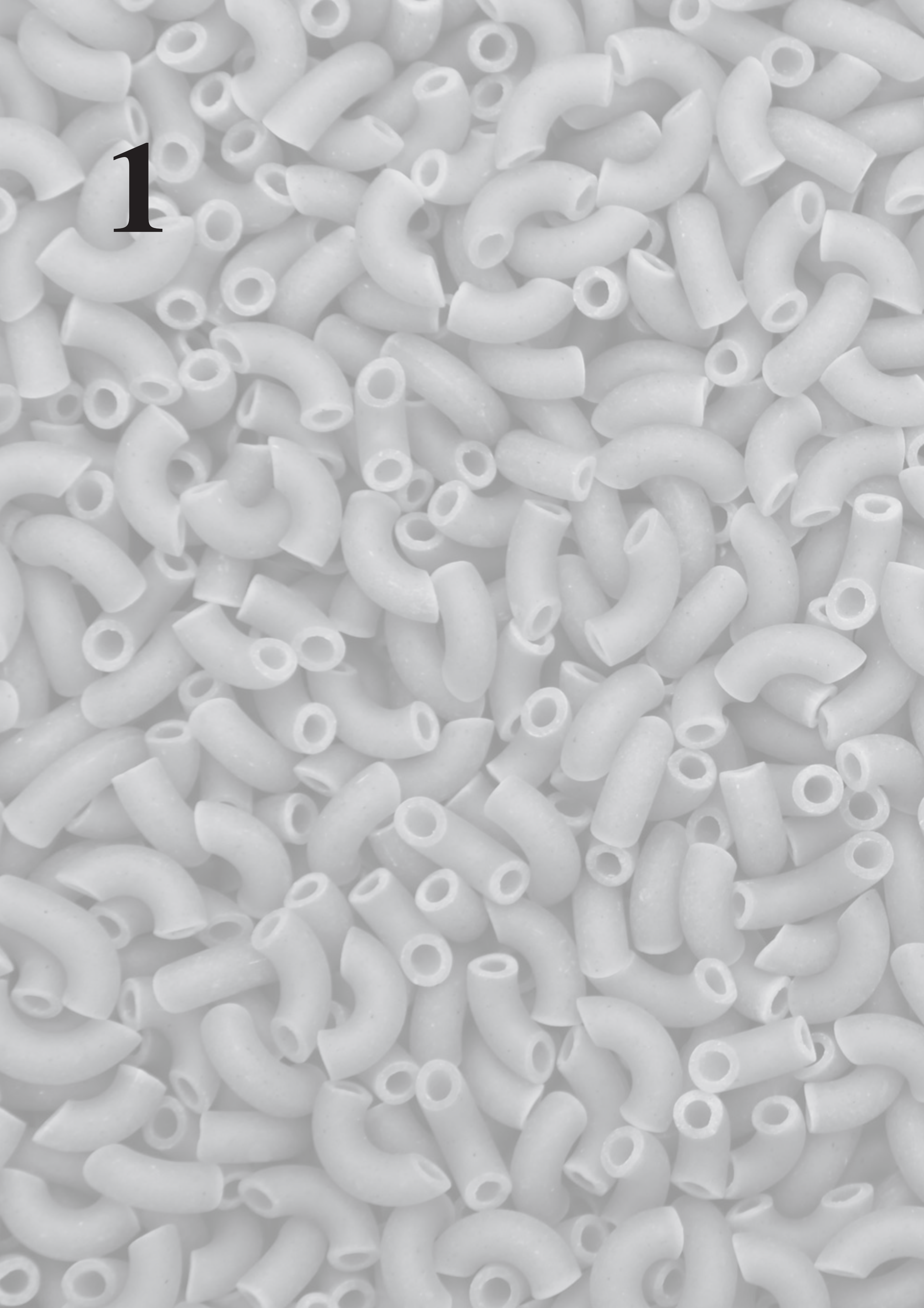
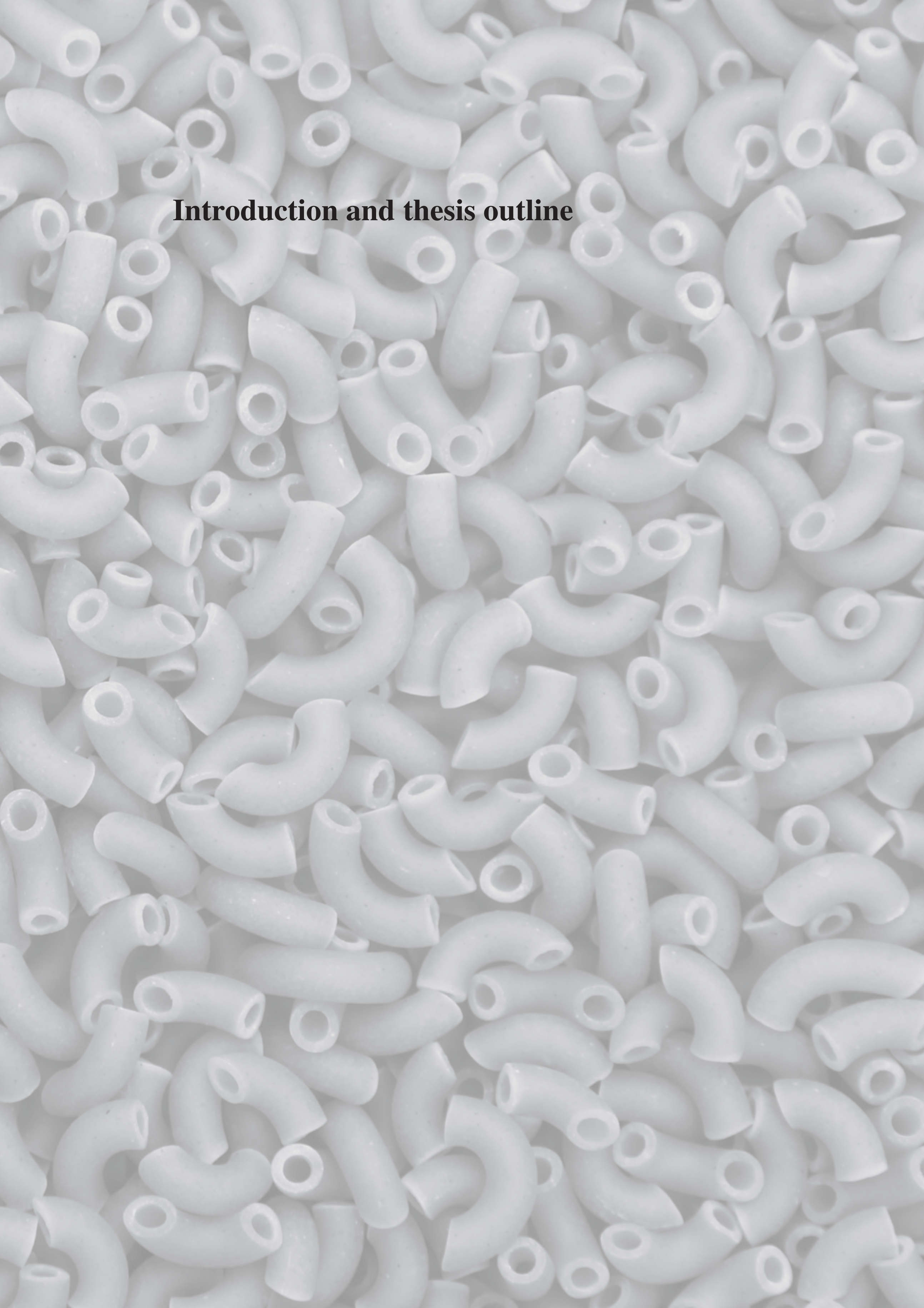


Introduction and thesis outline



Introduction

This thesis addresses the major issues encountered in the diagnosis and treatment of adult elbow dislocation. Firstly, a literary review (Chapters Five and Eight) makes it clear that there is much uncertainty regarding trauma mechanism, biomechanics, and even anatomy (Chapter Two). Furthermore, an overview of the treatment options indicates that there is no uniformity in the treatment modalities applicable to elbow dislocation (Chapter Six). And last but not least, there is no Dutch questionnaire which can be used to determine the outcome of treatment. In order to address these issues, this thesis presents the validation of a new Dutch questionnaire (Chapters Three and Four) and includes the publication of protocols and a trial management system for the performance of two unique, prospective multicenter studies (Chapters Seven and Ten) that will evaluate the outcome of treatment modalities with respect to traumatic elbow dislocation.

a) Definitions, distribution and classifications

Trauma to a joint can lead to fracture, strain or dislocation of the joint. A dislocation of the joint is defined as an abnormal displacement of one bone upon another at a joint [1]. Elbow dislocations are classified as simple or complex types [2]. Simple dislocations are dislocations without fractures. Complex dislocations are associated with fractures of the radial head, proximal ulna and/or coronoid process. The combination of an elbow dislocation with a radial head and a coronoid process fracture is called a “terrible triad” due to the high rate of complications.

Elbow dislocations can also be classified by the direction of forearm bone displacement, i.e. posterior and anterior. Posterior dislocations are subdivided into medial and lateral dislocations.

In adults, 96.2% of the dislocations were of the posterior or posterior-lateral type. Studies that distinguished between posterior and posterior lateral types showed a frequency distribution of 60% for posterior and 40% for posterior-lateral types. Anterior dislocations were rare (0.4% in adults). Table 1 presents the results of different studies, with respect to the distribution of dislocation type.

b) Anatomy and stability of the elbow joint

Numerous studies have examined the stability and biomechanics of the elbow joint in cadaver specimens. These in vitro biomechanical studies have important consequences for the diagnosis, treatment and rehabilitation of the elbow joint. The data obtained from these studies inform stability testing and aid in efforts to reduce elbow dislocations, immobilise the joint, and achieve successful surgical reconstruction of collateral ligaments and coronoid process fractures, including effective postoperative treatment. These in vitro biomechanical studies precisely describe the anatomy of the collateral ligaments. Chapter Two of this thesis describes the results of in vitro elbow joint studies.

c) Incidence of simple and complex elbow dislocations

Elbow joint dislocation is the second most commonly observed joint dislocation in adults and is the most common in children [3]. The annual incidence of elbow dislocations in the overall population is 6.1 per 100,000 [2].

Table 1 Types of elbow dislocations in adults, classified by forearm displacement

Study and population	Anterior	Posterior			Lateral	Medial
		Posterior	Posterior-lateral	Posterior-medial		
Josefsson et al. [4], adults; simple		11 (46%)	8 (33%)		5 (21%)	
Josefsson et al. [5], adults; simple		28 (93%)			2 (7%)	
Lansinger et al. [6], adults; simple + complex		33 (49%)	33 (49%)		1 (2%)	
Conn et al. [7], adults; simple + complex		47 (100%)				
Rafai et al.[8], adults; simple		50 (100%)				
Royle [9], adults; simple + complex		9 (28%)	23 (72%)			
Maripuri et al. [10], adults; simple		13 (30%)	25 (60%)	4 (10%)		
Riel et al. [11], adults; simple		29 (58%)	21 (42%)			
Protzman [12], adults; simple + complex		5 (20%)	19 (76%)	1 (4%)		
Mehlhoff [13], adults; simple		46 (88%)		4 (8%)		2 (4%)
Schippinger et al. [14], adults; simple	2 (4%)	31 (68%)	12 (26%)			1 (2%)
Forthman et al. [15], adults; complex		34 (100%)				
Kesmezacar et al. [16], adults; simple		21 (100%)				
Total (n=604)	2 (0.3%)	582 (96.4%)		9 (1.5%)	8 (1.3%)	3 (0.5%)
Distribution in combined group of posterior and posterior-lateral types		60%	40%			

The patients' characteristics are presented in Tables 2, 3 and 4. The elbow dislocations are often associated with fractures. The mean distribution of simple and complex dislocations was 63% and 37%, respectively [2,6,7,9,12].

The difference between the children and adults is the high percentage of medial (epi)condyle fractures in children. Complex elbow dislocations in adults are often associated with fractures of the radial head and coronoid processes; by contrast, elbow dislocations in children are more often complicated by avulsion of the epicondyle. Table 3 presents studies that included adults as well as children. The distribution of the fracture locations was radial head, 38%; coronoid fractures, 14%; olecranon, 5%; capitellum, 5%; medial (epi)condyle, 33%; and lateral (epi)condyle, 5%. Table 4 presents studies that included only adults. The distribution of the fractures was radial head, 49%; coronoid fractures, 26%; olecranon, 7%; capitellum, 6%; medial (epi)condyle, 6%; and lateral (epi)condyle, 6%.

d) Sex of the patients

The sex distribution of elbow dislocation is presented in Table 3. The incidence of fractures is higher in men (57%) than in women (53%) below the age of 55 years [17-19].

Table 2 Epidemiology of elbow dislocation

Study and population	**Type of dislocation**		**Sex**		**Side**		**Handedness**		**On dominant side**
	Simple	Complex	Female	Male	Right	Left	Right	Left	
Josefsson et al. (1986), children + adults [2]	131 (74%)	47 (26%)	85 (48%)	93 (52%)	74 (42%)	104 (58%)	-	-	
Josefsson et al. (1984), children + adults [4]	52 (100%)	-	22 (42%)	30 (58%)	22 (42%)	30 (58%)	52 (100%)	-	22 (42%)
Josefsson et al. (1987), adults [5]	30 (100%)		20 (67%)	10 (33%)	12 (40%)	18 (60%)	-	-	
Lansinger et al., adults [6]	38 (53%)	34 (47%)	35 (49%)	37 (51%)	28 (39%)	44 (61%)	-	-	
Conn et al., adults [7]	24 (51%)	23 (49%)	-	-	-	-	-	-	
Neviaser et al., children + adults [20]	n =115 (simple + complex)		43 (37%)	72 (68%)	37 (32%)	78 (68%)	-	-	
Rafai et al., adults [8]	50 (100%)		7 (14%)	43 (86%)	30 (60%)	20 (40%)	30 (60%)	20 (40%)	50 (100%)
Royle, adults [9]	12 (38%)	20 (62%)	15 (47%)	17 (53%)	11 (34%)	21 (66%)			
Maripuri et al., adults [10]	42 (100%)		23 (55%)	19 (45%)					20 (48%)
Protzman, adults [12]	32 (68%)	15 (32%)							16 (34%)
Mehlhoff, adults [13]	52 (100%)		18 (35%)	34 (65%)	25 (48%)	27 (52%)			
Schippinger et al., adults [14]	45 (100%)		19 (42%)	26 (58%)					
Farron et al., adults [21]	22 (100%)		12 (55%)	10 (45%)					7 (32%)
Van der Ley et al., adults [22]	20 (100%)		11 (55%)	9 (45%)					
Forthman et al., adults [15]		34 (100%)	15 (44%)	19 (56%)	15 (44%)	19 (56%)	30 (88%)	4 (12%)	15 (44%)
Egol et al., adults [23]		29 (100%)							17 (59%)
Eygendaal et al., adults [24]	41 (100%)		17 (41%)	24 (59%)	18 (44%)	23 (56%)			22 (54%)
Kesmezacar et al., adults [16]	21 (100%)		5 (24%)	16 (76%)					
Total			347 (43%)	459 (57%)	272 (41%)	384 (59%)	112 (82%)	24 (18%)	169/317 (53%)

Table 3 Fracture locations in complex elbow dislocations in clinical studies (adults and children)

Study and population	Fractures					
	radial head	**coronoid**	**olecranon**	**capitellum**	**medial (epi)condyle**	**lateral (epi)condyle**
Josefsson et al., (1986) children + adults [2]	17 (30%)	6 (11%)	2 (4%)	4 (7%)	22 (39%)	5 (9%)
Neviaser et al., children + adults [20]	12 (19.3%)	5 (8.0%)	2 (3.2%)	4 (6.5%)	35 (56.5%)	4 (6.5%)
Kotter et al., children + adults [25]	37 (52%)	14 (20%)	4 (6%)		16 (22%)	
Total	66 (38%)	25 (14%)	8 (5%)	8 (5%)	57 (33%)	9 (5%)
				Total (epi)condyle	82 (43%)	

Table 4 Fracture locations in complex elbow dislocations, in adults

Study and population	Fractures					
	radial head	**coronoid**	**olecranon**	**capitellum**	**medial (epi)condyle**	**lateral (epi)condyle**
Lansinger et al., adults [6]	20 (48%)	6 (14%)	5 (12%)	3 (7%)	2 (5%)	6 (14%)
Conn et al., adults [7]	14 (58%)	4 (17%)		1 (4%)	3 (13%)	2 (8%)
Royle, adults [9]	12 (43%)	6 (21%)	4 (14%)	1 (4%)	4 (14%)	1 (4%)
Riel et al., adults [11]	5 (42%)	3 (25%)		2 (17%)	1 (8%)	1 (8%)
Forthman et al., adults [15]	30 (52%)	23 (40%)	2 (3%)	3 (5%)		
Total	81 (49%)	42 (26%)	11 (7%)	10 (6%)	10 (6%)	10 (6%)

e) Side of dislocation and patient handedness

In isolated fractures, the majority of upper limb fractures proximal to the wrist occur on the left side. Conversely, fractures distal to the wrist occur more frequently on the right side in isolated injuries [26]. The clinical impression has been that elbow dislocations occur more often on the left and non-dominant side. In the first edition of Morrey's book, *The elbow and its disorders*, the author of the chapter on elbow dislocations assumed that this was the result of employment of the dominant arm or unconscious protection of the dominant arm at the time of injury [3]. Table 3 presents the side of the elbow dislocation and the handedness of the patients from different studies on elbow dislocations. Fifty-nine percent of the patients had a dislocation on the left side. Fifty-three percent of the dislocations were on the dominant side. Therefore, elbow dislocations are more often seen on the left side, but this probably has no relation with handedness.

f) Motions of the elbow joint

The normal range of motion of the elbow joint has been studied and documented. The elbow is a hinge joint allowing flexion and extension. The proximal radio-ulnar joint permits rotation, which is called pronation and supination. According to The American Academy of Orthopaedic Surgeons, which is based on four studies, the average ranges of elbow motion are: flexion, 146°; extension, 0°; pronation, 71°; and supination, 84° [27]. During the progression from extension to full flexion, the elbow joint travels from the valgus to the varus position. The forearm moves from internal rotation to external rotation [28].

Is it possible to compare the range of motion of the elbow with the other side? Günal et al. compared the range of motion of the left and right elbow joint, as estimated with a manual goniometer in 1,000 healthy male subjects with right-hand dominance [29]. Significant differences were found between the left and right sides and between active and passive motion, with higher values for the left side and for passive ranges of motion. Therefore, comparisons with the contra lateral elbow joint may not always be a reliable control.

How reliable are measurements of the range of motion of the elbow joint? Armstrong et al. examined the reliability of standardised range-of-motion measurements of the elbow with three different devices [30]. Intra-tester or intra-observer reliability is the correlation of two measurements by the same tester or observer. Inter-tester or inter-observer reliability is the correlation of two measurements by two different testers or observers. The universal standard mechanical goniometer showed meaningful changes in intra-tester standardised range of motion measurements if they were greater than 6° of flexion, 7° of extension or 8° of pronation or supination. The universal standard mechanical goniometer showed meaningful changes in inter-tester standardised range of motion measurements if they were greater than 10° of flexion, 10° of extension, 10° of pronation or 11 ° of supination.

The normal elbow joint motion and the amount of elbow motion needed for activities of daily living (ADL) has been investigated in three studies [31-33]. Morrey et al. examined the amount of elbow motion required for ADL in 33 healthy persons with an electrogoniometer. Most of the ADL could be accomplished with 100° of elbow flexion (from 30° to 130°) and 100° of forearm rotation (50° of pronation and 50° of supination) [31]. The functional elbow range of motion was determined with a standard goniometer in 50 healthy adults by Vasen et al. [33]. Subjects performed 12 ADL while elbow flexion and extension were limited by an orthesis in serial increments of 15°. The range of elbow motion was determined while allowing compensatory motion of other joints. With this study design, the functional elbow range of motion was established as 75°-120° of flexion. Raiss et al. studied the range of motion of the elbow with a three-dimensional motion analysis system in ten ADL [32]. To perform the ten ADL, elbow extension and flexion of 0°-36°-146° (total 110°) and pro- and supination of 55°-0°-72° (total 127°) were needed. A large number of activities of ADL occur with the upper extremity in a shoulder-abducted position and produce varus moments at the elbow joint.

g) Patient-reported outcome measures

The Cochrane Collaboration's definition of a patient-reported outcome measure (PROM) is "any report coming directly from patients about how they function or feel in relation to a health condition and its therapy, without interpretation of the patient's responses by a clinician, or anyone else" [34]. In the Netherlands, the *Quick*DASH questionnaire (Disability of the Arm, Shoulder and Hand questionnaire) is used to measure the state of the upper extremity before and after therapy [35]. The 11-item *Quick*DASH is a shortened version of the 30-item DASH, which was designed to measure physical function and symptoms in patients with musculoskeletal disorders of the upper limb. Both the DASH and *Quick*DASH have two four-item optional modules, one related to performing sports and/or playing a musical instrument and one related to work. The Oxford elbow score (OES) is a specific questionnaire that measures the quality of life of patients with disorders of the elbow joint [36]. The OES was designed to measure the outcome of elbow surgery from the patient's perspective. The OES is a 12-item PROM, which makes it an important outcome measure that is independent of the evaluation of the medical team. The OES was translated in Dutch because a Dutch language version was not available. Chapter three describes a study that investigated the development and evaluation of the reliability, validity and responsiveness of this Dutch language version of the OES.

h) Pathophysiology of elbow dislocation

Elbow dislocation is usually a low-energy trauma with severe soft-tissue injury. The most common cause is a fall on the outstretched hand, often during sport. A fall on the outstretched hand with the shoulder abducted produces an axial force on the elbow while flexing. As the body internally rotates on the hand and approaches the ground, external rotation and valgus stresses are applied to the elbow [37]. Table 5 presents the mechanism and circumstances of the injury that led to the dislocation.

Table 5 Pathophysiology of injury in elbow dislocations

Study and population	**Type dislocation**		**Mechanism and circumstances of injury**
	Simple	Complex	
Josefsson et al. (1986), children + adults [2]	131 (74%)	47 (26%)	N=178 fall (100%), n=51 fall at the same level, n=127 fall at a higher level or the same level + impact energy → n=56 sport, n=20 playing, n=18 traffic, n=57 other known, n=27 unknown
Josefsson et al. (1984), children + adults [4]	52 (100%)	-	N=13 sport, n=11 playing, n=11 bicycle, n=3 work
Neviaser et al., children + adults [20]	n =115 (simple + complex)		N=30 fall, n=29 direct trauma, n=56 unknown
Rafai et al, adults [8]	50 (100%)		N=23 fall (46%), n=16 sport (32%), n=1 other
Royle, adults [9]	12 (38%)	20 (62%)	N=23 fall (72%), n=6 sport, n=1 traffic, n=1 industrial accident, n=1 assault
Protzman, adults [12]	32 (68%)	15 (32%)	N=41 sport, n=6 traffic or industrial trauma or other
Lansinger et al., adults [6]	38 (53%)	34 (47%)	N=67 fall, n=3 traffic, n=2 direct trauma
Farron et al., adults [21]	22 (100%)		N=22 fall (100%) → n=12 daily activity, n=7 sport, n=2 work related, n=1 traffic
Forthman et al., adults [15]		34 (100%)	N=32 fall (94%), n=2 traffic
Eygendaal et al., adults [24]	41 (100%)		N=16 sport, n=17 at home, n=8 traffic

i) Treatment of simple and complex elbow dislocations

Residual loss of motion after elbow joint dislocation is common. Recurrent instability is rare because of the anatomy of the articulation and the dynamic stability that the muscles provide. After reduction of the simple dislocation, treatment options include immobilisation in a static plaster for different periods, surgical treatment of the ruptured medial and lateral collateral ligaments or so-called functional treatment, which is characterised by early active motion within the limits of pain with or without the use of a hinged brace or functional plaster. In theory, after reduction of a simple elbow dislocation, the joint retains an inherent stability, which is created by the contour of the intact joint surfaces. A systematic review of the literature has been performed to identify whether functional treatment is the best available treatment for simple elbow dislocations after closed reduction. The results of this review are described in Chapter Five of this thesis.

In Chapter Six, a survey performed by Dutch surgeons is described in order to elucidate current treatment of simple elbow dislocations.

In Chapter Seven, the protocol of a randomised controlled trial comparing early functional treatment to plaster immobilisation following simple dislocation of the elbow is presented [38].

An analogy with the healing of the medial collateral ligament of the knee can help in choosing functional treatment with early motion for elbow dislocations. Enhanced healing and improved biomechanical properties have been observed in dogs and rabbits with injured medial collateral ligaments of the knee treated with early motion as compared with immobilisation [39,40].

The fundamental goal in the management of fracture dislocation of the elbow is the restoration of osseous-articular restraint. Therefore, the majority of these complex dislocations are treated with open reduction and internal fixation (ORIF) [41]. Unstable simple elbow dislocations can be treated by suturing the collateral ligaments and with or without a hinged external fixator. A systematic review of the literature to identify the results of available treatment options for complex elbow dislocations and unstable simple elbow dislocations is described in Chapter Eight. A retrospective multicentre cohort study to assess the long-term outcomes of simple and complex elbow dislocations is presented in Chapter Nine [42]. In Chapter Ten, the protocol from a prospective cohort study using a hinged external fixator for complex dislocations of the elbow is presented. The aim of this cohort study is to determine the effect of early mobilisation with a hinged external elbow fixator on clinical outcome in patients with complex elbow dislocations with residual instability following open reduction and internal fixation (ORIF).

j) Treatment of radial head fractures

Adequate treatment of radial head fractures is extremely important, as it is the most frequent fracture in the context of complex elbow dislocation and because of its important role in valgus and axial instability of the forearm. Radial head fractures are common: the

annual incidence is 2.8 per 10,000 inhabitants. However, the association of radial head fractures with elbow dislocations is weak, only 2.5% [43].
Mason introduced a radiographic classification of radial head fractures that was extended by Johnston [44,45]. The radial head fracture classification proposed by Mason-Johnston is as follows:

- Type I undisplaced fracture,
- Type II displaced fracture,
- Type III comminuted fracture,
- Type IV with dislocation of the elbow.

This classification is moderately reliable, as the multirater kappa for interobserver reliability for Mason type I and II fractures was 0.45 [46].

Modern imaging techniques as three-dimensional computed tomography has shown that Mason type II fractures are usually multi-fragmented and often have small fragments by volume and surface area criteria [47].

Radial head fractures are often associated with fractures of the elbow (coronoid, olecranon) and with soft-tissue injuries, such as those of the MCL, LCL and interosseous membrane [48,49]. The classification of Mason types is associated with the severity of the soft-tissue injuries [48]. Mason type I fractures can be treated without operation with excellent results, especially when treated with early active motion [50]. Historically, Mason type II fractures were an indication for surgery when the dislocation of a displaced fragment was more than 2 mm, had a size larger than 33% of the articular surface, when this interfered with rotation of the elbow joint, or when this was associated with injuries that increase instability [51].

Different studies described fair to excellent results in non-comminuted Mason II and III fractures but unsatisfactory outcomes in comminuted Mason II and III fractures [52-55]. Because the radial head fractures with more than three fragments treated with ORIF are associated with worse outcomes, it is likely advisable to treat them with replacement of the radial head.

A prosthetic replacement should resist valgus and posterior instability forces and prevent proximal radial migration. The options for replacements are silicone or metallic prostheses or allografts. The use of radial head allografts showed favourable results in a study that included five patients [56]. However, this approach failed in another study of four cases with axial instability (Essex-Lopresti injury) [57]. A silicone radial head prosthesis did not improve valgus stability in an MCL-deficient cadaveric elbow study [58]. However, in this cadaveric study, the metallic radial head prosthesis improved valgus stability to a level approaching that of an intact head. The results of metallic radial head implants with a modular design in patients with radial head fractures with gross instability were good to excellent after a follow-up of 12.1 years [59]. Therefore metallic prostheses are preferred. In placing the prosthesis, care should be taken not to overstuff the joint [60].

k) Heterotopic ossification

Heterotopic ossification is a complication after elbow trauma, occurring in up to 55% of elbow dislocations [61]. Concomitant head trauma is a risk factor for this complication. The incidence of heterotopic ossification with combined head and elbow injuries was 89% [62]. Symptoms are pain, loss of motion and impaired function. Radiologic assessment is carried out by antero-posterior and lateral radiographs and with computed tomography scans [63]. Determination of the activity of heterotopic ossification by estimating the level of serum alkaline phosphatase has been advised, but its relevancy is doubtful [64]. Progression should be evaluated radiographically. Maturation of heterotopic ossification can take about three to six months [63]. In a recent randomised controlled trial, single-fraction radiation therapy was compared with a control group as prophylaxis for heterotopic ossification [65]. This study was terminated because of the high rate of non-union in the treatment group (38% versus 4%). Because of the low sample size at the time of termination, the efficacy of the prophylaxis could not be determined.

Non-steroidal anti-inflammatory drugs are used to prevent the occurrence of heterotopic ossification. In the context of hip arthroplasty, these drugs have shown to reduce risk (62% reduction) for heterotopic ossification in a Cochrane meta-analysis [66]. Unfortunately, no randomised controlled trials have been performed with non-steroidal anti-inflammatory drugs as prevention for heterotopic ossification in the elbow [63].

If limited elbow range of motion prevents functional use of the upper extremity, the heterotopic ossification can be treated by surgical excision [61]. During surgery, special care should be taken of the nerves, when compressed by the heterotopic ossification. The ulnar nerve is most commonly affected. According to general opinion, the incidence of a recurrence of heterotopic ossification is increased after its excision, especially when performed during the early acute phase.

l) Post-traumatic stiffness of the elbow

As already discussed in the diagnosis section, most of the ADL could be accomplished with 100° of elbow flexion (from 30° to 130°) and 100° of forearm rotation (50° of pronation and 50° of supination). For most professions and for most activities, an extension deficit of more than 15° and a flexion deficit of more than 20° of the elbow joint can be defined as a stiff elbow. However, some professions, such as police work and flying an airplane, and activities such as biking, are difficult to perform with this level of stiffness. These activities demand a better range of motion. In a stable elbow joint, post-traumatic stiffness might be prevented with early motion. Chapter Five presents a systematic review of the literature to identify whether functional treatment with early motion is the best available treatment for simple elbow dislocations after closed reduction and can prevent elbow stiffness. The optimal treatment for stiff elbow is dictated by the cause of injury. When the stiffness is caused by contracture of the soft tissues around the elbow, non-surgical treatment starts with the use of splints [61,63]. When conservative treatment fails, surgical release of the elbow can be performed using an open or arthroscopic procedure. Another possibility is closed distraction with an external fixator intra-operatively, followed by mobilisation with a hinged external fixator postoperatively to maintain distraction in the joint [67,68].

Thesis outline

Chapter One is the introduction and thesis outline.

Chapter Two presents a literature overview of the stability of the elbow joint with relevant anatomy and clinical implications of in vitro biomechanical studies.

Chapter Three presents a study on the reliability, validity and responsiveness of the Dutch Oxford elbow score.

Chapter Four consists of a Rasch analysis of the Dutch version of the Oxford elbow score.

Chapter Five is a systematic review of the literature on the treatment of simple elbow dislocations.

Chapter Six presents a survey on treatment of simple elbow dislocations in the Netherlands.

Chapter Seven presents a study protocol comparing functional treatment versus plaster immobilisation for simple elbow dislocations using a randomised controlled trial design.

Chapter Eight is a systematic review of treatment of complex elbow dislocations.

Chapter Nine reports results of a retrospective multicentre study of 86 patients with an elbow dislocation.

Chapter Ten presents a study protocol for complex elbow dislocations using a hinged external fixator using a prospective cohort design.

Chapter Eleven is the discussion.

Chapter Twelve is the summary.

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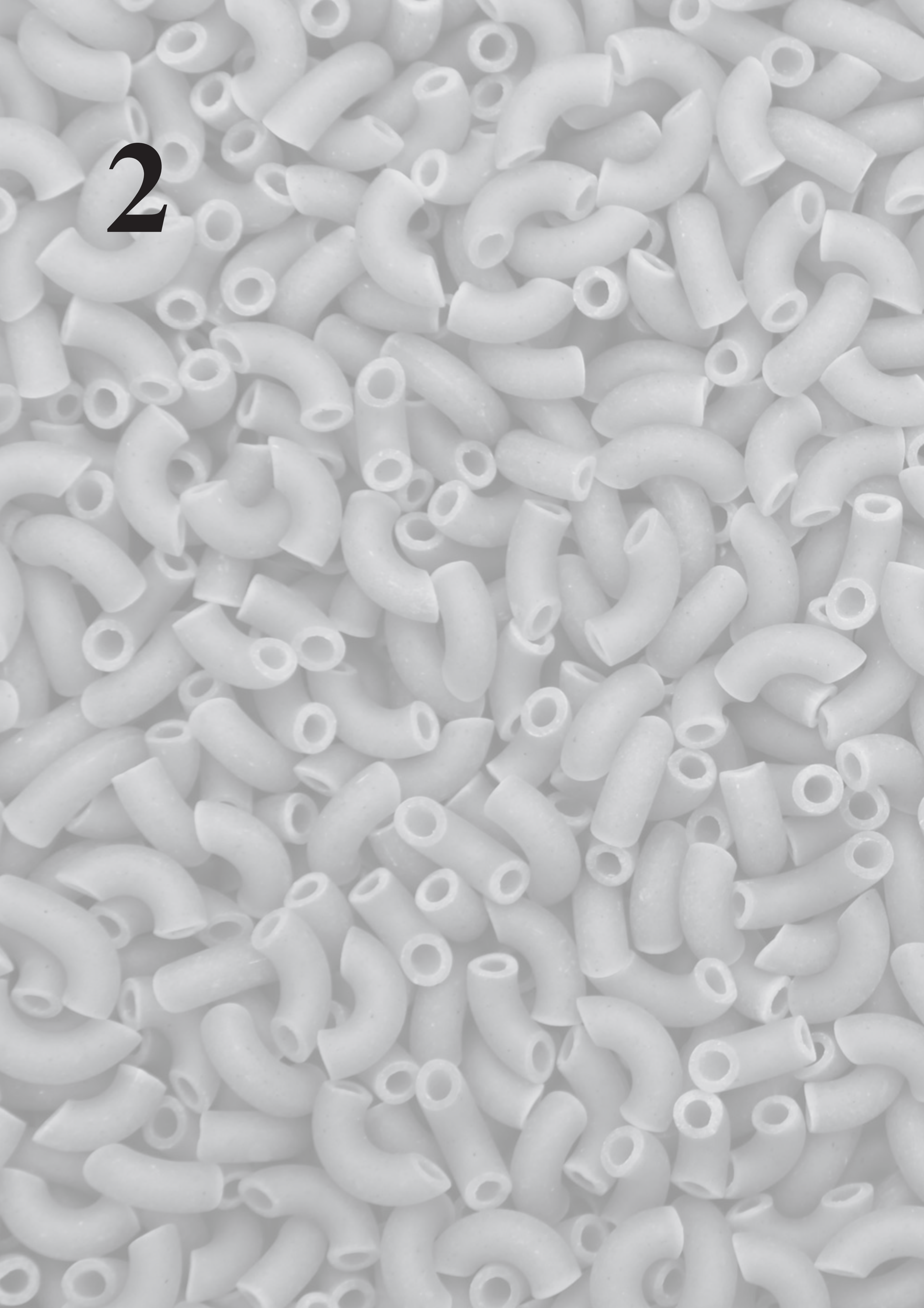

Stability of the elbow joint: relevant anatomy and clinical implications of in vitro biomechanical studies

J. de Haan
N.W.L. Schep
D. Eygendaal
G-J. Kleinrensink
W.E. Tuinebreijer
D. den Hartog

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Abstract

The aim of this literature review is to describe the clinical anatomy of the elbow joint based on information from *in vitro* biomechanical studies. The clinical consequences of this literature review are described and recommendations are given for the treatment of elbow joint dislocation.

The PubMed and EMBASE electronic databases and the Cochrane Central Register of Controlled Trials were searched. Studies were eligible for inclusion if they included observations of the anatomy and biomechanics of the elbow joint in human anatomic specimens.

Numerous studies of the kinematic, kinesiology and anatomy of the elbow joint in human anatomic specimens yielded important and interesting implications for trauma and orthopaedic surgeons.

Introduction

The elbow joint is the second most commonly dislocated joint in adults [1]. During a period of twelve years, Josefsson et al. reported 178 elbow dislocations (simple and complex) in a population of approximately 243,000 persons, making the annual incidence of elbow dislocations in children and adults 6.1 per 100,000 [2].

Elbow dislocations are classified as simple or complex [3]. Simple dislocations are dislocations without fractures. Complex dislocations are associated with fractures of the distal humerus, radial head, proximal ulna and/or coronoid process. The combination of an elbow dislocation with a fracture of the radial head and the coronoid process is called a "terrible triad" due to the high rate of complications. Surgeons treating elbow dislocation are concerned about two complications: stiffness and instability of the elbow joint. Stiffness or restricted range of motion and instability can be seen as contrasts on a seesaw (Fig. 1). Range of motion can be measured reliably with a standard goniometer for assessing stiffness [4]. Instability can be classified, according to the timing, as acute or chronic instability or recurrent dislocation. In a review of simple elbow dislocation, including eight studies with a total of 342 patients, only one recurrent dislocation was mentioned [5]. Despite this low recurrence rate, surgeons prefer long immobilisation to prevent instability over early functional treatment to prevent restricted range of motion [6]. This preference is valid because it is easier to treat stiffness than instability of the elbow joint. For most activities of daily living, restricted range of motion is not a major problem. In a study by Morrey et al., most of the activities of daily living could be accomplished with a 100° arc of motion (from 30° to 130°) and 100° of forearm rotation (50° of pronation and 50° of supination) [7].

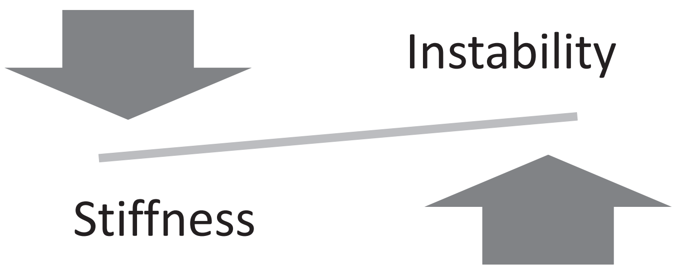

Fig 1 The two contrasting complications of elbow joint dislocations: stiffness and instability

During dislocation of the elbow joint, ligamentous damage occurs in a circle from lateral to medial, as described by O'Driscoll [8]. Shortly after dislocation, the elbow joint is unstable when examined during general anaesthesia. In three studies analysing patients with simple elbow dislocations, all (n=123) were evaluated and classified as unstable for valgus stress, when compared to the uninjured side examined under anaesthesia [9-11]. In two of these studies, varus stress was evaluated as well and was present in 39% (24/61) of all patients. Posterolateral rotatory stability was not assessed in any of these studies [9,11]. The operated cases in these studies (n=78) were all explored at the medial side of the elbow. The medial collateral ligament was completely ruptured or avulsed from the epicondyle in all cases. In 46 of the 78 operated cases (59%), the lateral side was explored, and in all cases, the lateral collateral ligament was completely ruptured or avulsed from the epicondyle. Despite these ruptures of both collateral ligaments, patients can be treated functionally, which is characterised by early active motion within the limits of pain with or without the use of a sling, hinged brace or functional plaster. This functional treatment is possible because of the functional, dynamic joint stability. Dynamic joint stability is due to compression forces produced by the muscles crossing the elbow joint. Physical examination of the elbow joint during circumstances that eliminate this dynamic stability can reveal chronic instability long after dislocation of an elbow. For instance, in 24 of the 41 examined cases (59%), Eygendaal et al. reported persistent medial instability on dynamic radiographs with valgus loads after an average of 9 years after a simple dislocation. Magnetic resonance imaging combined with arthrography revealed that 42% (n=19 tested) of these cases with medial instability on dynamic radiographs had a rupture of the medial collateral ligament. No recurrent elbow dislocations were noted [12].

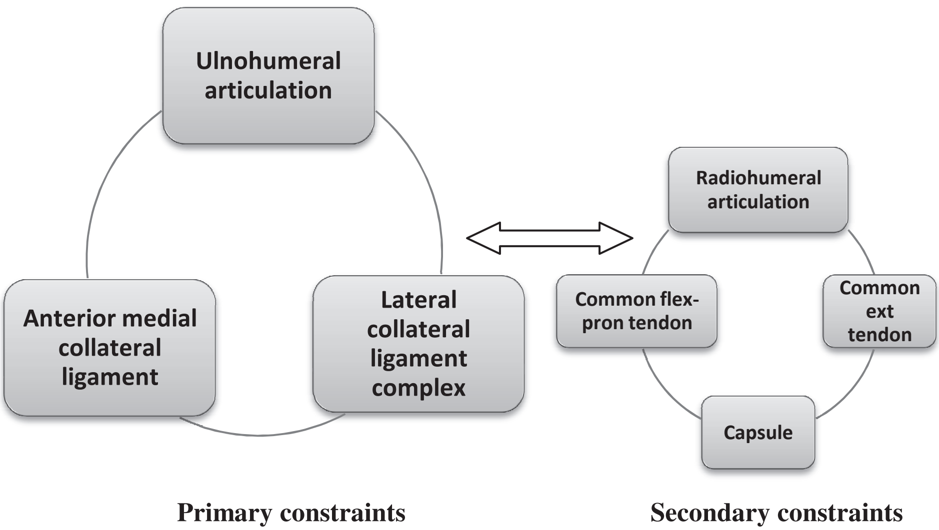

Fig 2 Primary and secondary constraints to elbow joint stability

The stability and biomechanics of the elbow joint have been examined in numerous studies of human anatomic specimens [13,14]. Joint stability can be functionally

divided in static and dynamic aspects. Static stability is controlled by the osteoarticular architecture and the capsule and ligamentous parts. Dynamic stability is determined by neuromuscular factors. In the elbow joint, this specifically means that the static part is mainly provided by the congruency between the articulating surfaces at the elbow joint. The other static stabilisers are the anterior joint capsule, the medial and lateral collateral ligaments and the interosseous membrane. The dynamic part includes the muscles that cross the elbow joint. The stabilisers of the elbow joint are divided into primary and secondary constraints (Fig. 2). A primary constraint is defined as a constraint where release causes laxity, and a secondary constraint is a constraint where release alone is insufficient to cause laxity, but where release after division of the fist constraint increases the laxity of the joint. The primary constraints are the anterior medial collateral ligament (AMCL), the lateral collateral ligament complex (LCLC) and the ulnohumeral articulation. The secondary constraints are the radiohumeral articulation, the common flexor-pronator tendon, the common extensor tendon and the capsule.
Stability studies on elbow joints of anatomic specimens often start with an extensive anatomical examination of the collateral ligament complexes. These *in vitro* biomechanical studies also have important consequences for diagnosis, treatment and rehabilitation of (post)-traumatic injuries of the elbow joint. The aim of this literature review was to describe the clinical anatomy of the elbow joint. The clinical consequences of this literature review are described and recommendations are given for the treatment of dislocation of the elbow joint.

Materials and methods

The authors have systematically screened the PubMed (until September 2010), EMBASE (1980 - September 2010) and Cochrane Controlled Trials Register electronic databases. As main keywords, we used 'Elbow; Adult; Elbow Joint/in [Injuries]; Elbow Joint/su [Surgery]; English Abstract; Dislocation; Fractures/su [Surgery]; Human; Male; Female; Radius; Radial head; Radius Fractures; Radius Fractures/su [Surgery]; Radius Fractures/tr [Treatment].' Articles in languages other than English, French, German or Dutch were excluded. Of all the articles selected, the reference lists were searched for additional articles, surgical reconstruction techniques and postoperative treatments. Studies were eligible for inclusion if they included anatomy and biomechanics of the elbow joint, as observed on human anatomic specimens.

Results

Anatomy of ligamentous elbow joint stability

The literature search retrieved 108 studies. Thirty-nine studies examining biomechanics and anatomy of the elbow joint on human anatomic specimen were selected for this review. Studies about biomechanics of the elbow joint often refer to the article by Schwab et al., published in 1980 [15]. This study describes the anatomy of the elbow joint and biomechanics of the medial collateral ligament from the clinical point of view. Many of the author's insights were later proven to be true in studies on elbow joints of human anatomic specimens. The humeral origin of the medial collateral ligament (MCL) is reported to be located eccentrically with respect to the axis of rotation of the joint. The MCL consists of an anterior bundle, AMCL, posterior bundle or PMCL and a transverse ligament; the last structure does not span the joint and therefore does not contribute to stability. The AMCL is divided in two functional components and is taut throughout the full range of flexion and extension because the components are alternatively tightening throughout this range of motion. The posterior part of the AMCL is taut from 80° flexion to full flexion; in contrast, the anterior part of the AMCL is taut in extension. The AMCL is a stronger ligament than the PMCL and acts as the major medial ligamentous joint stabiliser. According to Schwab's article, the lateral collateral ligament (LCL) runs from the lateral epicondyle to the annular ligament (AL) without attachments to the ulna, so the lateral ulnar collateral ligament (LUCL) and the accessory lateral ligament were not described. Morrey and An studied the functional anatomy of the ligaments of the elbow in ten fresh-frozen upper extremities and a quantitative dissection and described the collateral ligaments (Fig. 3) [16]. They describe an MCL complex (MCLC) consisting of the separately defined anterior (oblique) bundle (AMCL), a posterior bundle (PMCL) and a transverse segment. The transverse segment runs from the coronoid to the tip of the olecranon, i.e., one part of the ulna to another part of the ulna. It is often not well defined and apparently contributes little to nothing to elbow stability because it originates from and inserts on the ulna. The transverse part of the MCL is also called Cooper's ligament [17]. The LCLC consists of the AL, radial collateral ligament or LCL, accessory lateral ligament and the LUCL (Fig. 4). The LCL is poorly demarcated and runs from the lateral epicondyle to the annular ligament. The accessory posterior ligament runs from the lateral epicondyle to the crista supinatoris of the ulna together with the inferior margin of the AL. In five of the ten specimens, the LUCL runs from the lateral epicondyle to the crista supinatoris of the ulna. In a later publication, this ratio of 5 to 10 was corrected: it was found in nine of the specimens and, in the tenth, was present but underdeveloped [18]. In this later anatomical study, the LUCL was observed in all 17 examined fresh-frozen elbows [18]. This LUCL was already described in 1958 by Martin as a bundle, but without naming it: "a definite bundle which normally crosses the annular band and gains attachment to the supinator crest, frequently to a special tubercle on that crest" [19].

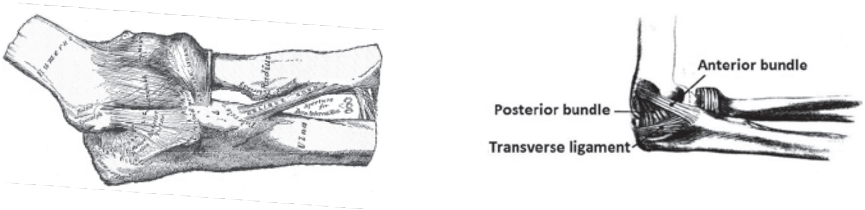

Fig 3 Left elbow joint with medial collateral ligaments [20]

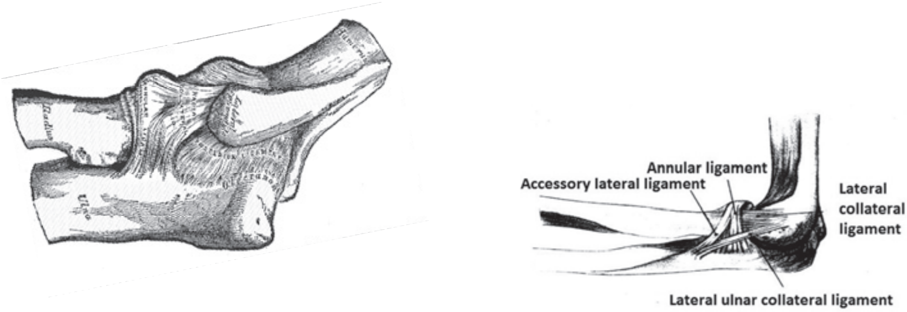

Fig 4 Left elbow joint with lateral collateral ligaments [20]

Regan et al. [21] extended the functional anatomy study of Morrey and An [16], which defined the axis of rotation of the LCL and MCL and the elongation-tension relationships of the AMCL, PMCL and the LCL. In the first part of this study, the ranges of the elbow joint angle were examined. In this area, the ligaments of the elbow are tense or taut. The AMCL and LCL were taut throughout almost the entire arc of flexion. The PMCL was taut only when the elbow was in a flexed position. In the second part of this study, the structural properties of each collateral ligament were determined. The load to failure of each ligament was studied. The AMCL was the strongest and stiffest ligament, followed by the LCL. The weakest ligament was the PMCL.

Cohen et al. examined 40 elbows of human anatomic specimens to characterise the anatomy of the LCLC [22]. The LCL and the AL formed a broad conjoined insertion onto the proximal aspect of the ulna in all 40 specimens (Fig. 5). This conjoined tendon became taut with the forearm upon supination. In 22 specimens, the LCLC had a double, bidirectional insertion onto the ulna. In 18 specimens, a single broad conjoined ligament inserted onto the ulna. A separate band from the lateral epicondyle to the ulna, such as the LUCL in Figure 3, was not identified. The LCL and AL became confluent with the overlying supinator tendon and so the supinator tendon reinforced the LCL and AL. A distinct band of the extensor carpi ulnaris fascia coursed from the inferior aspect of the lateral epicondyle to the ulna in 36 specimens.

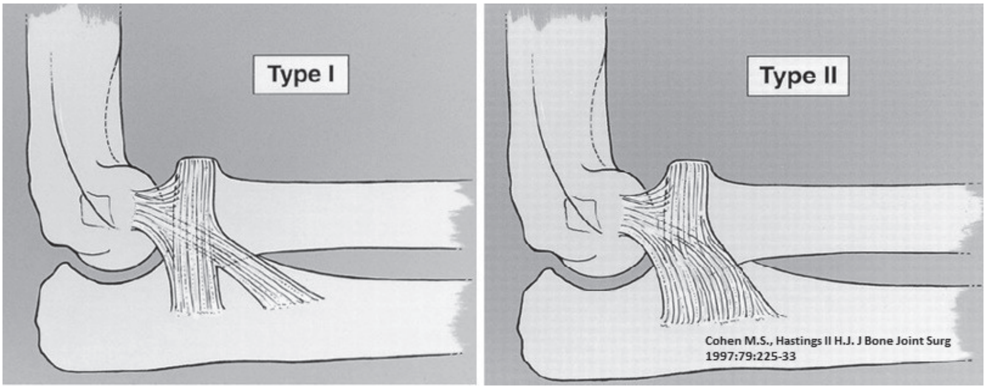

Fig 5 Insertion (type 1 and 2) of the lateral collateral ligament and annular ligament onto the ulna. (Reprinted from Journal of Bone and Joint Surgery American, 1997, volume 79, 2, Rotatory instability of the elbow. The anatomy and role of the lateral stabilizers, Cohen MS and Hastings H, 225-233, with permission from Rockwater and Journal of Bone and Joint Surgery)

Another anatomical study was performed by Beckett et al., who examined the anatomical variations of the medial and lateral collateral ligament complexes [23]. These variations occurred on the medial side in 50% of the 39 cadaveric elbow joints and on the lateral side in 25%. The MCLC and LCLC were divided in four distinct groups.
Group MCLC 1 (49%) was the normal group with classic AMCL, PMCL and transverse or oblique band anatomy.

Group MCLC 2 was the strong oblique group (28%), with a broad fan-shaped insertion of the transverse or oblique band not only at the coronoid process but also in the anterior band. Group MCLC 3 (8%) resembled the normal group but had an additional band passing from the posterior capsule to the oblique or transverse band.

Group MCLC 4 (15%) exhibited a pattern that was a combination of that exhibited in groups 2 and 3.

In group LCLC 1 (23%), only the LCL and AL were present.

In group LCLC 2 (44%), the LCL, AL and LUCL were present.

Group LCLC 3 (25%) exhibited the LCL, the AL and an accessory collateral ligament.

Group LCLC 4 (7%) exhibited a pattern that was a combination of that exhibited in groups 2 and 3.

A remarkable result of this study is that the transverse or oblique band of the MCLC is not poorly developed, as reported earlier [16]. The accessory collateral ligament of the LCLC was already described in the study by Martin and the study by Morrey and An as the “accessory posterior ligament” [16,19].

Callaway et al. examined the anatomy of the anterior bundle of the medial collateral ligament (AMCL) in 28 anatomic specimens [24]. The AMCL consisted of anterior and posterior bands that tightened in reciprocal fashion as the elbow was flexed and extended. The anterior band of the AMCL is taut in extension and relaxed in flexion; the posterior band of the AMCL behaves in a reciprocal fashion. Isometric fibres are found between the anterior and posterior bands of the AMCL (Fig. 6).

Fuss also examined the MCL by visual inspection for the presence of taut fibre bundles [17]. He also concluded that the posterior part of the MCL was taut when the elbow was fully flexed. The anterior part of the MCL contained some fibres that were taut in full extension and some that were taut in any position (isometric fibres). Because this bundle guides the joint's movements, Fuss called these fibres "the guiding bundle".

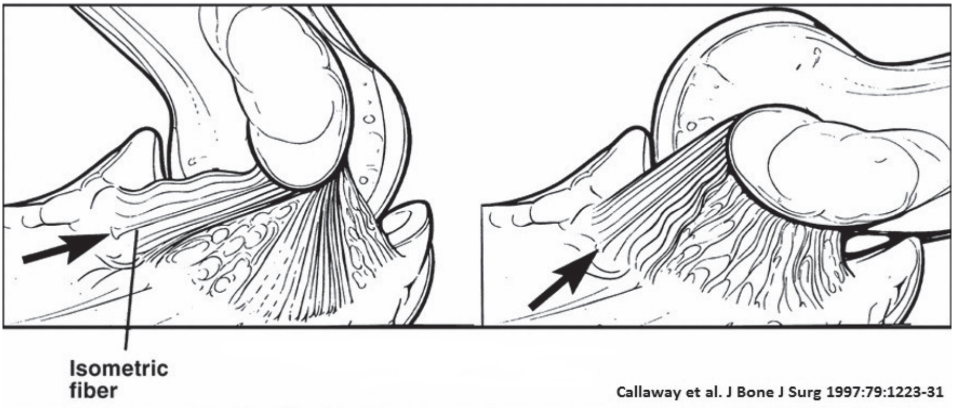

Fig 6 The anterior and posterior bands of the anterior bundle (AMCL) tighten in reciprocal fashion as the elbow is flexed and extended; they are separated by isometric fibres (arrows). (Reprinted from Journal of Bone and Joint Surgery American, 1997, volume 79, 8, Biomechanical evaluation of the medial collateral ligament of the elbow, Callaway GH, Field LD, Deng XH, *et al.* 1223-1231, with permission from Rockwater and Journal of Bone and Joint Surgery)

However, Armstrong et al. could not find true isometric fibres in the AMCL during combined supination and passive flexion in twelve elbow specimens [25]. The smallest distance between the attachment sites of the AMCL on the medial epicondyle and the ulna was found on the lateral aspect of the attachment site of the AMCL on the medial epicondyle. This point was near the axis of rotation.

An anatomic and histological study of the LCLC was performed by Imatani et al. [26]. Fifteen elbow specimens were examined to characterise macroscopic and microscopic aspects of the LCLC. The LUCL adhered closely to the supinator and extensor muscles, its intermuscular fascia and the anconeus muscle. The LUCL lies posterior to the LCL and the extensor carpi ulnaris muscle. Microscopically, the LUCL was a slender and vague structure and consisted of the thick area of the capsuloligamentous layer.

Floris et al. examined the anatomy of the AMCL in 18 osteoligamentous elbow joint specimens [27]. In all specimens, the AMCL was a distinct structure with a macroscopically visible ridge between the anterior and posterior bands.
Seki et al. published a study of the LCLC in five osteoligamentous elbow preparations, which was a continuation of a previous study written in Japanese [28]. This Japanese study revealed that the LCLC of the elbow has a Y-shaped configuration, which consists of a superior, an anterior and a posterior band (Fig. 7).

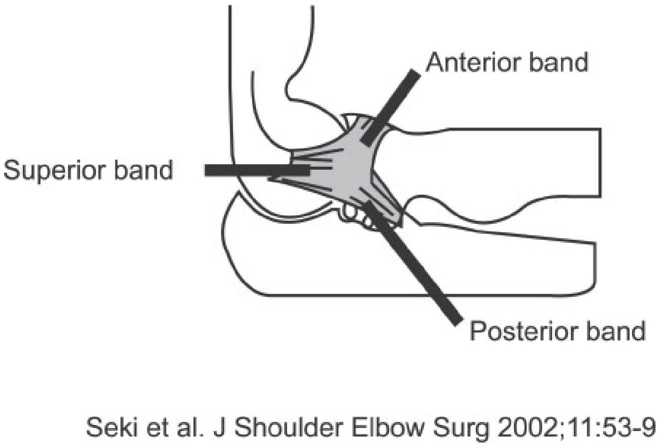

Fig 7 The three bands of the Y structure in the lateral collateral ligament complex (LCLC). (Reprinted from Journal of Shoulder and Elbow Surgery, volume 11, Seki A, Olsen BS, Jensen SL, Eygendaal D, Sojbjerg JO, Functional anatomy of the lateral collateral ligament complex of the elbow: configuration of Y and its role, 53-59, Copyright 2002, with permission from Elsevier)

Regan and Morrey examined 35 patients with a coronoid fracture of the ulna and developed a classification system for coronoid fractures: type I with avulsion of the tip, type II with a fragment involving 50% or less of the process, and type III with a fragment involving more than 50% of the coronoid process [29]. This classification correlated well with the clinical outcome.

Cage et al. investigated 20 elbows of human anatomic specimens to identify the soft tissue attachments of the coronoid process and correlated this anatomy with the radiographic classification of Regan and Morrey [30]. The AMCL insertion had an average distance of 18.4 mm dorsal to the coronoid tip and was attached to the free bone fragment, only in type III fractures. The capsule inserted an average distance of 6.4 mm distal to the coronoid tip; in only three of the 20 specimens, the capsule inserted to the tip of the coronoid. Type I fractures are usually intra-articular and the anterior capsule is attached to the fragment of type II fractures. The brachialis muscle had insertions at the elbow capsule, coronoid and proximal ulna. The bony insertion had an average length of 26.3 mm, with its proximal margin an average distance of 11 mm to the coronoid tip. Only type III fractures are large enough to include the brachialis tendon insertion and the AMCL insertion.

Takigawa et al. have investigated the anatomy and function of the LUCL in 26 fresh-frozen anatomic specimens [31]. The LCLC consisted of three main fibre bundles. The LCL ran from the inferior part of the lateral epicondyle and blended with the AL. The AL ran around the radial head and was confluent with the LCL and the LUCL. The LUCL was found in all 26 specimens and was thin and slender. The LUCL ran from the inferior part of the lateral epicondyle and blended with the AL. The distal part of the LUCL, which ran from the AL to the supinator crest of the ulna, had three configurations. The first two types were the same as type I (n=8, bilobed) and the broad conjoined type II (n=9) from the study by Cohen and Hastings [22]. Takigawa and co-workers also described a third type in nine specimens in which the lateral ligaments inserted to the ulnar supinator crest in a broad single expansion, accompanied by a thin membranous fibre between the proximal and distal fibres.

Load transfer to the elbow joint

In a study on seven upper limbs of anatomic specimens, the static axial load to the hand with the elbow extended was transferred to the radiohumeral joint among 57% of patients and to the ulnohumeral joint among 43% [32]. Morrey and co-workers observed the highest load on the radiohumeral joint with the forearm in pronation and between zero and 30° of flexion [33]. Flexion and pronation increase the contact between the radial head and capitellum. With the elbow in valgus alignment, defined as contact between the radial head and the capitellum, the load was transferred to the ulnohumeral joint in 3% of patients [34]. In varus alignment of the elbow, defined as no contact between the radial head and capitellum, the load was transferred to the ulnohumeral joint in 93% of patients. Therefore, load transfer is dependent on the rotational position of the forearm, the amount of flexion, and the varus or valgus position of the elbow.

The role of muscle load in providing elbow joint stability

Dunning et al. determined the contribution of muscle force and forearm position to the stability of the LCLC-deficient elbow in ten fresh-frozen upper extremities, using a testing system that was capable of simulating active motion [35]. Simulated motion revealed less variability in measurements in comparison with manual passive motion [36,37]. The distal tendons of three elbow flexors (biceps, brachialis and brachioradialis), the principal extensor (triceps) and the pronator teres were connected to steel cables and could be selectively and sequentially loaded to generate the desired motion. The LCL was divided at its insertion at the lateral epicondyle. At each angle of elbow flexion, the varus and valgus laxity of the ulna relative to the humerus were calculated. The extremity was examined in the following positions: vertical, varus and valgus gravity orientations. Gross instability was present after LCL transection during passive elbow flexion, with the arm in the varus orientation. With the arm in vertical orientation and the forearm in supination, sectioning of the LCL increased rotatory instability compared to values obtained with the forearm in pronation and with the intact LCL. Therefore forearm pronation stabilised the LCL-deficient elbow during passive flexion with the arm in the vertical orientation. This rotatory instability with the forearm supine was reduced significantly when active flexion was simulated. The authors suggest that, in patients with acute posterolateral rotatory instability after elbow dislocations and extended lateral surgical exposures, passive elbow flexion with the forearm in pronation can be used for rehabilitation. Furthermore, splinting of these elbows should be performed using a brace, with the forearm held in full pronation. Armstrong et al. repeated the former study in ten cadaveric upper extremities, but instead of the LCL, the MCL (AMCL and PMCL) was sectioned to generate valgus instability [38]. Following transection of the MCL, the elbow was more stable in supination than pronation during passive flexion. Rotatory instability with the forearm pronated was reduced significantly when active flexion was simulated. The authors advise active motion for the MCL-deficient elbow during the early stages of healing because active motion provides stability similar to that of an intact joint. In contrast, passive motion may cause insignificant stability, particularly with the forearm maintained in pronation. Therefore splinting and passive mobilisation for the MCL-deficient elbow should be done with the forearm in supination.

Kinematics of the elbow joint

The elbow is a hinge joint allowing flexion and extension. The proximal radioulnar joint permits rotation, which involves both pronation and supination. According to guidelines proposed by The American Academy of Orthopaedic Surgeons, which are based on four sources, the average range of elbow motion is: flexion 146°, extension 0°, pronation 71° and supination 84° [39].

In a study with five fresh frozen upper extremities, maximum of 7.6° was observed in the valgus-varus direction of the ulnohumeral joint during flexion, with the weight of the forearm as stress [40]. Maximal internal and external rotation of the ulnohumeral joint (5.3°) were observed during flexion of the elbow joint.

Clinical significance of in vitro biomechanical studies of the elbow joint

When interpreting biomechanical studies, it is important to distinguish between studies with or without simulation of active muscle loading. It is important that the testing apparatus be able to measure the dynamic muscular aspect of joint stability. The stability provided by muscular loading across the elbow joint produced less variable measurements [36,37].

Stability testing of the elbow joint

Stability testing should be performed in positions such that the collateral ligaments are lax.

The optimal positions for valgus testing in different studies were diverse. Therefore, a final conclusion with regard to the best position is not possible; the positions with the greatest laxity were: 90° of flexion [41], 60-70° of flexion [42], in pronation to compensate for the deficient lateral structures (if stable in pronation, the AMCL can be assumed to be intact) [8], 90° of flexion with respect to the AMCL [24], pronation or neutral forearm rotation [43], AMCL at 30-40° and entire MCL at 80-100° of flexion [27], 70-90° of flexion, and forearm in pronation or neutral forearm rotation (to prevent radial head luxations in cases of additional LCLC lesions) [44].

The results for the pivot shift test according to different studies were: supination of the forearm; application of valgus stress and an axial compression force to the elbow while it was flexed from full extension [45]; neutral or varus stress in a semi-flexed position (10-30°) of the elbow and supination of the forearm [46].

Positions for varus testing were described in two studies. In the first study, the flexion angle was not a significant factor [41]. In the second study, the maximum joint laxity in forced varus and external rotation (supination) occurred between 90-110° of flexion [47].

Reducing elbow dislocations and related postoperative treatment

O'Driscoll et al. recommended that posterior elbow dislocations should be reduced in supination [8]. After reducing the dislocation, the elbow should be tested for valgus stability in pronation. If the elbow is stable in pronation, the AMCL can be assumed to be intact and the elbow can be treated immediately with a hinged cast-brace, with the forearm in full pronation. Jensen et al. concluded that supination provided the greatest stability during postoperative treatment for anteromedial dislocations; neutral rotation provided the greatest stability for posteromedial dislocation; pronation of the forearm was most effective for posterolateral dislocations [48]. Dunning et al. performed a study with simulated active motion and found that in patients with acute posterolateral rotatory instability after elbow dislocations and in patients with extended lateral surgical exposures, passive elbow flexion with the forearm in pronation can be used in rehabilitation because forearm pronation stabilised the LCL-deficient elbow [35]. Splinting of these elbows should be done using a brace with the forearm held in full pronation. Instability of the LCL-deficient elbow was not observed during simulated active flexion. It can be concluded that muscle activity is an important posterolateral stabiliser of the elbow; strengthening of these muscles might reduce symptoms of chronic posterolateral rotatory instability.

A very large number of activities of daily living occur with the upper extremity in a shoulder-abducted position and produce varus moments at the elbow joint. This is the reason that the LCLC of the elbow joint should be protected from varus stress after a dislocation by keeping the forearm pronated.

Postoperative treatment for MCL repair

Immobilisation, when deemed necessary after repair of the MCL, should be performed with some degree of flexion. The anterior and posterior band of the AMCL tighten in reciprocal fashion during flexion and extension of the elbow. The anterior band/part of the AMCL is the most important band and flexion may relax this important band. Dunning et al. advised active motion for the MCL elbow during the early stages of healing because active motion provides stability similar to that of an intact joint [38]. In contrast, passive motion may cause significant stability, particularly with the forearm maintained in pronation. Consequently, splinting and passive mobilisation for the MCL-deficient elbow should be performed with the forearm in supination.

Surgical reconstructions

Nielsen and Olsen observed no influence of capsule puncture or transection of the anterior and/or posterior capsule on joint laxity in any studied direction or on the pivot-shift test [49]. Therefore, the authors advise against closure of the joint capsule after elbow surgery in elbows with intact collateral ligaments to prevent capsular contractures.

When performing a surgical procedure at the lateral side of the elbow joint, either the LUCL or the LCL should remain intact to prevent posterolateral rotatory instability [50]. Deutch et al. came to the same conclusion: either the anterior or posterior part of the LCLC can be transected without inducing posterolateral rotatory instability [51]. Reconstructing the LUCL, e.g., for posterolateral rotatory instability, should be done between 30-40° of flexion, which were the initial values for strain in the LUCL [31]. It is not necessary to fully pronate the forearm because maximum strains in the proximal fibres of the LUCL were not influenced by forearm position.

In the case of a ruptured MCL with a fractured radial head, isolated repair of the ligament is superior to the isolated prosthetic replacement and may be sufficient to restore valgus and internal rotatory stability [52]. In the case of a ruptured LCL with a fractured radial head, isolated repair of the ligament is superior to isolated prosthetic replacement and may be sufficient to restore varus and external rotatory stability [53,54].

When treating an isolated coronoid process fracture type I or II, early motion may be allowed, as there appears little risk of posterior subluxation. However, even an isolated coronoid process fracture type III can lead to a posterior subluxation, especially during 60 - 105° elbow flexion [55]. Therefore open reduction and internal fixation are preferred for coronoid process fracture type III. Beingessner and co-workers advise repair of coronoid fracture type II and III in combination with LCLC repair [56]. During rehabilitation, the preferred position of the forearm is supination. Schneeberger and co-workers recommend coronoid reconstruction and radial head replacement with a rigid implant for the elbow in cases of coronoid process/radial head fracture [57]. If elbow instability persists after an elbow dislocation combined with a type I coronoid fracture, repair of both collateral ligaments with an intact, repaired or replaced radial head should restore elbow stability [58]. In these cases, suture fixation of type I coronoid fracture had little effect on elbow stability.

Hinged external fixator

The study of Stavlas and co-workers involved use of the Orthofix elbow external fixator (Orthofix, Verona, Italy) and showed that the hinged external fixator restored the stability of the unstable elbow joint after division of the LCL and MCL in eight cadaveric elbow joints [59]. Although the range of motion decreased, the extensor and fixator forced the unstable joint toward the varus position, as compared with the intact elbow. The authors suggest that this constraint to extension may result from the constant and fixed flexion-extension axis in the external fixator tested. This is in contrast with the physiology of the joint, in which the flexion-extension axis of the elbow joint is not constant during motion.

Another study with a laterally applied hinged external fixator (Dynamic Joint Distractor II, Stryker Howmedica, Rutherford, New Jersey) was performed by Kamineni et al. in the intact elbow and after division of the LCL and/or MCL in six fresh-frozen anatomic specimens of upper extremities [60]. Varus displacements could be prevented with the external fixator. However, valgus displacements occurred during a load of seven Newtons after either sectioning the LCL or MCL and occurred during every load after sectioning both the LCL and MCL. Therefore, patients with a hinged external fixator for elbow instability should be told not to lift more than the weight of a glass of water. However, during the activities of daily living, valgus stress is rare and short, while most functions generate a sustained varus stress.

Conclusions

Numerous studies of the kinematics/kinesiology and anatomy of the elbow joint based on human anatomic specimens of elbow joints yielded important and interesting implications for trauma and orthopaedic surgeons.

Testing of instability should be done with lax collateral ligaments, which means flexion (from 10° to 90°) and pronation of the forearm for valgus testing of the MCL and flexion and supination for varus testing. The pivot-shift test is performed with the forearm supine and with application of valgus stress and an axial compression force to the elbow while it is flexed from full extension. Rehabilitation should be performed with a stable joint, which for valgus instability involves supination of the forearm and for varus instability requires pronation. For both instabilities, active mobilisation should be stimulated to improve muscular stability. Reduction of a posterior elbow dislocation should be carried out with a lax LCLC and therefore with a supinated forearm. Mobilisation with a pronated forearm should be performed subsequently. A surgical approach to the lateral side of the elbow should protect either the LUCL or the LCL. Open reduction and internal fixation of coronoid fracture type II and III in combination with LCLC repair is advisable. A laterally applied hinged external fixator protects primarily against varus stress, so valgus stress should be avoided.

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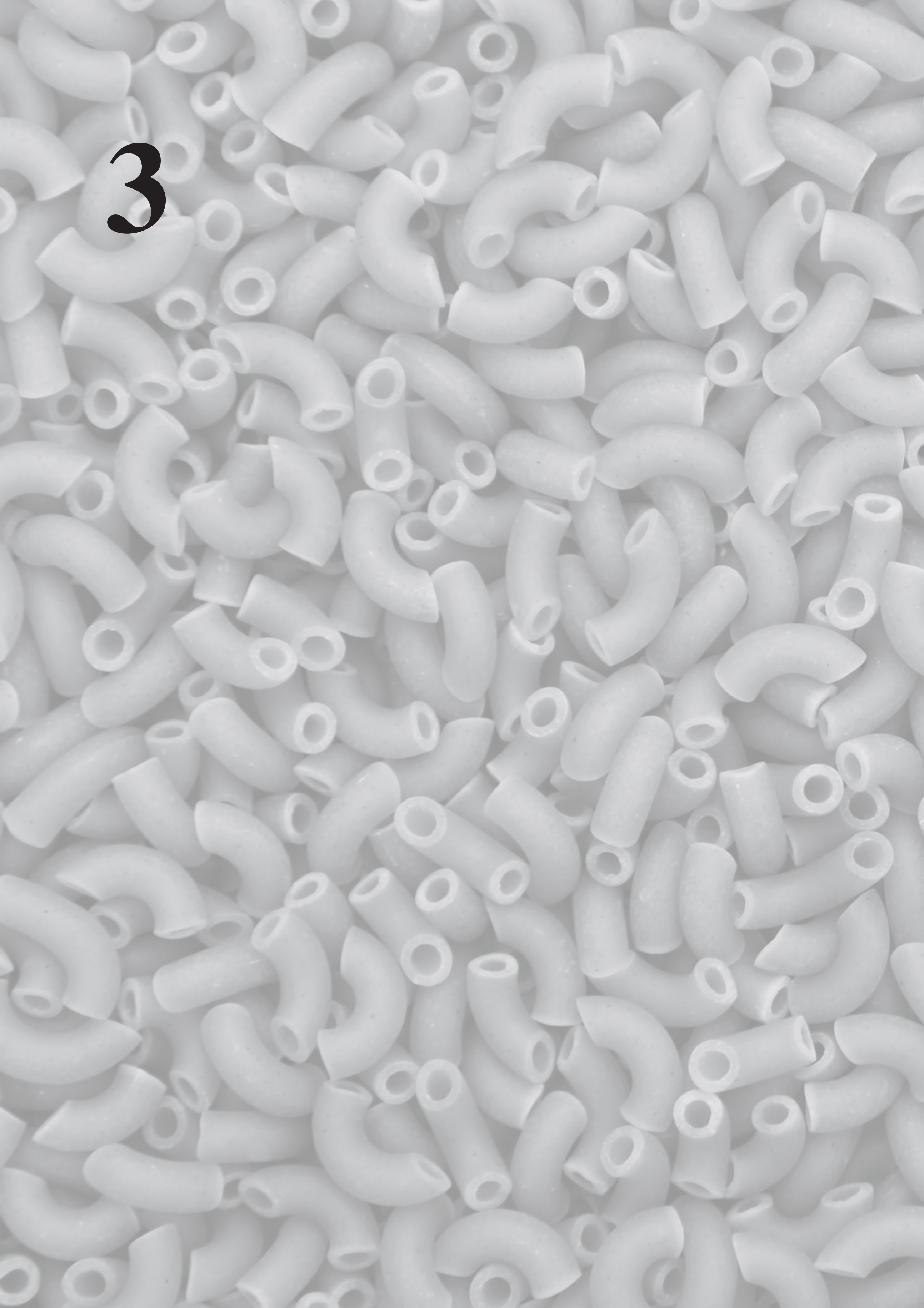

3

The reliability, validity and responsiveness of the Dutch version of the Oxford elbow score

J. de Haan
H. Goei
N.W.L. Schep
W.E. Tuinebreijer
P. Patka
D. den Hartog

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Abstract

Background

The Oxford elbow score (OES) is an English questionnaire that measures the patients' subjective experience of elbow surgery. The OES comprises three domains: elbow function, pain, and social-psychological effects. This questionnaire can be completed by the patient and used as an outcome measure after elbow surgery. The aim of this study was to develop and evaluate the Dutch version of the translated OES for reliability, validity and responsiveness with respect to patients after elbow trauma and surgery.

Methods

The 12 items of the English-language OES were translated into Dutch and then back-translated; the back-translated questionnaire was then compared to the original English version. The OES Dutch version was completed by 69 patients (Group A), 60 of whom had an elbow luxation, four an elbow fracture and five an epicondylitis. *Quick*DASH**,** the visual analogue pain scale (VAS) and the Mayo Elbow Performance Index (MEPI) were also completed to examine the convergent validity of the OES in Group A. To calculate the test-retest reliability and responsiveness of the OES, this questionnaire was completed three times by 43 different patients (Group B). An average of 52 days elapsed between therapy and the administration of the third OES (SD=24.1).

Results

The Cronbach's α coefficients for the function, pain and social-psychological domains were 0.90, 0.87 and 0.90, respectively. The intra-class correlation coefficients for the domains were 0.87 for function, 0.89 for pain and 0.87 for social-psychological. The standardised response means for the domains were 0.69, 0.46 and 0.60, respectively, and the minimal detectable changes were 27.6, 21.7 and 24.0, respectively. The convergent validity for the function, pain and social-psychological domains, which were measured as the Spearman's correlation of the OES domains with the MEPI, were 0.68, 0.77 and 0.77, respectively. The Spearman's correlations of the OES domains with *Quick*DASH were -0.43, -0.44 and -0.47, respectively, and the Spearman's correlations with the VAS were -0.33, -0.38 and -0.42, respectively.

Conclusions

The Dutch OES is a reliable and valid 12-item questionnaire that can be completed within several minutes by patients with elbow injuries. This Dutch questionnaire was useful as an outcome measure in patients with elbow trauma.

Introduction

Patient-reported outcome measures (PROMS) quantify the patients' or populations' subjective experience in relation to a health condition and its therapy [1]. It is important to measure quality of life for several reasons [2]. A patient's self-assessment of their own quality of life may differ from the judgment of the medical staff, especially with symptoms such as pain. PROMS can reveal this difference of judgment in routine clinical practice. In addition, PROMS can be used in research studies to compare two different treatments. Quality of life measures can be categorised as generic or specific for diseases or conditions [1]. The Oxford elbow score (OES) is a specific questionnaire that measures the quality of life of patients with disorders of the elbow joint [3]. The OES was designed to measure the outcomes of elbow surgery from the patient's perspective. The OES is a 12-item, patient-reported questionnaire, which makes it an important outcome measure that is independent of the evaluation of the medical team. In the Netherlands, the *Quick*DASH questionnaire (Disability of the Arm, Shoulder and Hand Questionnaire) is used to measure the state of the upper extremities before and after therapy [4]. The 11-item *Quick*DASH questionnaire is a shortened version of the 30-item DASH questionnaire, which was designed to measure physical function and symptoms in patients with musculoskeletal disorders of the upper limbs. Both DASH and *Quick*DASH have two four-item optional modules, one related to performing sports and/or playing a musical instrument and one related to work. The test-retest reliability of *Quick*DASH in a study of 101 patients was 0.90 [5]. The DASH questionnaire has been examined for reliability and validity in a group of 50 Dutch patients [6], and in that study, the Cronbach's alpha coefficient was 0.95, and the test-retest reliability, calculated as the Pearson's correlation, was 0.98, although this is not a test of agreement. This questionnaire, however, was not specifically developed to assess the elbow region [7]. The *Quick*DASH questionnaire also differs from the OES because it only asks patients about their experiences during the preceding week, whereas the OES asks patients about the preceding four weeks. The OES includes three domains: an elbow function domain, a pain domain (severity and time of day when the pain occurs) and a social-psychological condition domain; each domain is assessed using four questions. The answers are recorded on a five-point Likert scale. Every domain score is calculated to a final score that ranges from 0 (worst) to 100 (best) [3]. In a study of 104 patients who had undergone a combined total of 107 elbow operations for osteoarthritis, rheumatoid arthritis, post-traumatic stiffness and epicondylitis, the OES was found to be both reliable and valid [3]. In another study, this questionnaire was found to have a good responsiveness or ability to detect changes six months post-surgery [8]. The difference in the patients' scores before versus after elbow surgery was higher with the OES than with the DASH questionnaire.

The aim of the present study was to develop and evaluate the reliability, validity and responsiveness of the Dutch language version of the OES.

Patients and Methods

The 12 items of the OES were translated into Dutch according to the generally accepted rules for translation of non-Dutch questionnaires [9-11]*. The OES was translated into Dutch by four clinicians involved in orthopaedic trauma surgery. One clinician was an epidemiologist with experience in clinimetrics. The four translated versions were compared, and the differences were resolved by discussion. The Dutch version of the OES was then back-translated to English by a certified English translator (and native English speaker). The four clinicians compared this back-translation with the original English version of the OES, and they edited the Dutch translation to make it more accurate. After the translation process, mistakes were encountered in the tense of the Dutch version of questions seven and eight, which referred to pain during the past four weeks. These mistakes were found after the back-translation and were corrected.

The OES was validated by calculating the Spearman's rank correlation with *Quick*DASH, the Mayo Elbow Performance Index (MEPI) [12] and the visual analogue scale for pain (VAS) [13]. The MEPI is one of the most widely used physician-rated classification systems for elbow function and its relation to the overall quality of life [14]. This index consists of four parts: pain, ulnohumeral motion, stability and the ability to perform five functional tasks [12]. The MEPI was chosen for validation because it is an objective, physician-rated questionnaire that is available in the Netherlands. The pain level was determined with a 10-point VAS, in which zero implied no pain and ten implied the worst possible pain. The VAS was chosen because it provides a simple way to record subjective estimates of pain intensity, and the fact that pain has a large influence on questionnaires that assess elbow function [15].

To validate the Dutch OES, the present study examined a cohort of 69 patients (Group A) who were seen for elbow trauma at four clinical sites. Patients 15 years of age or older with a simple or complex elbow dislocation (n=60), epicondylitis (n=5) or fracture in the elbow region (n=4) were included from four hospitals (three rural teaching hospitals and one university hospital). The patients with previous elbow dislocations were in a chronic stage with a mean follow-up of 3.3 years, and the other nine cases were in an acute stage. Patients younger than 15 years and patients unable to read Dutch were excluded from the study. The elbow dislocations were treated either with plaster or with a sling for three weeks. The elbow fractures were reduced and internally fixated. The patients with epicondylitis were injected locally with platelet-rich plasma. Sixty-nine patients completed the OES and *Quick*DASH, and 58 patients completed the VAS for pain. The MEPI was completed by the physician for 49 patients, and four domains were assessed: pain (maximum score of 45 points), ulnohumeral movement (maximum score of 20 points), stability (maximum score of 10 points) and the patient's ability to accomplish five functional tasks (maximum score of 25 points). The five functional tasks were 1) the ability to comb one's hair, 2) the ability to feed oneself, 3) the ability to perform personal hygiene tasks, 4) the ability to put on a shirt and 5) the ability to put on one's shoes.

The patient's pain level was assessed with the following question, "How much pain do you have in your elbow?" This question was scored using a 10-point VAS for pain, with 0 indicating no pain and 10 indicating the worst possible pain imaginable.

*Quick*DASH is a standardised and validated questionnaire that assesses a patient's symptoms and disabilities at work and during leisure activities [4]; the *Quick*DASH questionnaire can be downloaded free of charge from the following website: www.dash.iwh.on.ca. This questionnaire, which assesses the entire upper extremity, was completed by the patients themselves. The *Quick*DASH questionnaire consists of three modules. The first module includes 11 questions about symptoms and the ability to perform certain activities. The second and third modules, which are both optional, contain four questions each. The first optional module asks questions about how the patient is affected at work, and the other module asks questions about how they are affected while playing sports or a musical instrument. All of the questions are scored on a five-point scale. The total score of each of the three modules is summed and corresponds to an overall score on a scale of 0 (no disabilities) to 100 (severe disabilities). All three of the modules were used for the present analysis. Lastly, the validity of the Dutch OES was measured by calculating the correlation between the Dutch OES, *Quick*DASH, the VAS for pain and the MEPI.

In a separate cohort (Group B) of 43 patients, the OES was administered three times. The elbow dislocations in this second Group B were either treated with plaster or with a sling for three weeks. The elbow fractures were reduced and internally fixated. After the operation patients were allowed to exercise. The patients with epicondylitis were injected locally with platelet-rich plasma. The timing of the administration of the second OES differed between patients and was performed after a median time-period of one day (interquartile range=6.0). The second test allowed us to calculate the test-retest reliability.

The OES test was also administered a third time to the patients of Group B; this third administration allowed us to analyse the ability of the OES to detect changes in patient status (i.e., to determine its responsiveness). An average of 52 days elapsed between therapy and the administration of the third OES (SD=24.1, minimum 28 days, maximum 103 days), as clinically detectable changes were expected after the treatment of the elbow fractures and dislocations. The first administration of the OES in Group B was performed during the acute stage of the disorder, with a mean of 16.6 days (SD=22.6, minimum 7 days, maximum 86 days) after the therapy to increase the possibility of observing a change between the first administration and third administration of the OES. The OES refers to the period of "the past 4 weeks", and the interval between the trauma and the administration of the OES reduced the possibility of problems for those patients with an acute trauma to complete the questionnaire.

Statistical Analyses

The questionnaires were imported into the PASW Statistics 18.0 software package and analysed using the same computer program. The test reliability was analysed by calculating the Cronbach's α coefficient and the intra-class correlation coefficient (ICC). As a measure of test-retest agreement for each domain, the standard error of measurement was calculated

by dividing the mean difference in score between the initial test and the retest by the square root of two [16]. Using the standard error of measurement, the minimal detectable changes (MDC) of the three domains were calculated using the following formula:
MDC=1.96*√2*standard error of measurement [16]. The standard error of measurement and MDC were both expressed on the same scale of measurement as the OES (i.e., 0-100).

The convergent validity was estimated by calculating the Spearman's correlation coefficients among the OES scores and those for *Quick*DASH, the VAS for pain and the MEPI. Spearman's correlation coefficients were used because the data of the questionnaires were not normally distributed.

The ability of the OES to detect changes in patient status (i.e., responsiveness or longitudinal validity) was calculated by determining the effect size and the standardised response means. The effect size was calculated by dividing the difference in patients' scores between the first administration and third administration of the OES by the standard deviation of the score from the first administration. The mean standardised response was calculated by dividing the mean change in score by the standard deviation of the change in scores.

The percentages of scores below 25 and above 75 for the three domains of the OES were calculated to assess floor and ceiling effects.

Results

The patient characteristics are presented in Table 1. The mean age of the patients in Group A was 43.4 (SD=14.8) years and 50.9 (SD=12.8) years in Group B. In Group A, 52 of the total patients (75%) were female, whereas in Group B, 27 patients (63%) were female.

Table 1 Patient characteristics

Characteristics	Group A	Group B
N	69	43
Gender (N)		
female	52	27
male	17	16
Age (years)	43.4 (SD=14.8)	50.9 (SD=12.8)
Diagnosis (N):		
elbow dislocation	60	19
elbow fracture	4	14
epicondylitis	5	5
arthrolysis		2
other elbow conditions		3

The outcomes of the OES analysis are shown in Table 2. By removing the question "How would you describe the pain you usually had from your elbow?" from the pain domain, Cronbach's α coefficient of this domain increased slightly to 0.90. Removal of any other questions decreased the Cronbach's α coefficient for the respective domain. When a single question from the function domain, either question 1, 2, 3 or 4, was removed from the analysis, the Cronbach's α coefficients were 0.87, 0.87, 0.88 or 0.87, respectively. When either question 7, 8, 11 or 12 (from the pain domain) was removed from the analysis, the Cronbach's α coefficients were 0.78, 0.79, 0.86 or 0.90, respectively; the Cronbach's α coefficients were 0.88, 0.87, 0.85 or 0.89, when question 5, 6, 9 or 10 (from the social-psychological domain), respectively, was removed from the analysis.

Table 2 Results of the analysis of the OES

	OES domains		
	Function	**Pain**	**Social-psychological**
Mean score (SD) pre-intervention data	66.7 (28.8)	69.2 (27.5)	62.5 (30.2)
Cronbach's α pre-intervention data	0.90	0.87	0.90
Intra-class correlation coefficient (95% CI)	0.87 (0.75, 0.93)	0.89 (0.78, 0.94)	0.87 (0.73, 0.93)
Standard error of measurement	9.9	7.8	8.7
Minimal detectable change	27.6	21.7	24.0
Effect size	.56	.49	.54
Standardised response mean	.69	.46	.60
% scores <25 pre-intervention data	16.2	11.1	19.2
% scores >75 pre-intervention data	42.5	47.6	38.4

CI=confidence interval

The Spearman correlation coefficients among the three domains of the OES and *Quick*DASH, the VAS for pain, and the MEPI (which were calculated to evaluate the convergent validity of the OES among the patients in Group A) are shown in Table 3.

Table 3 Correlation between the three domains of the Oxford elbow score, the *Quick*DASH domains, the visual analogue pain scale (VAS), and the Mayo Elbow Performance Index (MEPI)

Oxford elbow score domain	**Function N=69**	**Pain N=69**	***Quick*DASH total N=69**	***Quick*DASH work N=53**	***Quick*DASH sports/music N=48**	**VAS pain N=58**	**MEPI N=49**
Function			-.43**	-.23	-.35*	-.33*	.68**
Pain	.85**		-.44**	-.32*	-.42**	-.38**	.77**
Social-psychological condition	.84**	.89**	-.47**	-.38**	-.46**	-.42**	.77**

** $p<0.01$ and * $p<0.05$. Spearman's correlation coefficients were calculated to assess the relationship between the results of each OES domain and the questionnaires listed above.

Discussion

In the present study, the reliability (expressed as Cronbach's α coefficient for internal consistency) and the test-retest reliability of the Dutch version of the OES were both high for all three of the domains. In a study by Dawson et al., the Cronbach's α coefficients for the three domains were also found to be high: for the elbow function domain, it was 0.90; for the pain domain, it was 0.89; and for the social-psychological domain, it was 0.84; the ICC values for each domain in this study were 0.89, 0.98 and 0.87, respectively [3].

The effect sizes and standardised response means, which are a measure of the test's responsiveness or its ability to detect changes in patients' conditions, were moderate. This finding was in contrast to the study of Dawson et al., which found that the English OES domains had large effect sizes (i.e., 0.79, 1.14 and 1.18 for the function, pain and social-psychological domains, respectively) [8]. This difference in effect sizes and standardised response means can be explained by our shorter period of follow-up at the third administration of the OES. Except for pain, the standard error of measurement and the MDC measurements of the three domains were comparable to those in the Dawson et al. study [8]. The standard error of measurements for the function, pain and social-psychological domains in the Dawson et al. study were reported to be 8.23, 3.58 and 8.51, respectively, and the MDCs were 18.73, 8.25 and 18.85, respectively [8]. The difference in the standard error of measurement and MDC for pain can be explained by the different time period between the first administration and second administration of the OES in our study (interquartile range=6.0 days) and the study of Dawson et al. (an interval of 2 days for all of the patients) [3, 8]. Terwee et al. also found a large variation in the values of minimal important change of PROMS by the same method across studies and across different methods within studies [17]. The authors stated that caution was needed when interpreting and using published minimal important change values.

The distribution of the domain scores showed that a high percentage of patients had superior scores above 75. This finding could point to a ceiling effect of the OES, which is a failure to detect differences between patients with a high score; differences at the high end of the scale could be too small to reliably distinguish individuals. But it is usual to obtain skewed scores in opposite directions for pre and postsurgical interventions in orthopaedics and ceiling effects are more relevant to item level rather than to the overall score analysis.

The correlation between the three domains of the Dutch version of the OES and the MEPI was high, which indicates that the OES has a good convergent validity. The MEPI score was mainly determined by the contribution of elbow pain (45%) to the patients' overall elbow functioning. Doornberg et al. have concluded that pain has a large influence on questionnaires that assess elbow function, both those that are completed by physicians and those that are completed by the patients [15]; however, it should be noted that Doornberg et al. did not examine the OES in their study. In our study, the correlation between the OES and the *Quick*DASH questionnaire was moderate. Dawson et al., however, have found a high degree of correlation between the 30-item DASH and the function domain of the OES (-0.84) but only a moderate degree of correlation between the DASH and the pain (-0.66) and social-psychological domains (-0.59) [3]. Interestingly, in a continuation study that was performed in a different patient population, Dawson et al. found a moderate correlation between the OES and the 30-item DASH (-0.51, -0.54 and -0.58 for the function, pain and social-psychological domains, respectively), which was more in accordance with our findings [8]. The moderate correlation between the OES and *Quick*DASH can be attributed to the difference in time recall because the *Quick*DASH questionnaire asks patients about the preceding week, and the OES addresses the past four weeks. The VAS for pain had a moderate correlation with the OES, which was probably because the OES assesses a patient's pain under specific circumstances, such as during the night. In contrast, the VAS for pain assesses a patient's mean overall pain intensity at the present moment and does not ask if the degree of pain changes under specific circumstances.

This study had several limitations, including the small sample sizes and a homogeneous patient population (i.e., patients with elbow trauma) in the two studied cohorts. The reliability of a measuring instrument in classical test theory is characteristic of the sample tested. Another limitation of this study was the variation in the time that elapsed between the first administration and second administration of the OES as well as between the first administration and third administration. The OES refers to the preceding four weeks, and, during this period, the patients were treated for their elbow dislocation with a plaster or sling, which could have interfered with their movements that were addressed by the questions of the OES. This problem could have affected the correlations with the other instruments which used different periods of recall. The variability in time between the administrations could have lowered the ICCs of the OES domains. In addition, the variability in the length of time between the OES administrations could have influenced the standard error of the measurements, the MDC and the effect size measures.

Because our patient population included a relatively homogeneous group, future studies should examine OES results in patients with other types of elbow disorders. An analysis of the OES via modern test theory would also be necessary to examine the ordering of the five scoring categories.

Conclusion

The Dutch OES is a reliable and valid 12-item questionnaire that can be completed within several minutes by patients with elbow injuries. This Dutch questionnaire was useful as an outcome measure in patients with elbow trauma, and the Dutch language version can now be applied in the Dutch population.

Future studies will use this Dutch OES in a randomised controlled trial for the evaluation of the functional treatment of simple elbow dislocations [18]. In addition, the Dutch OES will be used in an observational study of surgeries of complex elbow dislocations.

Specified notice

Acknowledgement

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**Footnote* Permission for the translation and the use of the OES for two studies was obtained from Oxford and Isis Outcomes, which is part of Isis Innovation Limited (website: http://www.isis-innovation.com/).

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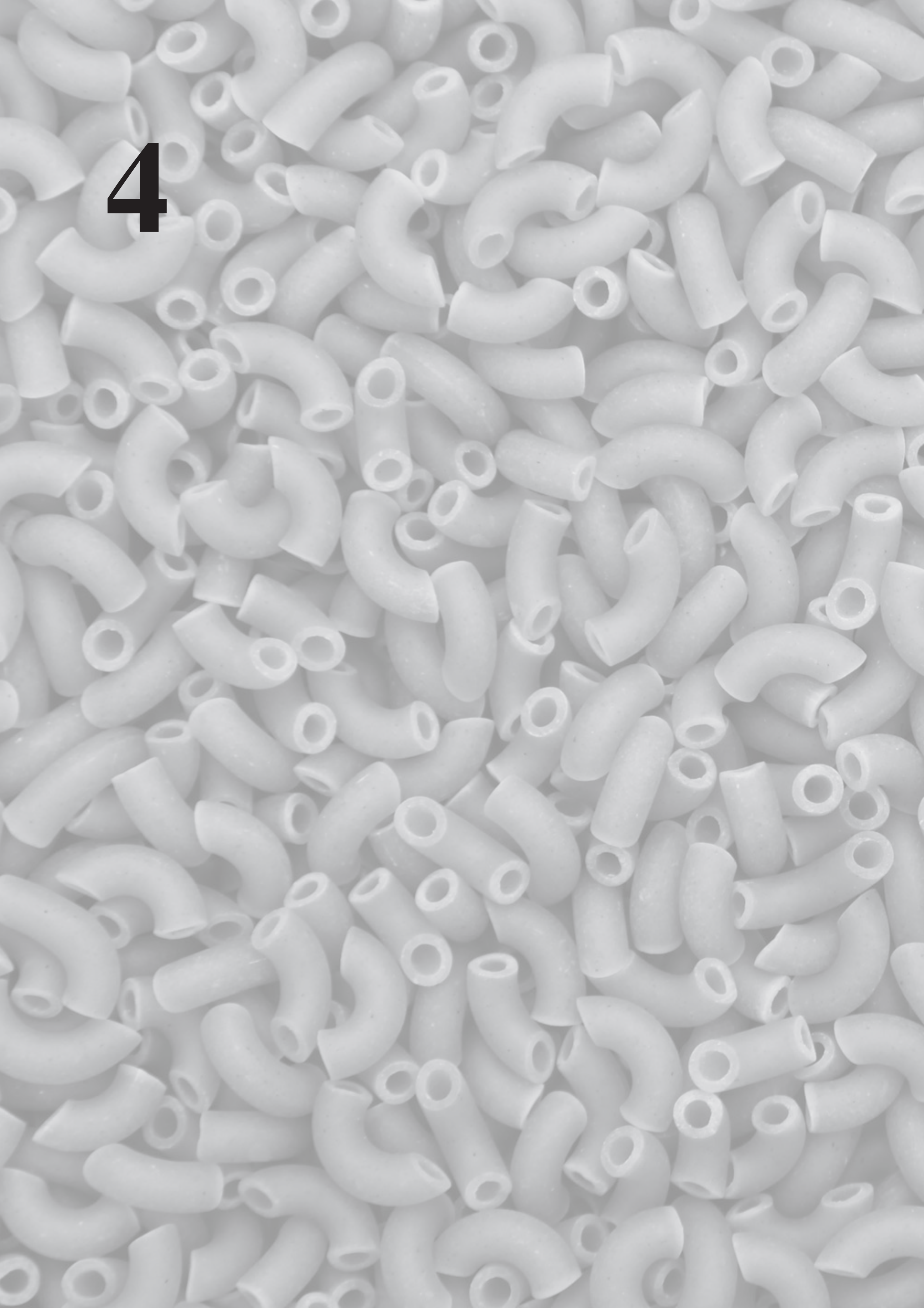

Rasch analysis of the Dutch version of the Oxford elbow score

J. de Haan
N.W.L. Schep
W.E. Tuinebreijer
P. Patka
D. den Hartog

Patient Related Outcome Measures 2011; 2: 145-49

Abstract

Background
The Oxford elbow score (OES) is a patient-rated, twelve-item questionnaire that measures the quality of life in relation to elbow disorders. This English questionnaire has been proven to be a reliable and valid instrument. Recently, the OES has been translated into Dutch and examined for its reliability, validity and responsiveness in a group of Dutch patients with elbow pathology. The aim of this study was to analyse the Dutch version of the OES (OES-DV) in combination with Rasch analysis or the one-parameter item response theory to examine the structure of the questionnaire.

Methods
The OES-DV was administered to 103 patients (68 female, 35 male). The mean age of the patients was 44.3 years (SD=14.7, range 15-75 years). Rasch analysis was performed using the Winsteps® Rasch Measurement Version 3.70.1.1 and a rating scale parameterisation.

Results
The person separation index, which is a measure of person reliability, was excellent (2.30). All the items of the OES, had a reasonable mean square infit or outfit value between 0.6 and 1.7. The thresholds of items were ordered, so the categories function as intended. Principal component analysis of the residuals partly confirmed the multidimensionality of the English version of the OES. The OES distinguished 3.4 strata, which indicates that about three ranges can be differentiated.

Conclusion
Rasch analysis of the OES-DV showed that the data fit to the stringent Rasch model. The multidimensionality of the English version of the OES was partly confirmed, and the four items of the function and three items of the pain domain were recognised as separate domains. The category rating scale of the OES-DV works well. The OES can distinguish 3.4 strata. This conclusion can only be applied to elbow dislocations, which were the largest group of patients studied.

Background

The Oxford Elbow Score (OES) is a patient-rated twelve-item questionnaire (table 1) that measures quality of life in relation to elbow disorders [1]. The development of this English questionnaire has involved Rasch analysis as well as analysis with classical test theory [1]. This English version comprises three domains, ie, elbow function, pain and social-psychological factors. The answers are recorded on a five-point Likert scale. Every domain score is calculated for a final score that ranges from 0 (worst) to 100 (best). Another study reported responsiveness and minimal change for the OES following elbow surgery [2]. These studies showed that the OES questionnaire is a reliable and valid instrument. Recently, the 12 items of the OES were translated into Dutch according to the generally accepted rules for translation of non-Dutch questionnaires and examined for their reliability, validity and responsiveness among a group of Dutch patients who had experienced elbow trauma [3-6]. However, that study was performed with classical test theory. Modern test theory has many advantages, such as a thorough examination of dimensionality, analysis of the fit of the data to the Rasch model and category function analysis [7,8]. Therefore, the objective of this study was to analyse the Dutch version of the OES (OES-DV) with Rasch analysis or the one-parameter item response theory.

Table 1 The 12 items of the Oxford elbow score

"During the past 4 weeks....."
1. Have you had difficulty lifting things in your home, such as putting out the rubbish, because of your elbow problem?
2. Have you had difficulty carrying bags of shopping, because of your elbow problem?
3. Have you had any difficulty washing yourself all over, because of your elbow problem?
4. Have you had any difficulty dressing yourself, because of your elbow problem?
5. Have you felt that your elbow problem is "controlling your life"?
6. How much has your elbow problem been "on your mind"?
7. Have you been troubled by pain from your elbow in bed at night?
8. How often has your elbow pain interfered with your sleeping?
9. How much has your elbow problem interfered with your usual work or everyday activities?
10. Has your elbow problem limited your ability to take part in leisure activities that you enjoy doing?
11. How would you describe the worst pain you had from your elbow?
12. How would you describe the pain you usually had from your elbow?

Methods

The OES was translated into Dutch by four trauma surgeons. One clinician was also an epidemiologist with experience in clinimetrics. The four translated versions were compared, and the differences were resolved by discussion. The Dutch version of the OES was then back-translated to English by a certified English translator (and native English speaker). The four clinicians compared this back-translation with the original English version of the OES, and edited the Dutch translation to make it more accurate. After the translation process, mistakes were encountered in the tense of the Dutch version of questions seven and eight, which referred to pain during the past four weeks. These mistakes were found after the back-translation and were corrected.

The sample population consisted of 103 patients (68 female, 35 male). The mean age of the patients was 44.3 (SD=14.7, range 15-75) years. This group of patients consisted of 67 patients with elbow luxation, 24 patients with a recent fracture of the elbow region, seven patients with active epicondylitis, two patients who were undergoing arthrolysis of the elbow and three patients with other elbow conditions (eg, bursitis).

Forty-three patients were randomly selected to complete a second OES following treatment for their elbow disorder after a mean follow-up of 52 days (SD=24.1); thus, 146 questionnaires were available for analysis. This group of 43 patients consisted of 19 patients with elbow luxation, 14 patients with a recent fracture of the elbow region, five patients with active epicondylitis, two patients who were undergoing arthrolysis of the elbow and three patients with other elbow conditions (eg, bursitis).

Rasch analysis was performed with Winsteps measurement software (Winsteps® Rasch Measurement Version 3.70.1.1). The following analyses were performed: construction of the person and item or Wright map, testing of the (mis)fit between the data and the model, estimation of the person and item reliability and separation coefficient, testing of the ordering of the categories, and analysis of the dimensionality.

Results

Of the 146 observations collected, all were available for analysis, including 17 extreme scores. A rating scale parameterisation was used because all the items had the same numbers of categories.

The person and item map is shown in Figure 1. The items on the right side are in order based on the logit scale. Natural logarithms of the odds are called logits and range from minus infinity to plus infinity. The default mean difficulty was set to zero. The OES covered about seven logits (range 5.08 to -1.60). The OES was coded with the highest values for the better patients and the lowest values for the bad cases. The item map also shows the hierarchy of the item difficulties on the right side. The items at the top are those items the patients easily endorsed. For example, item 1 (difficulty in lifting objects) was easier to confirm than item 12 (describing the pain you usually experienced).

On the left of the Wright map the patient performances are represented by numbers. Most patients were located opposite and above the items (mean person estimate 1.04, sd=1.52), which was above the default mean item difficulty of zero; therefore, the items were moderately well targeted for this person group, meaning that the items represent the patients' level of quality of life. Overall, the patient group had good OES scores, indicating few complaints concerning the affected elbow.

The item reliability coefficient was 0.95, and the item separation coefficient was 4.40. The person reliability was 0.84, and the person separation index was 2.30, so the reliability was good. Reliability coefficients have a ceiling of 1.0, but separation coefficients and indexes have no ceiling. The person separation was used to calculate the

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Figure 1 Person (n=146) and item (12 items) or Wright map for the OES scale. Positive scores indicate better quality of life, whereas negative scores indicate poorer quality of life. Items from the scale are shown on the right-hand side of the figure, and person measures are highlighted by a '#' or '.' Each '#' represents two subjects, and each '." one subject. M, mean; S, 1 SD from the mean; T, 2 SD from the mean number of distinct levels of quality of life (strata) that the items could distinguish (Strata = [4 x person separation index + 1] / 3) = 3.4 [9.10]. The strata that the OES distinguished was 3.4, which indicates that about three ranges could be differentiated.

The items are placed according the hierarchy of the item difficulties in Table 2. The measures are the item difficulty estimates. Items 2, 6 and 11, items 1, 2 and 10 and items 1, 8, and 9 and items 3 and 8 had inter-item separations less than 0.15 logits, indicating overlap between these item difficulties.

The individual item fit statistics are presented in Table 2. To determine how well the empirical data fit the Rasch model, chi-square fit statistics were calculated. These fit statistics are the infit mean square (Infit MNSQ) and the oufit mean square (Oufit MNSQ). The infit MNSQ represents the information-weighted mean square residual difference between observed and expected responses. The infit statistics are sensitive to unexpected responses near the person's ability level. The outfit statistic is the usual unweighted mean square residual and is more sensitive to outliers. High infit and outfit reflect underfit, which means lack of predictability of an item. Low mean square infit and outfit reflect overfit, which means over-predictability of an item. Mean square infit or outfit values should range between 0.6 and 1.4 for rating scales or 0.5 to 1.7 for clinical observations [7]. All the items in the OES had reasonable mean square infit or outfit values between 0.6 and 1.7. Item 12 had the highest in- and outfit values of all the items, 1.70 and 1.53, respectively, indicating some underfit, which means an unpredictable interpretation (ie, erratic response or noise).

Table 2 Item statistics, OES Dutch version

Item	Count	Measure	Infit MNSQ	Outfit MNSQ
6	146	0.57	1.02	1.26
11	146	0.57	0.68	0.65
2	146	0.47	1.08	0.96
10	146	0.41	1.19	1.05
1	146	0.35	0.99	0.91
9	146	0.28	0.69	0.61
5	146	-0.01	0.89	0.89
7	146	-0.17	1.19	0.96
8	146	-0.36	1.11	0.99
3	146	-0.44	1.03	0.97
4	146	-0.66	0.81	0.85
12	144	-1.02	1.70	1.53

Table 3 presents the functioning of the five categories of the OES Dutch version. All categories were well represented except for the zero category, which had a low frequency of 109 observations. The zero category included the patients with the worst quality of life; therefore, the low frequency is consistent with the few cases with a bad or very bad outcome. The observed average measures increased in a smooth distribution from -0.99 to 2.39. The threshold of the categories increased monotonically (so were never decreasing). None of the categories showed a misfit.

Table 3 Summary of the category structure of the OES Dutch version

Category label/score	Observed count	Observed count %	Observed average	Outfit mean square	Threshold
0	109	6	-0.99	1.14	none
1	276	16	-0.63	0.95	-1.77
2	258	15	0.38	0.67	-0.02
3	335	19	1.31	0.89	0.51
4	772	44	2.39	1.22	1.28

Figure 2 shows the category probability curves of the categories with a smooth distribution. The thresholds were ordered. In this Rasch-Andrich model (one of the polytomous models), the rating scale structure was defined to be equal for all items. The category rating scale worked well.

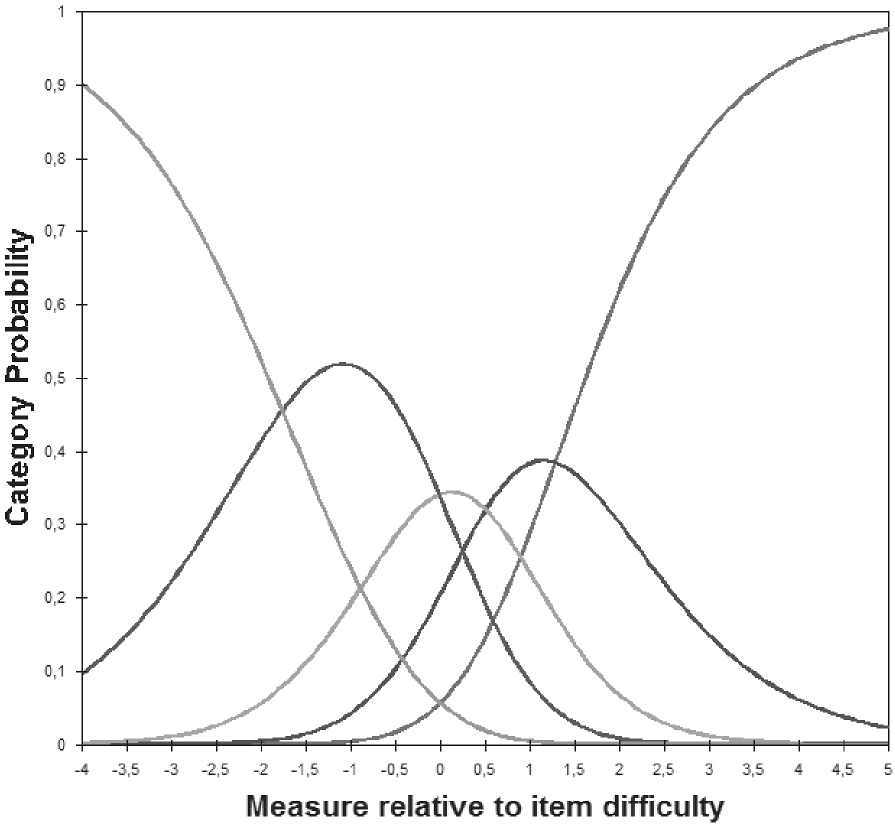

Figure 2 Category probability curve of the Dutch version of the OES scale showing the probability of assigning to any particular category (y-axis) given the difference in estimates between any patient quality of life measurement and any item difficulty. The threshold estimates correspond to the intersection of rating scale categories

According to the Rasch model, when the data fit the Rasch model, the Rasch dimension is the only dimension in the data. Rasch factor analysis is a factor analysis of the residuals that remain after the linear Rasch measure has been extracted from the data set. A secondary dimension in the data must explain at least 2 items (also called 2 Eigenvalue units) worth of variance, ie, unless a component has the strength of at least 2 items it may merely due to an idiosyncratic item. A Rasch principal components analysis (PCA) of the residuals of the OES-DV was performed. The raw variance of the OES explained by the Rasch measure was 36.2% (expected by the model 35.7%). The unexplained variance in the first contrast was 7.4% (2.4 Eigenvalue units), and in the second contrast was 6.0% (2.0 Eigenvalue units). The first contrast consisted of three of the four pain items. The second contrast consisted of the function items 1 to 4.

Discussion

Rasch analysis of the OES-DV showed that the data fit to the stringent Rasch model. The person separation index as a measure of reliability was high. Three statistically distinct levels of quality of life, ie, good, intermediate, and poor, could be differentiated by the OES-DV. The category rating scale of the OES-DV worked well. The patients could discriminate the five levels of the items.

Our factor analysis of the OES-DV with the classical test theory showed only one factor, which is in contrast with the original English version (unpublished data). Factor analysis of the English OES showed three domains, ie, function, pain and socio-psychological [1]. In the Rasch analysis, the PCA was performed on the differences between the model and observed data, called residuals. The multidimensionality was partly confirmed by the PCA of the residuals of the OES-DV. The four items of the function and three items of the pain domain were recognised as separate domains. Two contrasts had a strength of two or more Eigenvalue units. This supports the idea that the OES-DV is a multidimensional instrument. The difference in dimensionality between the OES-DV and the original OES can be explained by differences in the composition of the study population, context, intervention and timing of assessments. Our study population, which consisted mainly of elbow dislocations, was very different from the original developmental study.

This study had several limitations, including the small sample size and a homogeneous patient population (ie, patients with elbow trauma). Our conclusions can only be applied to elbow dislocations, which were the largest group of patients studied. A flaw of our study is that we did not ask the patients to predict the hierarchy of the Wright map and use these predictions to study the predictive validity of the OES-DV. We could have asked the patients to order the items according to how difficult they were to perform and endorse them positively or negatively. If the order of difficulty of the items was correctly predicted by the patients, this would have enhanced the validity of the OES. Another limitation was the poorly targeted population. Patients on the poor side of the quality of life spectrum were missing.

Future studies with the OES-DV should examine patients with other types of elbow disorders in a larger population, because dimensionality examinations of questionnaires are influenced by the study population, and the greater the sample size, the greater the power in detecting misfit.

Conclusion

Rasch analysis of the OES-DV showed that the data fit the stringent Rasch model. The multidimensionality of the English version of the OES was partially confirmed. The four items of the function and three items of the pain domain were recognised as separate domains. The category rating scale of the OES-DV worked well. The OES distinguished

3.4 strata. This conclusion can only be applied to elbow dislocations, which were the largest group of studied patients.

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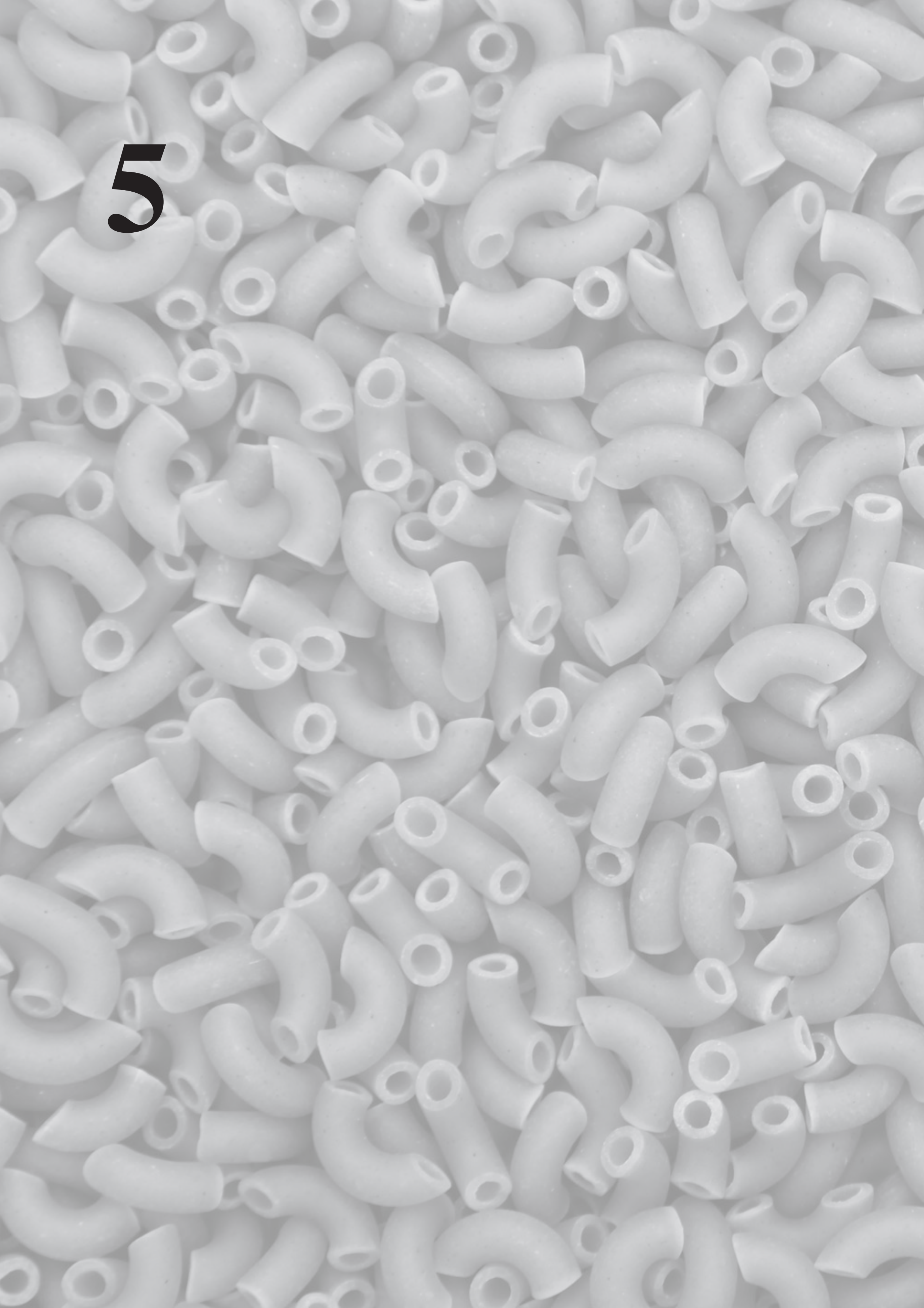

5

Simple elbow dislocations: a systematic review of the literature

J. de Haan
N.W.L. Schep
W.E. Tuinebreijer
P. Patka
D. den Hartog

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Abstract

Objective
To identify if functional treatment is the best available treatment for simple elbow dislocations.
Search strategy
Electronic databases MEDLINE, EMBASE, LILACS, and the Cochrane Central Register of Controlled Trials.
Selection criteria
Studies were eligible for inclusion if they were trials comparing different techniques for the treatment of simple elbow dislocations.
Data analysis
Results were expressed as relative risk for dichotomous outcomes and weighted mean difference for continuous outcomes with 95% confidence intervals.
Main results
This review has included data from two trials and three observational comparative studies. Important data were missing from three observational comparative studies and the results from these studies were extracted for this review. No difference was found between surgical treatment of the collateral ligaments and plaster immobilisation of the elbow joint. Better range of movement, less pain, better functional scores, shorter disability and shorter treatment time were seen after functional treatment versus plaster immobilisation.

Introduction

The elbow joint is the second most commonly dislocated joint in adults. The annual incidence of simple and complex elbow dislocations in children and adults is 6.1 per 100.000 [1]. Elbow dislocations are classified as simple or complex types [2]. The simple dislocation is characterized by the absence of fractures, while the complex dislocation is associated with fractures. The terrible triad is an example of a complex posterior dislocation with intra-articular fractures of the radial head and coronoid process. The annual incidence of complex elbow dislocations in children and adults is 1.6 per 100.000, or 26% percent of all elbow dislocations [1]. Conn et al. found 414 injuries of the elbow in their fracture service, including 58 elbow dislocations in children and adults [3]. Elbow injuries accounted for 6.8% of all treated fractures. Seventy-six percent of the patients with elbow dislocations were older than 20 years. In 51% of these adults, the dislocations were simple, a lower percentage than the 74% found in Josefsson's study [1]. Elbow dislocations can also be classified by the direction of their displacement. Nearly all the dislocations are of the posterior or posterolateral types. In Conn's study, 96% of the dislocations were posterior or lateral [3] and Joseffson reported no anterior dislocations in his study of 52 patients [4]. In 58% of patients, the simple elbow dislocations were on the non-dominant side [4]. Following reposition and treatment in plaster of simple dislocations, recurrent dislocations and chronic instability are not or only rarely seen [2]. For instance in Joseffson's study one obviously unstable joint was seen in his study of 52 patients after a mean follow-up of 24 years [4]. After reposition of the simple dislocation, treatment options include immobilisation in a static plaster for different periods, surgical treatment of the ruptured medial and lateral collateral ligaments or so-called functional treatment, which is characterised by early active movements within the limits of pain with or without the use of a sling, hinged brace or functional plaster. In theory, after repositioning of a simple dislocated elbow, the joint retains an inherent stability caused by the contour of the intact joint surfaces. This stability may allow the patient to exercise the joint shortly after the reposition. This functional treatment should prevent stiffness or restricted range of motion without risking increased joint instability.

The primary objective of this systematic review of the literature was to identify if functional treatment is the best available treatment for simple elbow dislocations after closed reduction.

Materials and Methods

We conducted an electronic search including MEDLINE, EMBASE, LILACS and the Cochrane Central Register of Controlled Trials (CENTRAL). We did not limit the search by language or publication date. We used the following search terms in different combinations as MeSH (Medical Subject Heading) terms and as text words: elbow joint, dislocation, treatment outcome, surgery, controlled clinical trial, comparative study.

Manual searches including reference lists of all included studies were used to identify trials that the electronic search may have failed to identify.

Two reviewers independently assessed the titles and abstracts of all reports identified by electronic and manual searches. Each report was labelled as (a) definitely exclude, (b) unsure or (c) definitely include. Full text articles of abstracts labelled as "unsure" were reassessed according to the inclusion criteria for this review. Any differences were resolved through discussion. Studies labelled as "definitely exclude" were excluded from the review, while studies labelled as "definitely include" were further assessed for methodological quality.

Two reviewers independently extracted the data for the primary and secondary outcomes and entered the data into data collection forms developed for this purpose. Discrepancies were resolved by discussion. All data were entered into Review Manager [RevMan, (Computer program. Version 5.0. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2008)].

Two reviewers independently assessed the included studies for sources of systematic bias in trials. The studies were evaluated with the following criteria: allocation concealment (selection bias), rates of follow-up and intention to treat analysis (attrition bias). Allocation concealment was graded as (a) adequate, (b) inadequate or (c) unsure. Differences between the two reviewers were resolved by discussion. Masking of outcome assessors in the included studies was assessed.

Dichotomous outcomes (e.g., presence/absence of normal extension) were reported as proportions and were directly compared (difference in proportions). We used these proportions to calculate risk ratios (RRs) and absolute risk reductions (risk differences) with 95% confidence intervals (CIs). For continuous data (e.g., range of motions, function scores) results are presented as weighted mean differences (WMD). We used Review Manager 5.0 software (RevMan 5.0, Cochrane software) for generating the figures and statistical analyses. We explored heterogeneity using the chi-squared test with significance set at a P-value less than 0.10. The quantity of heterogeneity was estimated by the I-squared statistic.

Because prior statistical evidence existed for homogeneity of effect sizes, the planned analysis used a fixed effect model.

Results

A total of two randomised controlled trials (RCTs) and six observational comparative studies comparing different treatments for elbow dislocations were included with a total enrolment of 342 patients with available follow-up (see Table 1, 2, 3, 4, 5, 6, 7 and 8 for characteristics of the included studies). The full text of every study was retrieved.

Because only two RCTs were retrieved we expanded the review with observational comparative studies. Non comparative observational studies were excluded. All studies included simple elbow dislocations. One study consisted of patients with simple and complex elbow dislocations [5]. No RCTs or comparative studies of complex elbow dislocations were retrieved.

Table 1 Characteristics of the study of Josefsson et al. [6]

Methods	Randomised controlled trial
Participants	30 consecutive patients included, acute dislocation of the elbow, age ≥ 16 years, mean age 34.5 years, free from elbow symptoms before injury. Dislocation with fracture excluded except small avulsed fragments < 2x3 mm, 10 male, 20 female, 18 dislocations left, 12 dislocations right side, 28 posterior or posterolateral and 2 lateral dislocations. Reduction in emergency room. Examination under general anaesthesia after mean of 4 days for examination stability: all elbows medial instability and 16 lateral instability. N=11 re-dislocated easily, most often in 45° of flexion
Interventions	Surgical treatment: N=15, exploration medial and lateral side joint through separate incisions Medial and lateral collateral ligaments found to be totally ruptured, although only 8 showed lateral instability. Suturing and re-fixation of ligaments. 6 of the 11 easily re-dislocated elbows treated surgically. Immobilisation in plaster, 90°, 19 days (SD=3). 1 patient in this group lost to follow-up. Non-surgical treatment: N=15, 5 of the 11 easily re-dislocated elbows treated non-surgically. Immobilisation 17 days (SD=2). 1 patient in this group lost to follow-up
Outcomes	Follow-up surgical group 31 months (SD =15), non surgical 24 months (SD=11). Range of motions at 5, 10 weeks and final examination > 1 year: no difference in motion, grip strength, pain, instability Loss of extension > 1 year: surgical group 18^{o} (SD=15) and non-surgical group 10^{0} (SD=14) Loss of flexion > 1 year: surgical group 1^{o} (SD=2) and non-surgical group 1^{0} (SD=2) For unstable elbows (N=11 of which 6 were treated surgically) the loss of extension > 1 year was 20^{0} (SD=19), and loss of flexion was 2^{0} (SD=3) No recurrent dislocations or episodes of instability in both groups.
Allocation concealment	Random selection by 30 sealed envelopes, 15 envelopes for surgical treatment and 15 for non-surgical treatment

Table 2 Characteristics of the study of Rafai et al. [7]

Methods	Randomised controlled trial
Participants	50 pure posterior luxations, adults, normal psychological profile, stable after reposition and tested under general anaesthesia, no previous elbow injury. Mean age 25 years (range 16-67 years), 43 male , 7 female, 30 right arm, 20 left arm
Interventions	Group I: N=26, reduction in general anaesthesia and testing stability. Immobilisation for 3 weeksGroup II: N=24, reduction in general anaesthesia and testing stability. Mobilisation after 3 days. Functional treatment
Outcomes	Normal extension: group I 81% and group II 96% (statistically significant difference concluded by authors) Stiffness (=loss of flexion): group I = 19% and group II = 4% (statistically significant difference concluded by authors) No difference in pain and ossifications No recurrent dislocations or episodes of instability in both groups
Notes	No *P* values are given, but only remarks declaring significant results
Allocation concealment	No details about randomisation

Table 3 Characteristics of the study of Royle [5]

Methods	Retrospective, observational study with 2 comparative groups with mean follow-up of 31 months
Participants	N=38, follow-up of N=32, period 1982-1987, mean age 35.8 years, 17 males (53%), 15 females (47%), N=23 (72%) posterolateral dislocation, N=9 (28%) posterior, N=20 (62%) associated fractures: N=12 radial head, N=6 coronoid, N=4 olecranon avulsion fracture, N=4 medial epicondyle, N=1 lateral condyle, N=1 capitellum, average time for reduction 3.8 h, general anaesthesia N=27 (84%), N=1 internal fixation radial head fracture, instability after reduction N=8 (tested in extension with valgus stress)
Interventions	Group I: N=9, closed reduction and plaster, mean duration 24.7 days Group II: N=23, reduction and sling, mean 17.5 days
Outcomes	Group I excellent (no pain and full extension) or good (minimal pain and extension loss <15^0) in 33.3 versus 83% in group II. Results were graded according to Lindscheid and Wheeler No recurrent dislocations
Notes	Age range 11-75 years; thus included children, also associated fractures N=20 (62%) Posterior dislocation 100% good/excellent result versus N=18 (56%) posterolateral dislocation Better outcome if reduction < 3 h 87 versus 53% good/excellent result Associated fractures N=8 (40%) fair (exertional pain and 15-30^0 extension loss) or poor (constant pain and >30^0 extension loss) versus N=2 (17%) without fractures The results of group I versus group II could be confounded by associated fractures, time of reduction and direction of dislocation
Bias	Heterogeneity of groups, children included, confounded by associated fractures, time of reduction and direction of dislocation

Table 4 Characteristics of the study of Maripuri et al. [8]

Methods	Observational retrospective comparative study
Participants	47 simple elbow dislocations in period 2000-2004, mean age 42.5 years, follow-up > 2 years, N=42 available for review. Inclusion criteria: age ≥ 16 years, simple dislocation, closed reduction, concentric relocation confirmed by radiography, follow-up > 2 years, no associated fractures, no neurovascular deficit. Posterolateral dislocation 60%, direct posterior 30%, posteromedial 10%
Interventions	Group I: N=20, plaster immobilisation, mean 14 days followed by physiotherapy until range of motions (ROM) 100° Group II: N=22, sling application and early mobilisation within pain limits
Outcomes	Group I: mean score Mayo Elbow Performance Index (MEPI) 83.8 (SEM=4.2, SD=18.8) Group II: mean score MEPI 96.5 (SEM=8.9, SD=8.9), P<0.05. MEPI score components are pain, ROM, stability, daily function, which are graded as excellent 90-100, good 75-89, fair 60-74, poor <60 Group I: mean score Quick Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire 12.8 (SEM=3.5, SD=15.7) Group II: mean score DASH 2.7 (SEM=1.5, SD=7.0), P<0.05. Of the DASH the disability and symptom section was used Weeks off work: group I mean 6.6 weeks (SEM=0.64, SD=2.86); group II 3.2 weeks (SEM=0.29, SD=1.36), P<0.001 20 patients (of 22) with excellent or good result in group II (depends on MEPI score). 12 patients (of 20) with excellent or good result in group I (depends on MEPI score) One recurrent dislocation in group I, treated surgically
Notes	Period of immobilisation depended on preference of the treating doctor
Allocation concealment	Retrospective study
Bias	Selection bias for therapy, attending physician decides, instability, time period, for co-interventions: only 50% of group 1 received physiotherapy at 2 weeks versus 100% of group II

Table 5 Characteristics of the study of Riel et al. [9]

Methods	Observational retrospective comparative study with a historical control group. Mean follow-up 8.2 (SD=4.5) years
Participants	In period 1976-1992 50 simple elbow dislocations, N=6 treated surgically, N=44 conservatively, last group re-examined. Reduction without anaesthesia (N=31) or in local anaesthesia
Interventions	Group I: period 1976-1985, N=20, reduction and immobilisation in plaster for 3-4 weeks, N=17 patients re-examined, N=1 telephone inquiry, follow-up 11 (SD=2.6) years, mean plaster period 24 (SD=3) days plus data from medical records, last examination after a mean of 6 months Group II: period 1985-1992, N=24 , reduction and functional treatment day after reposition, N=18 patients re-examined, N=3 telephone inquiry, follow-up 4 (SD=1.8) years, mean plaster period 2 (SD=1) days plus data from medical records, last examination after a mean of 4 months
Outcomes	Range of motions, stability and power not different between groups After-treatment period group I 12 (SD=3) weeks, group II 8 (SD=3) weeks, disability period group I 16 (SD=8) weeks, group II 8 (SD=3) weeks, physical rehabilitation period group I 6 (SD=3) months, group II 4 (SD=3) months
Notes	Sex had no influence on result. No recurrent dislocations
Allocation concealment	No RCT, observational comparative study with a historical control group

Table 6 Characteristics of the study of Protzmann [11]

Methods	Retrospective observational study with 3 comparative groups, mean follow-up 24.5 months
Participants	49 consecutive patients, military service, 1971-1976, from N=47 follow-up, range age 17-44 years, N=15 associated fractures of which 1 radial head fracture and one coronoid process (=only one which could influence stability). From N=25 X-ray: 19 posterolateral, 5 posterior, 1 posteromedial, no anterior dislocation
Interventions	Closed reduction without anaesthesia and group I immobilisation < 5 days, N=27; group II immobilisation 10-15 days, N=13; group III immobilisation > 20 days, N=7
Outcomes	Mean extension loss group I = 3°, group II = 11°, group III = 21°. Mean duration disability group I = 6 weeks, group II = 19 weeks, group III = 24 weeks. No SD given
Notes	No standard deviations given for outcome measures. No recurrent dislocations and no subjective complaints of instability. 28 patients of the 47 with follow-up had periarticular or ligamentous calcifications
Allocation concealment	No RCT, observational study, probably retrospective, comparative study, comparison = post-hoc, immobilisation period was decision of orthopaedic surgeon
Bias	Selection bias for therapy, treating doctor decided

Table 7 Characteristics of the study of Mehlhoff et al. [10]

Methods	Observational retrospective comparative study with 3 comparative groups, mean follow-up 34.3 months
Participants	90 consecutive patients, adults, simple dislocations, follow-up > 12 months, age > 18 years, no associated fractures. Stable after reduction. Period 1978-1985, follow-up from N=52 (56% follow-up), N=34 males, N=18 females. Dislocations: 90% posterolateral + posterior, 10 % posteromedial + medial
Interventions	Closed reduction, after reduction stability and ROM were tested and gravity stress photos were taken. Group I immobilisation 0-13 days; group II immobilisation 14-24 days; group III immobilisation ≥25 days
Outcomes	Ratings extension loss: < 5^0 excellent, <15^0 good, <30^0 fair, ≥30^0 poor Groups divided according to immobilisation period: Group I 0-13 days. Group II 14-24 days, Group III > 24 days Mean flexion contracture = loss of extension: group I: 5.1°; group III 30.1°; loss of flexion: group I 2.7°, group II 5.6°, group III 18.6°. Pain (McGill Pain Questionnaire): group I 80% no pain, group II 45% no pain, group III 10% no pain Instability non significant. No sample sizes of the groups and no SDs for the outcome measures are presented No gross instability of the elbow or recurrent dislocation
Notes	No correlation between age, sex or length of follow-up and flexion contracture, pain or instability (Chi-square test, multiple testing) Heterotopic ossification was seen in 55% of the radiographs, but there was no correlation with impairment of motion
Allocation concealment	No RCT, observational study, probably not prospective, comparative study, groups were formed post-hoc
Bias	Selection bias, 31 of 84 patients did not participate, selection bias for therapy, treating doctor decided

Table 8 Characteristics of the study of Schippinger et al. [12]

Methods	Retrospective observational study with comparative groups (posthoc). Mean follow-up 61.5 (SD=22.2) months
Participants	45 simple elbow dislocations, no or minor fractures (<2x3mm), 2 trauma centres, period 1989-1995, N=27 posterior, N=12 posterolateral, N=2 bilateral posterior, N=1 medial, N=1 anterior, N=1 divergent, N=1 anterolateral dislocation, age 44.5 years (SD=15.9)
Interventions	Closed reduction without general anaesthesia. Check for re-dislocation in various flexion positions. Group I immobilisation < 2 weeks; group II immobilisation 2-3 weeks; group III immobilisation > 3 weeks
Outcomes	Morrey scores and pain group I and II better than group III, but nonsignificant. Number of groups and scores of groups not given N=28 periarticular ossifications and N=11 heterotopic calcifications, but no correlation of ossifications with impairment of motion No recurrent dislocations
Notes	Period of immobilisation was dependent on preference of the orthopaedic surgeon
Allocation concealment	No RCT, observational study, retrospective, comparative study, groups were formed post-hoc, immobilisation period was decision of orthopaedic surgeon

One RCT comparing surgical and non-surgical treatment of simple elbow dislocation was included [6]. The other RCT compared functional treatment with immobilisation in plaster during 3 weeks [7]. The observational comparative studies compared functional treatment with immobilisation in plaster [5, 8, 9] or compared different periods of immobilisation [10-12].

Observational studies that did not compare different treatments were excluded because they provide a low level of evidence (level IV evidence, no control group).

In Josefsson's study [6] random selection was by the use of sealed envelopes, but in Rafai's study [7] no information on randomisation was published. In the observational studies from Schippinger [12] and Maripuri [8] the period of immobilisation, and thus the treatment allocation, was dependent on the preference of the treating doctor.

Since blinding of treatment is difficult or impossible in surgical treatments, the RCTs did not blind doctors or patients to treatment. No information is provided about blinding of the evaluators of the outcomes.

In the observational studies of Protzman [11] and Mehlhoff [10] no standard deviations of the outcome measures are given and in the study of Mehlhoff [10] the sample sizes of the treatment groups are also not provided. In Schippinger's study [12] the sample sizes and outcome scores of the three groups with different immobilisation periods are not provided.

In the observational studies of Schippinger [12] and Maripuri [8] the period of immobilisation was dependent on the treating doctor and was most likely biased by the severity of the trauma so that the patients with the most severe trauma received the longest period of immobilisation.

The results were expressed as relative risk (RR) for dichotomous outcomes and weighted mean difference (WMD) for continuous outcomes with 95% confidence intervals (CI).

Only data from two observational studies comparing functional treatment with plaster immobilisation could be pooled [5, 8]. The percentages of excellent or good results were pooled with the Mantel-Haenszel statistical method. For this pooling the fixed effects model was used since we assumed that all variation between the two studies was caused by chance and that the studies measured the same overall effect. Even if a random-effects model was used, our conclusions remained the same. Data from the other studies that compared different types of treatment and used different outcome measures could not be pooled due to clinical and methodological heterogeneity, and thus are described individually.

Surgical versus non-surgical treatment of simple elbow dislocations

Only one RCT was found that compared surgical with non-surgical treatment [6] (Table 9). At more than 1 year the loss of extension (Comparison 1.1: WMD 8.00, 95% CI -2.75 to 18.75; P=0.14) and loss of flexion (Comparison 1.2: WMD 0.00, 95% CI -1.48 to 1.48; P=1.00) were not statistically different between the two groups. Furthermore, at 10 weeks the loss of extension (Comparison 1.3: WMD 11.00, 95% CI -4.19 to 26.19; P=0.16) and loss of flexion (Comparison 1.4: WMD 6.00, 95% CI -0.11 to 12.11; P=0.05) were not statistically different. Moreover, at 5 weeks the loss of extension (Comparison 1.5: WMD 11.00, 95% CI -4.93 to 26.93; P=0.18) and loss of flexion (Comparison 1.6: WMD 9.00, 95% CI -0.88 to 18.88; P=0.07) were not statistically different. A post hoc power calculation on the mean loss of extension after one year with G*Power software (version 3.03, Kiel, Germany) showed a power of 29%.

Table 9 Surgical versus non-surgical treatment of simple elbow dislocation

Outcome	Studies	Participants	Statistical Method	Effect Estimate
1.1 Loss of extension at more than 1 year	1	28	Mean Difference (IV, Fixed, 95% CI)	8.00 [-2.75, 18.75]
1.2 Loss of flexion at more than 1 year	1	28	Mean Difference (IV, Fixed, 95% CI)	0.00 [-1.48, 1.48]
1.3 Loss of extension at 10 weeks	1	28	Mean Difference (IV, Fixed, 95% CI)	11.00 [-4.19, 26.19]
1.4 Loss of flexion at 10 weeks	1	28	Mean Difference (IV, Fixed, 95% CI)	6.00 [-0.11, 12.11]
1.5 Loss of extension at 5 weeks	1	28	Mean Difference (IV, Fixed, 95% CI)	11.00 [-4.93, 26.93]
1.6 Loss of flexion at 5 weeks	1	28	Mean Difference (IV, Fixed, 95% CI)	9.00 [-0.88, 18.88]

IV inverse variance; *CI* confidence interval

Functional treatment versus plaster treatment

One RCT and three observational studies are described (Table 10). The results of the RCT are described individually [7]. The percentages of normal extension (Comparison 2.1: RR 1.19, 95% CI 0.97 - 1.46; P=0.10) and flexion (Comparison 2.3: RR 1.19, 95% CI 0.97 - 1.46; P=0.10) and pronation and supination (Comparison 2.5: RR 1.25, 95% CI 0.99 - 1.56; P=0.06) at 1 year and normal flexion (Comparison 2.4: RR 1.25, 95% CI 0.99 - 1.56; P=0.06) at 3 months were not statistically different. The percentage of normal extension (Comparison 2.2: RR 1.78, 95% CI 1.23 - 2.57; P=0.002) at 3 months was statistically higher in the functional treatment group. A post hoc power calculation on the percentages of normal extension and flexion at one year with G*Power software (version 3.03, Kiel, Germany) showed a power of 19%.

Data from two studies could be pooled to analyze the percentage of excellent and good outcomes (Fig. 1) [5, 8]. At a follow-up time greater than 2 years, there was a significant difference between functional and plaster treatment for the outcome excellent and good results (Comparison 2.6: RR 1.76, 95% CI 1.19 - 2.60; P=0.004). The other outcome measures of Maripuri [8] study are described individually. Several other measures were statistically different: the mean differences of the Mayo Elbow Performance Index (MEPI) (Comparison 2.7: WMD 12.70, 95% CI 3.66 - 21.74; P=0.006), short Quick Disabilities of the Arm, Shoulder and Hand (Comparison 2.8: WMD -10.10, 95% CI -17.58 to -2.62; P=0.008) and weeks off work (Comparison 2.9: WMD -3.40, 95% CI -4.78 to -2.02; P<0.0001) all suggested better results following functional treatment. The MEPI is one of the most commonly used physician-based elbow rating systems. This index consists of four parts: pain (with a maximum score of 45 points), ulnohumeral motion (20 points), stability (10 points) and the ability to perform five functional tasks (25 points). The Quick DASH disability/symptom score is a summation of the responses to 11 questions on a scale of 1-5, with 0 (no disability) to 100 (severe disability).

	Functional (sling)		Plaster immobilisation			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Maripuri 2007	20	22	12	20	74.5%	1.52 [1.03, 2.22]
Royle 1991	19	23	3	9	25.5%	2.48 [0.97, 6.36]
Total (95% CI)		**45**		**29**	**100.0%**	**1.76 [1.19, 2.60]**
Total events	39		15			

Heterogeneity: Chi² = 1.10, df = 1 (P = 0.29); I² = 9%
Test for overall effect: Z = 2.85 (P = 0.004)

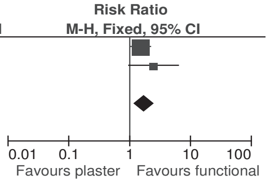

Fig 1 Forest plot comparing functional treatment (sling) and plaster immobilisation for the percentage of excellent or good results

The results of the observational study of Riel [9] are described individually. The physiotherapy time in weeks (Comparison 2.10: WMD -4.00, 95% CI -5.78 to -2.22; P<0.0001), disability period in weeks (Comparison 2.11: WMD -8.00, 95% CI -11.71 to -4.29; P<0.0001) and after-treatment time in months (Comparison 2.12: WMD -2.00, 95% CI -3.78 to -0.22; P=0.03) were statistically significant shorter in the functional group.

Table 10 Functional treatment versus plaster immobilisation

Outcome	Studies	Participants	Statistical Method	Effect Estimate
2.1 Percentage of patients with normal extension at 1 year	1	50	Risk Ratio (M-H, Fixed, 95% CI)	1.19 [0.97, 1.46]
2.2 Percentage of patients with normal extension at 3 months	1	50	Risk Ratio (M-H, Fixed, 95% CI)	1.78 [1.23, 2.57]
2.3 Percentage of patients with normal flexion at 1 year	1	50	Risk Ratio (M-H, Fixed, 95% CI)	1.19 [0.97, 1.46]
2.4 Percentage of patients with normal flexion at 3 months	1	50	Risk Ratio (M-H, Fixed, 95% CI)	1.25 [0.99, 1.56]
2.5 Percentage of patients with normal pro- and supination at 1 year	1	50	Risk Ratio (M-H, Fixed, 95% CI)	1.25 [0.99, 1.56]
2.6 Percentage patients with excellent or good results at > 2 years	2	74	Risk Ratio (M-H, Fixed, 95% CI)	1.76 [1.19, 2.60]
2.7 Mayo Elbow Performance Index (MEPI)	1	42	Mean Difference (IV, Fixed, 95% CI)	12.70 [3.66, 21.74]
2.8 Quick Disabilities of the Arm, Shoulder and Hand (DASH)	1	42	Mean Difference (IV[c], Fixed, 95% CI)	-10.10 [-17.58, -2.62]
2.9 Weeks off work	1	42	Mean Difference (IV, Fixed, 95% CI)	-3.40 [-4.78, -2.02]
2.10 Physiotherapy time (weeks)	1	44	Mean Difference (IV, Fixed, 95% CI)	-4.00 [-5.78, -2.22]
2.11 Period disability (weeks)	1	44	Mean Difference (IV, Fixed, 95% CI)	-8.00 [-11.71, -4.29]
2.12 After-treatment time (months)	1	44	Mean Difference (IV, Fixed, 95% CI)	-2.00 [-3.78, -0.22]

[a] M-H = Mantel-Haenszel statistical method; [b] CI = confidence interval; [c] IV=Inverse variance

Different periods of plaster immobilisation

The results of the observational studies [10-12] comparing different periods of plaster immobilisation could not be expressed as RR or WMD because data (sample sizes of the groups or scores and/or standard deviations) were missing. Thus, we could not judge the following conclusions made by the authors of the studies. Without making statistical inferences, Protzman [11] describes less extension loss and shorter mean disability in weeks for the shorter immobilisation group. Mehlhoff [10] describes less extension loss for the two shorter immobilisation groups (group I 0-13 days, group II 14- 24 days), with a significant correlation between extension loss and duration of follow-up (P=0.001). He also reported less flexion loss and less prevalence and severity of pain for the shorter immobilisation groups but did not analyze this data statistically. The number of patients with symptoms of instability of the elbow joints increased from the shorter immobilisation group to the longer immobilisation groups without reaching statistical significance at the 5% level. Schippinger [12] saw better Morrey scores, which are composed of the items pain, movement, strength, instability and function (activities of daily living), and better separate pain scores in the shorter immobilisation groups, though without statistical significance.

Stability testing of the elbow joint after reposition

Do the above results differ for stable or instable elbow joints after reduction? Nearly all cited studies only included stable joints after reduction. An exception is the study of Josefsson et al. [6]. In this study the elbows were tested for instability after reduction in general anaesthesia and compared with the other elbow in full but unforced extension. All the elbows showed medial instability and 16 of 30 elbows showed lateral instability. Eleven elbows re-dislocated easily. Royle's [5] study also included unstable elbow joints. The elbows were tested mainly in general anaesthesia in extension with valgus stress and eight of the 38 elbows showed instability. Mehlhoff et al. [10] and Schippinger et al. tested for instability [12] and did not include unstable elbows. Maripuri et al. [8] , Riel et al. [9] and Protzman et al. [11] did not test the elbows for instability. We carefully conclude that the majority of the patients, included in these studies, had simple dislocations, which remained stable after reposition.

Discussion

This review has included data from two trials and three observational comparative studies. Important data were missing from three observational comparative studies and the results from these studies were extracted for this review.

Only one RCT assessed suture repair of the collateral ligaments of the elbow joint versus conservative treatment with plaster [6]. No statistically significant differences were found either for loss of extension at 5 weeks, 10 weeks or after more than 1 year, or for loss of flexion after more than 1 year. A trend was found for less loss of flexion at 5 and 10 weeks for the conservative group. This study lacked the power to find a significant difference because of its small sample size.

Only one RCT compared functional treatment and plaster [7]. The percentages of patients with normal extension and flexion at 1 year were not statistically different. A significantly higher percentage of patients with normal extension at 3 months was found for the group with functional treatment. A trend was found for a higher percentage of patients with normal flexion at 3 months and normal pro- and supination at 1 year for the functional treatment group. This study also lacked the power to find a significant difference because of its small sample size. An important shortcoming of this study is that it did not describe the randomisation process, so allocation bias cannot be excluded.

To analyze the percentage of patients with excellent or good results at more than 2 years following either functional treatment or plaster immobilisation, two observational comparative studies were pooled [5, 8]. This classification of excellent or good depends on the amount of pain and range of movement. The results favoured the functional group. This functional treatment after the reposition consisted of early mobilisation in a sling without a plaster or brace.

For the outcome measures MEPI score, quick DASH score and weeks of work we used an individual observational study. Functional treatment resulted in significantly better outcomes. In addition, an individual observational study showed that patients in the functional group needed less time for physiotherapy and after-treatment and had a shorter disability period. Importantly, since treatment allocation was determined by the attending physician in these observational studies, it is likely that severe cases were prescribed longer immobilisation. In one study, outcome was in fact correlated with the presence of fractures, delay to reduction, and direction of dislocation [5]. Any of these variables could be a confounding factor in analysing the effect of treatment in study, as the heterogeneity could be introduced by combining patients with simple and complex dislocations.

Data from the studies comparing different periods of plaster immobilisation could not be extracted, while the authors of all three observational studies observed less movement loss after shorter immobilisations, but this finding was only statistically significant in one study. These studies could also be confounded by the severance of the injury, as worse cases probably underwent longer immobilisation periods.

In the eight included studies only one recurrent dislocation after treatment was mentioned [8] i.e., one recurrence on 342 patients (0.3%). No subjective or gross objective signs of instability were found after treatment, indicating that recurrent dislocations and instability are not a problem after simple posterior dislocations. The majority of the patients (323 out of 342 patients) probably had a stable elbow joint after reduction of the dislocation, although it was not clear in three studies if the patients were tested for instability.

Summary of main results

No difference was found between surgical treatment of the collateral ligaments and plaster immobilisation of the elbow joint. Better range of movement, less pain, better functional scores, shorter disability and shorter treatment time were seen after functional treatment versus plaster immobilisation. Since we did not find any RCTs or comparative studies that studied complex elbow dislocations, our conclusions can only address simple elbow dislocations. Our conclusions only apply to stable elbow joints after reduction.

The quality of the evidence is very low because of the lack of high-quality RCTs. Moreover, the available RCTs lack power due to their small sample sizes. The observational studies could be biased by confounding due to the use of a historical control group or treatment allocation by the treating physician rather than by randomisation. In addition, the treatment groups were not balanced for important potential confounders, and some observational studies did not provide important data as sample size and/or standard deviations.

We advise to test the elbow after reposition for instability by valgus and varus testing and by the lateral pivot-shift test [13]. When the elbow is considered stable one may consider functional after treatment with a pressure bandage. When plaster immobilisation is preferred to treat simple elbow dislocations one has to realise that immobilisation of more than 14 days may be associated with stiffness.

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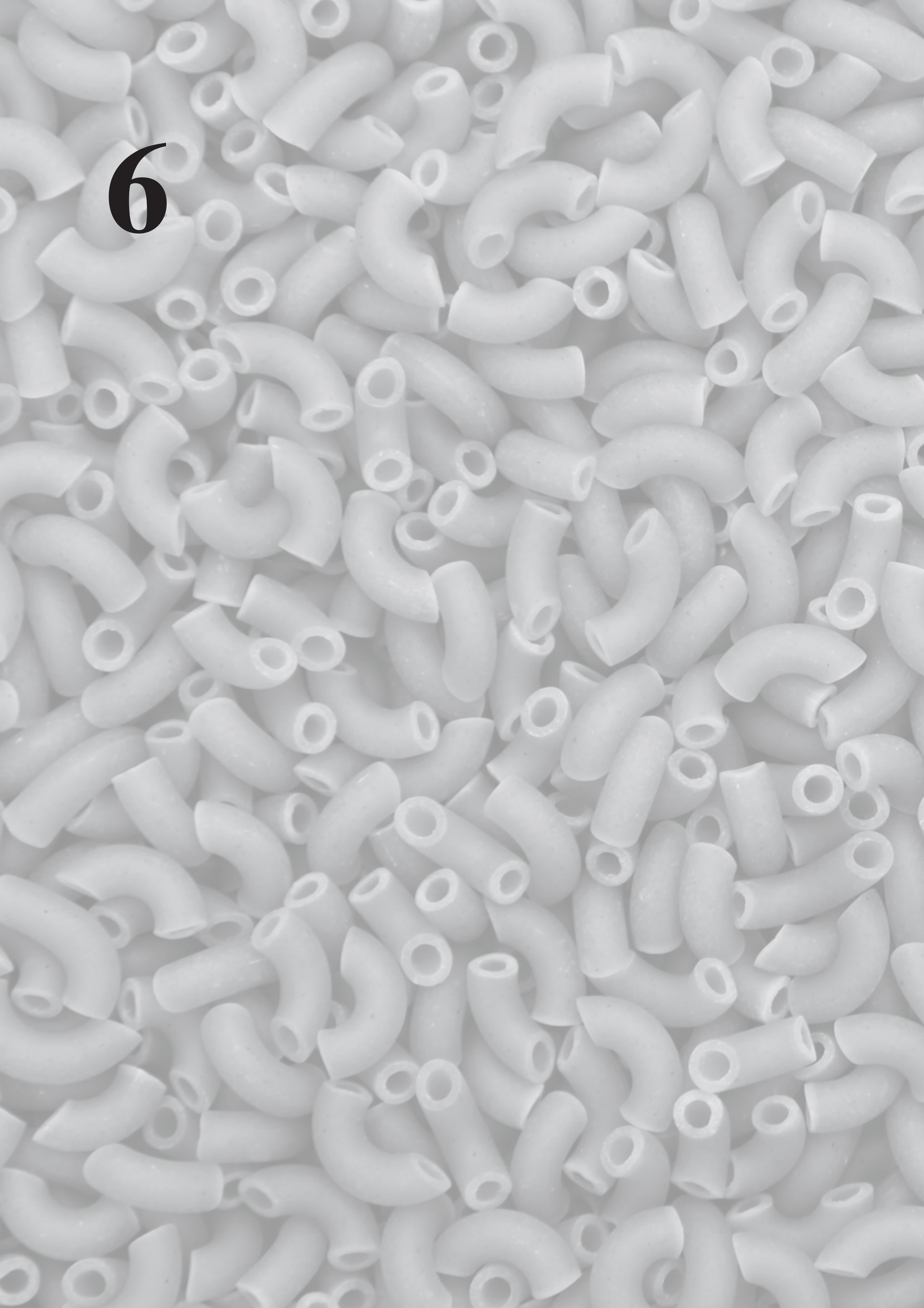

6

Simple elbow dislocations in the Netherlands: How do Dutch surgeons treat this injury?

J. de Haan
N.W.L. Schep
R.W. Peters
W.E. Tuinebreijer
D. den Hartog

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Abstract

There is little evidence related to the best way to treat simple elbow dislocations. However, there are indications that a simple elbow dislocation should not be immobilised for too long and that immobilisation can be followed by functional post-treatment. To gain insight into how simple elbow dislocations are treated in the Netherlands, we conducted a survey of members of the Netherlands Trauma Society. All members received an e-mail with the request to fill out an electronic survey pertaining to the treatment of elbow dislocations. The response percentage was 17% (n=90). Thirty-five (39%) surgeons did not attribute any implications to examinations of elbow stability after the elbow had been repositioned; 63% of these surgeons treated patients with a plaster cast for approximately 3.4 weeks. Fifty-five of the 90 respondents (61%) stated that the stability exam does influence the subsequent course of treatment. If the joint is stable, functional treatment is prescribed in approximately 64% of cases, whereas if the joint is unstable, 24% of the respondents prescribed functional treatment using a hinged external fixator. The results of the survey among Dutch surgeons show that most of those surveyed prefer immobilisation over functional treatment.

Introduction

After the shoulders, the elbow is the second most common joint dislocation in adults (an incidence rate of 6 per 100,000 person years) [1]. A differentiation is made between simple and complex dislocations. Simple dislocations of the elbow are dislocations without any additional fractures. Even though simple elbow dislocations are a common occurrence, little research has been done to identify the best approach to treatment.

Josefsson and associates conducted a randomised controlled trial (RCT) to compare immobilisation with a plaster cast to surgical fixation of the medial and lateral ligaments. After an average follow-up of 27.5 months, no difference in movement or strength could be established[2]. Rafai et al. used an RCT to compare a 3 week plaster cast treatment to functional treatment. Functional treatment was defined as active movement within the pain threshold, with or without the use of a sling, a hinged brace or a functional cast. The functional treatment appeared to be superior to treatment with a plaster cast, which resulted in a larger range of motion (ROM)[3]. Riel and Bernett conducted an observational study to compare functional treatment (mobilisation the day after repositioning) to immobilisation treatment in a plaster cast for a period of 24 days [4]. Both therapies had the same results in terms of stability, range of motion, and strength. Maripuri et al. also compared plaster cast immobilisation (2 weeks) to functional treatment in a retrospective series [5]. The functional treatment resulted in a higher average score on the Mayo Elbow Performance Index (96.5 versus 83.8).

Schippinger et al. divided their patients into three groups based on the duration of immobilisation, using plaster casts in a retrospective series. Patients whose treatment consisted of less than three weeks of immobilisation experienced less pain and displayed better Morrey scores [6].

Multiple authors found a correlation between prolonged immobilisation and poor results [7. 8].

Stability can be tested after repositioning an elbow with a simple dislocation. Redislocation, a positive pivot shift test and a positive valgus and varus test are signs of instability. However, instability after a simple dislocation is rare; a review of eight articles about simple elbow dislocations reported one dislocation out of 342 patients (0.3%) [9]. There is little known about the best treatment for unstable elbow dislocations. Recently an approach to treatment has been described that utilised a hinged external fixator [10]. This is an external fixation device that spans the joint, with a hinge located over the elbow's centre of rotation. When the hinge is in the dynamic state, it is possible to flex and extend the elbow. Therefore, there are some indications that simple elbow dislocations should not be immobilised for too long and that functional post-treatment can be prescribed.

To gain insight into how simple elbow dislocations are treated in the Netherlands, we conducted a survey of the members of the Netherlands Trauma Society.

Question 1
Do you test whether the elbow is stable after repositioning?
☐ Yes
☐ No (Continue to question 4)

Question 2
If stability is tested, do you use the following test (please select all answers that apply):
☐ Passive range of motion, flexion/extension
☐ Varus and valgus instability with the arm at 30° of flexion
☐ Stability of pronation and supination

Question 3
Does your clinic treat stable and unstable dislocations differently?
☐ No (continue to question 4)
☐ Yes (continue to questions 5 and 6)

Question 4a
All posterior elbow dislocations are treated as follows:

	1	2	3	4	5	6
Functional, mark 1 for yes	☐	☐	☐	☐	☐	☐
Upper arm plaster cast for __ weeks:	☐	☐	☐	☐	☐	☐
Functional brace for __ weeks:	☐	☐	☐	☐	☐	☐
Hinged external fixator for __ weeks:	☐	☐	☐	☐	☐	☐

Question 4b
If you treat posterior elbow dislocations differently than described above, please provide an answer below:

Question 5a
All stable posterior elbow dislocations are prescribed the following post-treatment:

	1	2	3	4	5	6
Functional, mark 1 for yes	☐	☐	☐	☐	☐	☐
Functional brace for __ weeks:	☐	☐	☐	☐	☐	☐
Upper arm plaster cast for __ weeks:	☐	☐	☐	☐	☐	☐
Hinged external fixator for __ weeks:	☐	☐	☐	☐	☐	☐

Question 5b
If you treat stable posterior elbow dislocations differently to the method stated above, please provide an answer below:

Question 6a
All unstable posterior elbow dislocations are post-treated as follows:

	1	2	3	4	5	6
Functional, mark 1 for yes	□	□	□	□	□	□
Upper arm plaster cast for __ weeks:	□	□	□	□	□	□
Functional brace for __ weeks:	□	□	□	□	□	□
Hinged external fixator for __ weeks:	□	□	□	□	□	□

Question 6b
If you treat unstable posterior elbow dislocations differently than stated above, please provide an answer below:

Fig 1 Survey sent via e-mail

Methods

All members of the Netherlands Trauma Society (n=515) received an e-mail with the request to fill out an anonymous electronic survey pertaining to the treatment of simple dislocations of the elbow (Fig. 1). Given the low response rate (n=90=17%), all level 1 trauma centres were asked to verify whether those contacted had returned the survey. This was confirmed in all cases.

They were asked which stability test(s) was (were) used after successful repositioning of a simple elbow dislocation, how much influence this test had on the treatment and what type of therapy was chosen for stable and unstable elbow joints after repositioning. Study participants were also asked to specify the duration of treatment. Most of the questions were multiple choice. Some questions included the option to make additional comments.

The information that was submitted was processed with the aid of descriptive statistics using SPSS 16.0 software.

Results

Seventy of the 90 respondents tested the stability of the elbow after repositioning. The majority of the respondents tested varus and valgus instability at 30° of flexion (Table 1).

Table 1 Data pertaining to whether stability tests are performed after repositioning the elbow joint and the method used for testing

Data about testing	N (%)
Use stability tests	
- yes	70 (78%)
- no	20 (22%)
Method used for testing stability	
- passive range of motion of flexion and extension	50
- varus and valgus instability with the arm at 30° of flexion	62
- stability of pronation and supination	37

Fifteen of the 70 respondents who tested the joint for stability indicated that the test results for instability had no influence on subsequent treatment. Together with the 20 respondents who did not perform stability tests, these 15 respondents formed a group of 35 (39%) that was analysed as a single group of respondents for whom the stability test results had no influence on subsequent treatment.

Twenty-two of these 35 surgeons (63%) treat simple dislocations with a plaster cast for an average of 3.4 weeks. Seventy-seven percent of these surgeons prescribe this plaster cast treatment for three weeks or longer (Table 2). Fifty-five (61%) of the 90 respondents have indicated that the treatment prescribed depends on the stability test results after repositioning. If the joint is stable, 9 (16%) surgeons prescribe a plaster cast for 3.1 weeks. This treatment lasts 3 weeks or longer for 78% of these surgeons. A total of 35 (64%) surgeons prescribe functional treatment: 13 prescribe treatment without a brace and 22 prescribe treatment with a brace. Eleven surgeons treat their patients with a plaster cast and functional brace (Table 3).

Table 2 Therapy for simple elbow dislocation when stability tests have no influence on the choice of treatment (n = 35 surgeons)

Treatment	N (%)	Average duration in weeks	% with duration ≥ 3 weeks
plaster cast	22 (63)	3.4	77 %
functional brace	3 (9)	5.3	
plaster cast + functional brace	8 (23)	1.9 (cast) + 3.3 (brace)	
plaster cast + hinged external fixator	1 (3)	1 + 5	
plaster cast + brace + hinged external fixator	1 (3)	2 + 4 + 6	
Total	35		

Table 3 Therapy for simple elbow dislocation if joint is stable after stability test (n = 55 surgeons)

Treatment	N (%)	Average duration in weeks	% with duration ≥ 3 weeks
functional without a functional brace or hinged external fixator	13 (24)		
plaster cast	9 (16)	3.1	78%
functional brace	22 (40)	2.0	32%
plaster cast + functional brace	11 (20)	3.4 (cast) + 2.0 (brace)	
Total	55		

If the joint is unstable, 19 (35%) surgeons prescribe an average of 3.3 weeks of plaster cast fixation. Seventy-four percent of these surgeons prescribed this treatment for 3 weeks or longer.

Thirteen (24%) surgeons treated with a hinged external fixator and 8 (15%) proceeded to treat the joint with surgery to repair the ligament. Thirteen surgeons treated the patient with a plaster cast and functional brace (Table 4).

Table 4 Therapy for simple elbow dislocations where the joint is unstable after stability exam (n = 55 surgeons)

Treatment	N (%)	Average duration in weeks	% with duration ≥ 3 weeks
plaster cast	19 (35)	3.3	74 %
hinged external fixator	13 (24)	5.2	100 %
cast + functional brace	13 (24)	2.2 (cast) + 3.5 (brace)	
cast + functional brace + hinged external fixator	1 (2)	1 + 5 + 6	
surgery (ligament recovery)	8 (15)		
unknown	1 (2)		
Total	55		

Discussion

A response rate of 17% is disappointing; however, all level 1 trauma centres responded. The survey was sent to all members of the Netherlands Trauma Society (NVT). However, it is unreasonable to expect the participation of 515 practicing trauma surgeons. To gain insight into how many trauma surgeons or general surgeons are actually working in traumatology in the Netherlands, we approached the Netherlands Trauma Society (Nederlandse Vereniging voor Traumatologie), the Netherlands Surgery Society (Nederlandse Vereniging voor Heelkunde) and the Medical Specialists Registration Committee (Medische Specialisten Registratie Commissie). Unfortunately, this information appeared not to be registered. Therefore, it was impossible to determine how many of the 515 members are practicing trauma surgeons, and the decision was made to use the term "surgeon" in the text instead.

The majority (78%) of the responding surgeons test the stability of the elbow joint after repositioning a simple elbow dislocation. A majority (61%) of the respondents stated that any stability or instability does indeed influence subsequent treatment. The majority of the trauma surgeons use multiple stability tests; the varus and valgus instability test with the arm at 30° of flexion is used most widely. The literature shows no consensus with regard to the best test method [11].

Surgeons who do not attach any value to the degree of stability tend to treat most cases with a plaster cast (63%) combined with a functional brace (23%). Because the combination treatment of plaster cast / functional brace still averages 1.9 weeks in duration, this treatment cannot be noted as functional therapy.

Sixty-four percent of surgeons who attach value to the degree of stability after repositioning the joint, use functional methods to treat stable dislocations.

This functional treatment consists of a sling / pressure bandage (24%) or a functional brace (40%). Unstable elbow dislocations are treated by 24% of the surgeons with a hinged external fixator. The non-functional treatment consists solely of immobilisation in a plaster cast (35%) or, alternately, starts with a plaster cast (24%), followed by a functional brace. A small percentage (15%) of surgeons treats the medial or lateral ligaments through surgical intervention.

Conclusion

The available literature states that functional therapy results in similar or better outcomes than immobilisation [3-5]. In addition, an RTC did not prove any advantages associated with the suture of medial and lateral ligaments followed by post-treatment in a plaster cast for 17 to 19 days [2]. Therefore, the treatment of simple elbow dislocations by Dutch surgeons can be considered as conservative. An RCT in multiple clinics to compare the functional treatment to treatment with a plaster cast could allow this conservative, evidence-based Dutch trend to evolve a preference for more functional courses of treatment. The protocol for this study has been presented to the Dutch Medical Ethics Committee (Medische Ethische Toetsingscommissie) for their review.

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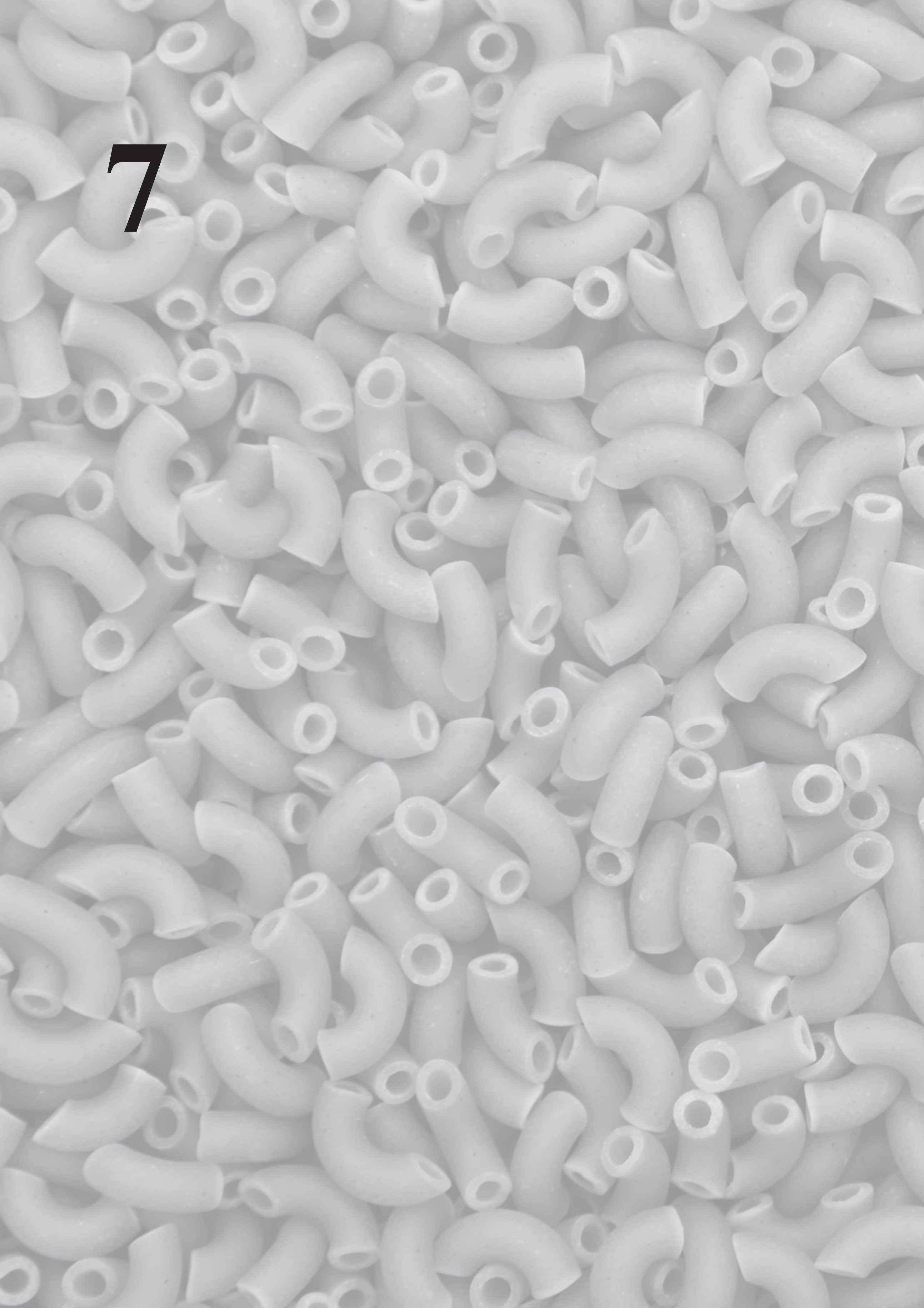

Functional treatment versus plaster for simple elbow dislocations (FuncSiE): a randomised trial

J de Haan
D den Hartog
W.E. Tuinebreijer
G.I.T. Iordens
R.S. Breederveld
M.W.G.A. Bronkhorst
M.M.M. Bruijninckx
M.R. De Vries
B.J. Dwars
D. Eygendaal
R. Haverlag
S.A.G. Meylaerts
J.W.R. Mulder
K.F. Ponsen
W.H. Roerdink
G.R. Roukema
I.B. Schipper
M.A. Schouten
J.B. Sintenie
S. Sivro
J.G.H. Van den Brand
H.G.W.M. Van der Meulen
T.P.H. Van Thiel
A.B. van Vugt
E.J.M.M. Verleisdonk
J.P.A.M. Vroemen
M. Waleboer
W.J. Willems
S. Polinder
P. Patka
E.M.M. van Lieshout
N.W.L. Schep

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Abstract

Background
Elbow dislocations can be classified as simple or complex. Simple dislocations are characterized by the absence of fractures, while complex dislocations are associated with fractures. After reduction of the simple dislocation, treatment options include immobilisation in a static plaster for different periods of time or so-called functional treatment. Functional treatment is characterized by early active motion within the limits of pain with or without the use of a sling, hinged brace or functional plaster. Theoretically, functional treatment should prevent stiffness without introducing increased joint instability. The primary aim of this randomised controlled trial is to compare early functional treatment versus plaster immobilisation following simple dislocations of the elbow.
Methods/Design
The design of the study will be a multicenter randomised controlled trial of 100 patients who have sustained a simple elbow dislocation. After reduction of the dislocation, patients are randomised between a pressure bandage for 5-7 days and early functional treatment or a plaster in 90 °s flexion, neutral position for pro-supination for a period of three weeks. In the functional group, treatment is started with early active motion within the limits of pain. Clinical function, pain, and radiographic recovery will be monitored at regular intervals over the subsequent 12 months. The primary outcome measure is the *Quick* Disabilities of the Arm, Shoulder, and Hand score. The secondary outcome measures are the Mayo Elbow Performance Index, Oxford elbow score, pain level at both sides, range of motion of the elbow joint at both sides, rate of secondary interventions and complication rates in both groups (secondary dislocation, instability, relaxation), health-related quality of life (Short-Form 36 and EuroQol-5D), radiographic appearance of the elbow joint (degenerative changes and ectopic ossifications), costs, and cost-effectiveness.
Discussion
The successful completion of this trial will provide evidence on the effectiveness of a functional treatment for the management of simple elbow dislocations.
Trial Registration
The trial is registered at the Netherlands Trial Register (NTR2025).

Background

The elbow joint is the second most commonly dislocated joint in adults. The annual incidence of elbow dislocations in children and adults is 6.1 per 100,000 [1]. Elbow dislocations are classified as simple or complex [2]. Simple dislocations are dislocations without fractures. Complex dislocations are associated with (avulsion) fractures of the distal humerus, radial head, ulna, or coronoid process. Conn et al. observed 414 injuries of the elbow, which included 58 elbow dislocations in both children and adults [3]. In 51% of these patients, the dislocations were of the simple type. Josefsson et al. observed 24 simple elbow dislocations in 52 patients (46%) who were 16 years old and older [4].

Elbow dislocations can also be classified by the direction of their displacement, i.e., posterior or anterior. Posterior dislocations can be subdivided into medial and lateral dislocations. Anterior dislocations are very rare. In the study by Conn et al., 96% of the dislocations were of the posterior or lateral type [3]. Moreover, Josefsson et al. observed no anterior dislocations in 52 elbow dislocations [4].

Different treatment modalities can be applied following reduction, including plaster immobilisation, surgical treatment of ruptured collateral ligaments, functional treatment, or combinations. There is little available literature about treatment of elbow dislocations. One randomised controlled trial (RCT) was identified in which suture repair of the collateral ligaments was compared with conservative treatment with plaster [5]. No differences were found for loss of extension and flexion after more than one year, although a trend was found for enhanced flexion at five and ten weeks for the plaster group. However, this study lacked power, with a sample size of only 14 patients in each arm. When comparing functional treatment versus plaster immobilisation, only one RCT was retrieved from the literature [6]. Extension and flexion of the elbow did not differ between the groups after one year. Nevertheless, a difference in elbow extension was observed at three months, favoring the patients treated functionally. Furthermore, when two observational studies were pooled comparing functional treatment with plaster immobilisation, functional treatment showed a statistically significant better result for pain and range of motion (ROM) [7, 8].

Three observational studies comparing different periods of plaster immobilisation after reduction showed a larger ROM after shorter immobilisation, but this finding was statistically significant in only one study [9-11]. Moreover, these studies may be confounded by the severity of the injury, as worse cases were probably immobilized longer.

An important question following reduction of simple elbow dislocations is whether or not the elbow is stable. Signs of instability are redislocation, a positive pivot shift test, positive valgus and varus stress testing, and radiographic incongruence. In the studies described above, stability testing was either not performed, or the tests differed between the studies. In these eight studies, only one recurrent dislocation after plaster treatment was mentioned [7] (i.e., one recurrence in 342 patients (0.3%)), and signs of gross instability were not mentioned. Therefore, we conclude that the majority of the patients included in these studies had simple dislocations, which remained stable after reduction. For this type of dislocation, literature suggests that plaster immobilisation for more than two weeks following reduction may lead to limited ROM [13]. Therefore some authors state that early functional treatment should be the treatment of choice. Functional treatment is defined as early active movements within the limits of pain with or without the use of a sling or a hinged brace [6-8].

A recent electronic survey of 90 trauma surgeons in the Netherlands revealed that 60% of the patients with a simple elbow dislocation were generally treated with plaster immobilisation for three weeks or longer [14].

The primary objective of this study is to compare the *Quick*-DASH (Disabilities of the Arm, Shoulder, and Hand) questionnaire scores after functional treatment versus plaster immobilisation in adult patients who sustained a simple elbow dislocation. Secondary aims are to examine the effect of functional treatment versus plaster immobilisation on functional outcome (Mayo Elbow Performance Index (MEPI) and Oxford elbow score), the level of pain (Visual Analog Scale (VAS)), ROM, the rate of secondary interventions and complications, health-related quality of life (Short Form-36 (SF-36) and EuroQol-5D (EQ-5D)), costs, and cost-effectiveness in these patients.

Methods/Design

Study design

The FuncSiE trial will follow a multicenter, randomised controlled trial design. Twenty-five centers in the Netherlands will participate. The study started August 26, 2009.

Recruitment and consent

Eligible patients presenting to the emergency department (ED) with a simple elbow dislocation will be informed about the trial at the ED after reduction of the dislocated elbow. They will receive written information and a consent form from the attending physician, the clinical investigator or a research assistant. After providing informed consent, eligible patients will be randomised within one week. Participants will be allocated to one of two treatment arms using a web-based randomisation program that will be available 24 hours a day. Variable block randomisation will be accomplished via a trial website. Allocation will be at random.

It is not possible to blind surgeons and patients for the allocated treatment. In order to reduce bias, an independent researcher without knowledge of the prescribed treatment will perform follow-up measurements. In addition, radiographs will be blinded and evaluated in duplicate, and analysis will be done in a blinded fashion.

Study population

All persons aged 18 years or older presenting with a simple elbow dislocation at the Emergency Departments of the participating clinics are eligible for inclusion.

Patients meeting the following inclusion criteria are eligible for enrolment:

1. Adult men or women aged 18 years and older (with no upper age limit)
2. A simple dislocation of the elbow (i.e., without associated fracture) that can be reduced by closed means. Presence of a dislocation and absence of fracture(s) will be confirmed by a plain X-ray
3. Provision of informed consent by patient

If any of the following criteria applies, patients will be excluded:

1. Polytraumatized patients
2. Patients with complex, pathological, recurrent or open dislocations
3. Additional traumatic injuries of the affected arm
4. Patients undergoing surgical repair of collateral ligaments of the dislocated elbow joint
5. Patients with an impaired elbow function (i.e., stiff or painful elbow or neurological disorder of the upper limb) prior to the injury
6. Retained hardware around the affected elbow
7. History of operations or fractures involving the elbow
8. Patients with rheumatoid arthritis
9. Likely problems, in the judgment of the investigators, with maintaining follow-up (e.g., patients with no fixed address)
10. Insufficient comprehension of the Dutch language to understand a rehabilitation program and other treatment information, which will be judged by the attending physician

Exclusion of a patient because of enrolment in another ongoing drug or surgical intervention trial will be left to the discretion of the attending surgeon on a case-by-case basis.

Intervention

Reduction can be performed under general, regional, or local anesthesia or without anesthesia, depending upon the preference of the surgeon. The method of choice will be recorded, but not standardized.

Following reduction, the affected arm will be put in either a pressure bandage (e.g., Tubigrip®) or a plaster of Paris for three weeks. Both treatment groups will be advised to use a sling; 5-7 days for the functional group, and up to three weeks in the plaster group.

In the functional group, early active movements within the limits of pain are allowed. Patients will be free to select their own physical therapist. Physical therapy is commenced after two days according to a predefined protocol. Patients will be asked to hand over to their physical therapist the following instructions. Exercises will be performed in a supine overhead position with the shoulder flexed at 90º. When coming into the overhead position, the shoulder is held in adduction and neutral to external rotation. The arm is not allowed to cross the midline. This position is controlled by holding the wrist with the healthy hand. In the supine position, with the shoulder in 90° of forward flexion and the forearm maintained in pronation (with the forearm resting on the forehead), gentle active assisted supination and pronation is performed. The second exercise is performed in the same position. The shoulder is placed in 90° of forward flexion and the elbow in 90° or more flexion. The forearm is held in full pronation. Gentle active and active assisted elbow flexion to full range and elbow extension are performed as tolerated and are not to exceed 30°. After three weeks, the sling will be removed, and the supine exercises will be replaced by active and active assisted elbow and forearm motions in the sitting or standing positions.

The plaster group is immobilized for three weeks and after removal of the plaster physical therapy is initiated according to the same protocol as described above.

Outcome measures

The primary outcome measure is the *Quick*-DASH (Disabilities of the Arm, Shoulder and Hand) score, which reflects both function and pain [15]. The DASH Outcome Measure is a validated 30-item, self-reported questionnaire designed to help describe the disability experienced by people with upper-limb disorders and also to monitor changes in symptoms and function over time [15, 16].

The *Quick*-DASH is a shortened version of the DASH Outcome Measure. Instead of 30 items, the Quick-DASH uses 11 items (scored 1-5) to measure physical function and symptoms in people with any or multiple musculoskeletal disorders of the upper limb. The right and left elbow will be assessed separately. At least 10 of the 11 items must be completed for a score to be calculated. The scores will be transformed to a 0-100 scale for easy comparison. A higher score indicates greater disability.

Like the DASH, the *Quick*-DASH contains 2 optional modules to measure symptoms and function in athletes, performing artists and other workers whose jobs require a high degree of physical performance. These optional models are scored separately; each contains four items, scored 1-5. All items must be completed for a score to be calculated.

The secondary outcome measures are:

- Functional outcome (Mayo Elbow Performance Index and Oxford Elbow Score)
- Pain level at both sides (VAS)
- Range of Motion of the elbow joint at both sides
- Rate of secondary interventions
- Rate of complications (secondary dislocation, instability, relaxation)
- Health-related quality of life: SF-36 and EQ-5D

- Radiographic appearance of elbow joint (degenerative changes and ectopic ossifications)
- Cost
- Cost-effectiveness

The MEPI index is one of the most commonly used physician-based elbow rating systems. This index consists of five parts: pain (with a maximum score of 45 points), ulnohumeral motion (20 points), stability (ten points), the ability to perform five functional tasks (5x5 points) and the patient response. If the total score is between 90 and 100 points, it is considered excellent; between 75 and 89 points, good; between 60 and 74 points, fair; and less than 60 points, poor [17].

The Oxford elbow score is a 12-item questionnaire. It is comprised of three one-dimensional domains: elbow function, pain and social-psychological, with each domain comprising 4 items with good measurement properties [18]. This is a validated questionnaire in the UK and was translated to Dutch by the proper translation procedure, which uses the technique of translation and back-translation [19]. Permission for translation and the use of the OES for this study was obtained from Oxford and Isis Outcomes, part of Isis Innovation Limited (website: http://www.isis-innovation.com/)

Pain level will be determined using a 10-point Visual Analog Scale (VAS), in which zero implies no pain and ten implies the worst possible pain.

ROM will be measured on both sides using a goniometer.

Secondary interventions within one year of initial treatment to relieve pain or improve function will be recorded. This includes secondary revision of collateral ligaments and external fixator placement.

Complications within one year of initial treatment will be recorded. These include redislocation, pressure necrosis (plaster group only), post-traumatic dystrophy, and neurologic deficit.

The Short-Form 36 (SF-36) is a validated multi-purpose, short-form health survey with 36 questions that represent eight health domains that are combined into a physical and a mental component scale [20]. The Physical Component Scale (PCS) combines the health domains of physical functioning (PF; ten items), role limitations due to physical health (RP; four items), bodily pain (BP; two items), and general health perceptions (GH; five items). The Mental Component Scale (MCS) combines the health domains of vitality, energy, or fatigue (VT; four items), social functioning (SF; two items), role limitations due to emotional problems (RE; three items), and general mental health (MH; five items). Scores ranging from zero to 100 points are derived for each domain, with lower scores indicating poorer function. These scores will be converted to a norm-based score and compared with the norms for the general population of the United States (1998), in which each scale was scored to have the same average (50 points) and the same standard deviation (ten points).

The EuroQol-5D is a validated questionnaire for health-related quality of life [21, 22].

Radiographic appearance (anteroposterior and lateral X-ray at one year): ectopic ossification will be classified according the classification scheme of Broberg and Morrey as a bone exostosis or as a soft tissue ossification of a ligament, capsule or muscle ("myositis ossificans") [23]; degenerative changes will be classified as grade zero (no change), grade 1 (slight narrowing of the joint space with small osteophytes), grade 2 (moderate narrowing of the joint space, osteophytes and subchondral sclerosis), and grade 3 (severe narrowing of the joint space, large osteophytes, subchondral sclerosis and cystic deformation).

The incremental cost-effectiveness ratio of functional versus plaster treatment will be expressed in a cost-utility ratio, i.e., in terms of cost per QALY. The economic evaluation will be performed from a societal perspective, and will include both health care costs and costs of production losses. Health care costs will include costs of general practice care, medical specialist care, physical therapy, hospitalization, medication, and other costs directly associated with diagnosis, treatment and rehabilitation. Patients will be asked to administer a custom-made questionnaire to register their health care needs and production loss.

In addition to the outcome variables mentioned above, the following data will be collected:

a) Intrinsic variables (baseline data): age, gender, American Society of Anesthesiologists' ASA classification, tobacco consumption, alcohol consumption, comorbidity, social status / household composition, dominant side, and medication use.

b) Injury related variables: affected side, mechanism of injury, and assessment of varus, valgus and posterolateral rotatory instability.

c) Intervention-related variables: reduction delay (i.e., time between dislocation and reduction), time between injury and start of physical therapy, days of sling use, and number of physical therapy sessions.

Study procedures [Table 1]

Clinical assessments will occur at the time of admission (baseline), one week (3-10-day window), three weeks (11-28-day window), six weeks (4-8-week window), three months (11-15-week window), six months (5-7-month window), and 12 months (12-14-month window) after start of treatment.

At each FU visit, the research coordinator or research assistant will ascertain patient status (i.e., secondary interventions, adverse events/complications, deaths) and will verify information within medical records.

At each FU visit, the patients will be asked to indicate the pain level on a VAS. At each visit from six weeks onwards, the ROM of the elbow will be measured using a goniometer by a doctor blinded for the treatment of the dislocation. This will be used to calculate the MEPI index. In addition, patients will be asked to complete the questionnaires relating to disability (*Quick*-DASH score including optional modules, Oxford Elbow Score), health-related quality of life (SF-36, EQ-5D), and healthcare consumption.

Plain X-rays of the elbow will be made at the time of presentation in the hospital (baseline), post-reduction, and at the follow-up visit after one week and one year. The X-ray at 12 months will be taken in order to determine the amount and location of heterotopic ossification and the grade of degenerative joint changes. This is common practice in this type of patient. At the last visit, the surgeon will document any surgery that may be planned for the patient.

Table 1 Schedule of events

	Screening	Enrolment	Baseline	1 week	3 weeks	6 weeks	3 months	6 months	12 months
				(3-10 d)	(11-28 d)	(4-8 we)	(11-15 we)	(5-7 mo)	(12-14 mo)
Screening	X								
X-ray	X		X (<24h post-reduction)	X					X
Informed Consent		X							
Randomisation		X							
Baseline data			X						
Clinical follow-up				X	X	X	X	X	X
Revisision surgery				X	X	X	X	X	X
Complications				X	X	X	X	X	X
Pain (VAS)				X	X	X	X	X	X
Quick-DASH						X	X	X	X
MEPI						X	X	X	X
Oxford Elbow Score						X	X	X	X
SF-36						X	X	X	X
EQ-5D						X	X	X	X
Health care consumption						X	X	X	X
ROM						X	X	X	X
Early withdrawal				*	*	*	*	*	*

* only if applicable

Sample size calculation

Calculation of the required sample size is based upon the assumption that the mean *Quick*-DASH will be 12.5 in plaster treated patients and five in the functional group, assuming a standard deviation of 15 for the plaster group and 7.5 for the functional group [7]. A 2-sided test with an α level of 0.05 and a β level of 0.2 requires 41 patients in each group. Anticipating a dropout rate of 20% loss to follow-up a sample size of 50 patients in each arm is required.

Statistical analysis

Data will be analyzed using the PASW Statistics version 18.0.1 or higher (SPSS, Chicago, Illinois, USA). Normality of continuous data will be tested with the Shapiro-Wilk and

Kolmogorov-Smirnov test and by inspecting the frequency distributions (histograms). The homogeneity of variances will be tested using the Levene's test.

The analysis will be performed on an intention to treat basis. Patients with protocol violations will be followed up, and data will be recorded. Data will be analyzed with and without inclusion of patients with protocol violation.

Descriptive analysis will be performed to report baseline characteristics (intrinsic variables and injury-related variables) in both treatment groups. For continuous data (e.g., age, Quick-DASH score at baseline) mean ± SD (parametric data) or medians and percentiles (non-parametric data) will be calculated. For categorical data (e.g., gender, ASA grade, alcohol and tobacco consumption, dominant and affected side) frequencies will be calculated.

The mean difference between the mean *Quick*-DASH scores of the functional group and the plaster group will be tested. Univariate analysis will be performed to test the difference in the primary and secondary outcome measures between the functional and the plaster groups. Continuous data will be tested using a Student's T-test (parametric data) or a Mann Whitney *U*-test (non-parametric data). Chi-square analysis will be used for statistical testing of categorical data. A p-value <0.05 will be taken as the threshold of statistical significance.

A multivariable linear regression analysis will be performed to model the relationship between different covariates and the *Quick*-DASH score. Intrinsic and injury-related variables that display a p-value <0.5 in the univariate analyses will be added as a covariate.

Ethical considerations

The study will be conducted according to the principles of the Declaration of Helsinki (59th World Medical Association General Assembly, Seoul, October 2008) and in accordance with the Medical Research Involving Human Subjects Act (WMO).

The Medical Ethics Committee Erasmus MC (Rotterdam, The Netherlands) acts as central ethics committee for this trial (reference number MEC-2009-239; NL28124.078.09). Approval has been obtained from the local Medical Ethics Committees in all participating centers. An information letter notifying the patients' participation will be sent to their general practitioners, unless a patient does not agree with this.

The Medical Ethics Committee Erasmus MC has given dispensation from the statutory obligation to provide insurance for subjects participating in medical research (article 7, subsection 6 of the WMO and Medical Research (Human Subjects) Compulsory Insurance Decree of 23 June 2003). The reason for this dispensation is that participation in this study is without risks.

Discussion

The FuncSiE trial will compare management of simple elbow dislocations by early functional treatment with treatment by plaster immobilisation. Early functional treatment may lead to a better ROM and prevent elbow stiffness. To date no RCT for the management of simple elbow dislocation has been performed with a sample size of 100 patients. Inclusion of patients has been started August 26, 2009 and the expectation is to include 8 patients per month. With a follow-up of one year the presentation of data will be expected in the beginning of 2012.

List of abbreviations used

ASA, American Society of Anesthesiologists; BP, Bodily Pain; CONSORT, CONsolidated Standards of Reporting Trial; DASH, Disabilities of the Arm, Shoulder and Hand score; ED, Emergency Department; EQ-5D, EuroQol-5D; GH, General Health perception; HR-QoL, Health-related Quality of Life; MCS, Mental Component Scale; MEPI, Mayo Elbow Performance Index; MH, general Mental Health; NTR, Netherlands Trial Registry (in Dutch: Nederlands Trial Register); PCS, Physical Component Scale; PF, physical functioning; QALY, Quality-Adjusted Life Years; QoL, Quality of Life; RCT, Randomised Controlled Trial; RE, Role limitations due to Emotional problems; ROM, Range Of Motion; RP, role limitations due to physical health; SF, Social Functioning; SF-36, Short Form 36; SPSS, Statistical Package for the Social Sciences; VAS, Visual Analog Scale; VT, vitality, energy, or fatigue.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

JDH, DDH, WET, EMMVL, and NWLS developed the trial and drafted the manuscript. NWLS will act as trial principal investigator. SP assisted in the design of the healthcare consumption questionnaire and will perform the health economic analyses. WET, EMMVL and NWLS will perform statistical analysis of the trial data. JDH, DDH, GITI, RSB, MWGAB, MMMB, MRDV, BJD, DE, RH, SAGM, JWRM, KJP, GRR, IBS, MAS, JBS, SS, JGHVDB, HGWMVDM, TPHVT, ABVV, EJMMV, JPAMV, MW, WJW, PP, and NWLS will participate in patient inclusion and assessment. All authors have read and approved the final manuscript.

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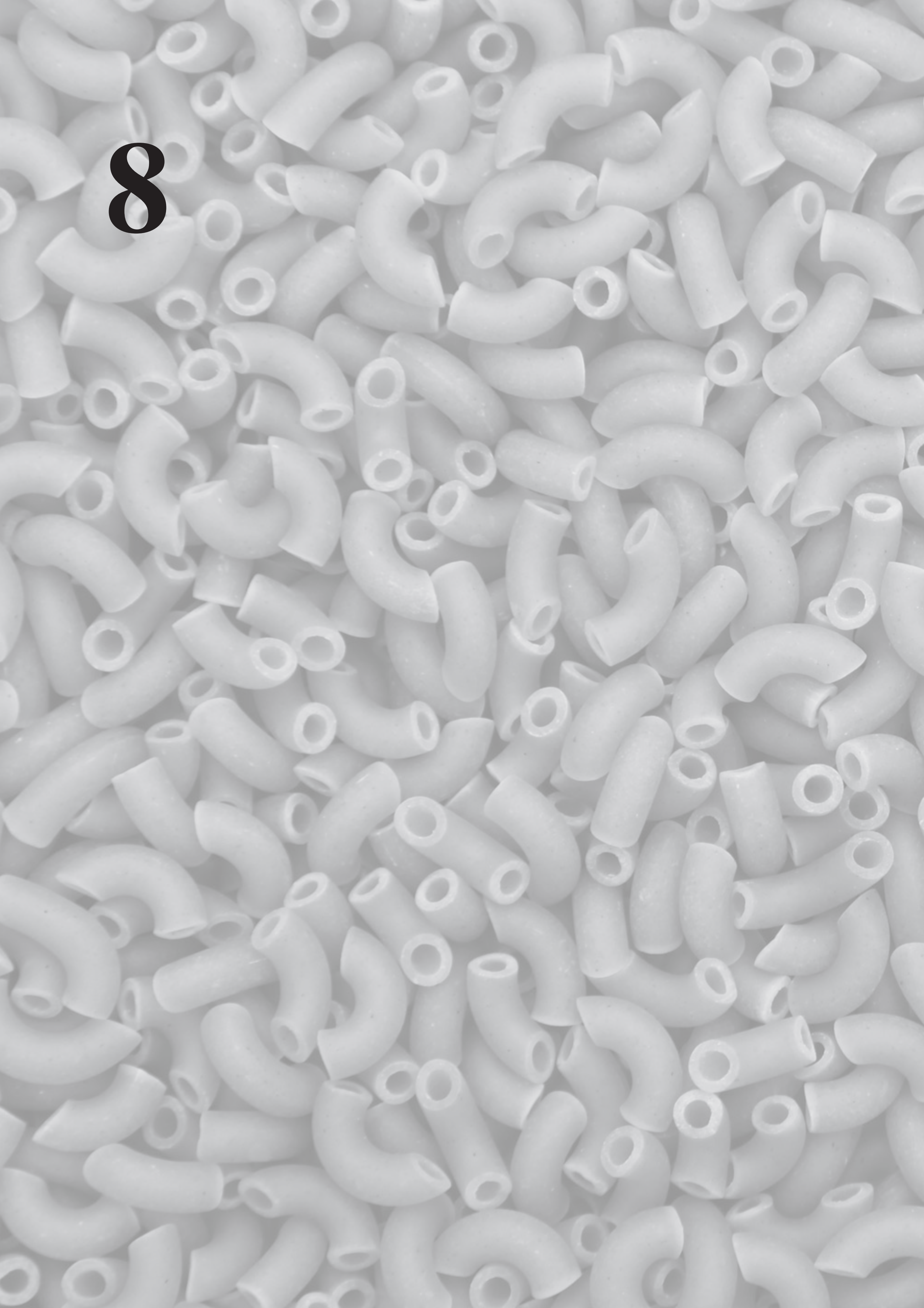

Complex and unstable simple elbow dislocations: a review and quantitative analysis of individual patient data

J. de Haan
N.W.L. Schep
W.E. Tuinebreijer
D. den Hartog

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Abstract

Objective
The primary objective of this review of the literature with quantitative analysis of individual patient data was to identify the results of available treatments for complex elbow dislocations and unstable simple elbow dislocations. The secondary objective was to compare the results of patients with complex elbow dislocations and unstable elbow joints after repositioning of simple elbow dislocations, who were treated with an external fixator versus without an external fixator.

Search strategy
Electronic databases MEDLINE, EMBASE, LILACS, and the Cochrane Central Register of Controlled Trials.

Selection criteria
Studies were eligible for inclusion if they included individual patient data of patients with complex elbow dislocations and unstable simple elbow dislocations.

Data analysis
The different outcome measures (MEPI, Broberg and Morrey, ASES, DASH, ROM, arthrosis grading) are presented with mean and confidence intervals.

Main results
The outcome measures show an acceptable range of motion with good functional scores of the different questionnaires and a low mean arthrosis score. Thus, treatment of complex elbow dislocations with ORIF led to a moderate to good result. Treatment of unstable simple elbow dislocations with repair of the collateral ligaments with or without the combination of an external fixator is also a good option.

The physician-rated (MEPI, Broberg and Morrey), patient-rated (DASH) and physician- and patient-rated (ASES) questionnaires showed good intercorrelations.

Arthrosis classification by X-ray is only fairly correlated with range of motion.

Elbow dislocations are mainly on the non-dominant side.

Introduction

The elbow joint is the second most commonly dislocated joint in adults. The annual incidence of simple and complex elbow dislocations in children and adults is 6.1 per 100,000 [1]. Elbow dislocations are classified as simple or complex types [2]. The simple dislocation is characterised by the absence of fractures, while the complex dislocation is associated with fractures. Complex dislocations are associated with fractures of the distal humerus, radial head, ulna or coronoid process. Radial head fractures occur in 36%, coronoid process fractures occur in 13% and olecranon in 4% of dislocations of the elbow [1].

Rare fractures in adults include those in the supracondylar humerus, capitellum, and trochlea. Fewer than 2% of elbow fractures affect the distal humerus. Mehdian states that capitellar fractures account for 0.5-1% of elbow injuries, and trochlear fractures are less common.

The radial head and coronoid process are considered to be important bony stabilisers of the elbow. Moreover, an avulsed condylar fracture of the distal humerus may lead to instability due to loss of function of the collateral ligaments [3]. The fundamental goal in the management of fracture dislocation of the elbow is the restoration of the osseous-articular restraints. Therefore, the majority of these complex dislocations are treated with open reduction and internal fixation (ORIF) [4].

Operative treatment of complex dislocations is only described in observational studies [2, 4-8]. However, the surgical goal, namely the restoration of anatomy and early mobilisation, is the same as in other fracture treatments. Assessment of the elbow stability is essential following ORIF of complex elbow dislocations. Signs of instability are redislocation, a positive pivot shift test and positive valgus and varus stress testing. At present, the postoperative management of unstable elbows following ORIF consists of a period of plaster immobilisation in most cases. The objective of this immobilisation is to prevent redislocation of the elbow joint and to prevent fracture dislocations [8].

Yet, studies performed in patients with a simple elbow dislocation, i.e., without fractures, indicated that plaster immobilisation exceeding two weeks and following reposition may lead to a limited range of motion [9-11]. Functional treatment could possibly prevent a limited range of motion. Functional treatment is defined as early active movement within the limits of pain with or without the use of a sling or with or without the use of a hinged brace [12, 13].

Theoretically, a period of plaster immobilisation after ORIF of a complex elbow dislocation may result in a limited range of motion and a stiff elbow with subsequent major disability. Theoretically, a hinged external elbow fixator may provide enough stability to start early mobilisation after ORIF of complex dislocations with signs of residual instability [7, 14]. Up to now, only small observational studies about this treatment modality have been published. No randomised controlled trials or observational studies comparing hinged external fixation and immobilisation are available. This is due to the fact that a complex elbow dislocation with remaining instability after ORIF is a rare injury.

The primary objective of this review of the literature with quantitative analysis of individual patient data was to identify the results of available treatment for complex elbow dislocations and unstable simple elbow dislocations. The secondary objective was to compare the results of patients with complex elbow dislocations and unstable elbow joints after reposition of simple elbow dislocations, which were treated with an external fixator versus those treated without an external fixator.

Materials and Methodology

We conducted an electronic search including MEDLINE, EMBASE, LILACS and the Cochrane Central Register of Controlled Trials (CENTRAL). We did not limit the search by language or publication date. We used the following search terms in different combinations as MeSH (Medical Subject Heading) terms and as text words: elbow joint, dislocation, treatment outcome, surgery, controlled clinical trial, and comparative study. Manual searches, including reference lists of all included studies, were used to identify trials that the electronic search may have failed to identify.

Two reviewers independently extracted the data for the primary and secondary outcomes and entered the data into data collection forms developed for this purpose. Discrepancies were resolved by discussion. All data were entered into PASW Statistics (version 17.0; SPSS Inc., Chicago, Illinois). The following variables were retrieved from the studies when available: gender, age, length of follow-up, time between injury and operation, direction of dislocation, side of dislocation, dominance, radial head fracture and treatment, coronoid fracture and treatment, olecranon fracture and treatment, capitellum/trochlea fracture and treatment, terrible triad, external fixator treatment, treatment medial and collateral ligament, ulnar nerve complications, arthritis, contracture release, arthroplasty, ipsilateral injury, pintrack infection, flexion, extension, pronation, supination, motion arc, rotation arc, DASH (Disabilities of the Arm, Shoulder and Hand) score, Broberg and Morrey score, ASES (American Shoulder and Elbow Surgeons Elbow Evaluation instrument) score, and MEPI (Mayo Elbow Performance Index) score. The DASH, ASES, Broberg and Morrey and MEPI scores range from 0 to 100 points. Higher DASH scores indicate worse upper extremity function, and higher Broberg and Morrey, MEPI and ASES scores indicate better elbow function. The MEPI consists of the physician's assessment of pain, ulnohumeral motion, stability and the ability to perform five functional tasks. The Broberg and Morrey rating system is based on the physician's assessment of motion, strength, stability and pain. The MEPI and Broberg and Morrey scores are ranked categorically according to the following ranks: poor (MEPI and Broberg and Morrey < 60 points), fair (MEPI 60-74, Broberg and Morrey 60-79), good (MEPI 75-89, Broberg and Morrey 80-94) and excellent (MEPI > 89, Broberg and Morrey >94). The ASES Elbow Evaluation Instrument combines the patient's assessment of pain, the ability to perform functional tasks and satisfaction with the physician's evaluation of flexion arc, forearm rotation, strength, stability and physical findings. The DASH questionnaire is completed by the patient and evaluates difficulty with performing specific tasks, as well as symptoms, social function, work function, sleep and confidence in relation to the upper limb [15]. Arthritis was classified according to three grades: grade 1 mild, grade 2 moderate and grade 3 severe [16].

In the first analysis, the database was considered as one database and not as a database of different studies. Descriptive statistics were calculated for the complex elbow dislocations and unstable simple elbow dislocations separately. Pearson product-moment correlations were calculated between the continuous outcome measures, and Spearman rho correlations were calculated between the categorical rankings. For the agreement between the MEPI categories and Broberg and Morrey categories, quadratic weighted Kappa correlation coefficients were calculated with StatXact 5 (Cytel Software Corporation). Different variables values between patients with or without an external fixator were compared using unpaired t-tests. The relationship between the motion and rotation arc and treatment with an external fixator was estimated using multiple regression, allowing for the time from injury to operation and length of follow-up. The results are presented as regression coefficients and 95% confidence intervals (CI). This analysis was stratified by study by including a dummy covariate for each study.

Results

No randomised trials or comparative studies were retrieved from the literature. Only studies with individual data of the patients were included. The systematic review included 10 observational studies encompassing 170 patients with complex elbow dislocations (n=134, 78.8%) or unstable simple elbow dislocations (n=36, 21.2%). Five studies included only complex elbow dislocations [17-21], two studies only simple elbow dislocations [22, 23] and three studies included complex elbow dislocations as well as unstable simple dislocations [14, 24, 25]. The two studies with only unstable simple elbow dislocations published individual data from the same patients [22, 23], therefore the study with the largest sample size was included [23]. The results of the patients with complex elbow dislocations and the results of the unstable simple elbow dislocations will be presented separately.

Complex elbow dislocations

From 85 of the 134 patients where the gender was retrieved from the articles, 48 were male (56.5%) and 37 were female (43.5%). The mean age in 105 patients was 41.2 years (SD=16.7). In 38 patients the side of trauma was noted: in 21 patients the left elbow (55.3%) was affected, and in 17 cases it was the right elbow (44.7%). In these 38 cases, the hand dominance was as follows: two patients were (5.3%) left-handed and 36 (94.7%) were right-handed. Fifty seven patients (83.8%) had a posterior dislocation, 11 patients an anterior dislocation (16.2%) and in the other 66 patients the dislocation type was not recorded. In eight patients (6%) an ipsilateral injury was recorded. Seventy-nine patients (59.0%) had coronoid fractures, 112 (83.6%) had radial head fractures, 27 (20.1%) had olecranon fractures and 4 (3%) had capitellum or trochlea fractures. Terrible triad (posterior dislocation with coronoid and radial head fracture) was in seen in 67 patients (50%). The mean time in days between the injury and the operation in 34 patients was 13.5 days (SD=14.3; min 1, max 53). The mean length of follow-up in months in 103 patients was 87.4 months (SD=94.8; min 10, max 408). The operative treatment of the radial head fracture was as follows: ORIF (n=27, 20.1%), prosthesis (n=46, 41.1%), allograft (n=1, 0.9%), excision (n=24, 21.4%) and no operative treatment (n=14, 12.5%). Eight of the 24 patients with radial head excision were treated with an external fixator. The treatment of the coronoid fractures was as follows: ORIF or suturing (n=43, 54.4%), no operative treatment (n=30, 38.0%) and unknown (n=6, 7.6%). The 30 coronoid fractures, which were not operated, were in 77% type I fractures. The treatment of the olecranon fractures was as follows: ORIF (n=24, 88.9%) and unknown (n=3, 11.1%). The treatment of the capitellum/trochlea fractures was as follows: ORIF (n=3) and unknown (n=1). In 48 cases the lateral collateral was repaired, and in four cases the medial collateral ligament was repaired. Thirty patients (22.4%) were treated with an external fixator after treatment of a fracture and/or ligament, except for two cases in which the external fixator was the only operative treatment. One patient was treated with radiocapitellar transfixation with a Kirschner wire. Ten patients (7.5%) had a contracture release. Two patients had an arthroplasty (1.5%) after failed primary treatment, but outcome measures of these patients were not recorded. In five cases the ulnar nerve was released, in one case it was transposed primarily and in seven cases it was transposed secondarily. Two patients had a pin track infection as a result of the external fixator treatment.

Table 1 shows the different outcome measures of the treatment of complex elbow dislocations.

Table 1 Different outcome measures of the treatment of complex elbow dislocations

Outcome measures	N	Mean	SD	95% CI
Flexion in degrees	83	134.7	13.1	131.9; 137.6
Extension in degrees	83	-17.7	13.8	-20.8; -14.7
Pronation in degrees	83	67.3	23.2	62.2; 72.4
Supination in degrees	83	63.8	26.8	57.9; 69.6
DASH score	44	12.8	18.8	7.1; 18.5
MEPI score	37	85.7	14.9	80.7; 90.6
Broberg and Morrey score	67	86.5	11.2	83.8; 89.2
MEPI category	66	1.95	0.87	1.74; 2.17
Boberg and Morrey category	116	2.09	0.88	1.93; 2.26
ASES score	43	89.6	13.0	85.6; 93.6
Arthritis Broberg and Morrey	80	0.83	0.93	0.62; 1.03
Motion arc in degrees	83	117.0	22.2	112.1; 121.8
Rotation arc in degrees	83	131.1	44.9	121.3; 140.9

The results of the MEPI categories were as follows: excellent (n=23, 34.8%), good (n=26, 39.4%), fair (n=14, 21.2%) and poor (n=3, 4.5%). The results of the Broberg and Morrey categories were as follows: excellent (n=32, 27.6%), good (n=49, 42.2%), fair (n=27, 23.3%) and poor (n=8, 6.9%). The results of the arthritis Broberg and Morrey categories were as follows: no arthritis (n=34, 42.5%), grade 1 (n=33, 41.3%), grade 2 (n=6, 7.5%) and grade 3 (n=7, 8.8%).

The MEPI scores showed excellent agreement with the Broberg and Morrey scores (r=0.90, n=24), ASES scores (r=0.84, n=23), and DASH scores (r=-0.89, n=24), the Broberg and Morrey scores showed good agreement with the ASES scores (r=0.91, n=23) and DASH scores (r=-0.84, n=24) and the ASES scores correlated well with the DASH scores (r=-0.81, n=43). The Broberg and Morrey categories showed substantial agreement with the MEPI categories (weighted Kappa coefficient=0.75, CI 0.63; 0.86, n=53). The motion and rotation, in degrees, showed moderate agreement with the MEPI (r=0.45; 0.46, n=38) and Broberg and Morrey (r=0.59; 0.62, n=78) scores and poor agreement with the ASES (r=0.12; 0.31, n=23) and DASH (r=0.09; -0.11, n=24) scores. The agreement (Spearman's correlation) between the arthritis classification from Broberg and Morrey and the MEPI was 0.21 (n=24), and the Broberg and Morrey score was -0.34 (n=71), and the ASES score was -0.15 (n=43), and the DASH score was -0.06 (n=44), and the motion arc was -0.29 (n=91), and the rotation arc was -0.30 (n=71). The arthrosis classification from Broberg and Morrey showed slight agreement with the Broberg and Morrey categorical rankings (weighted Kappa coefficient=0.16, CI 0.04; 0.29, n=91) as well as with the MEPI categorical rankings (weighted Kappa coefficient=0.16, CI 0.00; 0.39, n=44)

Table 2 shows the results of the unpaired t-tests comparing patients with versus without an external fixator for the treatment of a complex elbow dislocation.

Table 2 Comparison of different variables in patients without an external fixator and those with an external fixator in the treatment of complex elbow dislocations (unpaired t-tests)

Variables	No fixator	N	Fixator	N	95% CI difference	P value
Age in years	40.5 (16.7)	88	45.1 (16.7)	17	-13.3; 4.2	0.31
Length follow-up (mths)	99.5 (99.0)	86	26.3 (20.3)	17	49.8; 96.5	0.00
Time to operation (days)	5.5 (4.6)	21	26.5 (15.3)	13	-30.4; -11.6	0.00
Flexion in degrees	137 (10.9)	66	125.9 (17.1)	17	2.0; 20.2	0.02
Extension in degrees	-17.2 (13.9)	66	-20.0 (13.8)	17	-4.7 ; 10.4	0.45
Supination in degrees	67.4 (23.9)	66	49.7 (33.1)	17	-0.2; 35.5	0.052
Pronation in degrees	71.0 (18.9)	66	53.2 (32.4)	17	0.56; 34.9	0.04
Motion arc in degrees	119.8 (19.5)	66	105.9 (28.6)	17	2.3; 25.7	0.02
Rotation arc in degrees	138.3 (36.5)	66	102.9 (62.3)	17	2.4; 68.4	0.04
MEPI score	88.8 (13.6)	24	80.0 (16.1)	13	-1.4; 18.9	0.09
Broberg and Morrey category	2.02 (0.87)	102	2.64 (0.84)	14	-1.11; -0.14	0.01

Tables 3 and 4 show the results of the multiple regression of the outcome measure motion and rotation arc on the use of an external fixator, time from injury to operation and length of follow-up.

Table 3 Effects of external fixator, time between injury and operation and the length of follow-up on the motion arc in degrees in 33 patients with complex elbow dislocations (multivariate analysis)

Variable	Coefficient	95% CI	P value	Standardised coefficient
External Fixator[1]	-54.0	-74.3; -33.6	0.000	-1.1
Time from injury to operation (days)	1.4	0.75; 2.1	0.000	0.83
Length of follow-up (months)	- 0.1	-0.26; 0.01	0.074	-0.26

[1] Compared with no external fixator (reference category).

Table 4 Effects of external fixator, time between injury and operation and length of follow-up on the rotation arc in degrees in 33 patients with complex elbow dislocations (multivariate analysis)

Variable	Coefficient	95% CI	P value	Standardised coefficient
External Fixator[1]	-102.9	-146.1; -59.8	0.000	-1.0
Time from injury to operation (days)	2.7	1.3; 4.1	0.001	0.77
Length of follow-up (months)	- 0.3	-0.57; 0.00	0.05	-0.30

[1] Compared with no external fixator (reference category).

Unstable simple elbow dislocations

Of the 36 patients 25 were male and 11 were female. The mean age in the 36 patients was 42.6 years (SD=18.5). In 33 patients the side of trauma was noted: in 16 patients the left elbow was affected and in 17 cases the right elbow was affected. In 13 cases the dominance was recorded and was as follows: three patients were left-handed and 10 were right-handed. Fifteen patients had a posterior dislocation, and in the other 21 patients the dislocation type was not recorded. No ipsilateral injury was noted. The time between the injury and operation was only recorded in one patient. In 27 cases the lateral collateral and in 17 cases the medial collateral ligament was repaired; twelve of these cases were bilateral operations. Twenty-five patients were treated with an external fixator, with suturing of the lateral collateral ligament in 18 cases and with suturing of the medial collateral ligament in 13 cases. In two patients, the unstable elbow was stabilised with two Kirschner wires. In the patients without external fixator treatment it was not possible to retrieve exact data about the postoperative period of immobilisation. The mean length of follow-up in months for 34 patients was 29.0 months (SD=11.7; min 8, max 60).

In one case the ulnar nerve was released secondarily. One patient had a pin track infection as a result of the external fixator treatment. Two patients had a contracture release.

Table 5 shows the different outcome measures of the treatment of unstable simple elbow dislocations.

The results of the MEPI categories were as follows: excellent (n=15), good (n=5) and poor (n=1). The results of the Broberg and Morrey categories were as follows: excellent (n=3), good (n=7) and fair (n=1). The results of the arthrosis Broberg and Morrey categories were as follows: no arthritis (n=23), grade 1 (n=7) and grade 3 (n=7).

Table 5 Different outcome measures of the treatment of unstable simple elbow dislocations

Outcome measures	N	Mean	SD	95% CI
Flexion in degrees	34	127.6	11.0	123.8; 131.5
Extension in degrees	34	-13.7	9.6	-13.7; -17.0
Pronation in degrees	14	69.3	16.4	59.8; 78.7
Supination in degrees	14	68.6	21.4	56.2; 80.9
Broberg and Morrey score	11	89.4	8.5	83.6; 95.1
Arthritis Broberg and Morrey	31	0.32	0.65	0.08; 0.56
Motion arc in degrees	34	114.0	18.4	107.6; 120.4
Rotation arc in degrees	14	137.9	33.1	118.8; 157.0

Table 6 shows the results of the unpaired t-tests comparing patients with versus without an external fixator for the treatment of an unstable simple elbow dislocation.

Table 6 Comparison of different variables in patients without an external fixator and those with an external fixator in the treatment of unstable simple elbow dislocations (unpaired t-test)

Variables	No fixator	N	Fixator	N	95% CI difference	P value
Age in years	56.8 (19.8)	11	36.3 (14.1)	25	8.8; 32.3	0.001
Length follow-up (months)	25.3 (16.2)	9	30.3 (9.7)	25	-14.3; 4.2	0.28
Motion arc in degrees	117.2 (17.3)	9	112.8 (18.9)	25	-10.3; 19.1	0.54
Rotation in degrees	143.3 (33.5)	9	128.0 (33.5)	5	-25.4 ; 56.1	0.43

Discussion

This review has included data from 10 observational studies with individual patient data of 170 patients with complex and unstable simple elbow dislocations. Because a lack of randomised controlled trials and comparative studies, no treatment effects could be calculated, and only single group summaries were available. The outcome measures (Tables 1 and 5) show an acceptable range of motion with good functional scores of different questionnaires and a low mean arthritis score. Thus, treatment of complex elbow dislocations with ORIF led to a moderate to good result. Treating unstable simple elbow dislocations with repair of the collateral ligaments with or without the combination of an external fixator is also a good option.

Comparing the patients with a complex elbow dislocation with an additional external fixator versus no external fixator (only ORIF) in univariate analysis showed better flexion, better pronation, and better Broberg and Morrey categories in the patient group that did not receive a external fixator. The patients treated with an additional external fixator had a shorter follow-up time, and the time between trauma and operation was longer. The influence of these two variables was that a shorter follow-up time and a longer interval between trauma and operation was correlated with a higher range of motion. A multivariate regression analysis showed that the motion and rotation was worse in the additional external fixator group when adjusted for the time between trauma and operation and follow-up time. But the external fixator group was small, and the difference between the fixator and non-fixator groups is probably not a real difference but is rather the result of bias; the worst cases were treated with an external fixator. All the patients with the long interval between trauma and fixator placement were from one study [25]. In this study the patients the patients were initially managed in other institutions and the external fixator placement must be interpreted as secondary treatment.

It was not possible to compare patients with or without an external fixator in unstable simple elbow dislocations because of the low sample sizes of the two groups. The only remarkable finding in these patients was the lower mean age in the fixator group (36 versus 57 years). The external fixator was probably reserved for younger patients.

Because no randomised trials and comparative studies were available, we only included studies with individual data. Are our results comparable with reviews of case-series? Many reviews are rather about operative management and give algorithms for treatment [4, 5]. For instance, if after treating the fractures, the elbow is still unstable, the treatment can be completed with an external fixator or with restriction of motion by protection with a cast or brace. Healing of the fractures is given precedence over mobilisation of the elbow, because chronic instability is more difficult to treat than stiffness. A case-series of 36 terrible triads of the elbow showed after a follow-up period of 34 months a flexion-extension arc of 112^0, a forearm rotation of 136^0 and a mean MEPI score of 88 points [26]. These patients were treated with a standard surgical protocol [27] . These results are comparable with our analysis.

The physician-rated (MEPI, Broberg and Morrey), patient-rated (DASH) and physician- and patient-rated (ASES) questionnaires showed good intercorrelations. The categorical ranking of the MEPI and Broberg and Morrey showed substantial agreement. Turchin et al. also found good correlations between the MEPI and Broberg and Morrey raw scores (0.89), but their Kappa correlation coefficient between the categorical rankings of the MEPI and Broberg and Morrey was lower (0.43, CI 0.26; 0.60) [28]. Because of this low agreement, they advised the use of raw aggregate scores and not the categorical rankings. Also the correlations of the MEPI and Broberg and Morrey scores with the patient completed functional DASH questionnaire were lower at -0.55 and -0.56 respectively. This difference with our results could be explained by their diverse sample of patients with elbow problems, while our sample was restricted to elbow dislocations. Validation of questionnaires depends on the examined clinical condition [29]. Correlations of the motion and rotation arc were moderate with the physician-rated (MEPI, Broberg and Morrey) questionnaires and slight with the (partially) patient-rated questionnaires (ASES, DASH). Doornberg et al. also saw moderate correlations between MEPI scores (r=0.40; 0.38) and Broberg and Morrey scores (r=0.54, 0.50) with a range of flexion-extension and pronation-supination, respectively, but their correlations with the DASH and ASES were much higher (flexion-extension r=-0.42 with DASH, 0.56 with ASES; pronation-supination r=-0.34 with DASH, 0.50 with ASES) [30]. Doornberg et al. also examined patients with intra-articular fractures of the elbow, and they found pain and flexion-extension arc as significant predictors for the MEPI, Broberg and Morrey, ASES and DASH scores. Pain even had the strongest influence on the outcome measures. The discrepancy with our correlations between motion and DASH and ASES can be caused by the fact that we only had data from 24 DASH questionnaires and range of motion all from one study [19], in contrast with the sample size of 104 in the study of Doornberg et al.

Arthritis classification was fairly correlated with MEPI, Broberg and Morrey, motion and rotation arc and slightly with DASH and ASES. Josefsson et al. concluded after a mean follow-up of 24 years of 52 simple elbow dislocations that radiographic changes were associated with somewhat decreased extension but rarely caused problems or symptoms [31]. Thus, Josefsson's clinical impressions that degenerative joint changes are slightly correlated with the complaints of the patient are confirmed by the correlations from this review. However, we found no studies that quantitatively correlated arthritis scores of the elbow with functional elbow scores.

The incidence of the radial head, coronoid process and olecranon fractures were much higher in this series than in Josefsson's study [1]. This is caused by the high incidence of medial epicondyle fractures in the patients with elbow fractures of Joseffson's sudy.

In our review, 55% of the complex elbow dislocations were found on the left side and in Josefsson study 58% [1]. About only 6% of a studied American population was left handed [32], so elbow dislocations are mainly found on the non-dominant side. The exact cause of the preponderance of the non-dominant side is unknown, but it could be the result of the employment of the dominant arm during a fall or the unconscious protection of the dominant arm during a fall.

The quantitative analysis of the data in this review showed that a favourable prognosis may generally be anticipated after ORIF of a complex elbow dislocation and of an unstable simple dislocation treated by suturing the collateral ligaments and/or placing an external fixator. The exact role of the external fixator in the treatment of complex elbow dislocations could not be determined from our extracted data. For instance, it would be interesting to know if the external hinged fixator could be used after only minimal ORIF without suturing the collateral elbow ligaments. The benefit of this procedure would be that the patient can start exercising immediately after the operation instead of having the elbow joint immobilised in a plaster for several weeks.

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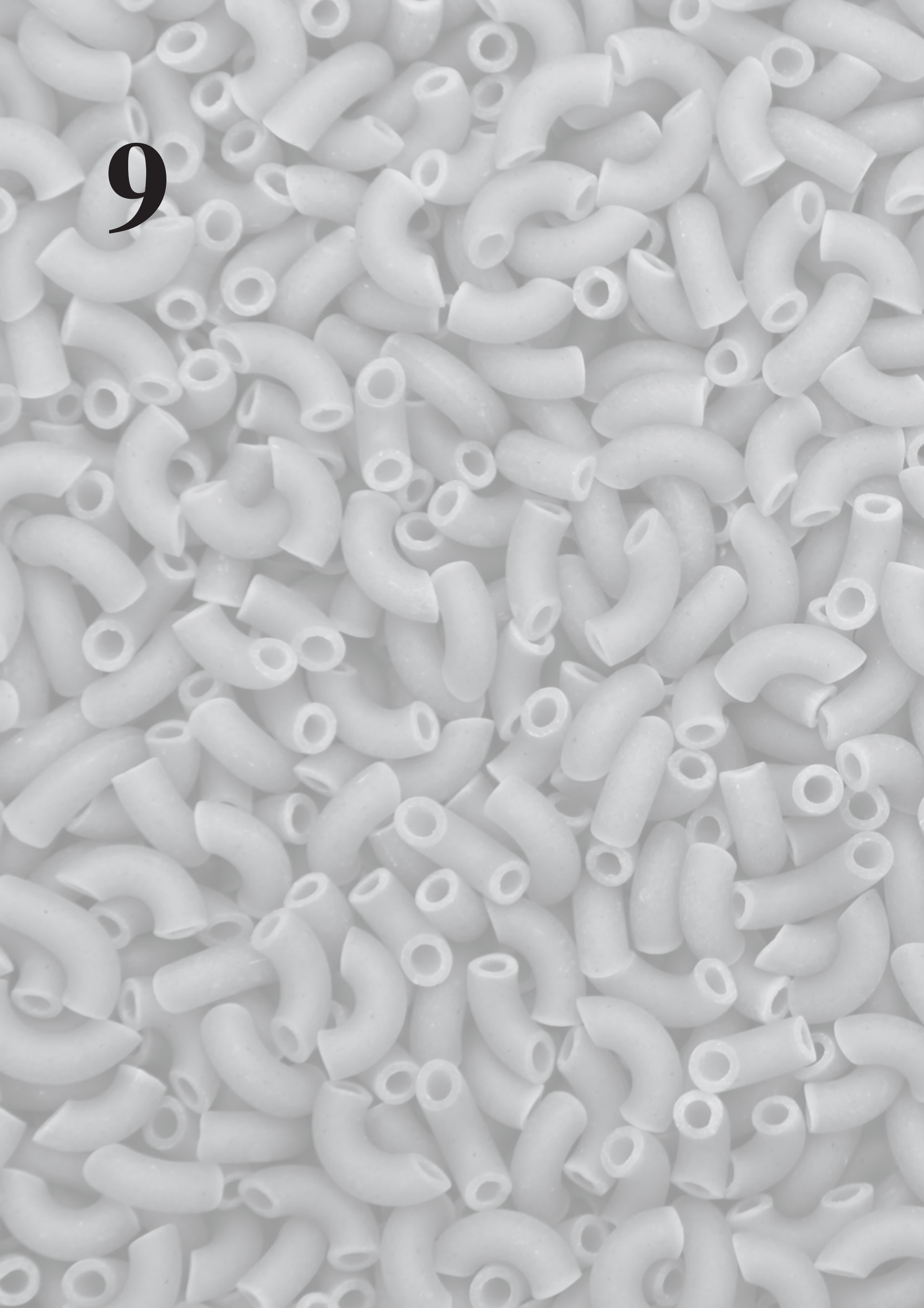

Dislocation of the elbow: a retrospective multicentre study of 86 patients

J. de Haan
N.W.L. Schep
I. Zengerink
J. van Buijtenen
W.E. Tuinebreijer
D. den Hartog

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Abstract

The objective of this retrospective multicentre cohort study was to prospectively assess the long-term functional outcomes of simple and complex elbow dislocations.

We analysed the hospital and outpatient records of 86 patients between 01/03/1999 and 25/02/2009 with an elbow dislocation. After a mean follow-up of 3.3 years, all patients were re-examined at the outpatient clinic for measurement of different outcomes.

The mean range of motion was ROM 135.5°. The Mayo Elbow Performance Index (MEPI) scored an average of 91.9 (87.5% of the patients were rated excellent or good). The average Quick disabilities of the arm, shoulder and hand (Quick-DASH) score was 9.7, the sports/music score 11.5 and work score 6.1. The Oxford function score was 75.7, Oxford pain score 75.2 and Oxford social-psychological score 73.9.

Elbow dislocation is a mild disease and generally, the outcome is excellent. Functional results might improve with early active movements.

Introduction

The elbow joint is the second most commonly dislocated joint in adults. The annual incidence of simple and complex elbow dislocations in children and adults is 6.1 per 100,000 [1]. Elbow dislocations can be classified as simple or complex [2]. The simple dislocation is characterized by the absence of fractures, while the complex dislocation is associated with fractures. The terrible triad is an example of a complex posterior dislocation with intra-articular fractures of the radial head and coronoid process. The annual incidence of complex elbow dislocations in children and adults is 1.6 per 100,000, or 26% percent of all elbow dislocations [1]. After reposition of the simple dislocation, treatment options include immobilisation in a static as well as a functional plaster for different periods, surgical treatment of the ruptured medial and lateral collateral ligaments or so-called functional treatment, which is characterised by early active movements within the limits of pain with or without the use of a sling or hinged brace. The primary objective of this retrospective multicentre observational study was to assess the functional outcomes of simple and complex elbow dislocations. The long-term outcomes were collected prospectively and assessed with different questionnaires for the upper extremity.

Patients and Methodology

We conducted a retrospective multicentre study of elbow dislocations. All charts of elbow dislocations treated in-hospital and at the outpatient departments at three teaching hospitals in the Netherlands from 01/03/1999 to 25/02/200 were collected. Eighty-six cases were identified. Forty-two patients returned for a long-term follow-up examination at the outpatient clinic and an additional 17 patients only filled in the questionnaires. At follow-up range of motion of the elbow was recorded (extension, flexion, pronation, and supination). Each elbow was evaluated using the Mayo Elbow Performance Index (MEPI), a visual analogue scale for pain (VAS), the Quick-DASH (Disabilities of the arm, shoulder, and hand) and the Oxford elbow score.

The MEPI includes five points of interest: pain (with a maximum score of 45 points), ulnohumeral motion (20 points), stability (10 points) and the ability to perform five functional tasks (25 points). If the total score is included between 90 and 100 points, the result was excellent; with a score between 75 and 89 points: good; between 60 and 74 points: fair and poor when under 60 [3].

Pain level was determined using a 10-point Visual Analogue Scale (VAS), in which 0 implies no pain and 10 implies the worst possible pain.

The Quick-Disabilities of the Arm, Shoulder and Hand (DASH) Outcome Measure is a validated 30-item, self-report questionnaire designed to describe the disability experienced by people with upper-limb disorders [4; 5]. The DASH outcome measure includes three components: the disability/symptom section (11 items, scored 1-5) and two optional modules: one for work and one for sport/music (each optional module has four items, scored 1-5). The DASH disability/symptom score is a summation of the responses to

11 questions on a scale of one to five, with a total score ranging from zero (no disability) to 100 (severe disability). The questions evaluate the degree of difficulty in performing a variety of physical activities with arm, shoulder, or hand problems (six items). They also investigate the severity of pain and tingling (two items), as well as the effect of the upper limb problem on social activities, work and sleep (three items). A higher score indicates greater disability.

The Oxford elbow score is a 12-item questionnaire [6]. It comprises three one-dimensional domains: "elbow function", "pain" and "social-psychological", with each domain comprising four items with good measurement properties [7]. Every question can be answered using a five-point Likert scale, corresponding to a score between zero and four. Every dimension's score is converted to a score of zero (worst) to 100 (best). A Dutch version of the UK validated questionnaire was obtained using the technique of translation and back-translation [8].

Statistical analysis

The statistical analysis was performed with PASW Statistics 17.0 on a personal computer. All proportional data are presented as percentages and all continuous data are given as means with standard deviations (SDs) when normally distributed, and otherwise as medians with the interquartile range (IQR).

The Student independent t-test was used to compare the range of motion for the patients with and without fractures. The Pearson correlations were calculated between the duration of plaster immobilisation, ranges of motion, the MEPI, Quick DASH, VAS and Oxford elbow scores.

Results

Between 01/03/1999 and 25/02/2009, 86 elbow dislocations were found in 86 patients: 53 were women and 33 men (Table 1). The mean age of these patients was 44 years (SD=16), with a range of 18 to 84 years. The mechanism of injury was a fall in 89% of cases (n=74), direct trauma in 8% (n=7) and not recorded in five patients. The reason for the trauma was related to sports in 29% of cases (n=18), traffic in 20% (n=12), an accident at home in 26% (n=16), work in 5% (n=3), violence in 5% (n=3) and leisure in 15% (n=9), and in 25 patients it was not recorded.

The type of dislocation was anterior in 1% of patients (n=1), posterior in 44% (n=30), posteromedial in 9% (n=6), posterolateral in 46% (n=31) and in 18 cases the type of dislocation was missing. Four patients (5%) sustained polytrauma. In 69% (n=59) of the cases the dislocations occurred on the left side. In 89% (n=41) of the cases in which dominance was recorded (n=46), it was on the right. In 54 % (n=25) of the cases the dislocation was on the non-dominant side; this tendency compared with the dominant side was insignificant (p=0.63). Complex dislocations were diagnosed in 49% of the patients (n=42). The accompanying fractures were categorised as follows: coronoid n=18, radial head n=24, humerus n=5, olecranon n=3. Four patients sustained a coronoid fracture as well as a radial head fracture, the so-called terrible triad. A total of six radial head fractures were operated on, of which three received open reduction and internal fixation (ORIF), one received radial head resection, one a partial radial head resection, and one a prosthesis (because of re-dislocation after one week in plaster). One coronoid fracture was treated with ORIF (AO screw). Thirty- five small avulsions were not operated on. One loose body within the joint due to a coronoid fracture necessitated removal.

A total of three dynamic fixators were mounted, one for medial instability, one due to re-dislocation in plaster (both of which were simple elbow dislocations) and one as functional treatment (complex elbow dislocation). We recorded 4 cases of re-dislocation. One re-dislocation occurred after sufficient trauma three months after the primary dislocation. Routine X-ray examination after one week in plaster detected another two. One of these had an associated radial head fracture and received radial head prosthesis. In the other one a functional external fixator was applied (as stated above).The fourth patient with a re-dislocation was diagnosed after four weeks and the re-dislocation was reduced surgically.

Dislocation was primarily reduced at the emergency department in 72 (84%) and in the theatre in 14 (16%) cases. In 8 of the 72 cases primarily reduced at the emergency department, the reduction did not succeed and these elbows were then reduced secondarily in the operating theatre. In 18 patients, stability testing was recorded in the medical history.

In two of the 18 patients, the collateral ligaments were sutured. Seventy-four patients were either exclusively treated with a plaster cast or started with a plaster cast followed by functional treatment in a hinged brace (n=23), sling (n=1) or pressure bandage (n=4).

Three patients had only a pressure bandage, three patients a sling and one patient a brace and sling. Thirty-two percent of the patients had a plaster immobilisation longer than three weeks and 49% of the elbows were immobilised for three weeks or longer.

Two cases presented with a sensory deficit and one had a vascular injury. One patient required an ulnar nerve release.

The median period of treatment was 6.0 weeks (IQR=7). The mean period in plaster was 2.6 weeks (SD=1.7).

Six weeks after reduction of the elbow dislocations, the mean extension loss was 18.3^0 (SD=19.0) and the following range of motions were found: the mean flexion was 131.0^0 (SD=20.8), pronation 79.9^0 (SD=21.8), and supination 78.2^0 (SD=22.9). No statistically significant differences were found for range of motions (ROM) between patients with versus without fractures. The duration of plaster immobilisation had no correlation with the range of motions at the end of the treatment and at long-term follow-up.

The time between the dislocation and the follow-up examination was 3.3 (SD=2.6) years. The results of this examination are presented in table 2. No statistically significant differences were found between patients with versus without fracture (independent t-test).

Table 1 An overview of the patient population (n=86)

	N
Sex	
Female	53 (61.6%)
Male	33 (38.4%)
Mean age in years	43.8 (SD=16.2)
Cause of injury (N=3 missing)	
Fall	74 (89.2%)
Direct trauma	7 (8.4%)
Pulled elbow mechanism	2 (2.4%)
Polytrauma (N=2 missing)	
No	80 (95.2%)
Yes	4 (4.8%)
Associated injuries	
Hand	1 (1.2%)
Wrist	2 (2.3%)
Dislocation side	
Left	59 (68.6%)
Right	27 (31.4%)
Type of dislocation (N=18 missing)	
Anterior	1 (1.5%)
Posterior	30 (44.1%)
Posteromedial	6 (8.8%)
Posterolateral	31 (45.6%)
Fracture (N=1 missing)	
No	43 (50.6%)
Yes	42 (49.4%)
Fracturetype	
Coronoid fracture	18
Radial head fracture	24
Humerus	5
Olecranon	3
Coronoid + radial head fracture	4
Sensibility deficit	2 (2.3%)
Vascular injury	1 (1.2%)

The Pearson correlation between the duration of plaster immobilisation and the Oxford function score were significant for the whole group (r=-0.40, p=0.006, n=46) and for the patients without fractures (r=-0.58, p=0.004, n=22). The Pearson correlation for the whole group (n=46) between the duration of plaster immobilisation and the Oxford pain score was -0.37 (p=0.012) and with the Oxford social-psychological score was -0.37 (p=0.011).

Table 2 An overview of the results after a mean follow-up of 3.3 years (SD=2.6)

Range of motion:	**Mean (SD)**
Extension loss (n=42)	5.5° (11.0)
Flexion (n=42)	141.0° (7.5)
Pronation (n=36)	89.7° (1.7)
Supination (n=36)	88.3° (8.5)
Pain Visual Analogue Scale – VAS (n=50)	1.98 (7.0)
MEPI total score (max 100 points) (n=40):	91.9 (11.8)
MEPI pain score (max 45)	37.5 (11.8)
MEPI ulnohumeral motion (max 20)	19.8 (1.1)
MEPI stability (max 10)	9.6 (1.3)
MEPI function (max 25)	25 (0)
MEPI categories (n=40):	
Excellent (90-100 points)	26 (65%)
Good (75-89 points)	9 (22.5%)
Fair (60-74 points)	4 (10%)
Poor (<60 points)	1 (2.5%)
Quick DASH questionnaire:	
Disability score (n=59)	9.7 (13.0)
Sports/music score (n=44)	11.5 (19.2)
Work activities (n=49)	6.1 (12.4)
Oxford elbow score (n=57):	
Elbow function	75.7 (27.1)
Pain	75.2 (28.3)
Social-psychological	73.9 (26.6)

Discussion

Conn et al. found 414 injuries of the elbow in their fracture service, including 58 elbow dislocations in children and adults [9]. Elbow injuries accounted for 6.8% of all treated fractures. Seventy-six percent of the patients with elbow dislocations were older than 20 years. In 51% of these adults, the dislocations were simple, a lower percentage than the 74% found in Josefsson's study [1]. In another study by Josefsson, 46% of the patients with simple dislocation were 16 years or older [10]. In our study 52% of the dislocations were of the simple type however, in our study only patients of 18 years and older were selected.

Elbow dislocations are defined by the direction of their displacement. Nearly all the dislocations are of the posterior or posterolateral types. In Conn's study, 96% of the dislocations were posterior or lateral [9] and Joseffson reported no anterior dislocations in his study of 52 patients [10]. In our study 89.7% of the dislocations were of the posterior or posterolateral type and 1.5% were of the anterior type.

In a case-control study only 6% of a studied American population (n=5033) was left handed and left-handedness was a risk factor for fractures [11]. In another study fractures proximal to the wrist occurred more frequently on the left side, but were unrelated to dominance [12]. In 58% of the patients of Joseffson, the simple elbow dislocations were on the non-dominant left side [10]. In our study 69% of the dislocations were found on the left side. In our patients records dominance was in 47% not recorded, but in the recorded cases 54% of the dislocations were on the non-dominant side. This occurrence was non-significant. The exact cause of the preponderance of elbow dislocations on the left side is unknown, but it is probably not related to dominance.

Following reposition and treatment in plaster of simple dislocations, recurrent dislocations and chronic instability are rare [2, 13]. In Joseffson's study one obviously unstable joint was described in his study of 52 patients after a mean follow-up of 24 years [10]. We observed four redislocations (3%), however, one redislocation was caused by an adequate trauma and was not considered a result of persistent instability. Of the three remaining patients, two had a complex elbow dislocation with a radial head fracture, which was primarily left untreated and one polytrauma patient had probably an unstable elbow after reduction.

In theory, after repositioning of a simple dislocated elbow, the joint retains an inherent stability caused by the contour of the intact joint surfaces. This stability may allow the patient to exercise the joint shortly after the repositioning. In these cases, functional treatment may enhance recovery of a full range of motion without risking increased joint instability. Nearly half of our patients were immobilised in plaster three weeks or longer. Shorter periods of plaster immobilisation after reduction of elbow dislocations has been associated with better range of motions. Protzmann [14] describes less extension loss and shorter mean disability in weeks for the shorter immobilisation group without making statistical inferences. Mehlhoff [15] describes less extension loss for the shorter immobilisation groups, with a significant correlation between extension loss and duration of follow-up. He also reported less flexion loss and less prevalence and severity of pain for the shorter immobilisation groups but did not analyze this data statistically. The number of patients with symptoms of instability of the elbow joints was lower in the shorter immobilisation group without reaching statistical significance at the 5% level. Schippinger [16] described better Morrey scores, which are composed of the items pain, movement, strength, instability and function (activities of daily living), and better separate pain scores in the shorter immobilisation groups, though without statistical significance. In our study, there was no correlation for the entire patient group between range of motion and duration of immobilisation, which lasted three weeks or longer for 49% of the patients. However, the weak correlation between the duration of immobilisation and the three Oxford elbow scores after a mean of 3.3 years was negative and significant; so, the shorter the immobilisation, the better the Oxford elbow scores were. This is probably due to methodological bias: the simpler cases got shorter immobilisation. Furthermore, even in the patient group without fractures, these correlations were moderate. In a retrospective analysis this is probably due to methodological bias: the simpler cases got shorter immobilisation.

Our patient sample consisted mainly (92%) of elbow dislocations without or with small avulsions. Stability was not routinely tested and was only in 21% recorded in the hospital charts. Serious injury of the collateral ligaments was not described. So our prudent conclusions are probably only relevant to the simple stable elbow dislocations. Our results seem to suggest that elbow dislocation with and without small fractures is a mild condition that can be treated with good results. Functional treatment and early active movement within the limits of pain can probably improve the final Oxford elbow score.

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A hinged external fixator for complex elbow dislocations: a multicenter prospective cohort study

N.W.L. Schep
J. de Haan
G.I.T. Iordens
W.E. Tuinebreijer
M.W.G.A. Bronkhorst
M.R. de Vries
J.C. Goslings
S.J. Ham
S. Rhemrev
G.R. Roukema
I.B. Schipper
J.B. Sintenie
H.G.W.M. van der Meulen
T.P.H. van Thiel
A.B. van Vugt
E.J.M.M. Verleisdonk
J.P.A.M. Vroemen
P. Wittich
P. Patka
E.M.M. van Lieshout
D. den Hartog

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Abstract

Background
Elbow dislocations can be classified as simple or complex. Simple dislocations are characterized by the absence of fractures, while complex dislocations are associated with fractures of the radial head, olecranon, or coronoid process. The majority of patients with these complex dislocations are treated with open reposition and internal fixation (ORIF), or arthroplasty in case of a non-reconstructable radial head fracture. If the elbow joint remains unstable after fracture fixation, a hinged elbow fixator can be applied. The fixator provides enough stability to the elbow joint, and allows for early mobilization. The latter may be important for preventing stiffness of the joint. The aim of this study is to determine the effect of early mobilization with a hinged external elbow fixator on clinical outcome in patients with complex elbow dislocations with residual instability following fracture fixation.
Methods/Design
The design of the study will be a multicenter prospective cohort study of 30 patients who have sustained a complex elbow dislocation and are treated with a hinged elbow fixator following fracture fixation. Early active motion exercises within the limits of pain will be started immediately after surgery under supervision of a physical therapist. Outcome will be evaluated at regular intervals over the subsequent 12 months. The primary outcome is the *Quick* Disabilities of the Arm, Shoulder, and Hand score. The secondary outcome measures are the Mayo Elbow Performance Index, Oxford Elbow Score, pain level at both sides, range of motion of the elbow joint at both sides, radiographic healing of the fractures and formation of periarticular ossifications, rate of secondary interventions and complications, and health-related quality of life (Short-Form 36).
Discussion
The outcome of this study will, for the first time, yield quantitative data on the functional outcome patients with a complex elbow dislocation and who are treated with ORIF and additional stabilization with a hinged elbow fixator.
Trial Registration
The trial is registered at the Netherlands Trial Register (NTR1996).

Background

The elbow joint is the second most commonly dislocated joint in adults. The annual incidence of elbow dislocations in children and adults is 6.1 per 100,000 [1]. Elbow dislocations are classified as being simple or complex [2]. Simple dislocations are dislocations without fractures. Complex dislocations are associated with fractures of the radial head, olecranon, or coronoid process. In patients with an elbow dislocation the incidence of radial head fractures is 36%, whereas coronoid process fractures occur in 13%, and olecranon fractures in four percent of patients [1].

The radial head and coronoid process are considered to be important bony stabilizers of the elbow. The fundamental goal in the management of complex elbow dislocations is the restoration of the osseous-articular restraints. Therefore, the majority of these complex dislocations is treated with open reposition and internal fixation (ORIF) [3] or primary arthroplasty in case of non-reconstructable radial head fractures.

Assessment of stability of the joint following ORIF of a complex elbow dislocation is essential. Signs of instability are redislocation, a positive pivot shift test and positive valgus and varus stress testing. At present instability following ORIF or arthroplasty is usually treated with primary ligament repair and/or a period of plaster immobilisation.

A period of plaster immobilisation may result in a limited range of motion and a stiff elbow with subsequent disability. A hinged external elbow fixator, on the other hand, may provide enough stability to start early mobilization after ORIF or arthroplasty and may prevent residual instability and stiffness [4, 5]. No randomized controlled trials comparing hinged external fixation and immobilisation are available. This may be due to the low incidence of patients with a complex elbow dislocation with remaining instability after ORIF or arthroplasty. Until now only small observational studies of patients with complex elbow dislocations have been published [2, 3, 5-12]. These studies showed promising functional results following treatment with a hinged elbow fixator [11, 12].

The primary objective of this prospective cohort study is to study the functional outcome, pain, and health-related quality of life in patients who sustained a complex elbow dislocation and were treated with ORIF and/or arthroplasty of the radial head and a hinged external fixator due to residual instability. Our hypothesis is that early mobilization will prevent stiffness and will result in satisfactory functional outcome at one year.

Methods/Design

Study design

Multi-center cohort study in all consecutive patients who sustained a complex elbow dislocation and were treated with a hinged external fixator for residual instability after ORIF and/or arthroplasty of the radial head. Sixteen centers in the Netherlands will participate. The study started August 28, 2009.

Recruitment and consent

The decision to apply the hinged fixator will be left to the discretion of the surgeon. If a fixator is applied, patients will receive information and a consent form from the attending physician, the clinical investigator or a research assistant. Patients meeting all inclusion criteria and none of the exclusion criteria will be included at the time of their first outpatient visit (two weeks after surgery), which will give them on average one week to consider their participation.

Study population

Patients meeting the following inclusion criteria are eligible for enrolment:

1. Men or women aged 18 years and older (with no upper age limit)
2. Patient with a complex elbow dislocation (i.e., dislocation of the elbow joint, combined with at least a fracture of the radial head, coronoid process, or olecranon)
3. Patient was treated with a hinged external fixator after ORIF and/or arthroplasty due to persistent instability
4. Provision of informed consent by patient

Since there is currently no consensus regarding the most valid and reliable test for assessing elbow joint instability, this will be left to the discretion of the surgeon performing the operation. This reflects common practice, and will increase translatability of the outcome of our study. In order to warrant performance of stability tests across participating sites, a detailed description of stability tests (*i.e.*, varus stability, valgus stability, and lateral pivot shift test for posterolateral rotatory stability) is included in the protocol.

If any of the following criteria applies, patients will be excluded:

1. Patients with a concomitant distal humeral fracture
2. Patients with additional substantial traumatic injuries of the affected upper limb
3. Patients who underwent repair of the collateral ligaments
4. Patients with an impaired elbow function (i.e., stiff or painful elbow or neurological disorder of the upper limb) prior to the injury
5. Retained hardware around the affected elbow
6. Likely problems, in the judgment of the investigators, with maintaining follow-up (e.g., patients with no fixed address will be excluded)
7. Insufficient comprehension of the Dutch language to understand the rehabilitation program and other treatment information in the judgment of the attending physician

Exclusion of a patient because of enrolment in another ongoing drug or surgical intervention trial will be left to the discretion of the attending surgeon on a case-by-case basis.

Intervention

External elbow fixating is performed using the Orthofix® Elbow Fixator (Orthofix Verona, Italy). The surgical approach to the fracture site including the choice of using an olecranon osteotomy is left to the surgeon's discretion. Following ORIF of the fractures and/or arthroplasty of the radial head, the center of rotation of the elbow is identified. A two mm K-wire is inserted into the center point of the capitellum humeri which is identified on an exact lateral fluoroscopic image. Next, the external fixator is mounted, first fixating the proximal humeral clamp and subsequently the distal ulnar clamp. Exact reduction of the elbow joint is evaluated with image intensifier in lateral and anteroposterior direction during flexion and extension. The surgical technique is described in more details elsewhere [13]. After surgery, patients are allowed to use a sling for two days to one week. Pin-site care will be performed daily by the patient following instruction given by the treating physician. After surgery patients will receive indomethacin 2dd 50 mg for six weeks (in combination with acid blocking medication) in order to prevent heterotopic ossification of the elbow, unless NSAIDs are contraindicated [14]. The external fixator will be removed six weeks after surgery. Extension, flexion and pro- and supination active and passive exercises are started immediately after surgery if tolerated under supervision of a professional physical therapist, who they can freely select.

Outcome measures

The primary outcome measure is the *Quick*-DASH (Disabilities of the Arm, Shoulder and Hand) score, which reflects both function and pain [15]. The DASH Outcome Measure is a validated 30-item, self-reported questionnaire designed to help describe the disability experienced by people with upper-limb disorders and also to monitor changes in symptoms and function over time [15, 16].

The *Quick*-DASH is a shortened version of the DASH Outcome Measure. Instead of 30 items, the Quick-DASH uses 11 items (scored 1-5) to measure physical function and symptoms in people with any or multiple musculoskeletal disorders of the upper limb. The right and left elbow will be assessed separately. At least 10 of the 11 items must be completed for a score to be calculated. The scores will be transformed to a 0-100 scale for easy comparison. A higher score indicates greater disability. The test-retest reliability of the *Quick*-DASH was 0.90 [17].

Like the DASH, the *Quick*-DASH also has two optional modules intended to measure symptoms and function in athletes, performing artists and other workers whose jobs require a high degree of physical performance. These optional models are scored separately; each contains four items, scored 1-5. All items must be completed for a score to be calculated.

The secondary outcome measures are:

- Functional outcome (Mayo Elbow Performance Index and Oxford Elbow Score)
- Pain level at both sides (VAS)
- Range of Motion of the elbow joint at both sides

- Radiographic healing of the fractures
- Rate of secondary interventions
- Rate of complications
- Health-related quality of life (SF-36)

The Mayo Elbow Performance Index (MEPI) is one of the most commonly used physician-based elbow rating systems. This index consists of five parts: pain (with a maximum score of 45 points), ulnohumeral motion (20 points), stability (ten points), the ability to perform five functional tasks (5x5 points) and the patient response. If the total score is between 90 and 100 points, it is considered excellent; between 75 and 89 points, good; between 60 and 74 points, fair; and less than 60 points, poor [18].

The Oxford Elbow Score is a 12-item questionnaire. It is comprised of three one-dimensional domains: elbow function, pain and social-psychological, with each domain comprising of four items with good measurement properties [19]. This is a validated questionnaire in the UK and was translated to Dutch by the proper translation procedure, which uses the technique of translation and back-translation [20-22]. Permission for translation and the use of the Oxford Elbow Score for this study was obtained from Oxford and Isis Outcomes, part of Isis Innovation Limited (website: http://www.isis-innovation.com/)

Pain level will be determined using a 10-point Visual Analog Scale (VAS), in which zero implies no pain and ten implies the worst possible pain.

Range of motion (ROM) will be determined by measure flexion/extension and pro-/supination on both sides using a goniometer.

Radiographic healing will be determined using X-rays. Fractures are considered healed if one of the following three criteria is met: (a) Bridging of fracture by callus/bone trabeculae or osseous bone; (b) Obliteration of fracture line/cortical continuity; (c) Bridging of fracture at three cortices.

Secondary intervention within one year of initial treatment to promote fracture healing, relieve pain, treat infection, or improve function will be recorded. This includes incision and drainage for surgical site infection or deep infection, fixator exchange or removal, reosteosynthesis, implant removal, or ligament repair.

Complications within one year of initial treatment will be recorded. These include heterotopic ossification, infections, bleeding, venous thrombosis, and neurological deficit)

The Short-Form 36 (SF-36) is a validated multi-purpose, short-form health survey with 36 questions that represent eight health domains that are combined into a physical and a mental component scale [23]. The Physical Component Scale (PCS) combines the health domains of physical functioning (PF; ten items), role limitations due to physical health (RP; four items), bodily pain (BP; two items), and general health perceptions (GH; five items). The Mental Component Scale (MCS) combines the health domains of vitality, energy, or fatigue (VT; four items), social functioning (SF; two items), role limitations due to emotional problems (RE; three items), and general mental health (MH; five items). Scores ranging from zero to 100 points are derived for each domain, with lower scores indicating poorer function. These scores will be converted to a norm-based score and compared with the norms for the general population of the United States (1998), in which each scale was scored to have the same average (50 points) and the same standard deviation (ten points).

In addition to the outcome variables mentioned above, the following data will be collected:

1. Intrinsic variables (baseline data): age, gender, American Society of Anesthesiologists' ASA classification, tobacco consumption, alcohol consumption, comorbidity, dominant side, medication use, *Quick*-DASH score prior to the injury, pain level at both sides prior to the injury (VAS), and SF-36 score prior to the injury.
2. Injury related variables: affected side, mechanism of injury, and postoperative assessment of varus, valgus and posterolateral rotatory instability, fracture location (*i.e.*, radial head, coronoid process, olecranon), fracture classification coronoid process (Regan & Morrey) [24], and fracture classification radial head (Mason & Johnston) [25].
3. Intervention-related variables: surgical delay (*i.e.*, time between fracture and surgery), time between injury and start of physical therapy, and number of physical therapy sessions

Study procedures [Table 1]
Clinical assessments will occur at the time of admission to the hospital (baseline), two weeks (7-28 days window), six weeks (4-8 weeks window), three months (11-15 weeks window), six months (5-7 months window), and 12 months (12-14 months window) after surgery. At each follow-up moment, the research coordinator or research assistant will ascertain patient status (*i.e.*, secondary interventions, adverse events/complications), and will verify information within medical records. At the last visit, the surgeon will document any surgery that may be planned for the patient.

Anteroposterior and lateral X-rays of the elbow will be made at the time of presentation to the hospital (baseline), within 48 hours post surgery, and at all follow-up visits listed above. These X-rays will be used to determine the time to radiographic healing and amount and location of heterotopic ossification.

At baseline, patients will be asked to complete the *Quick*-DASH, VAS, and SF-36 questionnaires. This relates to the situation prior to the injury, so in order to minimize recall bias as much as possible, the questionnaires will be completed as soon after surgery as possible. At the two weeks follow-up visit and each visit thereafter, the range of motion of the elbow joint will be measured by a doctor or research assistant using a goniometer. At these follow-up visits, the patients will complete a questionnaire relating to pain (VAS). The MEPI index will be determined from six weeks onwards. At the six week follow-up visit and each visit thereafter patients will be asked to complete the *Quick*-DASH, Oxford Elbow Score, and SF-36 questionnaires.

Table 1 Schedule of events

	Screening	Enrolment	Baseline	< 48h post-surgery	2 weeks (7-28 d)	6 weeks (4-8 we)	3 months (11-15 we)	6 months (5-7 mo)	12 months (12-14 mo)
Screening	X								
X-ray	X			X	X	X	X	X	X
Informed Consent		X							
Baseline data			X						
Quick-DASH			X			X	X	X	X
Pain (VAS)			X		X	X	X	X	X
SF-36			X			X	X	X	X
Clinical follow-up					X	X	X	X	X
Revision surgery					X	X	X	X	X
Complications					X	X	X	X	X
ROM					X	X	X	X	X
MEPI						X	X	X	X
Oxford Elbow Score						X	X	X	X
Early withdrawal				*	*	*	*	*	*

* only if applicable

Sample size calculation

Calculation of the required sample size for this study is not constructive. This study is a case series based on the assumption that for introducing and acquiring experience in a new operative technique a sample size of 30 patients is required [26].

Statistical analysis

Data will be analyzed using the PASW Statistics version 18.0.1 or higher (SPSS, Chicago, Illinois, USA). Normality of continuous data will be checked by inspecting the frequency distributions (histograms) and normal Q-Q plots. Data will be reported in compliance with the CONSORT (CONsolidation of Standards of Reporting Trials) guidelines [27, 28]. In the unlikely event that a fixator will be removed within six weeks, patients will be followed and analyzed on an intention to treat basis.

Descriptive analysis will be performed in order to report baseline characteristics (*i.e.*, intrinsic, injury-related and fracture-related variables) and outcome measures. For continuous variables (*e.g.*, age, *Quick*-DASH score, MEPI, VAS, and SF-36 score) mean ± SD (if normally distributed) or medians and percentiles (if not normally distributed) will be calculated. For categorical variables (*e.g.*, gender, ASA grade, alcohol and tobacco consumption, dominant and affected side) frequencies will be calculated.

Multiple linear regression analysis will be performed in order to model the relation between different covariates and the *Quick*-DASH score. Intrinsic and fracture-related variables will be added as covariate. Similar models will be made to model the relation between covariates and the other outcome measures. A p-value <0.05 will be taken as the threshold of statistical significance.

Ethical considerations

The study will be conducted according to the principles of the Declaration of Helsinki (59th World Medical Association General Assembly, Seoul, October 2008) and in accordance with the Medical Research Involving Human Subjects Act (WMO).

The Medical Ethics Committee Erasmus MC (Rotterdam, The Netherlands) acts as central ethics committee for this trial (reference number MEC-2009-240; NL28503.078.09). Approval has been obtained from the local Medical Ethics Committees in all participating centers. Obtaining medical ethics approval has coordinated and organized by a central research coordinator (EMMVL), who is part of the key investigator team and employed by the initiating site Erasmus MC. She prepared all documents for the participating sites and answered questions of the local ethics committees if there were any. This was always following review and approval of the site principal investigator. All participating surgeons have had GCP training previously or were trained at the initiation visit in order to meet legal requirements.

An information letter notifying the patients' participation will be sent to their general practitioners, unless a patient does not agree with this.

The Medical Ethics Committee Erasmus MC has given dispensation from the statutory obligation to provide insurance for subjects participating in medical research (article 7, subsection 6 of the WMO and Medical Research (Human Subjects) Compulsory Insurance Decree of 23 June 2003). The reason for this dispensation is that participation in this study is without risks.

Discussion

The outcome of this study will yield quantitative data on the functional outcome patients with a complex elbow dislocation and who are treated with ORIF and additional stabilization with a hinged elbow fixator. Early functional treatment may lead to a better ROM and prevent elbow stiffness. Furthermore, the data as collected during this study may be used for designing future (randomised) clinical trials. Inclusion of patients has been started August 28, 2009 and the expectation is to include 2-3 patients per month. With a follow-up of one year the presentation of data will be expected at the end of 2012.

List of abbreviations used

ASA, American Society of Anesthesiologists; BP, Bodily Pain; CONSORT, CONsolidated Standards of Reporting Trial; DASH, Disabilities of the Arm, Shoulder and Hand score; GH, General Health perception; MCS, Mental Component Scale; MEPI, Mayo Elbow Performance Index; MH, general Mental Health; NTR, Netherlands Trial Registry (in

Dutch: Nederlands Trial Register); ORIF, Open Reposition and Internal Fixation; PCS, Physical Component Scale; PF, physical functioning; RE, Role limitations due to Emotional problems; ROM, Range Of Motion; RP, role limitations due to physical health; SF, Social Functioning; SF-36, Short Form 36; SPSS, Statistical Package for the Social Sciences; VAS, Visual Analog Scale; VT, vitality, energy, or fatigue.; WMO, Medical Research Involving Human Subjects Act (in Dutch: Wet Medisch-wetenschappelijk Onderzoek met mensen).

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

NWLS, JDH, WET, EMMVL, and DDH developed the trial and drafter the manuscript. DDH will act as trial principal investigator. WET, EMMVL and NWLS will perform statistical analysis of the trial data. NWLS, JDH, GITI, MWGAB, MRDV, JCG, SJH, SR, GRR, IBS, JBS, HGWMVDM, TPHVT, ABVV, EJMMV, JPAMV, PW, PP, and DDH will participate in patient inclusion and assessment. All authors have read and approved the final manuscript.

Specified notice

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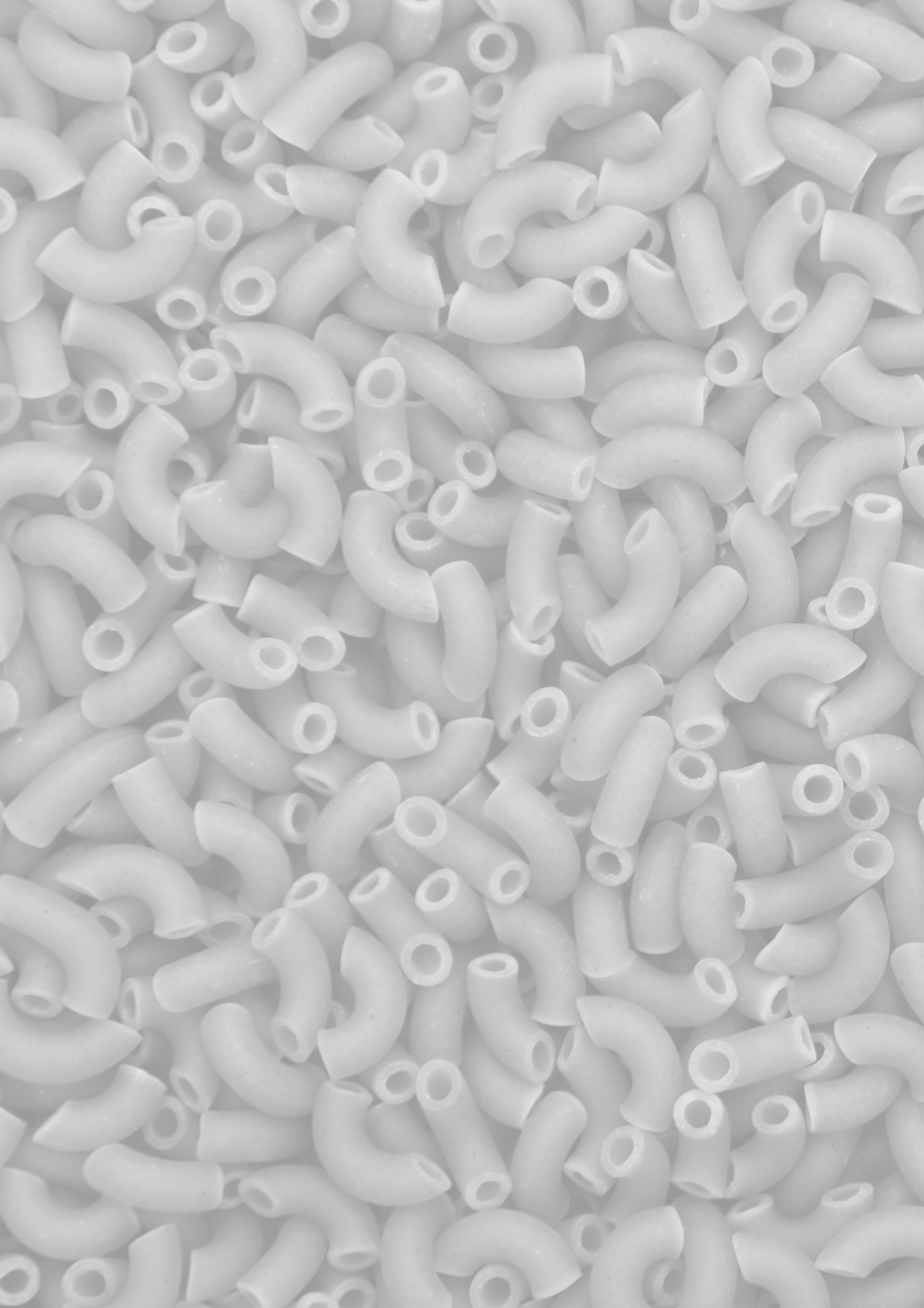
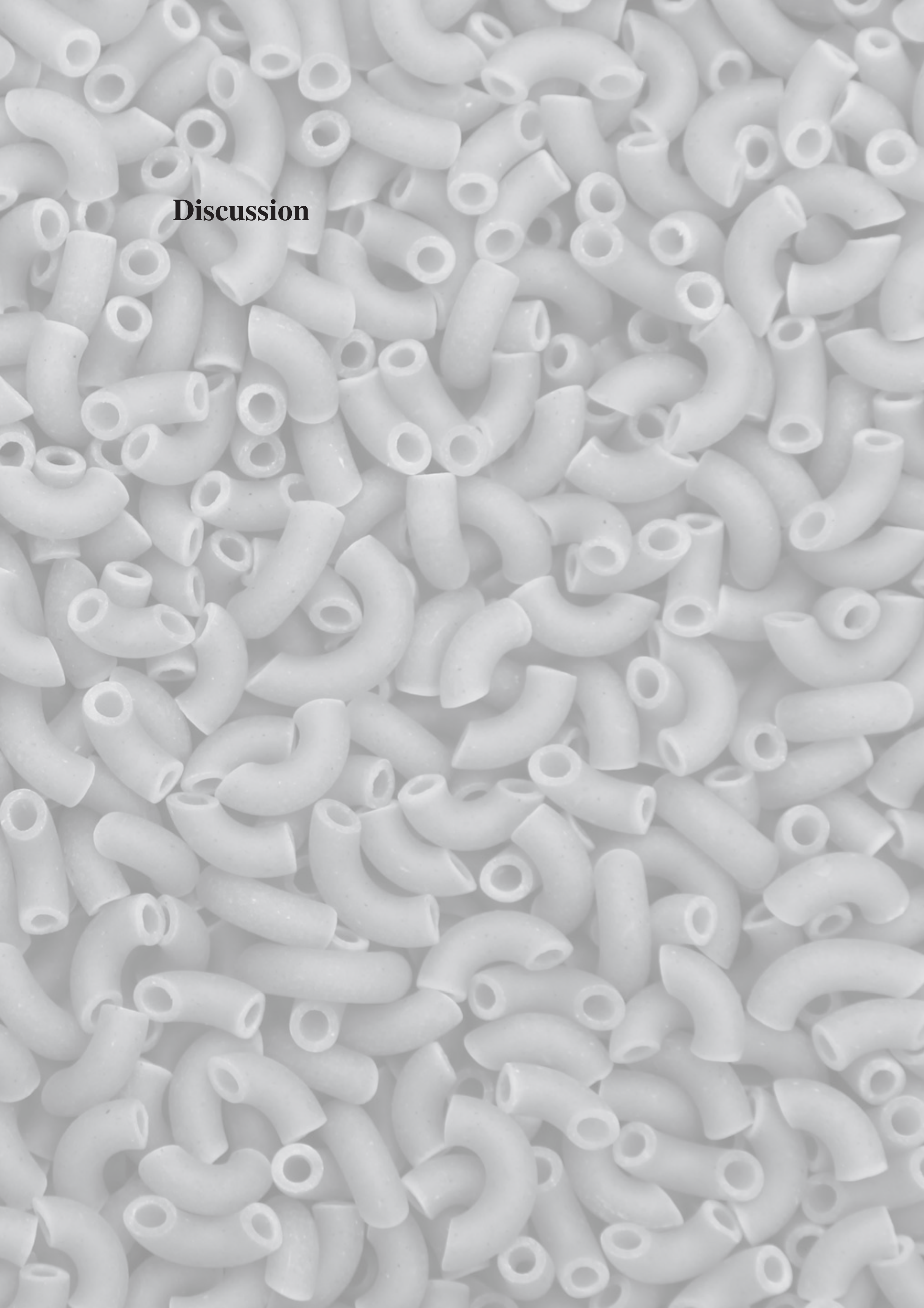


Discussion



This thesis has identified a large number of questions concerning the diagnosis and treatment of elbow dislocations. Unfortunately, it found few available answers, despite the frequency of common elbow disorders in clinical practice.

Elbow joint stability has been examined in many studies using human anatomic specimens. However, the reliability and validity of stability testing are not well known, especially with regard to elbow dislocation. The inter- and intra-observer variability in stability testing of the elbow joint has not been previously studied. O'Driscoll stated that a positive posterolateral rotatory instability test of the elbow or a positive pivot shift test is a result of a rupture of the lateral ulnar collateral ligament [1]. However, using human anatomic specimens, Deutch, Dunning and Seki et al. observed a positive pivot shift test only when the entire collateral ligament was transected [2-4].

A number of rating systems for the elbow joint or the upper extremity have been published in the English literature and include the American Shoulder and Elbow Surgeons Elbow (ASES-E) questionnaire, the Disability of Arm, Shoulder and Hand Outcome Measure (DASH), the *Quick*DASH questionnaire, the musculoskeletal function assessment (MFA), the Mayo Elbow Performance Index (MEPI) with variants, the Broberg and Morrey rating system, the Hospital for Special Surgery (HSS) scoring system, the Ewald scoring system, the Khalfayan score, the Flynn criteria, the Neviaser criteria, the Jupiter criteria and the Oxford Elbow Score (OES) [5]. Although only the DASH questionnaire has been translated into Dutch, it has been shown to be reliable with concurrent validity to the Canadian Occupational Performance Measure (COPM) in a group of 50 patients [6]. From this studied sample of 50 patients, only 2 had a single elbow disorder. Because the Dutch version of the DASH questionnaire was tested using the classical test theory, the reliability depends on the examined population sample. Furthermore, the DASH questionnaire is an instrument developed for the whole upper extremity; it is not specific only to the elbow joint. Therefore, it is unclear how reliable and valid the Dutch version of the DASH questionnaire will be in a population with only elbow disorders. In research related specifically to the elbow joint, we are interested in both the general and specific effects of the elbow disorder. Therefore, it would be more helpful to use a general outcome measure, such as quality of life, and a patient-reported outcome specific to the elbow, such as the OES. We evaluated the OES using the classical test theory and the item response theory. The latter is independent of the examined population, which is an important advantage. Further research on the Dutch version of the specific OES questionnaire is still necessary because we could only partly reproduce the multidimensionality (function, pain and social-psychology) of the original OES. The item-fit analysis in the item response theory can require a large patient sample. As such, a future study has been planned to evaluate the Dutch version of the OES in a larger sample with 130 to 400 observations. As with the OES and the *Quick*DASH, Patient-Reported Outcome Measures (PROMs) should be used in clinical research to compare different treatments and also in clinical practice to evaluate the progress of patient recovery in a reliable and valid way.

Our systematic review of the literature describing the treatment of simple elbow dislocations yielded moderate evidence for nonsurgical treatment modalities and weak evidence for functional treatment modalities [7]. Nonetheless, Dutch surgeons primarily treat elbow dislocations by immobilisation for three weeks or longer, despite the evidence for functional treatment [8]. Currently, strong evidence is not available to support a treatment for simple elbow dislocations. We believe that the randomised clinical trial (FuncSiE trial) described in Chapter seven (which is presently running) will provide this evidence when it is completed [9].

No randomised controlled trials (RCTs) have evaluated the treatment of complex elbow dislocations. Nevertheless, most cases of complex dislocations are treated with open reduction and internal fixation (ORIF) [10]. The consensus is to treat non-displaced radial head fractures by early motion and displaced radial head fractures by ORIF. Multi-fragmented cases are treated by radial head excision and radial head replacement. Coronoid fractures, classified as Regan and Morrey type I, in stable elbows can be treated nonsurgically, whereas Regan and Morrey type III fractures are generally treated by ORIF. Surgical intervention for a coronoid fracture, Regan and Morrey type II, is currently controversial. Olecranon fractures should be treated by ORIF [11-13]. It is necessary to develop a reliable classification system for fractures of the elbow before an optimal algorithm for the different treatment options can be proposed. Two classification systems exist for fractures of the coronoid process [14,15]. Both classification systems have a moderate inter-observer reliability [16], but neither has an evidence-based relationship with a clinical outcome. The O'Driscoll classification system is associated with specific injury patterns, which is very useful for planning and managing operative treatment [14]. Most surgeons agree that Regan and Morrey type III and O'Driscoll type 2 (anteromedial facet fracture of the coronoid) fractures require surgical correction because the medial collateral ligament must be inserted because of its buttress function against posterior dislocation. If instability of the elbow joint remains after ORIF or if the internal fixation is unstable, a hinged external fixator can be used. However, according our survey, most Dutch surgeons applied a plaster cast for at least three weeks in such cases [8]. With an external fixator, a full range of motion of the elbow joint is possible immediately after the operation, and this can prevent joint stiffness. Nevertheless, hinged external fixators have not been studied in randomised controlled trials, and the exact role of the fixator in the treatment of complex elbow dislocations is unclear [17]. It is unknown whether elbow joint instability caused by a ruptured collateral ligament can be counteracted using a hinged external fixator. The disadvantages of the hinged external fixator are its demanding technique and the difficulty of using X-ray examination during the surgical procedure. Additionally, its application can lead to restriction of extension and supination and force the elbow into a varus position during extension of the arm.

Because the fracture patterns in complex elbow dislocations are diverse and the incidence of complex elbow dislocations is low, a study protocol for an RCT was not developed. As such, a prospective cohort study protocol was elaborated and implemented clinically and is presented in this thesis.

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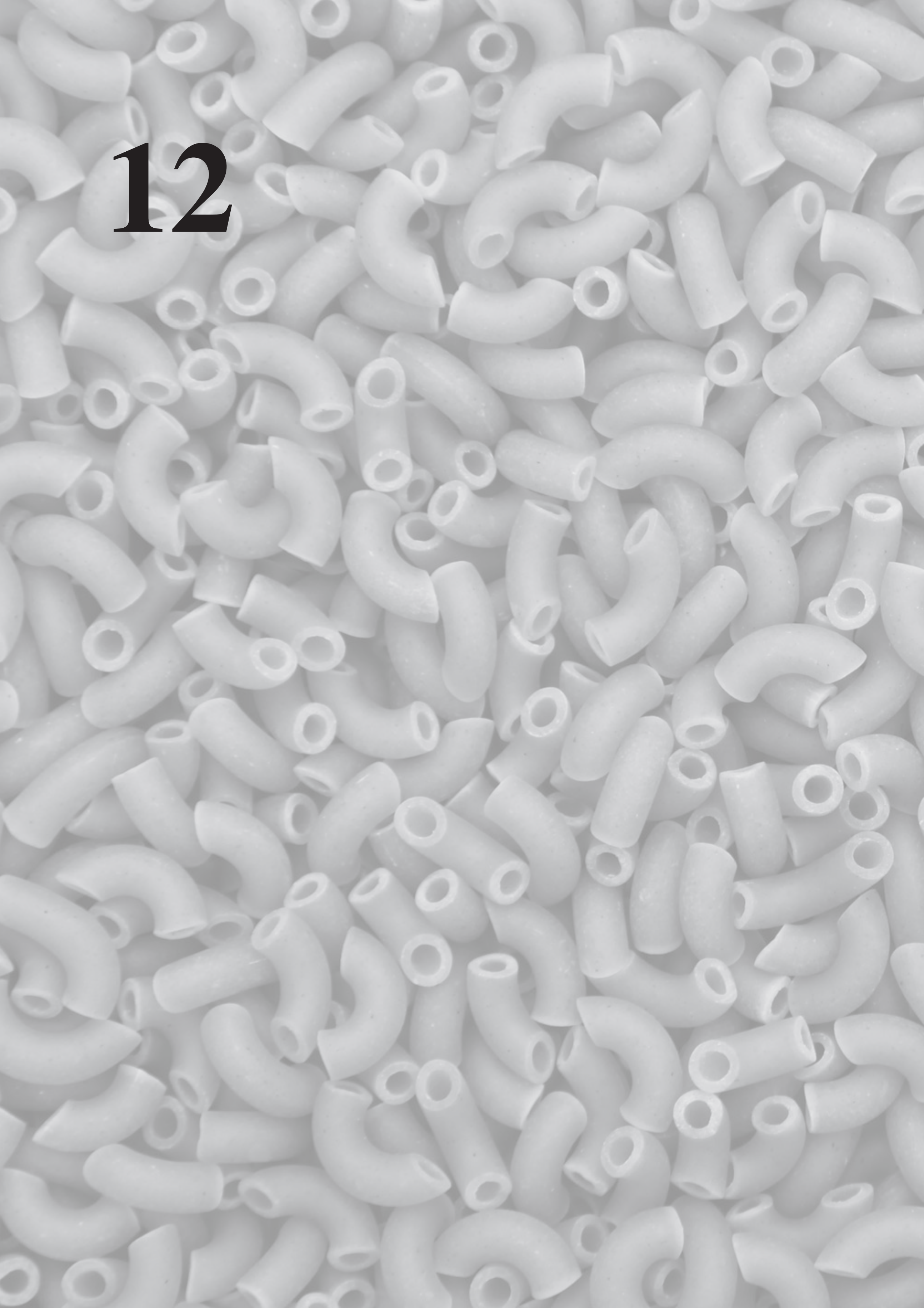
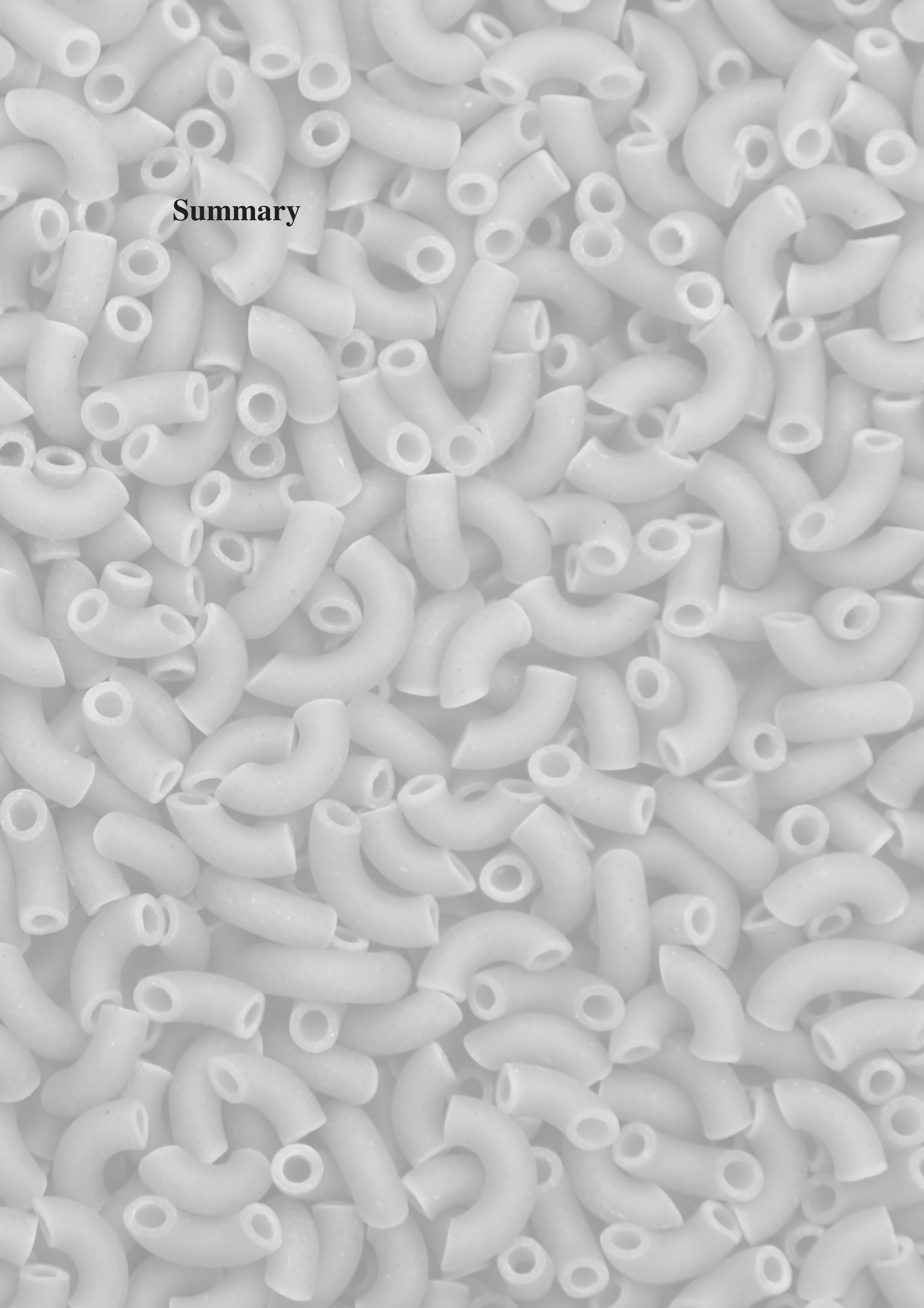


Summary



This thesis handles all aspects of adult elbow dislocation. Although elbow dislocation is a relatively common occurrence and is treated in all emergency and trauma surgery departments, little is known about the most effective treatment for this injury. In order to provide recommendations for effective treatment, it is necessary to systematically identify the problem (trauma mechanism and biomechanical research, functional and topographic anatomy- and clinical stability research) and to determine the frequency of occurrence, as well as treatment outcomes. Therefore, this thesis presents a systematic literary review of what is known in the field of anatomical and biomechanical studies with respect to the stability of the elbow. It includes a list of treatment instances - and outcomes of these instances - relevant to elbow dislocation. A literary review and survey should provide insight into the various treatment options and their outcomes, and there are English questionnaires which are used to determine the subsequent performance and quality of life. However, there is no Dutch questionnaire which can be used for the purpose of determining subsequent performance and quality of life with respect to (the implications of) elbow dislocation. The objective is thus the translation of an English questionnaire and, particularly, its validation to make it useful within the region in which Dutch is predominantly spoken.

Using this data and a validated Dutch-language tool that can determine quality of life, it will be become possible to develop a prospective study that will provide answers to all questions left unanswered. The ultimate goal of this thesis is to lay a solid foundation for the performance of prospective multicenter studies, the results of which will form the groundwork for the development of a national evidence-based guideline for the treatment of elbow dislocation.

Chapter One introduces simple and complex elbow dislocation as the subject of this thesis. The difference between simple and complex elbow dislocations is that complex dislocations are associated with fractures. Elbow dislocations can be classified by their direction of displacement. In adults, 96% of dislocations are of the posterior or posterior-lateral type.

The elbow joint consists of three joints: humero-ulnar, humero-radial and proximal radio-ulnar joints. The capsule-ligamentous anatomy is made up of the medial and lateral collateral ligament complex and, the anterior and posterior joint capsule. The medial collateral ligament complex (MCLC) is composed of three parts: the anterior medial collateral ligament (AMCL), the posterior bundle (PMCL), and the transverse ligament. The lateral collateral ligament complex (LCLC) consists of four components: the lateral or radial collateral ligament (LCL), lateral ulnar collateral ligament (LUCL), the annular ligament (AL), and the accessory collateral ligament. The stability of the elbow joint can be divided into a static and a dynamic part. The dynamic part includes the muscles that cross the elbow joint, and the primary constraints of this part are the AMCL, LCLC, and the humero-ulnar articulation. The secondary constraints are the humero-radial articulation, the common flexor-pronator tendon, the common extensor tendon, and the capsule.

The annual incidence of simple and complex elbow dislocations in children and adults is 6.1 per 100,000. Complex elbow dislocations in adults are often associated with fractures of the radial head and coronoid processes. In contrast, elbow dislocations in children are more often complicated by avulsion of the epicondyle. The incidence of simple and complex elbow dislocations is more frequent in men than women. Elbow dislocations are more often seen on the left side, but this probably has no relation to left-handedness.

According to The American Academy of Orthopaedic Surgeons, the average ranges of elbow motion are 146° of flexion, 0° of extension, 71° of pronation and 84° of supination. Most of the activities of daily living can be accomplished with 100° of elbow flexion (from 30° to 130°) and 100° of forearm rotation (50° of pronation and 50° of supination).

Patient-Reported Outcome Measures (PROMs) quantify the patients' or populations' subjective experience in relation to a health condition and its therapy. In the Netherlands, the *Quick*DASH questionnaire (Disability of the Arm, Shoulder and Hand questionnaire) is used to measure the state of the upper extremity before and after therapy. The Oxford elbow score (OES) is a specific questionnaire measuring quality of life of patients with elbow joint disorders.

The most common cause of an elbow dislocation is a fall on the outstretched hand, often during sport.

After reposition of the simple dislocation, treatment options include immobilisation in a static plaster for different periods of time, surgical treatment of the ruptured MCLC and LCLC or so-called functional treatment, which is characterised by early active movements within the limits of pain, with or without the use of a sling, hinged brace or functional plaster. A majority of complex dislocations are treated with open reduction and internal fixation (ORIF). Residual instability after ORIF can be treated with a hinged external fixator.

Heterotopic ossification is a complication after elbow trauma and can occur in up to 55% of elbow dislocations. Post-traumatic stiffness when caused by contracture of the soft tissues around the elbow can be treated non-surgically with the use of splint. When conservative treatment fails, surgical release of the elbow can be performed with an open or arthroscopic procedure or by closed distraction with an external fixator.

The aim of the literature review in **Chapter Two** was to describe the clinical anatomy of the elbow joint, based on information from *in vitro* biomechanical studies. The clinical consequences of this literature review were described, and recommendations were given for the treatment of elbow joint dislocation.

The PubMed and EMBASE electronic databases as well as the Cochrane Central Register of Controlled Trials were searched for this review. Inclusion criteria included observations of the anatomy and biomechanics of the elbow joint in human anatomic specimens.

Numerous studies of the kinematics/kinesiology and anatomy of the elbow joint in human anatomic specimens yielded important and interesting implications for trauma and orthopaedic surgery.

The aim of the study in **Chapter Three** was to develop and evaluate the Dutch version of the translated OES for reliability, validity and responsiveness, with respect to patients after elbow trauma and surgery. The OES is an English questionnaire that measures the patients' subjective experience of elbow surgery. The OES comprises three domains: elbow function, pain and social-psychological factors. This questionnaire can be completed by the patient and used as an outcome measure after elbow surgery.

The 12 items of the English-language OES were translated to Dutch and then back translated; the back-translated questionnaire was then compared to the original English version. The OES was completed by 69 patients (Group A), 60 of whom had an elbow dislocation, four of whom had an elbow fracture and five of whom had epicondylitis. The *Quick*DASH**,** the visual analogue pain scale (VAS) and the Mayo Elbow Performance Index (MEPI) were also completed to examine the convergent validity of the OES in Group A. To calculate the test-retest reliability and responsiveness of the OES, this questionnaire was completed three times by 43 patients (Group B).

Cronbach's α-coefficients for elbow function, pain and social-psychological domains were 0.90, 0.87 and 0.90, respectively. The intra-class correlation coefficients for the domains were 0.87, 0.89 and 0.87 for function, pain and social-psychological factor, respectively; the standardised response means for these domains were 0.69, 0.46 and 0.60, respectively; and the minimal detectable changes were 27.6, 21.7 and 24.0, respectively. The convergent validities for the function, pain and social-psychological domains, which were measured as the correlation of the OES domains with the MEPI, were 0.68, 0.77 and 0.77, respectively. The correlations of the OES domains with the *Quick*DASH were -0.43, -0.44 and -0.47, respectively, and the correlations with the VAS were -0.33, -0.38 and -0.42, respectively.

The objective of the study in **Chapter Four** was to analyse the Dutch version of the OES (OES-DV) in combination with Rasch analysis or the one-parameter item response theory, to examine the structure of the questionnaire.

The OES-DV was administered to 103 patients (68 female, 35 male). The mean age of the patients was 44.3 (SD=14.7, range 15-75) years. Rasch analysis was performed using the Winsteps® Rasch Measurement Version 3.70.1.1 and a rating scale parameterisation.

The person separation index, which is a measure of person reliability, was excellent (2.30). All the items of the OES, had a reasonable mean square infit or outfit value between 0.6 and 1.7. The thresholds of items were ordered, so the categories function as intended. Principal component analysis of the residuals partly confirmed the multidimensionality of the English version of the OES. The OES distinguished 3.4 strata, which indicates that about three ranges can be differentiated.

In conclusion, Rasch analysis of the OES-DV showed that the data fit to the stringent Rasch model. The multidimensionality of the English version of the OES was partly confirmed, and the four items of the function and three items of the pain domain were recognised as separate domains. The category rating scale of the OES-DV works well.

The OES can distinguish 3.4 strata. This conclusion can only be applied to elbow dislocations, which were the largest group of patients studied.

Chapter Five presents a systematic review of the literature regarding simple elbow dislocations. The objective was to determine whether functional treatment is the best available treatment for simple elbow dislocations.

The electronic databases MEDLINE, EMBASE, LILACS, and the Cochrane Central Register of Controlled Trials were searched. Studies were eligible for inclusion if they were trials comparing different techniques for the treatment of simple elbow dislocations. Results were expressed as relative risk for dichotomous outcomes and weighted mean difference for continuous outcomes, with 95% confidence intervals.

The reviewers include data from two trials and three observational, comparative studies. Important data were missing from three observational, comparative studies, and the results from these studies were extracted for this review. No difference was found between surgical treatment of the collateral ligaments and plaster immobilisation of the elbow joint. Better range of movement, less pain, better functional scores, shorter disability and a shorter treatment time were observed after functional treatment, as opposed to plaster immobilisation.

A survey is presented in **Chapter Six**. There is little evidence related to the best way to treat simple elbow dislocations. However, there are indications that a simple elbow dislocation should not be immobilised for too long and that immobilisation can be followed by functional post-treatment. To gain insight into how simple elbow dislocations are treated in the Netherlands, we conducted a survey of members of the Netherlands Trauma Society. All members received an e-mail with the request to fill out an electronic survey pertaining to the treatment of simple elbow dislocations. The response percentage was 17% (n=90). Thirty-five (39%) surgeons did not attribute any implications to examinations of elbow stability after the elbow had been repositioned; 63% of these surgeons treated patients with a plaster cast for approximately 3.4 weeks. In total, 55 of the 90 respondents (61%) stated that the stability exam does influence the subsequent course of treatment. If the joint was stable, functional treatment was prescribed in approximately 64% of cases, whereas if the joint was unstable, 24% of the respondents prescribed functional treatment using a hinged external fixator. The results of the survey among Dutch surgeons show that most of those surveyed prefer immobilisation to functional treatment.

Chapter Seven is the study protocol from a randomised controlled trial. After reduction of the simple elbow dislocation, treatment options include either functional treatment or immobilisation in a static plaster for different periods of time. Functional treatment is characterised by early active motion within the pain limits, with or without the use of a sling, hinged brace or functional plaster. Theoretically, functional treatment should prevent stiffness without introducing increased joint instability. The primary aim of this randomised controlled trial is to compare early functional treatment versus plaster immobilisation following simple dislocations of the elbow.

The design of the study will be a multi-centre, randomised controlled trial of 100 patients who have sustained a simple elbow dislocation. After reduction of the dislocation, patients are randomised to treatment involving either a pressure bandage for 5-7 days, which also uses early functional treatment, or a plaster in 90° flexion, which involves neutral position for pro-supination for a period of three weeks. In the functional group, treatment is started with early active motion within the limits of pain. Clinical function, pain, and, radiographic recovery will be monitored at regular intervals over the subsequent 12 months. The primary outcome measure is the *Quick*DASH. The secondary outcome measures are the Mayo Elbow Performance Index (MEPI), OES, pain level at both sides (VAS), range of motion of the elbow joint on both sides, rate of secondary interventions and complication rates in both groups (e.g. secondary dislocation, instability, and reluxation), health-related quality of life (Short Form-36 and EuroQoL-5D), radiographic appearance of the elbow joint (i.e., degenerative changes and ectopic ossifications), costs, and cost-effectiveness.

The successful completion of this trial will provide evidence on the effectiveness of a functional treatment for the management of simple elbow dislocations. The trial is registered at the Netherlands Trial Register (NTR2025).

The primary objective of the review of the literature with quantitative analysis of individual patient data in **Chapter Eight** was to identify the results of available treatments for complex elbow dislocations and unstable simple elbow dislocations. The secondary objective was to compare the results of patients, who were treated with an external fixator as compared to those treated without an external fixator, with complex elbow dislocations and unstable elbow joints after repositioning of simple elbow dislocations.

The electronic databases MEDLINE, EMBASE, LILACS, and the Cochrane Central Register of Controlled Trials were searched. Studies were eligible for inclusion if they included individual patient data for patients with complex elbow dislocations and unstable simple elbow dislocations. The different outcome measures (i.e., MEPI, Broberg and Morrey, American Society for Elbow Surgery (ASES) questionnaire, DASH, range of motion [ROM], and arthrosis grading) are presented with means and confidence intervals. The outcome measures show an acceptable range of motion with good functional scores on the different questionnaires and a low mean arthrosis score. Thus, treatment of complex elbow dislocations with ORIF led to a moderate-to-good result. Treatment of unstable simple elbow dislocations with repair of the collateral ligaments with or without the combination of an external fixator is also a good option.

The physician-rated (MEPI, Broberg and Morrey), patient-rated (DASH) and physician- and patient-rated (ASES) questionnaires showed good intercorrelations.

Arthrosis classification by X-ray is only fairly correlated with range of motion.

In **Chapter Nine,** a retrospective multi-centre study is presented. The objective of this retrospective multi-centre cohort study was to prospectively assess the long-term functional outcomes of simple and complex elbow dislocations.

We analysed the hospital and outpatient records of 86 patients who presented between 01/03/1999 and 25/02/2009 with an elbow dislocation. After a mean follow-up of 3.3 years, all patients were re-examined at the outpatient clinic to measure different outcomes.

The mean ROM was 135.5°. The MEPI scored an average of 91.9 (i.e., 87.5% of the patients were rated excellent or good). The average *Quick*DASH score was 9.7, the sports/music score was 11.5 and the work score was 6.1. The Oxford function score was 75.7, Oxford pain score was 75.2, and Oxford social-psychological score was 73.9.

Elbow dislocation is a mild phenomenon, and generally, the outcome is excellent. Functional results might improve with early active elbow movements.

Chapter Ten is the study protocol for a prospective cohort study for complex elbow dislocations, treated with hinged external fixators. The aim of this study is to determine the effect of early mobilisation with a hinged external elbow fixator on clinical outcome in patients with complex elbow dislocations who have residual instability following fracture fixation.

The design of the study will be a multi-centre prospective cohort study of 30 patients who have sustained complex elbow dislocation and were treated with a hinged elbow fixator following fracture fixation. Patients are allowed to use a sling for up to one week after surgery. Early active motion exercises within the limits of pain will be started immediately after surgery, following a standard protocol and under supervision of a physical therapist. Outcomes will be evaluated at regular intervals over the subsequent 12 months. The primary outcome measure is the *Quick*DASH. The secondary outcome measures are the MEPI, OES, pain level at both sides (VAS), ROM of the elbow joint on both sides, radiographic healing of the fractures, rate of secondary interventions and complications, and health-related quality of life (Short Form-36).

The outcome of this study will, for the first time, yield quantitative data on the functional recovery and pain perception after operative treatment of a complex elbow dislocation treated with a hinged elbow fixator.

The trial is registered at the Netherlands Trial Register (NTR1996).

Samenvatting

In dit proefschrift worden alle aspecten van een elleboogluxatie bij volwassenen besproken. Ondanks dat een elleboogluxatie een relatief veel voorkomend letsel is en in alle spoedeisende hulp- en traumachirurgie afdelingen behandeld wordt, is er slechts weinig bewijs voor de beste behandeling van dit letsel. Om tot een goed behandeladvies te kunnen komen is het noodzakelijk dit probleem systematisch te inventariseren (traumamechanisme, biomechanisch onderzoek, functionele en topografische anatomie en klinisch stabiliteitsonderzoek) en de frequentie van het voorkomen met de behandelresultaten vast te stellen. Daarom wordt in dit proefschrift systematisch literatuuronderzoek naar wat er bekend is op het gebied van anatomische en biomechanische studies in relatie tot de stabiliteit van de elleboog gepresenteerd. Verder wordt een inventarisatie van de behandeling en uitkomsten van de behandelingen voor een elleboogluxatie gepresenteerd. Een literatuurreview en enquête zal inzicht geven over de diversiteit van de behandelopties en de uitkomst van behandeling. Er zijn Engelstalige vragenlijsten bekend voor het meten van functie of kwaliteit van leven. Er bestaat echter nog geen Nederlandstalige vragenlijst specifiek voor het meten van functie of kwaliteit van leven na een elleboogluxatie. Het is de bedoeling om een Engelstalige vragenlijst te vertalen en vooral te valideren en geschikt maken voor het gebruik in de Nederlandstalige regio.

Met deze gegevens en een gevalideerd Nederlandstalig instrument voor het meten van de kwaliteit van het leven is het mogelijk om een prospectieve studie te ontwerpen waarin alle nog openstaande vragen worden beantwoord. Het uiteindelijke doel van dit proefschrift is een solide fundament te leggen voor prospectieve multicenter studies, waarvan de resultaten de basis zullen vormen voor het ontwikkelen van een nationale evidence based richtlijn voor het behandelen van elleboogluxaties.

In **hoofdstuk een** werden de eenvoudige en complexe elleboogluxatie als onderwerp van dit proefschrift gepresenteerd. Het verschil tussen eenvoudige en complexe elleboogluxaties is dat complexe elleboogluxaties met fracturen samengaan. Elleboogluxaties kunnen ingedeeld worden naar de richting van verplaatsing. Bij volwassenen zijn 96% van de dislocaties van het posterieure of postero-laterale type.

Het ellebooggewricht bestaat uit drie gewrichten: humero-ulnaire, humero-radiale en proximale radio-ulnaire gewricht. De capsulo-ligamentaire anatomie bestaat uit het mediale en laterale collaterale ligamentaire complex en het anterieure en posterieure gewrichtkapsel. Het mediale collaterale ligamentaire complex (MCLC) bestaat uit drie gedeelten: het anterieure mediale collaterale ligament (AMCL), de posterieure band (PMCL) en het transverse ligament. Het laterale collaterale ligamentaire complex (LCLC) bestaat uit vier componenten: het laterale of radiale collaterale ligament (LCL), het laterale ulnaire collaterale ligament (LUCL), het annulaire ligament (AL) en het accessoire collaterale ligament. De stabiliteit van het ellebooggewricht kan in een statisch en dynamisch deel worden onderscheiden. Het dynamische gedeelte bestaat uit de spieren, die het ellebooggewricht kruisen. De primaire “constraints” zijn het AMCL, LCLC en het humero-ulnaire gewricht. De secundaire “constraints” zijn het humero-radiale gewricht, de flexor-pronator communis pees, de extensor communis pees en het kapsel.

De jaarlijkse incidentie van eenvoudige en gecompliceerde elleboogluxaties bij kinderen en volwassenen is 6.1 per 100,000. Complexe elleboogluxaties bij volwassenen gaan vaak samen met fracturen van het radiuskopje en de processus coronoideus. Bij kinderen worden in tegenstelling elleboogluxaties vaker gecompliceerd door avulsie van de epicondylus. De incidentie van eenvoudige en complexe elleboogluxaties is hoger bij mannen dan bij vrouwen. Elleboogluxaties worden vaker gezien aan de linker zijde, maar dit heeft waarschijnlijk geen relatie met links handigheid.

Volgens de “The American Academy of Orthopaedic Surgeons” zijn de gemiddelde bewegingsuitslagen van de elleboog: flexie 146°, extensie 0°, pronatie 71° en supinatie 84°. De meeste dagelijkse activiteiten kunnen gedaan worden met een “range of motion” (ROM) van 100° elleboogflexie (van 30° tot 130°) en 100° onderarmrotatie (50° pronatie en 50° supinatie).

Patiëntgerapporteerde uitkomstmaten (Patient-reported outcome measures, PROMs) kwantificeren de subjectieve ervaring van patiënten of populaties in relatie tot een gezondheidstoestand en zijn behandeling. Men gebruikt in Nederland de *Quick*DASH vragenlijst (“Disability of the Arm, Shoulder, and Hand Questionnaire”) om de symptomen en de mogelijkheid om bepaalde handelingen van de bovenste extremiteit te verrichten te beoordelen. De Oxford elleboogscore (OES) is een specifieke vragenlijst, die kwaliteit van leven meet bij patiënten met aandoeningen van het ellebooggewricht.

De frequentste oorzaak van een elleboogluxatie is een val op de uitgestrekte hand meestal tijdens sporten.

Na repositie van de eenvoudige elleboogluxatie bestaan behandelingsopties uit immobilisatie in een statisch bovenarmsgips gedurende verschillende perioden, chirurgische behandeling van de gescheurde mediale en laterale collaterale ligamenten of zogenaamde functionele behandeling, die gekenmerkt wordt door vroege actieve bewegingen binnen de pijnlimiet met of zonder gebruik van een scharnierbrace of functioneel gips. Het grootste deel van complexe luxaties wordt behandeld met open reductie en interne fixatie (ORIF). Resterende instabiliteit na een ORIF kan behandeld worden met een bewegingsfixateur of gips.

Heterotope ossificatie is een complicatie na een elleboogtrauma en kan voorkomen tot 55% na elleboogluxaties. Indien posttraumatische stijfheid veroorzaakt wordt door een contractuur van de weke delen rond de elleboog, kan deze ook zonder operatie behandeld worden met behulp van spalken. Indien conservatieve behandeling faalt, kan een chirurgische release van de elleboog verricht worden door middel van een open of arthroscopische procedure of door middel van gesloten distractie met een uitwendige fixateur.

Het doel van het literatuur overzicht in **hoofdstuk twee** was het beschrijven van de klinische anatomie van het ellebooggewricht gebaseerd op informatie uit *in vitro* biomechanische studies. De klinische implicaties van dit literatuur onderzoek werden beschreven en aanbevelingen werden gedaan voor de behandeling van elleboogluxaties.

De elektronische databanken PubMed en EMBASE en de Cochrane Central Register of Controlled Trials (CENTRAL) werden doorzocht. Artikelen kwamen in aanmerking voor inclusie als ze betrekking hadden op onderzoek van de anatomie en biomechanica van het ellebooggewricht van menselijke kadavers.

Talrijke studies van de kinematica/ kinesiologie van het ellebooggewricht bij menselijke kadavers leverden belangrijke en interessante implicaties op voor traumachirurgen en orthopedisch chirurgen.

Het doel van de studie in **hoofdstuk drie** was het ontwikkelen en evalueren van de Nederlandse versie van de OES op betrouwbaarheid, validiteit en responsiviteit in relatie tot patiënten na elleboogtrauma en elleboogchirurgie. De OES is een Engelse specifieke vragenlijst, die de subjectieve ervaring van de patiënt meet in relatie tot elleboogchirurgie. De OES omvat drie domeinen: elleboog functie, pijn en sociaal psychologisch domein. Deze vragenlijst wordt door de patiënt ingevuld en is te gebruiken als uitkomstmaat na chirurgie van de elleboog.

De 12 items van de Engelse versie van de OES werden vertaald in het Nederlands en vervolgens terugvertaald; de terugvertaalde vragenlijst werd vervolgens vergeleken met de originele Engelse versie. De OES werd ingevuld door 69 patiënten (groep A), waarvan 60 een elleboogluxatie, vier een elleboog fractuur en vijf een epicondylitis hadden. De *Quick*DASH, de visueel analoge pijn schaal (VAS) en de Mayo Elbow Performance Index (MEPI) werden ook ingevuld voor een onderzoek naar de convergente validiteit van de OES in groep A. Om de test-hertest betrouwbaarheid en responsiviteit te berekenen werd de OES door 43 andere patiënten (groep B) driemaal ingevuld.

De Cronbach's α coëfficiënten van de functie, pijn en sociaal psychologische domeinen waren respectievelijk 0.90, 0.87 en 0.90. De intraclass correlatiecoëfficiënten van de domeinen waren 0.87 voor functie, 0.89 voor pijn en 0.87 voor sociaal psychologisch. De gestandaardiseerde respons gemiddelden van de domeinen waren respectievelijk 0.69, 0.46 en 0.60 en de minimale detecteerbare veranderingen waren respectievelijk 27.6, 21.7 en 24.0. De convergente validiteiten van de functie, pijn en sociaal psychologische domeinen, die werden gemeten als de correlatie van de OES domeinen met de MEPI, waren respectievelijk 0.68, 0.77 and 0.77. De correlaties van de OES domeinen met de *Quick*DASH waren respectievelijk -0.43, -0.44 en -0.47 en de correlaties met de VAS waren respectievelijk -0.33, -0.38 and -0.42.

De Nederlandse versie van de OES bleek een betrouwbare en valide vragenlijst met een goede responsiviteit te zijn.

Het doel van de studie in **hoofdstuk vier** is het analyseren van de Nederlandse versie van de OES (OES-DV) in combinatie met Rasch analyse of éénparameter itemresponstheorie om de structuur van de vragenlijst te onderzoeken.

De OES-DV werd ingevuld door 103 patiënten (68 mannen, 35 vrouwen). De gemiddelde leeftijd van de patiënten was 44.3 jaar (SD=14.7, range 15-75 jaar). Rasch analyse werd uitgevoerd met Winsteps® Rasch Measurement Version 3.70.1.1.

De "person separation index" als een maat voor de personen betrouwbaarheid was 2.30. Alle items van de OES-DV hadden redelijke gemiddelde 'square infit" of "outfit" waarden tussen 0.6 en 1.7. De OES-DV kon 3.4 strata onderscheiden, wat betekent dat ongeveer drie niveaus van kwaliteit van leven kunnen worden onderscheiden.

De drempels van de items waren geordend, dus de categorieën functioneerden zoals bedoeld. Principale componenten analyse van de residuen bevestigde gedeeltelijk de multi-dimensionaliteit van de Engelse versie van de OES.

Concluderend: Rasch analyse van de OES-DV liet zien dat de data fit vertoonden met het stringente Rasch model. De multi-dimensionaliteit van de Engelse versie van de OES werd gedeeltelijk bevestigd. De categorieën van de OES-DV functioneerde goed en de OES kon drie strata onderscheiden

Hoofdstuk vijf was een systematische review van de literatuur over eenvoudige elleboogluxaties. Het doel van dit onderzoek was om vast te stellen of functionele behandeling de best beschikbare therapie voor eenvoudige elleboogluxaties is.

De elektronische databanken MEDLINE, EMBASE en LILACS en de Cochrane Central Register of Controlled Trials (CENTRAL) werden doorzocht. Artikelen kwamen in aanmerking voor inclusie als ze voldeden aan de criteria van gerandomiseerde studies, waarin verschillende technieken voor de behandeling van eenvoudige elleboogluxaties werden vergeleken. De resultaten werden weergegeven als relatief risico voor dichotome uitkomsten en als een gewogen gemiddelde van de verschillen voor continue uitkomsten met 95%-betrouwbaarheidsintervallen.

De reviewers includeerden data van twee trials en drie observationele vergelijkende studies. Belangrijke data ontbraken van drie observationele vergelijkende studies en deze studies werden individueel beschreven. Geen verschil werd gevonden tussen chirurgische behandeling van de collaterale ligamenten en immobilisatie van het elleboogewricht in gips. Betere bewegingsuitslagen, minder pijn, betere functionele vragenlijst scores, kortere duur van de functie beperking en kortere duur van behandeling werden gevonden voor functionele behandeling versus gipsimmobilisatie.

In **hoofdstuk zes** werd een enquête gepresenteerd. Er was weinig bewijs voor de optimale behandeling van eenvoudige elleboogluxaties. Wel zijn er aanwijzingen dat eenvoudige elleboogluxaties niet te lang moeten worden geïmmobiliseerd en functioneel kunnen worden nabehandeld. Om een overzicht te krijgen van de manier waarop eenvoudige elleboogluxaties in Nederland werden behandeld, verrichtten wij een enquête onder leden van de Nederlandse Vereniging voor Traumachirurgie.

Alle leden ontvingen een e-mail met het verzoek een digitale vragenlijst over de behandeling van elleboogluxaties in te vullen. Het response percentage was 17% (n=90). Vijfendertig (39%) chirurgen verbond geen consequenties aan stabiliteitsonderzoek van de elleboog na repositie. 63% van deze chirurgen behandelde de patiënten met een gipsverband gedurende gemiddeld 3.4 weken. Bij 55 (61%) van de 90 respondenten beïnvloedde het stabiliteitsonderzoek wel de vorm van behandeling. Bij een stabiel gewricht werd in ongeveer 64% van de gevallen een functionele behandeling voorgeschreven en bij een instabiel gewricht behandelde 24% van de respondenten functioneel met een functionele fixateur. De resultaten van de enquête onder Nederlandse traumachirurgen liet zien dat de meeste ondervraagden immobilisatie verkiezen boven functionele behandeling.

Hoofdstuk zeven was een studie protocol van een gerandomiseerde gecontroleerde trial. Na repositie van de eenvoudige elleboogluxatie zijn verschillende behandelingsopties mogelijk zoals immobilisatie in een gips voor verschillende perioden of zogenaamde functionele behandeling. Functionele behandeling is gedefinieerd als vroeg actief bewegen binnen de pijngrens met of zonder gebruik van een slingerverband, scharnierbrace of functioneel gips (brace). Theoretisch zou functionele behandeling stijfheid kunnen voorkomen zonder toename van gewrichtsinstabiliteit. Het primaire doel van deze gerandomiseerde gecontroleerde trial is het vergelijken van functionele behandeling versus gipsimmobilisatie na eenvoudige elleboogluxaties.

Het design van deze studie zal een multicentrische gerandomiseerde gecontroleerde trial zijn met 100 patiënten, die een eenvoudige elleboogluxatie hebben opgelopen. Na repositie van de luxatie worden patiënten gerandomiseerd tussen vroege functionele behandeling met een drukverband voor vijf tot zeven dagen of een gips in 90 graden flexie en neutrale pro-supinatie positie gedurende drie weken. In de functionele groep wordt de behandeling begonnen met vroege actief bewegen binnen de pijngrens. Klinische functie, pijn en röntgenologisch herstel zullen vervolgd worden in regelmatige intervallen over de volgende 12 maanden. De primaire uitkomstmaat is de *Quick*DASH score na een jaar. De secundaire uitkomstmaten zijn de MEPI, OES, pijn niveau beiderzijds (VAS), beweeglijkheid van de elleboggewrichten beiderzijds, aantal secondaire interventies en complicaties in beide groepen (secundaire dislocatie, instabiliteit, reluxatie), gezondheid gerelateerde kwaliteit van leven (Short Form-36 en EuroQoL-5D), röntgenologisch beeld van het elleboggewricht (degeneratieve veranderingen en ectopische ossificaties), kosten en kosteneffectiviteit.

Het succesvol afsluiten van deze trial zal bewijs leveren over de effectiviteit van een functionele behandeling van eenvoudige elleboogluxaties. De trial is ingeschreven bij het Nederlands Trial Register (NTR2025).

Het primaire doel van het literatuuronderzoek met kwantitatieve analyse van individuele patiënten data in **hoofdstuk acht** was om de resultaten te beoordelen van beschikbare behandelingen voor complexe elleboogluxaties en instabiele eenvoudige elleboogluxaties. Het secundaire doel was om de resultaten te vergelijken van patiënten met complexe elleboogluxaties en instabiele elleboggewrichten na repositie van eenvoudige elleboogluxaties, die behandeld werden met een externe fixateur versus zonder een externe fixateur.

De elektronische databanken MEDLINE, EMBASE en LILACS en de Cochrane Central Register of Controlled Trials (CENTRAL) werden doorzocht. Artikelen kwamen in aanmerking voor inclusie als ze individuele data van patiënten met complexe elleboogluxaties en instabiele eenvoudige elleboogluxaties bevatten. De verschillende uitkomstmaten (MEPI, Broberg en Morrey, American Society for Elbow Surgery (ASES) questionnaire, DASH, bewegingsuitslagen, ernst van artrose) werden weergegeven met gemiddelden en betrouwbaarheidsintervallen.

De uitkomstmaten lieten een acceptabele bewegingsuitslag zien met goede functionele scores van de verschillende vragenlijsten en een lage gemiddelde artrose score. De behandeling van complexe elleboogluxaties met ORIF leidde dus tot een matig tot goed resultaat. Behandeling van instabiele eenvoudige elleboogluxaties met herstel van collaterale ligamenten met of zonder de combinatie met een externe fixateur is eveneens een goede optie. De door de arts ingevulde (MEPI, Broberg en Morrey), patiënt ingevulde (DASH) en arts en patiënt ingevulde (ASES) vragenlijsten vertoonden goede inter-correlaties.

Artrose classificatie door middel van röntgenfoto's was slechts matig gecorreleerd met bewegingsuitslag.

In **hoofdstuk negen** werd een retrospectieve multicentrische studie gepresenteerd. Het doel van deze retrospectieve multicentrische cohort studie was om prospectief de lange termijn functionele uitkomsten van eenvoudige en complexe elleboogluxaties te identificeren. Wij doorzochten de ziekenhuis en polikliniek statussen van 86 patiënten met een elleboogluxatie van 01.03.1999 tot 25.02.2009. Na een gemiddelde follow-up van 3.3 jaar werden alle patiënten opnieuw onderzocht op de polikliniek voor het meten van de verschillende uitkomsten.

De gemiddelde bewegingsuitslag voor flexie en extensie was 135.5°. De MEPI scoorde een gemiddelde van 91.9 (87.5% van de patiënten werden beoordeeld als uitstekend of goed). De gemiddelde *Quick*DASH score was 9.7, de sport/muziek score 11.5 en arbeid score 6.1. De Oxford functie score was 75.7, Oxford pijn score 75.2 en Oxford sociaal psychologische score 73.9.

Elleboogluxatie is een milde aandoening en in het algemeen is de uitkomst uitstekend. Functionele resultaten kunnen mogelijk verbeteren door vroegtijdig beginnen met actieve oefentherapie van de elleboog.

Hoofdstuk tien was een studie protocol van een prospectieve cohort studie voor complexe elleboogdislocaties, die met een functionele fixateur worden behandeld. Het doel van deze studie is het effect van vroeg mobiliseren met behulp van een dynamische elleboogfixateur te bepalen op de klinische uitkomst bij patiënten met complexe elleboogluxaties met blijvende instabiliteit na anatomische repositie en fractuur osteosynthese.

Het studie design is een multcentrische prospectieve cohortstudie van 30 patiënten, die een complexe elleboogluxatie hebben opgelopen en die werden behandeld met een dynamische elleboogfixateur na fractuurfixatie. Patiënten mogen gedurende een week postoperatief een slingerverband dragen. Vroege actieve bewegingingsoefeningen worden direct begonnen na de operatie op geleide van de pijn volgens een standaard protocol onder begeleiding van een fysiotherapeut. De uitkomsten worden op vooraf vastgestelde tijdstippen gedurende een jaar bepaald. De primaire uitkomstmaat is de *Quick*DASH. De secundaire uitkomstmaten zijn de MEPI, OES, pijn niveau beiderzijds (VAS), bewegingsuitslagen beiderzijds, röntgenologische consolidatie, aantal secundaire interventies en complicaties, en gezondheid gerelateerde kwaliteit van leven (Short Form-36).

De uitkomst van deze studie zal voor de eerste keer kwantitatieve data opleveren over het functionele herstel en de pijnbeleving na operatieve behandeling van een complexe elleboogluxatie, die behandeld wordt met een dynamische elleboogfixateur.

De trial is ingeschreven bij het Nederlands Trial Register (NTR1996).

Dankwoord

Promoveren en het schrijven van een proefschrift is te vergelijken met topsport. Zonder een uitstekend team is een promotie onmogelijk. Daarom wil ik nadrukkelijk het "elleboogteam" bedanken voor het halen van de eindstreep.
Het elleboogteam bestaat uit Dennis den Hartog, Wim Tuinebreijer, Niels Schep, Esther van Lieshout en Peter Patka.

Professor Patka,
Peter,
Het was stimulerend om je als opleider in de VUMC en nu als promotor in het Erasmus MC te hebben. Grote waardering heb ik voor jouw rustige manier van aansturen en corrigeren. Jouw kracht is dat je eerst “de jonge honden” laat uitrazen om ze vervolgens in de gewenste richting te laten lopen. Dit is volgens mij de ultieme manier van managen. Dank voor de tijd die je voor mij vrij hebt gemaakt.

Dennis,
Jij bent de grote organisator en aanvoerder van het elleboogteam. In het Rode Kruis Ziekenhuis te Beverwijk hadden we een onvergetelijke tijd als assistent. Wie had toen ooit kunnen denken dat jij mijn copromotor zou worden? Jaren later, onderweg in een vliegtuig naar Boedapest, werd het idee van een onderzoek naar de behandeling van elleboogluxatie geboren. Tijdens je eigen promotie vond je toch nog tijd om mij te motiveren en te stimuleren om het elleboogproject tot een succes te maken. Zelfs na deze dissertatie ga je hiermee door. Dank voor dit alles en ik kijk uit naar voortzetting en uitbouwen van onze samenwerking in de toekomst.

Wim,
Opleider, fietsmaat en “soulmate”, maar bovenal VRIEND. Jij hebt “wetenschap op de fiets” geïntroduceerd. Altijd relativerend en stimulerend. Dit proefschrift is dankzij jou tot stand gekomen en je was de motor van dit proefschrift. Je wist mij te motiveren de chirurgie wetenschappelijker te benaderen. Voor mij geeft dit een nieuwe dimensie aan de inhoud van ons vak en maakt het inzichtelijker en transparanter. Ik kijk uit naar de vele fiets- en discussie kilometers, die nog komen gaan!! Ook Frieda wil ik bedanken voor de vele espresso's en lunches, die altijd weer klaar stonden. Een betere studieplek kon ik mij niet wensen.

Niels,
Het idee dat er weinig tot niets bekend is over de behandeling van elleboogluxaties kwam van jou. Het feit dat er weinig bewijs bestond over het nut van het hechten van de collaterale banden van de elleboog is de aftrap geweest van het elleboog project. Jouw correcties waren altijd van grote waarde en hebben bijgedragen tot verbetering van dit proefschrift. We nemen er nog één in de Hutte van Ome Henne!

Esther,
Zorgzaam, professioneel en nauwgezet waak je over de onderzoekers van de traumatologie van het Erasmus MC. Je maakt de titel coördinator meer dan waar: altijd benaderbaar voor vragen en advies, betrouwbaar en nauwgezet. Zelfs tijdens weekeinden is het includeren van patiënten geen enkel probleem. Ook inhoudelijk ben je precies op de hoogte. Het is een geruststellende gedachte, dat jij direct de telefoon opneemt binnen het hectische bedrijf Erasmus MC, als zich een probleem voordoet met het onderzoek. Dank daarvoor.

Naast het vaste team zijn er nog vele mensen die een bijdrage geleverd hebben bij het tot stand komen van dit proefschrift. Jesse van Buijtenen en Imme Zengerink hebben een groot deel van het statusonderzoek verricht voor de retrospectieve studie. Dank hiervoor en Jesse veel succes met je eigen promotie.

Rolf, het was een genoegen je als collega te hebben leren kennen ook al was het maar van korte duur. Je hebt een grote bijdrage geleverd aan het tot stand komen van de enquête. Ik wens je een prachtige carrière toe in het AMC. We blijven in dezelfde regio!

Tevens wil ik een ieder bedanken die deelneemt aan de FuncSiE trial en de Complex elbow cohort studie en ik wens Gijs Iordens veel succes met het afronden van het onderzoek en zijn proefschrift. Ik weet zeker dat er iets “moois van komt”.

Naast het verrichten van wetenschap moet ook het "gewone" werk worden gedaan. Daarom is het belangrijk je gesteund te voelen door je maten. Dit is zeker het geval binnen de vakgroep chirurgie van het Westfriesgasthuis. Anja, Arno, Eric, Jan Willem, Joost, Joris, Jur en Marc: we hebben samen een team opgebouwd waarin samenwerking centraal staat. Dit geeft rust en vertrouwen. Ik wil jullie hiervoor bedanken en de hoop uitspreken dat dit altijd zo mag blijven.

Arnoud en Marc het is goed jullie als paranimf te hebben. Ik weet zeker dat het een onvergetelijke dag gaat worden.

Lieve Pa & Moe,
ik ben erg dankbaar dat jullie deze dag erbij kunnen zijn en dat we samen deze mijlpaal kunnen vieren. Ik hoop nog lange tijd van jullie aanwezigheid te kunnen genieten.

Werken als chirurg en ook nog promoveren kan alleen met een met een thuisfront dat je steunt en waar je energie van krijgt. Lieve Nienke, Lotte, Aycke, Femke en Bente bij jullie heb ik dat gevonden. Ik houd van jullie.

PhD Portfolio Summary

Summary of PhD training and teaching activities

Name PhD student: J. de Haan Erasmus MC Department: Surgery-Traumatology Research School: Erasmus MC	PhD period: 2007-2011 Promotor: Prof. dr. P. Patka Supervisor: Dr. D. den Hartog	
1. PhD training		
	Year	**Workload (ECTS)**
Presentations		
- Presentation “Trauma dagen” Survey Dutch surgeons: “How do Dutch surgeons treat simple elbow dislocation?”	2008	1
- Presentations at Trauma nights about FunCSiE trial and external fixator study	2009	2
- Mini Battle “Trauma dagen”: Repair or not to repair the collateral ligaments in elbow dislocation?	2009	2
- Poster presentation ESTES: “The reliability, validity and responsiveness of the Dutch version of the Oxford elbow score”	2011	1
(Inter)national conferences		
- European Congress of Trauma and emergency surgery	2008	0.5
- AO Advances Hand symposium. Joint injuries	2008	0.2
- AO Advances Symposium Fractures around the elbow	2008	0.2
- Traumadagen NVT	2008	0.4
- European Congress of Trauma and emergency surgery	2009	0.5
- AO trauma Update on LCP	2009	0.2
- Traumadagen NVT	2009	0.4
- Rotterdam Advanced Elbow Course	2009	0.3
- AO Trauma Advances and Ankle symposium	2010	0.3
- 4e post olympisch sportcongres NVT	2010	0.3
- European Congress of Trauma and emergency surgery	2010	0.5
- Advanced Trauma Life Support (provider course)	2010	2
- AO Bekken symposium	2010	0.3
- AO Benelux Advances symposium	2010	0.5
- AO-trauma fractuurbehandeling en weke delen benadering	2010	0.5
- Traumadagen (NVT)	2010	0.4
- AO-trauma advanced osteotomy symposium	2010	0.3

- Rotterdam Advanced Elbow Course - 12th European Congress of Trauma and Emergency Surgery - AO Trauma Symposium	2010 2011 2011	0.3 0.5 0.3
Seminars and workshops - Orthofix course and workshop on internal and/or external fixation of the upper limb - Orthofix course and workshop on internal and/or external fixation of the lower limb - Elbow Cadaver workshop Leuven	 2008 2008 2009	 0.5 0.5 0.5
Didactic skills **-** Teach-the-teacher course	 2009	 1
Other		

2. Teaching activities

	Year	Workload (ECTS)
Lecturing **-** Rotterdam Advanced Elbow Course **-** AO Trauma Cadaver Course	 2009 2011	 0.5 1
Supervising practicals and excursions - Supervising surgical resident with collecting and analysing data, writing, revising and submitting a manuscript	 2009-2011	 10
Supervising Master's theses - PhD medical student traumatology	 2009-2011	 12
Other -		

List of Publications

[1] de Haan J, Mackaay AJ, Cuesta MA, Rauwerda JA: Posterior approach for the simultaneous, bilateral thoracoscopic sympathectomy. J Am Coll Surg 2001, 192: 418-20

[2] de Haan J, Schep NWL, Peters RW, Tuinebreijer WE, den Hartog D: [Simple elbow dislocations in the Netherlands: what are Dutch surgeons doing?]. Netherlands Journal of Traumatology 2009, 17: 124-7

[3] de Haan J, den Hartog D, Tuinebreijer WE, Iordens GIT, Breederveld RS, Bronkhorst MWGA, Bruijninckx MMM, De Vries MR, Dwars BJ, Eygendaal D, Haverlag R, Meylaerts SAG, Mulder JWR, Ponsen KJ, Roerdink WH, Roukema GR, Schipper IB, Schouten MA, Sintenie JB, Sivro S, Van den Brand JGH, Van der Meulen HGWM, Van Thiel TPH, van Vugt AB, Verleisdonk EJMM, Vroemen JPAM, Waleboer M, Willems WJ, Polinder S, Patka P, van Lieshout EMM, Schep NWL : Functional treatment versus plaster for simple elbow dislocations (FuncSiE): a randomised trial. BMC Musculoskelet Disord 2010, 11: 263

[4] de Haan J, Schep NWL, Tuinebreijer WE, den Hartog D: Complex and unstable simple elbow dislocations: a review and quantitative analysis of individual patient data. Open Orthop J 2010, 4: 80-6

[5] de Haan J, Schep NWL, Zengerink I, van Buijtenen J, Tuinebreijer WE, den Hartog D: Dislocation of the elbow: a retrospective multicentre study of 86 patients. Open Orthop J 2010, 4: 76-9

[6] de Haan J, Schep NWL, Tuinebreijer WE, Patka P, den Hartog D: Simple elbow dislocations: a systematic review of the literature. Arch Orthop Trauma Surg 2010, 130 (2): 241-9

[7] den Hartog D, de Haan J, Schep NWL, Tuinebreijer WE: Primary shoulder arthroplasty versus conservative treatment for comminuted proximal humeral fractures: a systematic literature review. Open Orthop J 2010, 4: 87-92

[8] Schep NWL, de Haan J, Iordens GIT, Tuinebreijer WE, Bronkhorst MWGA, de Vries MR, Goslings JC, Ham SJ, Rhemrev S, Roukema GR, Schipper IB, Sintenie JB, van der Meulen HGWM, van Thiel TPH, van Vugt AB, Verleisdonk EJMM, Vroemen JPAM, Wittich P, Patka P, van Lieshout EMM, den Hartog D: A hinged external fixator for complex elbow dislocations: a multicenter prospective cohort study. BMC Musculoskelet Disord 2011, 12: 130

[9] de Haan J, Schep NWL, Eygendaal D, Kleinrensink G-J, Tuinebreijer WE, den Hartog D. Stability of the elbow joint: relevant anatomy and clinical implications of *in vitro* biomechanical studies. Open Orthop J 2011, 5: 168-76

[10] de Haan J, Goei H, Schep NWL, Tuinebreijer WE, Patka P, den Hartog D. The reliability, validity and responsiveness of the Dutch version of the Oxford elbow score. J Orthop Surg Res 2011, 6: 39

[11] de Haan J, Schep NWL, Tuinebreijer WE, Patka P, den Hartog D. Rasch analysis of the Dutch version of the Oxford elbow score. Patient Related Outcome Measures 2011, 2: 1-5

Curriculum Vitae

Jeroen de Haan werd geboren op 10 februari 1964 te Amsterdam. Later dat jaar verhuisde hij naar Oegstgeest. In 1982 behaalde hij zijn VWO diploma aan de Louise de Cologny scholengemeenschap in Leiden, alwaar hij aansluitend geneeskunde ging studeren aan de Universiteit Leiden.

In 1991 behaalde hij zijn artsdiploma en diende als officier arts bij de Koninklijke Marine voor 2 jaar. Hierna werd hij AGNIO-chirurgie in het Medisch Centrum Alkmaar (prof. dr. A.B. Bijnen), om vervolgens bij prof. dr. J.A. Rauwerda in het VUMC een onderzoek op te starten naar de regulatie van de microcirculatie van diabetes patiënten en deel uit te maken van het hyperhomocysteïne project.

In 1995 ging zijn opleiding tot chirurg van start in het Rode Kruis Ziekenhuis te Beverwijk (dr. R.S. Breederveld) en in het VUMC te Amsterdam (prof. dr. H.J.T.M. Haarman). Op 1 januari 2001 werd hij geregistreerd als chirurg en startte hij als chef de clinique chirurgie in het Rode Kruis Ziekenhuis in Beverwijk. Later dat jaar werd hij lid van de vakgroep chirurgie in het WestfriesGasthuis in Hoorn, waar hij tot op heden met veel plezier deel van uit maakt.

In 2007 ging hij zich differentiëren in de traumachirurgie, wat leidde tot contacten met de afdeling traumatologie van het Erasmus MC te Rotterdam (prof. dr. P. Patka en dr. D. den Hartog). Een promotie onderzoek werd aangevangen naar de behandeling van elleboogluxatie. Dit onderzoek heeft geresulteerd in het proefschrift dat voor u ligt.

Sinds 25 september 1993 is hij getrouwd met Nienke Kruidering met wie hij 4 prachtige kinderen heeft: Lotte, Aycke, Femke en Bente.